

Regulatory compliance in  
Scotland's tattooing and  
cosmetic body piercing industry:  
A concurrent mixed methods study

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## **Abstract**

The objective of any regulation is to realise the goal(s) that justified its intervention. One means of demonstrating this is to determine the extent of regulatory compliance. This study intended to determine the extent of regulatory compliance with the Civic Government (Scotland) Act 1982 (Licensing of skin piercing and tattooing) Order 2006 in Scotland's tattooing and cosmetic body piercing industry. Implemented in Scotland in 2006, its aim was to minimise risk to health from skin piercing and tattooing.

Philosophically underpinned by pragmatism, a concurrent mixed methods study was undertaken. All 220 practitioners and 78 enforcers engaging with this regulation across Scotland were invited to participate. Through analysis and interpretation of data from semi-structured questionnaires (n=107, 36%), qualitative focused interviews (n=35) and non-participant observations (n=8), users' experiences of regulatory implementation were explored and explained, to more fully understand regulatory compliance.

Integrative analysis and interpretation of this study's mixed methods data determined neither substantive compliance (compliance with the collective goals of regulation) nor rule compliance (compliance with the regulatory standards) had been achieved following implementation of this new regulation. The existence of a significant level of shared activity between practitioners and enforcers during regulatory implementation was however established, where partnership working had derived from the 'specialist' nature of industry practice. Consequently, it was deduced that 'compliance' (defined in this context as 'doing what was asked to conform to the law') poorly reflected the events of regulatory implementation. Instead, 'concordance' has been discerned as the primary activity. The concept of concordance as 'working towards agreement' more accurately depicted the experiences of practitioners and enforcers during the process of regulatory implementation.

Subsequently, the extent of 'concordance' was determined: The divergent attitudes/experiences on the consistency of regulatory implementation and its ability to achieve its aim, coupled with the ambiguous understanding of 'risk to health' and converse working perspectives of practitioners and enforcers led to the conclusion that goal concordance (agreement on the collective goal(s) of the regulation) had not been achieved. On the other hand, despite evidence of apparent inadequacies and omissions in industry practices, practitioner and enforcer confidence in industry infection control practices led to the conclusion that rule concordance (agreement on the regulatory standards to be met) had been achieved. From these collective findings, a 'Specialist Industry Concordance-Compliance Model' was developed to explain the achievements of practitioners and enforcers as a result of implementing new regulation/ meeting regulatory requirements within a specialist industry.

Complementing rather than conflicting with existing literature, this study offers 'concordance' as an alternative and/or intermediate output of regulatory implementation, explaining the process by which practitioners and enforcers implement new regulation/meet regulatory requirements within a specialist industry. Moreover, the study findings provide a framework to support better understanding of the potential output from implementation, monitoring and review of regulatory interventions, frequently associated with sub-optimal compliance. In turn, through combined understanding of concordance and compliance, the design of good regulation can be promoted, thereby facilitating maximum reduction in risk/ risk to health through regulatory intervention.

## Statement of Authorship

I, Claire Chalmers, confirm that this thesis, submitted in partial fulfilment of the requirements of Edinburgh Napier University, for the award of Doctor of Philosophy is my own. Generated by me as the result of my own original research, it is expressed in my own words. Use made within it of other authors' work is clearly attributed at the point of use. No other person's work has been used without due acknowledgement in the main text of the thesis.

A full list of references have been included, encompassing reference to parts of this work previously published:

- Chalmers, C., 2009. Charting the existence and approaches to management of the tattooing and body piercing industry – a historical overview. *Journal of Infection Prevention*, **10** (3) pp102-105.
- Chalmers, C., 2009. Appraising the need for tighter control over the practices of the tattooing and body piercing industry. *Journal of Infection Prevention*, **10** (4) pp134-137.
- Chalmers, C., 2009. Debating the appropriateness and effectiveness of regulation as a mechanism to manage and control the risk to health from tattooing and body piercing activities. *Journal of Infection Prevention*, **10** (5) pp180-183.
- Chalmers, C., 2010. Responding to regulation of the tattooing and cosmetic body piercing industry in Scotland: The evolution of a mixed methods study. *Environmental Health Scotland*, **22** (2) pp10-11.

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Date: \_\_\_\_\_

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*“Vision without action is only dreaming.  
Action without vision is only passing time.  
A vision with a plan can change the world.”*

(Joel A. Barker)

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*“If you can imagine it, you can achieve it.  
If you can dream it, you can become it.”*

(William Arthur Ward)

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## List of abbreviations

<b>A-G</b>	
BRTF	Better Regulation Task Force
BBV	Blood Borne Virus
CDC	Centers for Disease Control
DH	Department of Health
EHO	Environmental Health Officer
EU	European Union
FOI	Freedom of Information
<b>H-Q</b>	
HPN	Health Protection Nurse
HPS	Health Protection Scotland
NPHP	National Public Health Partnership
NZHS	New Zealand Health Service
PHRU	Public Health Research Unit
<b>R-S</b>	
RCT	Randomised Controlled Trial
REHIS	Royal Environmental Health Institute for Scotland
SCIEH	Scottish Centre for Infection and Environmental Health
SEHD	Scottish Executive Health Department
SGHD	Scottish Government Health Directorate
SLSPWTWG	Scottish Licensing of Skin Piercing and Tattooing Working Group
SME	Small and Medium Enterprise
SNBTS	Scottish National Blood Transfusion Service
<b>T-Z</b>	
TSO	Trading Standards Officer
UK	United Kingdom
US(A)	United States (of America)
WHO	World Health Organisation

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# Chapter 1

## Background to the study

## 1.1 Introduction and overview

On 1<sup>st</sup> April 2006, Scotland implemented the Civic Government (Scotland) Act 1982 (Licensing of skin piercing and tattooing) Order 2006 (hereafter referred to as ‘the Order’) (See Appendix 1), with a transitional period of 12 months given for existing businesses to ensure they met its requirements. The aim of the Order was, through consistent controls, to minimise risk to health from activities including tattooing and cosmetic body piercing (Health Protection Scotland (HPS), 2006).

Until this point in time, Scotland’s approach to controlling the activities of the tattooing and cosmetic body piercing industry had relied solely on general health and safety related legislation, predominantly the Health and Safety at Work Act 1974, the Prohibition of Female Circumcision Act 1985<sup>1</sup> and the Tattooing of Minors Act 1969. With the resurgence in popularity of tattooing and cosmetic body piercing over the past two decades however, apprehension of threat to public health from such practices led to calls for tighter controls over the industry. Based predominantly on concerns over risk to health from infection, tighter control through regulation was proffered as an effective approach to “*minimising related health risks*” (Walters, 2001: 52).

The objective of any regulation is to realise the goals that justified intervention. As such, the effectiveness of this Order relies upon securing a reduction in risk to health. One possible means of demonstrating effectiveness and ascertaining risk reduction is to determine the extent of regulatory compliance (World Health Organisation (WHO), 2008).

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<sup>1</sup> In March 2004, the Prohibition of Female Circumcision Act 1985 was repealed and replaced by the Female Genital Mutilation Act 2003 in England, Wales and Northern Ireland. The Prohibition of Female Genital Mutilation (Scotland) Act 2005 repealed and re-enacted the provision of the 1985 Act for Scotland.

## **1.2 Background**

This chapter begins by briefly outlining the history of tattooing and cosmetic body piercing, setting in context the background from which these activities have emerged into mainstream western society. Demonstrating the global shift in approach to industry management from self to state-controlled regulation, it will argue that the approach to the management of tattooing and cosmetic body piercing in Scotland reflects that of much of western society.

The chapter continues by considering the use of regulation as one possible mechanism to manage risk to health, within a wider range of behaviour change/ risk reduction strategies. Broadly, the range of strategies have been categorised as interventions that seek to reduce risks to whole populations and those which target individuals. As many interventions aiming to reduce risk to health involve an element of behaviour change, this shall also be discussed and appraised.

The chapter will introduce the notion that if regulatory intervention is to be justified, its effectiveness must be demonstrated (WHO, 2008). Faced with difficulties in establishing targeted behaviours as causal risk factors, and frequently amidst limited evidence of past performance of interventions to change targeted behaviours and achieve anticipated outcomes, regulatory compliance will be offered as an appropriate means of demonstrating effectiveness. The concept of regulatory compliance will thereafter underpin the development of this work.

Before moving onto Chapter 2 – ‘Review of the literature’, the arguments of Chapter 1 will be summarised. Also, an overview of the organisation and structure of the remainder of this thesis will be provided, to signpost the work’s intended direction.

### 1.3 Tattooing and cosmetic body piercing

Tattooing and cosmetic body piercing are two categories of skin piercing, which fall within the wider phenomena of body art, adornment or modification – all terms used to describe activities that alter the human body in either a permanent or semi-permanent yet deliberate way for non-medical reasons. Often terms such as piercing, body piercing, skin piercing and cosmetic body piercing are used interchangeably, although skin piercing is now used more frequently in its widest sense to include acupuncture, cosmetic body piercing, electrolysis and tattooing activities (Scottish Executive Health Department<sup>2</sup> (SEHD), 2001).

#### 1.3.1 History of tattooing and cosmetic body piercing

The history of tattooing (defined for the purposes of this work as the insertion into the skin of any colouring materials designed to leave a semi-permanent or permanent mark) and cosmetic body piercing (defined for the purposes of this work as the perforation of the skin and underlying tissues in order to create a tunnel in the skin through which jewellery may be inserted) is well documented (Chalmers 2009a). Recognised as phenomena as old as history (Denton, 2001; Mason, 2004), they are activities practiced around the world for many centuries. As distinct forms of body art, they utilise the skin as “a *blank canvas, upon which to write a testimony to what we are*” (di Folco, 2004: 8). Through time, and often associated with condemnation of social norms or veneration of cultural heritage, tattooing and cosmetic body piercing have served as ways to signal societal status, record symbolic moments, or celebrate life transitions (di Folco, 2004; Wroblewski, 2004).

Recent decades have witnessed tattooing and cosmetic body piercing emerge into mainstream society as a significant fashion, and on a worldwide scale (Denton, 2001). Previously, these were activities considered synonymous with the marginalised and delinquent.

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<sup>2</sup> The Scottish Executive was established in 1999 as the executive arm of the devolved government of Scotland. Following the 2007 Scottish Parliament election, the Scottish National Party changed the term ‘Executive’ to ‘Government’. Also in 2007, the individual departments of the Scottish Executive were re-aligned into directorates. The Scottish Executive Health Department (SEHD) was subsumed with the new Scottish Government Health Directorates (SGHD), responsible for NHS Scotland.

The legacy of such historic ‘rebel’ association is evident by the continuing debate over the association between tattooing/ cosmetic body piercing and wider risk taking behaviours. Findings from such research however have been mixed: Forbes (2001) reported those with body modifications engage with other risk-taking behaviours. Conversely, Freyenberger (1998) found tattooed students to be higher academic achievers with very little risk-associated behaviour.

Recognising that those working within the industry have often been accepted and indoctrinated into the industry through their personal engagement in it (Kuwahara, 2005), such interpretations could be utilised within policy development to maximise the potential for public health improvement. Resultantly, it has been suggested that understanding those who engage in tattooing and cosmetic body piercing activities, why they choose to do so, and how this correlates with engagement in wider risk-taking behaviours may yet offer a degree of understanding of the level and scope of risk prepared to be taken during the process of being tattooed or pierced (Chalmers, 2009b).

### 1.3.2 *Inherent risk from tattooing and cosmetic body piercing*

As invasive procedures<sup>3</sup>, there can be no doubt that tattooing and cosmetic body piercing pose inherent risk to health from both local and systemic infection. This inherent risk to health and associated infection risk must however be tempered with the realism and acknowledgement that actual risk of infection is minimal when tattooing and/or cosmetic body piercing is carried out under appropriately aseptic conditions (Denton, 2001; SEHD, 2001). Mayers, Judelson, Moriarty and Rundell (2002) inferred the existence of such good practice within the tattooing and cosmetic body piercing industry when they reported no complications from tattoos in their study of university undergraduates. Equally, Braverman (2006) reported that as of 2000, there were no proven cases of human immunodeficiency virus (HIV) infection from US commercial establishments.

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<sup>3</sup> An invasive procedure is defined generally as a medical procedure that enters (invades) the body by cutting or puncturing the skin or by inserting instruments into the body. Tattooing and cosmetic body piercing are considered invasive procedures through due process of piercing or puncturing skin or mucous membrane.

Similarly, the Centers for Disease Control (CDC) argue that although some studies have found an association between hepatitis C and hepatitis B in selected populations, it is difficult to generalise these data to the general population, concluding there is currently no data to suggest tattooing or cosmetic body piercing alone places a person at increased risk from these blood borne viruses (CDC, 2006).

Local and systemic infections associated with tattooing and cosmetic body piercing (including the transmission of blood-borne virus infection) are however documented in the medical literature, with several outbreaks reportedly linked to non-sterile tattooing procedures (Scottish Centre for Infection and Environmental Health (SCIEH), 1998; Ghorpade, 2002; SCIEH, 2003a; SCIEH, 2003b). This evidence, coupled with related costs (Steedman & Younossi, 2000; Steinbrook & Drazen, 2001) have led researchers to conclude the association between infection and tattooing/cosmetic body piercing is not new and as such cannot be ignored (Tweeten & Rickman, 1998; Makkai & McAllister, 2001; Ghorpade, 2002). This will be explored in greater detail as a theme within the literature review chapter of this work.

Adding further to this debate is to recognise that tattoos and cosmetic body piercings take time to heal. Some take many weeks or months, during which time the hygiene and infection control practices of the practitioner are only two of many factors impacting upon the potential for infection. The possible attribution of local infection to inadequate care of the tattoo or piercing is very much under-researched (Armstrong, 2005; Venta, Lakoma, Haahtela, Peltola, Ylipaavalniemi & Turtola, 2005). Likewise, the responsibility of the client to heed aftercare advice and the role this may play in any reported infection is not a significant feature of the published literature (Armstrong, 2005). To this end, Venta et al. (2005: 549) argue:

*“although piercings are associated with complications in the initial phase as well as later, these implications are necessary side-effects that belong to the self-care process.”*

### 1.3.3 Management of tattooing and cosmetic body piercing

The growth in public interest and diversification of tattooing and cosmetic body piercing within and across mainstream society has fuelled debate on the level of legislation and control over industry practices. Questions over the acceptability of approaches, and calls for tighter control over industry practices have been met with mixed reactions: Some believe those who engage in activities such as tattooing and cosmetic body piercing, either as practitioners or recipients, should simply be left to get on with it (Ferguson, 1999), and for much of history, this has indeed been the case. Likewise, pockets of practitioners promoting good practice, forming associations and interest groups, and contributing to the development of guidance and codes of practice have always been around. More generally however, this has been an industry traditionally controlled and managed by unlicensed and almost wholly unregulated personnel. Armstrong and Kelly (2001: 13) aptly summed up the level of responsibility, accountability and scrutiny typically experienced by the tattooing and cosmetic body piercing industry when they described it as “*an artist-customer regulated business*”. Others, concerned with risk to health have called for tighter industry controls, focusing their arguments almost wholly on the need to manage infection risk (Anderson, 2006; Noah, 2006).

Extract from reflexive journal, 28<sup>th</sup> June 2007

*I have spent the last few days at the Annual Public Health Conference, where I took the opportunity to explore my thoughts with fellow health professionals. Having highlighted the risk to health posed by tattooing and cosmetic body piercing as a driver for the introduction of regulation, I was challenged to defend this position with evidence. Reflecting upon this, I realised the danger I face in coming to this work with a biased view if I failed at this stage to establish the evidence base to support the claim. I need to complete my literature review....and to begin to differentiate between types of risk to health – inherent (due to the nature of activities), potential, perceived, actual, real..all these words are used in the literature to describe risk.*

While self-regulation remains an entrenched part of the global industry, widespread review of self-management approaches at international levels have led to a favouring of greater ‘state-control’ and a western society predilection towards tighter control.

Proclaiming to offer public protection through systems that monitor and control practice, the trend towards state-management in recent years has been particularly evident in the United States of America (USA). This is attested to in the writing of Armstrong (2005: 39-40), who cites the work of Goldstein (1979), Stauter (1989) and Tope (1995) when she writes of USA:

*“Over the past 25 years, there have been many documented changes nationwide to the regulations regarding body art, especially tattooing.*

*In 1979...only three states had standards or inspections in their regulations, and seven states prohibited tattooing...many states (n=36) did not report any statutes of any type, although 10 of those states reported local tattoo ordinances in their larger cities.*

*By 1989, 16 states had statutes of some form, requiring either licensing of the studio or licensing of the artist, while 31 states and the District of Columbia still did not have regulations.*

*As of September 2003, 34 states have regulations for both tattooing and body piercing. 39 states for tattooing only, and 35 states specifically for body piercing...While the language varies, state-wide regulations commonly address the definition of body art, the procedures needed for sanitation and sterilization, procedures for single use items, competency requirements for personnel, infection control, client records and retention, preparation and care of the body art area, and the enforcement measures and prohibitions related to the services.”*

Similarly in Australia, by 2002, all States and Territories regulated, in some form, invasive body art (which includes tattooing, body piercing and branding): Although differing across each State/ Territory, the principle of minimising risk of blood borne infections through provision of basic infection control standards has been applied to all services carrying out skin penetration procedures or infection risk procedures (National Public Health Partnership (NPHP), 2002). Around this same time in New Zealand, there was no dedicated legislation in respect of body art. Local Government enforcement of the Public Health Act could be applied, along with general consumer safety legislation and the use of guidelines on safe practice. It was expected that review of the Health Act might see the development of regulation, but to date, this has not happened.



Within the European Union (EU), member states' approaches to managing tattooing and body piercing industries range from no specific regulation; draft regulation; ageing regulation; and new regulation – covering a variety of definitions, activities and provisions (Papameletiou, Zenie & Schwela, 2003). The United Kingdom (UK), as a EU member state, makes use of the Local Government (Miscellaneous Provisions) Act 1982. This gives local authorities in England and Wales powers to demand registration of skin piercing businesses. Additionally, London has authority under the London Local Authority Act 1991, to regulate skin piercing businesses through licensing and inspection. In 2003, it was written:

*“The UK Government intends to introduce legislation, if Parliamentary time allows, to give local authorities outside London and in Wales specific powers to regulation cosmetic body piercing and micropigmentation businesses.*

*This would be done by an amendment to the Local Government (Miscellaneous Provisions) Act 1982. Many and perhaps most cosmetic body piercing businesses also carry out tattooing or ear piercing, which local authorities outside London do have powers to regulate. Local authorities, therefore, have the opportunity to work with businesses also offering cosmetic piercing to promote safe and hygienic practices”.*

(Papameletiou, Zenie & Schwela, 2003: 24)

Subsequently, in April 2004, a Local Government Act 2003 on the regulation of cosmetic piercing and skin-colouring businesses came into force in England and Wales: An amendment of the Local Government (Miscellaneous Provisions) Act 1982, it specifically related to persons operating cosmetic piercing and semi-permanent skin-colouring businesses, and supplemented already existing byelaws for acupuncture; ear-piercing; electrolysis and tattooing. Furthermore, it offered local authorities the option to implement locally (Department of Health (DH), 2004).

Scotland's approach at that time could, in many ways, be considered as a consolidation of available legislation from across the EU and UK, with Local Authorities relying, at the start of the 21<sup>st</sup> century, on general health and safety legislation (in the case of Scotland, this being the Health and Safety at Work Act 1974).

This legislation placed a duty upon employers to protect the health and welfare of employees and clients by ensuring '*as far as is reasonably practicable, that persons not in his employment who may be affected are not exposed to risk to their health and safety*'. It also provided enforcers with authority to serve notice on businesses considered a risk to clients or operators (McRae 2003: 18). Other related and supporting legislation in Scotland at that time included the Prohibition of Female Circumcision Act 1985 (noted earlier to be superseded by the Prohibition of Female Genital Mutilation (Scotland) Act 2005 and making it an offence to excise, infibulate or otherwise mutilate (or assist in excising, infibulating or otherwise mutilating) the whole or any part of the labia majora, labia minora or clitoris) and the Tattooing of Minors Act 1969 (making it an offence to tattoo a person under the age of eighteen unless medically prescribed and performed).

The appropriateness of this level of legislation came under formal consideration when, in January 2001, the Scottish Executive Health Department (SEHD) launched a consultation paper on the management of skin piercing in Scotland. Entitled 'Regulation of skin piercing: a consultation paper' (SEHD, 2001), it covered skin and body piercing, and presented a balanced, if somewhat unevidenced account of the differing risks associated with hygienic and unhygienic skin piercing and tattooing practices. Making specific reference to infection and other complications (such as deformity, scarring, bleeding, embedding of jewellery and allergy), the absence of a sound evidence base led some to subsequently question the appropriateness of risk to health/associated risk to health as a sound rationale for tightening control over industry practices (Chalmers 2009b; 2009c). At the time however, this did not deter key stakeholders involved in consultation, who responded overwhelmingly in favour of more stringent measures to govern such practices. The majority supported mandatory licensing or new primary legislation (Walters, 2001).

The focus on 'risk to health' continued into the analysis of written submissions to the consultation (Walters, 2001: 4), stating "*the consultation document identified a number of risks arising from skin and body piercing which justified the consideration of strengthening existing controls*" and positing that more stringent measures "*should be effective in minimising related health risks...by ensuring only those practitioners willing and able to practise safely remain in practice*" (Walters, 2001: 52). In June 2003, in response to the findings from this consultation, Ministers of the Scottish Executive approved plans for the introduction and content of Regulations under section 44 of the Civic Government (Scotland) Act 1982 relating to mandatory local authority licensing of businesses offering tattooing and skin piercing services across Scotland (Robertson, 2004). A draft Order was subsequently published on mandatory licensing supported by monitoring and non-compliance penalties, with a requirement for written parental consent for piercing of children below the age of 16 years.

Thereafter, the Order came into effect on 1<sup>st</sup> April 2006, with a transitional period of 12 months for existing businesses to ensure they met its requirements (HPS, 2006). This Order considers skin piercing to include acupuncture, cosmetic body piercing and electrolysis. Tattooing (both permanent and semi-permanent) includes micro-pigmentation (See Appendix 1). Since April 2006, a number of amendments have been agreed, these coming into effect in December 2006. In addition, a working group was set up to consider implementation of the Order as well as to prepare a set of standard National Conditions and guidance document for local authorities (Scottish Licensing of Skin Piercing and Tattooing Working Group (SLSPTWG), 2006; 2007). Complimenting the Order, both were launched in February 2007 (See Figure 1.1).

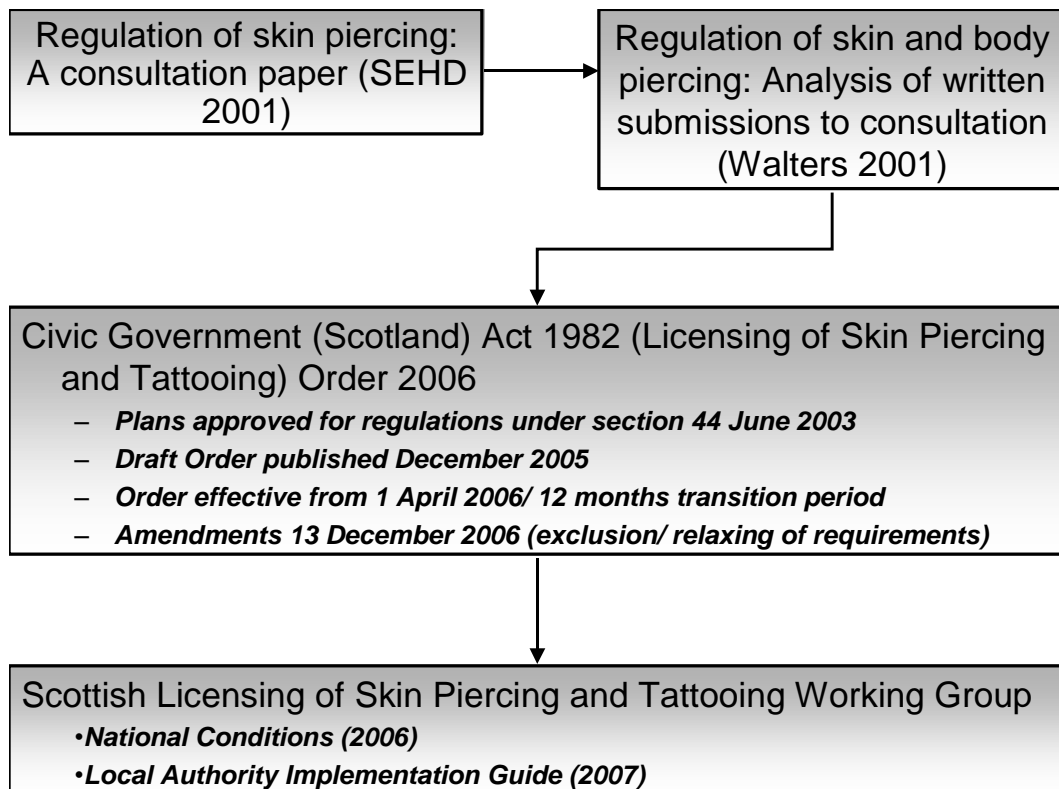


Figure 1.1: Summary of Process towards Regulation

From the evidence presented, it is notable that the approach taken to manage the tattooing and cosmetic body piercing industry's activities in Scotland mirror much of the global community, where widespread review of self-management approaches have led to a favouring of state-controlled regulation. To date however, Scotland has not followed the global direction in its approach to blood donor management from recipients of tattooing and cosmetic body piercing. While the USA and some parts of Europe no longer apply an annual exclusion from donating blood for persons tattooed or pierced in a state regulated/ licensed studio, Scotland continues to enforce its one-year exclusion period despite the implementation of regulation (Scottish National Blood Transfusion Service (SNBTS), 2010). This has the potential to impact considerably on available blood supplies. If tighter controls are to be utilised to their fullest potential, downgrading of such restrictions would seem appropriate (Chalmers, 2009b). Such action does however require confidence in the effectiveness of the regulatory process.

Two factors with the potential to limit confidence in the regulatory process are education/training and communication: Improvements to technology and equipment, and the emergence of new artists with both artistic and technical skills have arguably led to a better quality service for clients (Chalmers, 2009b). This does however remain an industry operating, on the whole, with a 100% practice-based apprenticeship model of teaching and learning, this capable of affecting the quality of practice within the tattooing and cosmetic body piercing industry. The need to identify an appropriate qualification was muted during the 2001 consultation process (SEHD, 2001), and has been progressed to some extent by the implementation of regulation in Scotland, with the Order setting out the requirement of the licensing authority:

*“...when determining whether the applicant is a fit and proper person to be the holder of the license, shall have regard to the knowledge, skill, training and experience which the applicant can demonstrate in relation to the activities which are to be carried out”*  
(SEHD, 2006a: 4)

This requirement is further re-iterated in both the National Conditions and Local Authority Implementation Guide (SLSPTWG, 2006; 2007). However, with no recognised qualification, certification or mechanism to assure competency, and an absence of any bona fide insight into industry practices at local or national levels pre-regulation, real dilemma presents for those required to meet or enforce tighter controls that demand evidence of educational attainment.

In terms of communication, scrutiny of the consultation distribution list (SEHD, 2001) suggests relevant parties were offered opportunity to engage in the debate over need for tighter controls at an early stage. However, there is no indication of how the distribution list was established and subsequently no way to assess its robustness. Furthermore, no evidence can be found of a dissemination strategy to ensure the findings from consultation were shared with the industry, wider professional groups and the public. Indeed, very few public communications can be traced through governmental sources or via the media during the period between consultation (2001) and implementation (2006).

One available press release encapsulates the potential impact of poor communication on effective implementation of the Order. It includes comment from a Royal Environmental Health Institute for Scotland (REHIS) Health and Safety spokesman, who states, almost one year on from implementation of the Order:

*“I firmly believe that many operators don’t even know that licensing has been introduced, and I would urge them to contact their Environmental Health Department immediately”*

(Chartered Institute of Environmental Health, 2007: 1)

Despite the apparent dubiety over the strength, breadth and communication of evidence claiming the need to tighten control over tattooing and cosmetic body piercing practices, regulation of the tattooing and cosmetic body piercing industry in Scotland has been invoked through the Order since April 2006. Given this apparent dubiety, the ability of the Order to effect a reduction in risk to health remains open to debate (Chalmers, 2009b; 2009c).

#### **1.4 The concept of regulation**

Regulation is considered as a set of rules that aim to monitor standards through a range of voluntary or compulsory means, sometimes under statute and either with or without a component of enforcement (Baldwin & Cave, 1999). In the broadest sense, it is widely accepted that appropriate regulation is both necessary and beneficial, providing protection to businesses, organisations and their clients; promoting sector confidence; and assuring effective delivery of services (Bolton, 2004). Lord Haskins, former Chair of the Better Regulation Task Force (BRTF) noted:

*“Good regulation is a symptom of an affluent and just society, because it is designed for the protection and enhancement of citizens’ rights....Bad regulation occurs when the state, in response to the demands of pressure groups, designs regulations which are over ambitious, over prescriptive, unjustifiably expensive and counterproductive”* (BRTF, 2005: 8)

The quality of proposed or existing regulation can be assessed using the five principles of good regulation: proportionality; accountability; consistency; transparency and targeting (BRTF, 2000). Failure of any regulation to meet each principle should lead to corrective action. In addition, regulation requires to be monitored for ongoing fitness for purpose and effectiveness once implemented.

To be effective, regulation should be responsive to the diversity within and across organisations. The inflexible approach of treating everyone alike should be replaced with more openness and adaptability, conditional to the outcome of previous experiences. This then requires that regulatory enforcers forge working relationships with the organisations they regulate, making available and using a wide range of interventions. Effective regulation also requires that enforcers are independent and accountable, to ensure maintenance of credibility and retention of an ability to act impartially (Walshe, 2002).

Specifically, risk regulation is concerned with control of risks. Here risk is defined as “*the probability that a particular adverse event will occur during a stated period of time, or result from a particular challenge*” (Royal Society, 1992, cited in Baldwin & Cave, 1999: 139). Aiming to control (but not eliminate) risk, it must reduce risk to an appropriate level if it is to be considered effective. Effective risk regulation is that considered capable of reducing risk efficiently (flexible and responsive) and accountably (fair and open). Various types of regulation exist.

*Self-regulation* involves a distinct group of people following or bound by a set of mutually agreed rules developed by those directly involved. Self-regulation offers an opportunity to reflect the needs of the sector to which the regulation applies, engendering a sense of ownership, and creating a climate for greater compliance. Often quicker to achieve than statutory regulation, it can be easily updated to reflect change. Offering a more straightforward means of recompense, it can also harness common interest, in respect of industry reputation and relationships.

Self-regulation is not without problem. For example, not everyone will understand how self-regulatory processes operate, nor will everyone within a self-regulated environment operate appropriately. This can provoke loss of confidence in the ability of self-regulation to protect clients and/or consumers, or deterioration of practices towards the lowest common denominator (BRTF, 1999; Ipsos MORI, 2007).

*State-controlled regulation* on the other hand (sometimes referred to as prescriptive state regulation, command and control regulation or classic regulation) is defined as “*the exercise of influence by imposing standards backed by criminal sanctions*” (Baldwin & Cave, 1999: 35) and involves passing of laws telling people what to do or not do. These rules are invoked either as primary legislation (that is, through an Act of Parliament) or as secondary legislation. The Better Regulation Commission (2006) argue this type of regulation is a very traditional attempt by the state to change behaviour, often in light of a need to address a problem (such as a health risk) or following a serious incident/significant event. Applying to everyone within scope, state-controlled regulation provides a framework from which to create a level playing field. Information, support and time all assist compliance, but consistent and effective enforcement is required to achieve full effect. Like self-regulation, state-controlled regulation is not without a downside. This approach can be costly to implement and enforce, standards can be open to interpretation, and as a result, invites non-compliance (Ipsos MORI, 2007).

Enforcers of state-controlled regulation may subscribe to one of two key regulatory approaches – deterrence or compliance, or indeed a combination of these. From the deterrence paradigm comes the assumption that those being regulated are untrustworthy and self-interested, and that strict enforcement is required to secure compliance. The compliance paradigm considers those regulated to be well-intentioned, and work to secure compliance is undertaken in a much more supportive manner (Walshe, 2002; Yapp & Fairman, 2005:2006).



## 1.5 Regulation within a range of strategies designed to reduce risk

In the knowledge that construction of risk varies according to many factors (such as social situation, status, role models and cultural norms) (Naidoo & Wills, 2005), regulation was only one of a number of policy options available to the Scottish Government to address concerns over risk to health from tattooing and cosmetic body piercing activities.

Extract from reflexive journal, 17<sup>th</sup> September 2010  
*From this week's supervisory discussions, the categorisation of strategies that aim to reduce risk need to be revisited – having originally categorised these options into three - measures to encourage change at individual levels (such as public information campaigns); measures to enable change at population level (such as taxation); and measures to restrict activities (such as regulation), it is true that regulation has indeed been considered a restrictive measure, when in fact it might well be enabling to some.*

Broadly, the options available can be categorised as interventions seeking to reduce risks to whole populations and those which target individuals. Measures to encourage change at individual levels often involve personal interaction with a health provider, such as one-to-one counselling. Activity such as public information campaigns are also at individual level, and often, both counselling and campaigns are used simultaneously.

Regulation is a population-level intervention. So too are awareness raising campaigns, legislation (such as banning or fining) and incentive structures such as taxation (WHO, 2002; 2008). The introduction of safety belts in motor vehicles, the provision of piped water and health promotion campaigns targeting the general population are all examples of population-level measures, working to alter the context within which health behaviour is produced. WHO (2008) argues that the potential to achieve population-wide reduction in risks to health has not as yet been realised. Rose (1992: 102), a supporter of population-based approaches to reducing risk to health argues:

*“It makes little sense to expect individuals to behave differently from their peers; it is more appropriate to seek a general change in behavioural norms and in circumstances which facilitate their adoption.”*

The decision to focus interventions at population or individual level takes cognisance not only of personal preference but also the issue of cost-benefit. For example, focusing on 'high risk level individuals' may reduce costs at a population level, but consideration must be given to the cost of identifying those individuals likely to benefit – and to do so may incur high costs. While focusing on interventions at individual level can be a cost effective way of impacting on population level health, the most cost effective approach will often be contextual, coupled with the prevalence of high-risk/risk-taking persons within the given population, the costs of identification and the costs of any planned intervention. Jochelson (2005) argues that while population based approaches on their own do not persuade people to behave differently, complementary education and information programmes, together with time, can progressively lead to a change in attitude, behaviour and social norm. As such, whichever approach is adopted, most interventions aimed at reducing risk to health involve an element of behaviour change, and so apply behaviour change theory.

## **1.6 Behaviour change theory and public policy decision-making**

The behavioural change theory that underlies much of the decision making around which approach to adopt within public policy is rational choice theory. This assumes people seek to maximise their own welfare, assessing their choices from a cost-benefit perspective and selecting the option that maximises net benefit. Traditionally, policy tools follow from this theoretical stance, recognising individuals can contribute to their own health and wellbeing by adopting health-enhancing behaviours or avoiding health-compromising behaviours (Conner & Norman, 2005).

Since the mid-1980s, a range of disciplines have focused their research efforts on identifying factors which underlie health behaviours, endeavouring to better understand the reason behind performance of individual behaviours, developing models to reflect their findings and thereafter designing interventions to affect the prevalence of such behaviours. While the aim has been to improve health at both individual and population based levels, to date research findings have been considerably varied.

What has become evident is that the ability to predict and understand who performs health behaviours contributes to understanding the varying distribution of health across society. Equally, such awareness enables the design of interventions targeted at specific health behaviours. From this work, distinction has been made between factors intrinsic to the individual and factors extrinsic to the individual.

#### *1.6.1 Factors intrinsic to the individual*

Factors intrinsic to the individual (sociodemographic factors, personality, social support, cognitions) have been studied with great interest, and a number of variables have been associated with health behaviour – accessibility to health care services; attitudes to health care; perceptions of disease threat; disease knowledge; social network characteristics; and demographic factors. Cognitive factors (beliefs, attitudes, knowledge) have however been the dominant focus, argued by some to be the most important determinants because of their capability to mediate the effects of other determinants and also because they are considered more open to change than other factors (Conner & Norman, 2005).

Social cognition models (models of how cognitive factors produce behaviours) have been developed and extensively applied to the understanding of health behaviours. These have contributed to a greater understanding of who performs health behaviours and how extrinsic factors may produce behaviour change. Conner and Norman (2005) suggest two broad types of social cognition model have emerged to explain health behaviours: The first of these they purport are the attribution models (such as the self-regulation model by Leventhal), concerned with individuals' causal explanations of health-related events. Work within this field focuses on how people respond to serious illness, illness representation and illness perception. Conner and Norman (2005) purport the second of these as models which examine cognitions, the intent being to predict future health-related behaviour/outcomes, and including the work of, for example, Becker, Ajzen & Fishbein and Bandura. In addition are those which focus on behaviour change through stages of change (such as the work of Prochaska & DiClemente).

Underpinned by the theory of rational choice, these social cognition models emphasise the rationality of human behaviour. Predicted health behaviour is considered the outcome of rational decision making, based upon deliberate and systematic processing of available information. In addition to their roots in rational choice theory, they are considered also to have foundations in Peak's expectancy value theory and Edwards' subjective expected utility theory, where it is assumed individuals prefer behaviours associated with the highest expected utility, and choose behaviours to maximise benefit. Allowing for subjective assessment of probability and utility, the assumption is that assessment is determined in a rational, consistent manner (Conner & Norman, 2005).

The main social cognitive models have however been criticised for the considerable overlap in constructs, bounded by the claim that differences can be attributed to labelling rather than underlying construct (Cummings, Becker & Maile, 1980). It has however been counter-argued that any overlap is evidence that the key social cognitions have been correctly identified. Building upon this argument, an integrated approach has been explored to create the "major theorists" or integrated model of behaviour (Noar & Zimmerman, 2005). Despite its lack of empirical testing, and failure to detail relationships between the key constructs, it does incorporate the main constructs of the foremost social cognitive models. It identifies eight variables as accounting for most of the variance in behaviour: Grouped into two, these are viewed as variables necessary for behaviour to occur (intention, skills and absence of environmental constraints) and variables which influence intention (perception of cost-benefit, social pressure, self-efficacy, emotional reaction and self-discrepancy) (Conner & Norman, 2005).

Over recent years, social cognition models have been increasingly utilised to develop interventions to change health behaviours. Arguably, they offer a mechanism to target interventional work on the basis of variables considered predictable and susceptible to change. While this has been welcomed, a number of unresolved issues remain.

Acknowledging that people do engage in health-risk behaviours, users of social cognitive models and approaches to health behaviour change recognise the limited predictive power of these models in respect of health-risk and health impairing behaviour. Gibbons and Gerrard (1995; 1997) (cited by Norman & Conner, 2005) endeavoured to address this issue, to the point of developing the willingness model. Using the model, they provide account of health-risk behaviour in young people, postulating that such behaviours are a reaction to a social event and as such are unintentional and unplanned. Also, it is argued that social cognition models do not account fully for the influence of past behaviour. Furthermore, their focus on initiation of behaviour means they do not offer the best understanding of factors determining maintenance of health behaviour. Where this has been explored, the findings have been mixed, so disputing whether the same or different factors are important in decisions associated with initiation and maintenance of a given health behaviour (Norman & Conner, 2005). Indeed, the World Health Organisation (2008: 2) notes:

*“Such models have been more successful in explaining or predicting behavioural intentions, the commonest primary end point of most efficacy or effectiveness trials, rather than in delivering better health outcomes, a rare endpoint for measuring true effectiveness”.*

Despite such varied outcomes, social cognitive models are increasingly utilised to inform the development of interventions aimed at changing behaviour en route to reducing risk to health. With the evidence of effectiveness of these interventions mixed, the full potential of social cognition approaches to predict and promote behaviour change remains unclear. Meantime, the somewhat over-exclusive approach to their use has the potential for neglect of other behaviour predicting constructs, and other potentially effective interventions associated with extrinsic factors such as incentive structures and legal restrictions (Norman & Conner, 2005).

### 1.6.2 *Factors extrinsic to the individual*

Government interventions based on factors extrinsic to the individual, such as regulation and taxation have a long, successful yet tumultuous history. Debate over the role of government in behaviour change has been longstanding, often ensuing between the extremes of interventionists and libertarians: Libertarians argue on one hand for the protection of individual freedom and view minimal government intervention as best, while on the other hand interventionists argue governmental interventions create opportunities, give consideration to inequalities and ultimately promote freedom (Jochelson, 2005). Either way, Jochelson's notion that state intervention does not in itself change behaviour and that time plays a part in attitudinal change is borne out when one reviews some historical trailblazing applications.

For example, in 1848, when local government was made responsible for water and sewage systems through the first British Public Health Act, opposition was founded on the notion that government intervention was paternalistic. So strong was this sentiment that opponents equated the intervention to slavery (Porter, 1999). Equally, when the Licensing Act of 1872 restricted public house opening hours and banned children from such premises, drinking establishments reputedly viewed this as an attack on private property (Jochelson, 2005). More recently, it took over ten years to implement the mandatory wearing of seatbelts in 1983, during which time members of parliament (MPs) fractiously debated against the legislation on the basis it restricted drivers' freedom of choice (Leichter, 1986). Indeed similar arguments were proffered during the preparatory stages of legislation to ban both smoking in public places (Scottish Executive Health Department, 2005), and now in the debates over minimum alcohol pricing (Christie, 2009).

Today, few people contest the individual and population level benefits of clean water and air. Although some of the more recent legislative measures could be considered "*personal choice*" (Jochelson, 2005; 5), few dispute the resulting societal gain.

Despite this, public and professional views on governmental intervention in health issues, behaviour change and reduction of risk remain ambivalent. Mixed views over the role of government in influencing individuals' health behaviour persist, debating the position of government as intrusive or enabling; nanny statist or stewardship; protective or limiting; with the people or to the people (Wanless, 2004; Jochelson, 2005). While some support government intervention when the intent appears to serve the interests of wider societal public health and where control of the particular issue is beyond individuals, others simply regard any governmental involvement as interference and unnecessary intrusion. For yet others there is a more balanced approach to these two extreme views, recognising the need for rules to protect the collective from the individual, but accepting that people have the right to take risk and expose themselves to harm so long as the behaviour does not impact on others (Wanless, 2004; Jochelson, 2005).

Notwithstanding the disparity of views, ongoing support for, and use of regulation/legislation (such as banning or fining) and incentive structures such as taxation have not waned. UK and Scottish Government reports set out their intention to continue using such structural approaches to facilitate informed health and lifestyle choices, acknowledging the need to balance between the dichotomous states of paternalism and inaction (SGHD, 2007a; 2007b; 2010a; 2010b; Wanless, 2004). Indeed, the recent introduction of legislation to ban both smoking in public places in Scotland (SEHD, 2006b), and the decisions to regulate activities such as skin piercing and tattooing (SEHD, 2006a) and sun bed usage (SGHD, 2009) demonstrate the Scottish Government's fervour for this as an effective way to change health behaviour and manage risk to health.

## 1.7 Justifying intervention to reduce risk to health

In light of the evidence above, any decision to implement an intervention aimed at reducing risk to health should not be made without prudent deliberation. To assist in such decision-making, the World Health Organisation (2008) suggests intervention must be founded on the premise that the targeted behaviour is a causal risk factor. Equally, its potential to reduce risk must be sufficiently high to justify intervention. To establish this, they urge consideration of available evidence on past performances of an intervention, its effectiveness in changing the targeted behaviour and whether it achieved the anticipated outcome.

Determining behaviours as causal factors is not however a straightforward process. Time and again governments have faced the predicament of whether causality has indeed been established (Donaldson & Donaldson, 2003). While it is often true that an association may have been found between a risk factor and an adverse health outcome, evidence to determine if the association is or is not causal may not be available. Despite this, there is often an expectation from the public that government/professionals will respond immediately, and at some point, a decision has to be made on the appropriateness of instigating an intervention aimed at reducing risk.

Ideally there would be a high-quality assessment of scientific evidence and relevant supplementary research to inform any such contemplation. In practice however, public concern or media pressure may be so great that early action without this level of supporting evidence is deemed the best and only option (Donaldson & Donaldson, 2003). Debating over the 'if and when and how' to manage a given health risk has led to the emergence of the use of the 'precautionary principle' (Inter-departmental Liaison Group on Risk Assessment (ILGRA), 2002). This asserts that action to protect public health should be taken to reduce or control risk "*in the meantime*", with the precautionary principle described as:

*"...essentially a judgement which must be applied in situations of scientific uncertainty where the postulated risk is serious and where action is being contemplated before the results of further research or investigation is to hand".*

(Donaldson and Donaldson, 2003: 456)



Whether applying the precautionary principle or not, open and transparent communication about health risk and the status of scientific evidence to back claims of risk are essential. This supports effective, efficient and sustainable implementation of any intervention, and avoids loss of public trust (ILGRA, 2002; Donaldson & Donaldson, 2003).

Equally, establishing the potential of an intervention to reduce risk, and present evidence of its effectiveness is not always easy. Re-visiting the comment of Jochelson (2005), historically, the ability of interventions such as regulation, legislation and taxation to change attitudes and social norm over time vary in their degree of effectiveness. In fact, genuine difficulties exist in demonstrating true cause and effect across periods of socio-economic, political, environmental and cultural change (Jochelson, 2005). In the face of such difficulty, justifying the implementation of an intervention can be considered in a wider sense. While its success depends upon whether and to what extent it secures a reduction in risk to health, its effectiveness can be determined on the basis of targeting, coverage and compliance (WHO, 2008). Accurate population targeting and the extent of population coverage relate to the design and implementation of the intervention. Compliance is deemed more complex, involving both provider and recipient of the intervention, and determined by a range of behavioural and environmental factors (WHO, 2008).

### **1.8 Regulatory compliance**

Generally speaking, compliance is about doing what is asked. Achieving regulatory compliance is therefore associated with conforming to the law (Fairman & Yapp, 2004). Risk regulation was noted earlier as aiming to control risk, where risk was defined as “*the probability that a particular adverse event will occur during a stated period of time, or result from a particular challenge*” (Royal Society, 1992, cited in Baldwin & Cave, 1999: 139). Baldwin, Hutter and Rothstein (no date: 46) however question the ease of defining risk in this way, on the basis that risk definitions and indeed risk tolerability change with time and circumstance.

Resultantly, they argue that as the definition of risk and risk tolerability change, “*what constitutes compliance is (also) subject to negotiation and change*”. This concurs with Edelman, Petterson, Chambliss and Erlanger (1991) who seek to emphasise compliance not simply as an event but as a process. From this perspective, achieving and securing compliance can thus be viewed as both immediate and/or longer term (Hutter, 1997). In contrast, Lange (1999) considers compliance as a formal concept that compares the conduct of the regulated against a formally defined legal requirement. From this stance Lange (1999) argues that viewing compliance as a negotiated process is constructed and flawed, too far removed from its official intent.

The debates over compliance as a process or event, prescribed or negotiated, serve to highlight the difficulties faced by those endeavouring to achieve and secure compliance. Yeung (2004) has further contributed to this debate by questioning the clarity of the term ‘regulatory compliance’, observing its use by some to refer to rule compliance (compliance with regulatory standards) and by others to refer to substantive compliance (compliance with the collective regulatory goals). The significance of such paradox is emphasised through the phenomenon described by Yeung (2004: 11) as:

*“creative compliance.... whereby technical compliance with rules may be achieved yet the underlying spirit and purpose of those rules might be simultaneously undermined”.*

From this perspective it is possible to achieve compliance without the intended reduction in underlying risk. In such instance, the link between compliance and risk reduction becomes somewhat tenuous. Reflecting upon appropriately focused and targeted regulation as measures of effectiveness, the fragility of this link is further accentuated, for under-inclusive regulation will not tackle all those generating the risk, while over-inclusive regulation may halt engagement. Both potentially lead to compliance without risk reduction (WHO, 2008).

In judging compliance, Yeung (2004: 11,12) offers differential terms to assist clarity of meaning, suggesting “*regulatory implementation*” as actions to secure substantive compliance, and “*regulatory enforcement*” as actions to secure rule compliance. Furthermore, Baldwin, Hutter and Rothstein (no date: 49) suggest compliance can be judged on a range of criteria, and across differing levels (organisation and individual), including:

*“organisation’s commitment to regulatory objectives ...attitude to compliance...record of compliance...quality of management ...ability to comply...treatment of staff... (and) size”*

From amidst this plethora of criteria and differential terminology, the complexity of compliance as diverse in meaning and dynamic in nature emerges (Hutter & Amodu, 2008). Considered practically, this is the starting point for businesses faced with the responsibility of responding to and complying with new regulation.

## **1.9 Chapter 1 summary**

The chapter began by briefly outlining the history of tattooing and cosmetic body piercing, setting in context the background from which these activities emerged into mainstream society. Demonstrating the global shift in approach to industry management from self to state-controlled regulation, it has shown how Scotland’s approach to management of tattooing and cosmetic body piercing activities reflects wider western society. The use of regulation as a mechanism to control risk to health was cited within the range of strategies designed to reduce risk. Categorised as those seeking to reduce risks to whole populations and those which target individuals, all involved an element of behaviour change, and so the concept of behaviour change was appraised.

The chapter also introduced the notion that if regulatory intervention is to be justified, its effectiveness must be demonstrated. Amidst difficulties of establishing targeted behaviours as causal risk factors, and limited evidence of interventions’ past performance in changing targeted behaviours/achieving anticipated outcomes, regulatory compliance was offered as an approach to understanding regulatory effectiveness and ascertaining risk reduction.

The complexity of compliance in terms of meaning and nature was however emphasised. Moreover, the practical implications this has for businesses in determining their response to regulation has been alluded to. Before drawing the chapter to a close, an overview of the structure and organisation of the remainder of this thesis will be presented. It serves to signpost the intended approach and direction of this work.

#### *1.9.1 Structure of thesis: signposting the intended direction of the work*

Chapter 2 – ‘Review of the literature’ will build from the introductory content of Chapter 1, to provide a systematic review of the associated literature on regulatory compliance and the tattooing and cosmetic body piercing industry. Beginning by addressing how the literature review is organised and outlining its broad content themes, the planned methods for searching, assessing and synthesising the literature will thereafter be detailed. Finally, systematic reviewing of the literature will detail search outcomes, appraise the content and methodological quality of those studies included and draw conclusions following synthesis and interpretation of findings. From this literature review process, the intent and rationale for this study will be presented. Finally, the research questions and study objectives, along with the scope of this study will be outlined.

Chapter 3 – ‘Conceptual framework’ will build from the conclusions of the literature review undertaken in Chapter 2. Identifying the compliance process model as the theoretical foundation for this study, it will detail its development and evolution. The chapter will continue by demonstrating how this theoretical model has been used to develop this study’s conceptual framework, situating it within the context of regulatory implementation and utilising it as a mechanism to determine the extent of compliance.

Chapter 4 – ‘Study design and methodology’ provides detail of the proposed design and methodology for this study, where the intent is to determine the extent of regulatory compliance with the Order within the tattooing and cosmetic body piercing industry in Scotland. It begins by reflecting upon personal beliefs and values and how these have influenced methodological decision-making.

The chapter continues by clarifying the definition of methodology utilised within this thesis. Rationalising the decision to design this study as concurrent mixed methods, it will detail pragmatism as the philosophical worldview underpinning the study and explore how pragmatism as a worldview fits with the decision to utilise a mixed methods study design. Finally, an overview of the design and research methods will be detailed, incorporating the study intent and research questions.

Chapter 5 – ‘Results and individual analyses’ begins by outlining the process of preparing and exploring the connected qualitative and quantitative data for analysis, appraising how the findings from these individual data contribute to determining the extent of regulatory compliance with the Order in Scotland’s tattooing and cosmetic body piercing industry. Proceeding from descriptive to inferential analysis, the output from quantitative data analysis will be reported using figure, tables and graphs. In addition, the themes arising from analysis of the qualitative data will be appraised. This will be presented in text and diagrammatic formats.

Chapter 6 – ‘Integrative analysis and interpretation’ progresses analysis of the study data. Initiating integration and interpretation of the data, concurrent exploration and explanation of users’ experiences of regulatory implementation will be undertaken to more fully understand regulatory compliance, and determine the extent of regulatory compliance with the Order in Scotland’s tattooing and cosmetic body piercing industry. This integrative analysis and interpretation will appraise the study findings relative to existing evidence.

Chapter 7 – ‘Conclusion’, as well as provided summation of the preceding chapters of this thesis, will be used to bring this work to an end. It will point out study limitations; offer a reflexive account of learning; highlight implications for policy and practice; make recommendations; and identify a strategy for dissemination, before proffering some concluding comments.

### 1.9.2 *Organisation of thesis: signposting the intended rhetoric, and approach to scholarly writing*

Having noted above that this study is of concurrent mixed method design, forethought must be given to the rhetoric of this thesis (Anaf & Sheppard, 2007). Sandelowski (2003) contends that writing a convincing mixed methods study requires skill and desire, if both the quantitative and qualitative reader are to be interested in the work and persuaded of its value. Producing a convincing mixed methods study is therefore associated with how well it meets the needs of both these readers, who belong to different philosophical communities, and hold different ideas on what is worthy of note (Golden-Biddle & Locke, 1993).

Varying in the use of numbers and words, qualitative and quantitative approaches each abide by their own genres or convention of writing, leaving writers of mixed methods studies to determine how best to write to meet the needs of both. Anaf and Sheppard (2007) and Creswell and Plano Clark (2007) both propose that writing convention for mixed methods studies, such as use of the first or third person, can be directed by the dominant research paradigm. Anaf and Sheppard (2007) acknowledge that this becomes a somewhat subjective decision if equal weight is offered to both. Creswell and Plano Clark (2007) on the other hand suggest adopting the point of view best fitting the study's mixed methods design, and endorse the use of both approaches in mixed methods studies where the point of view differs across different phases of the study. Although making direct reference to undergraduate studies, Anaf and Sheppard (2007: 190) state:

*“Examiners and reviewers should respect the justification that students ...have offered for their writing style, appreciating it in the context of their research aims, rather than blindly following standard procedure of clinical journal documentation”*

In ascertaining the rhetoric for this work, thought has been given to the study design (concurrent mixed methods), the weight afforded to the component parts of data collection (equal), and the audiences to whom this study is directed (government and policy makers, environmental health officers, and healthcare workers), who are equally familiar with both quantitative and qualitative research approaches, as well as mixed methods studies.

On this basis, alongside the opportunity to enhance appreciation of the subtleties of each research approach (Anaf & Sheppard, 2007), a decision has been made to write in both first and third person across the remainder of this work. Predominantly using the first person for qualitative aspects and the third person for quantitative elements, consideration will be given to alternating this where appropriate, particularly within the 'background' and 'summary' sections of each chapter and during the integrative analysis and integration of the data. Further support for such an approach can be found in the writing of Webb (1992), who argues it is acceptable to use the first person in circumstances such as making personal judgements or creating arguments based on evidence, irrespective of traditional academic writing conventions.

# Chapter 2

## Review of the literature



## **2.1 Introduction and overview**

There are a number of methods and techniques available for reviewing literature, each requiring a discrete time and resource, and achieving its own distinct outcome. Ultimately, the choice of approach should be based on that best suited to the needs of the proposed research, the aim being to provide a “*comprehensive study and interpretation of literature that relates to a particular topic*” (Aveyard, 2007: 5).

Today, traditional approaches to reviewing the literature (through narrative and expert commentaries) have been replaced with more systematic approaches, including full systematic reviews, multi-arm systematic reviews and rapid evidence assessment. Equally there can be qualitative, quantitative or mixed-method reviews. Either way, all serve as methods to summarise research evidence, seeking to identify, assess, synthesise and interpret evidence in an unbiased, impartial and balanced way. Rigour and replication are of foremost importance (Hemingway & Brereton, 2009).

## **2.2 Background**

Within Chapter 1, I provided a background to this study. Detailing the process towards implementation of the Order, I highlighted its derivation from the growth and interest in skin piercing and tattooing activities within mainstream society and the emerging concerns over risk to health from infection. In addition, I noted how regulatory compliance could be utilised as a means to demonstrate its effectiveness.

In this chapter, I will further explore the evidence base associated with state-controlled regulation, compliance, infection control practice and the tattooing and cosmetic body piercing industry. Adopting a thematic approach to organisation, I utilise the principles of rapid evidence assessment (Hemingway & Brereton, 2009), mixed studies review (Pluye, Gagnon, Griffiths & Johnson-Lafleur, 2009) and mixed method synthesis (Harden & Thomas, 2005) to undertake a systematic literature review that is sufficiently explicit and comprehensive to ensure rigour, reliability and replicability.

Beginning by explaining the planned methods for searching; assessing and synthesising the literature, I will reflect on how best to organise the literature review, noting the options available, rationalising the choices made, and outlining the broad content of the review. Thereafter progressing to systematically review the literature, I will appraise the literature in terms of topic content and methodological quality, drawing conclusions following synthesis and interpretation of the findings.

Before moving to Chapter 3 – ‘Conceptual framework’, I will present the purpose statement for my study, detailing the intent and outlining the methodology. It is here that the rationale for my study is provided, justifying the topic selection and need for the proposed research. In rationalising topic selection and need, my study’s ability not only to fill gaps in existing knowledge but most importantly to make a significant contribution to new knowledge will be evidenced. Before drawing this chapter to a close, I will specify my research questions and the overall scope of my study.

## **2.3 Approach to reviewing the literature**

### **2.3.1 Organisation**

Of the various options available to organise a literature review, chronology and methodology approaches have been excluded, in favour of a thematic approach. A thematic approach lends itself to review of differing research types on a range of policy and practice matters. It is designed to look beyond effectiveness/evaluation of interventions to include appropriateness, meaningfulness and feasibility (Evans & Pearson, 2001; Harden, 2010). In style, it is more iterative and cyclical than linear, viewed therefore as an approach, which supports transition through the range of subject areas associated with regulatory compliance within the tattooing and cosmetic body piercing industry (Harden, 2010). In turn, the thematic approach aids integration of both qualitative and quantitative evidence.

For this literature review, the themes derive from the content of Chapter 1 – ‘Background to the study’, which identified regulatory compliance within the tattooing and cosmetic body piercing industry in Scotland as the principal topic of this study. To focus both the search strategy and the themes, the principles upon which decisions are made to implement an intervention aimed at reducing risk to health were drawn upon, specifically:

- *The behaviour targeted should be a causal risk factor;*
- *There should be evidence of high relative risk;*
- *The possible reduction in risk should be sufficient to justify intervention;*
- *Evidence should exist to demonstrate that the intervention is effective/ capable of changing the targeted behaviour.*

(WHO, 2008:2)

To this end, the themes covered within the literature review are:

1. Evidence to support need for tighter controls – focusing on the issues of (a) prevalence and (b) infection, as two purported factors in raising concern over risk to health;
2. Professional and public opinion of the influence of regulation on health behaviour;
3. Evidence of the effect of regulation on compliance;
4. Evidence of compliance with infection control practice within healthcare;
5. Evidence of compliance with infection control practice within the tattooing and cosmetic body piercing industry;
6. The effectiveness of regulation and other interventions aimed at promoting compliance within the tattooing and cosmetic body piercing industry.

### 2.3.2 *Searching the literature*

A systematic approach to searching the literature has been adopted, utilising the principles of rapid evidence assessment (Hemingway & Brereton, 2009). Focusing on validity, rigour, credibility and relevance of published research and its findings, this approach exploits what has been learned from the inadequacies of “*traditional reviews*” (Hemingway & Brereton, 2009: 2). These inadequacies include difficulty in replication, lack of objectivity and completeness, failure to sufficiently extract and summarise current knowledge, and biased recommendations (Antman, Lau, Kupelnick, Mosteller & Chalmers, 1992).

While not considered a full systematic review, rapid evidence assessment review within this thesis has employed systematic review methods to explicitly and rigorously search and evaluate the literature, conceding only in breadth by limiting the search to published literature that can be sourced and which is in the English language. Deemed appropriate when “*there is uncertainty about the effectiveness of a policy or service and there has been some previous research*” (Hemingway & Brereton, 2009: 5), the decision to adopt such an approach was also based on the capability of rapid evidence assessment reviews to provide speedy summation of knowledge on a given topic or intervention. Acknowledging that systematic reviews may also experience biases, and given the nature of the study topic, such a decision is supported by Underwood, Thomas, Williams and Thieba (2007), who reflect that the rapidity of this more condensed approach outweighs the potential danger of introducing or increasing bias.

The search strategy aimed to identify primary research, and focused on the six themes identified above. For each of these themes, individual searches have been carried out, utilising selected search terms and Boolean principles. For each search, the EBSCOhost interface (simultaneously searching publications from within AMED (Alternative medicine); British Nursing Index; CINAHL; GreenFILE; Library, Information Science and Technology Abstracts; MEDLINE; and Psychology and Behavioural Sciences Collection databases), Emerald Journals (Emerald) database, and ScienceDirect (Elsevier) database were used. This supported systematic searching of the literature from both business and health perspectives. Date limits from 2000 to 2010 were set to broadly reflect the time period from Scotland’s consultation on skin piercing (SEHD, 2001) until present. Only those published in English and readily sourced were selected for inclusion. The individual strategy and outcome of each search has been detailed in Appendix 2.

### 2.3.3 *Assessing and synthesising the studies*

Recognising that qualitative, quantitative and mixed methods studies were to be reviewed as part of the literature review, how best to ensure rigour when appraising the methodological quality of these different types of studies was considered.

Equally, as evidence synthesis is often determined by the type of data within a review (Public Health Resource Unit (PHRU), 2006), consideration was also given on how best to combine the results of studies derived from different methodological stances. The aim was to generate fair and just conclusions.

Clinical appraisal tools and approaches to evidence synthesis have been developed to support the systematic appraisal and aggregation of different types of research studies (PHRU, 2006), these tending to examine qualitative and quantitative data separately in the first instance and thereafter conduct either a meta-synthesis (of the qualitative data) or meta-analysis/narrative summary (of the quantitative data, dependent upon the uniformity of that data). In addition, quality appraisal tools for mixed methods studies are now emerging to assess the quality of mixed methods studies (O’Cathain, Murphy & Nicholl, 2008), although the criteria utilised within these continues to be debated (Sale & Brazil, 2004; Creswell & Plano Clark, 2007).

Furthermore, a range of terms such as ‘integrative review’ (Nurius and Yeaton, 1987), ‘mixed methods review’ (EPPI-Centre, 2007), ‘mixed research synthesis’ (Sandelowski, Voils & Barroso, 2006), ‘synthesis of results of quantitative and qualitative studies’ (Popay, 2006), ‘mixed methods synthesis’ (Harden & Thomas, 2005) and ‘mixed approaches to evidence synthesis’ (Pope, Mays & Popay, 2007) are now recognised as descriptives for approaches that integrate the findings from different types of study within one review. Most recently, Pluye et al. (2009) developed a scoring system to simultaneously appraise the quality of qualitative, quantitative and mixed methods studies. This they describe as a ‘mixed studies review’. Using the term to incorporate the complete review process (from question through identification; selection; appraisal and synthesis), they argue that it offers greater precision, clarity and inclusiveness than any of the aforementioned terms.

An important means of maximising the potential of this mixed methods research study to produce integrated findings that are greater than the sum of their parts is to ensure substantial integration across the research design (Yin, 2006; Bryman, 2007; Woolley, 2009). Facilitating concurrent review of literature from qualitative, quantitative and mixed methods studies, the use of Pluye et al.'s (2009) mixed studies review approach would have supported integration at the literature review stage. However, Pluye et al. (2009: 540) advise its use "*should be applied with caution since its reliability has not been examined*". Additionally, they acknowledge it is not a substitute for standard reporting systems.

Utilising standard mechanisms to undertake a mixed studies review requires sufficient studies of one type to carry out a meta-analysis or meta-synthesis. This reflects the approach of Harden and Thomas (2005), who describe the development of a mixed method for integrating the findings from different types of studies within a single review. Whilst retaining separately defined inclusion criteria for qualitative and quantitative data, and continuing to assess quality based on the principles of individual study designs, their approach brings together the products of the process of meta-analysis and meta-synthesis into a third stage, which they refer to as 'mixed methods synthesis' (Harden & Thomas, 2005).

Appraising, combining and interpreting the literature within the literature review of this study is based upon the approach of Harden and Thomas (2005). This is considered to offer a more reliable process for conducting a systematic review that mixes different study and/or data types than that of Pluye et al. (2009). This approach preserves the integrity of each study design, and uses a critical appraisal framework to systematically appraise the content and methodological quality of the included studies, overall strengthening the quality of the review (Harden and Thomas, 2005). For this study, the critical appraisal framework is based on the work of Moule, Pontin, Gilchrist & Ingram (2003) (See Appendix 3).

## **2.4 Reviewing the literature**

### *2.4.1 Theme 1a: Evidence to support need for tighter controls - Prevalence*

Utilising the search terms “tattoo\*”, “pierc\*” and “prevalence” under Boolean principles, 590 results were returned, of which 569 were excluded from the review as they were not primary research or were related to blood borne virus prevalence, prevalence of infection control practice, risk taking, motivations for tattooing and cosmetic body piercing and medical sequelae associated with tattooing and cosmetic body piercing. Of the remaining 21, 7 were duplicates, leaving 14 articles suitable for inclusion within the review. Three articles could not be sourced; therefore 11 studies have been reviewed within theme 1a – prevalence.

In terms of prevalence of premises and practitioners, no source evidence could be found to substantiate figures associated with the United States News and World Report article (1996). This reportedly estimates 15,000 parlours operating within the United States, and alleges an average of one additional establishment being added to the countries total each day, ranking tattooing as the sixth fastest growing retail enterprise of the 1990s. Equally, the 2001 survey cited by di Folco (2004), which reportedly estimates 5% of the world’s population with a tattoo or cosmetic body piercing, based on the growth in tattooing businesses and sale of tattooing and piercing equipment in the United States, Japan and Europe since the early 1990s could not be sourced. In determining the need for tighter controls, the resurgence in popularity of tattooing and cosmetic body piercing, coupled with an increase in the numbers of premises and practitioners has been used as evidence of rising risk to health (Noah, 2006). No further empirical studies were identified in the search to confirm or refute the scale of the tattooing and cosmetic body piercing industry globally, nationally or locally. It is therefore concluded that lack of robust prevalence data (in respect of numbers of practitioners or premises) makes it inappropriate to directly associate prevalence with rising risk to health or to use prevalence as sound justification for regulatory intervention.

In respect of prevalence of tattooing and cosmetic body piercing activities, a number of studies have considered this issue since the early 2000s. In 2001, Makkai and McAllister published the findings of their 1998 tattoo and body piercing prevalence study of 10,340 Australians over the age of 14 years, which identified one in ten people as having a tattoo and one in twelve with a body piercing (excluding ear piercing). Overall, they report nearly 1 in 3 Australians as having some form of “body decoration” Given the title of the article as “Prevalence of tattooing and body piercing in the Australian community”, the introduction and literature reviewed does not identify any contemporary literature on the topic of prevalence and is unduly weighted towards health risk and regulation, particularly as the article notes tattooing and body piercing as an uncommon route for infection transmission. No research questions are provided, no clear rationale given for undertaking the study, and no study limitations are identified. These issues raise concern over the possibility of reporting bias (Kelley, Clark, Brown & Sitzia, 2003).

The method of data collection via the National Drug Strategy Household Survey is clearly identified, and the sampling approach, based on a stratified multi-stage approach is also clearly detailed. Given this was a survey, the use of self-administered questionnaires is appropriate, but there is no indication of the questions asked, nor are considerations of ethical issues such as consent, anonymity and confidentiality evidenced. It is therefore difficult to conclude that the presentation of results accurately reflects the data collected, or indeed whether data were collected ethically, or if all collected data collected has been presented. Equally, the results of the study may be subject to measurement bias (McKenna, Hasson & Keeney, 2006; Shuttleworth, 2009), where participants self-administering the questionnaire may not give true answers, particularly where the subject incorporates questions on the sensitive issue of drug and alcohol use. This highlights the limitations of a single method of data collection in gathering robust data.



The use of graphs is appropriate to demonstrate engagement in tattooing/piercing by age and gender. These are mainly descriptive in nature, and although Chi-square tests are mentioned, the text makes no reference and offers no explanation of the apparent statistically significant results found. The discussion of results continues by collectively reporting alcohol and drug use, and the relationships between drug and alcohol use, injection of illicit drugs and engagement in tattooing and cosmetic body piercing activities. There is no evidence of data collection on the drug injecting practices of participants, which would significantly influence risk of transmission of infection, leading to measurement bias (Hartman, Forsen, Marks, Wallace & Neely, 2002). Implications, future research and recommendations are omitted. Moreover, the discussion does not reflect the findings, nor are the assertions made effectively supported by the findings. When considered collectively, these issues generate reporting bias (Kelley et al., 2003), with significant implications for the quality of this work.

In 2006, Stirn, Hinz and Brahler reported on the prevalence of tattooing and body piercing in Germany as 8.5% and 6.5% respectively, from a representative survey of the general population. Data were collected during an annual survey on health behaviour and health perceptions, based on 210 sample points across Germany. Two thousand and forty three participants were recruited, aged between 14 and 93 years, equating to a 64% (n=1307) response rate. While this response rate is considered sufficiently acceptable to secure publication (Barclay, Todd, Finlay, Grande & Wyatt, 2002), the study lacks detailed explanation of how this reflects the total target population, and may still introduce sampling bias. Trained interviewers attended participants' homes and the questionnaire was filled in face to face. No indication is given on how contact was made and whether there was a cooling off period for participants to consider their involvement. Without such information, the risk of procedural bias presents. Given that the data collection is carried out face to face, response bias is also a risk (Kelley et al., 2003), where participants may give the answers they think the interviewer wants to hear.

SPSS was used to support statistical analysis. Three-way ANOVA was used, but no indication given that the assumptions applying to parametric tests such as this were appropriate. This highlights the importance of accurate reporting of research design, if suggestion of design bias is to be avoided. This said, the discussion reflects the results, relates back to earlier literature, and offers implications and recommendations for the findings.

Also in 2006, Laumann and Derick undertook a study of tattoos and body piercing in the United States, aiming to provide a national data set on prevalence. They concluded 24% (n=120) of respondents had tattoos and 14% (n=70) had body piercings. The article reports the use of random digit dialling technology to obtain a probability sample of 500 from 1515 members of the population across 48 US states – limitations of the 33% (n=500) response rate were discussed. The complicated nature of response rate calculation however, makes it difficult to determine how representative the eventual sample of 500 is, leading to potential sample bias (Hartman et al., 2002). The introduction is weak, making no reference to previous prevalence studies. Biased reporting is evident where the article notes increased popularity of some activities without the provision of evidence to support such a claim.

The method of data collection involved a telephone interview to complete a structured questionnaire, and the authors note the self-reporting nature of data collection as a study limitation. The implication of this is response bias, again highlighting the difficulties in collecting robust data from only one source (Yin, 2006). No ethical issues are discussed making it impossible to determine how robust the study has been in ensuring rigour ethically. Data are presented in tables, reflective of the quantitative approach of the research design. Descriptive and inferential statistics are reported, and the normal distribution of respondents and p-values are reported, highlighting the appropriate use of statistical tests. The discussion section reflects back on relevant literature, the authors noting their findings to concur with that of previous studies from some years earlier. Implications of these findings in relation to wider associations are offered, although no future research or recommendations are presented.

Looking at population sub-groups, the prison population has been studied: Braithwaite, Robillard, Woodring, Stephens and Arriola (2001) undertook, as part of a larger US study on relationships between alcohol/drug use and tattooing and body piercing, a preliminary study of self-reported tattooing and body piercing. A sample of 860 detainees from within two youth development campuses was accessed, although it is not evident from the report where these campuses are within the US. The study introduction focuses much on the larger study. The study found 29% (n=245) of the sample had at least one tattoo and 69% (n=593) had at least one body piercing. Approximately 20% (n=172) engaged in these activities without involving a professional artist<sup>4</sup>.

Detainees, aged 11-18 years were invited to participate in the study within the first three days of entering the campus, with consent from detainee and parent or guardian then formalised. Baseline information was collected approximately 4 weeks after entering the campus, followed by a face-to-face interview with a researcher, during which they were asked about their tattooing and piercing activity. Although a 4-week period passed between initial consent and data collection, there is no indication of how this cooling off period was utilised to enable the detainees to change their mind. The limitations of self-reporting in isolation are a concern in this work. In addition, the selection of the 860 detainees gives no indication of how representative these were of the total population on the youth campuses, and is therefore subject to sample/selection bias and ultimately measurement bias (Hartman et al., 2002; Shuttleworth, 2009). This negates the quality of the data analysis. Moreover, the inclusion of parametric techniques in analysis should have been precluded by detail on the normality of population distribution. Without this, it is not possible to determine the appropriateness of the statistical tests used (Argyrous, 2005). The conclusions drawn reflect the study findings, and limitations to these are reported, as are recommendations for future research (focusing on unusual piercings).

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<sup>4</sup> In this study, the terms 'professional' and 'unprofessional' are used to differentiate between those considered to operate within the law/ licensed (professional) and those who operate outwith the law/ unlicensed (unprofessional)

In considering the issue of professional and unprofessional activity, the notion that some professional establishments may not practice hygienically is purported without any evidence to support this claim – this introduces design bias, as the researcher failed to take account of their own inherent biases, and has significant implications for how intervention to manage professional practice is viewed. This affects the overall quality of the research (Shuttleworth, 2009).

Into 2007, Hellard, Aitken and Hocking published results of their 2001 cross-sectional survey of 5 prisons within the State of Victoria in Australia. Prisoners were invited to participate, completing the questionnaire voluntarily in communal rooms on their tattooing habits. The authors reported 449 (70%) had a tattoo, of whom 182 (41%) had been tattooed in prison. One hundred and fifty six (35%) reported engaging in these activities illegally while in prison. Six hundred and forty two prisoners participated, although it is not clear how this reflected the total population across the five prisons. Despite the detailed inclusion of the statistical approach to data analysis, the approach to sampling is biased. This impacts on the quality of data collected, which becomes subject to measurement bias. This is compounded by the risk of response bias, where participants' data are collected in a communal room, with scope to discuss responses (Kelley et al., 2003). Despite these issues, detail of the ethical approval process provides assurance of the study's ethical rigour. Implications for practice are indicated, making recommendations based on the large amount of tattooing activity based within prison settings.

In 2010, Abiona, Balogun, Adefuve and Sloan published the findings of a study from 2007 involving a cross-sectional survey of body art practices among randomly selected inmates in 17 state prisons in Illinois, and focus group discussions with 47 recently released ex-prisoners in Chicago. The study aimed to determine prevalence of tattooing and body piercing in prison, while exploring the context and identifying factors affecting engagement in these activities. The introduction focuses on blood borne transmission in prisons, with illegal tattooing and body piercing highlighted as a risk factor contributing to spread.

The use of mixed methods was employed in this study, however only the survey data was utilised to support determination of prevalence. This approach via questionnaire (asking questions on tattooing and body piercing activities inside and out of prison) incurs the limitations of self-reported behaviour, and an opportunity was missed to utilise the focus groups to strengthen this evidence (Yin, 2006). Evidence of sample size calculation to obtain a random sample is reported, so avoiding the risk of sample bias (Newell & Burnard, 2006; Shuttleworth, 2009). While 1819 participants engaged with the survey, it is unclear how this reflects the numbers from the randomly selected sample, with no response rate identified. The potential for measurement bias therefore presents (Hartman et al., 2002). The research found 67% (n=1218) of participants (equal for men and women) had tattoos, with 80% (1455) noting receipt of their tattoo from an unprofessional either in or outside prison. Inside prison, 8.7% (n=158) of female and 19.3% (n=351) male participants reported being tattooed in prison. Sixty percent (75.3% of women and 41% of men) (n=1091) had piercings, with only 1.3% (n=24) of respondents reporting piercing while in prison.

While the focus groups did not explore prevalence directly, they identified the difficulties in access to equipment to tattoo in prison, and how it is now less “fashionable” to be tattooed. In addition, these groups reported how some prisoners are in fact professional tattoo artists and that most of the time, tattooing was carried out by professional people. The value of understanding prevalence data in context can be seen by this mixed methods approach. The study concluded by referring to other similar prevalence studies, recognising prevalence to be higher than that reported in other national studies, yet commensurate with studies of prison populations. Implications for the study findings are conveyed. Recommendations for future management of tattooing and body piercing in prison environments highlight how illegality was not preventing activity. Interventions focusing on safe practice are suggested. Limitations of data collection using self-reporting in the questionnaire (van de Mortel, 2008) and the risk of response bias in the focus groups are also recounted. In addition, the authors cite sample bias as a limitation.

Students are a further sub-group of the population studied: In 2002, Mayers, Daniel, Judelson, Moriarty and Rundell reported findings from a 2001 survey of body art in university graduates. Four hundred and eighty one students (14.7% of the students enrolled on campus) were offered the chance to anonymously complete a questionnaire at the beginning of class or organisational meetings, with 454 (94.4%) taking up this offer. The prevalence of tattooing and body piercing was reported as 23% (n=104) and 51% (n=231) respectively. The topic and study intent is clearly identified in the introduction, with reference made to previous prevalence studies. The data collection tool was devised and piloted, but no indication is given of the outcome, therefore it is not possible to say that the tool was considered valid or reliable (Field, 2003). Offering the questionnaire to students on a voluntary and anonymous basis has implications for representativeness and accuracy in completing – this could be compounded by the decision to have self-administration at the beginning of lessons/meetings, when students may well rush to complete. These design issues have implications for sample/selection bias, design bias, and procedural bias (Hartman et al., 2002; Ioannidis, 2005; Shuttleworth, 2009). In turn, despite the use of SPSS and appropriate use and reporting of statistical tests, the sample bias is likely to impact on measurement bias and ultimately bias reporting (Newell & Burnard, 2006; Shuttleworth, 2009) – indeed, the claims that the study are the first of its kind and the notion of a 94.4% response rate accentuate over-reporting of results/outcomes.

A follow up survey in 2006 (Mayers and Chiffreller, 2008) details the prevalence of body piercing and tattooing as part of a larger study of medical complications, the intent being to compare results to the 2001 study of university undergraduates – this noted above as identifying an overall prevalence of 51% for piercing and 23% for tattooing. The study introduced the findings of the 2001 study (Mayers et al., 2002) and makes reference to publication of other similar findings. The limitations and biases inherent within this study reflect those reported in the 2001 study (Mayers et al., 2002). While this highlights the dangers of replication type studies, it does offer an opportunity to compare across the time period 2001-2006. The work involved 661 students (18.8%) of campus students, with a response rate of 98.3%.

Again the high response rate raises questions over the opportunity for students to decline involvement, with implications of procedural bias (Shuttleworth, 2009). The findings describe an overall prevalence for piercing of 51% (n=337) and 21.8% (n=144) for tattooing. The discussion compares these findings with the 2001 study results and concludes these activities are mainstream, given the similar prevalence rates.

A further but more specific study published by Venta et al. in 2005 considered prevalence of oral piercing in 277 first year university students in Finnish universities in 2002. All were invited to attend for routine dental examination, during which time a prevalence of 3.4% (n=8) was identified. The introduction reflects on the launch of dental examination for these students in 1982, at which time, no oral piercings were identified. This research appears to highlight an increasing prevalence over the two decades between 1982 and 2002, which can be supported by the high response rate (85%, n=234) and decision to use the exact criteria for sample collection across both studies (Argyrous, 2005). More generally however, the approach to sampling does not demonstrate representativeness of the total student population, with only those aged 20 years, born in the capital and living in the capital in 2002 invited to participate. Generalisability of the results to the wider populations should be treated cautiously due to the risk of sample bias (Newell & Burnard, 2006). Resultantly, the impact on measurement bias must be considered.

Closer to home, Bone, Ncube, Nichols and Noah (2008) carried out a prevalence study of body piercing in England. Between January - March 2005, 10, 503 adults from across England took part in the survey (although the researchers are unable to give a response rate due to uncertainty over the numbers refusing/ unable to be contacted) – the risk of this is measurement bias (Hartman et al., 2002; Shuttleworth, 2009). The approach to sampling is well detailed as a two stage process, firstly random sampling of geographical areas followed by quota sampling, stratified and proportional across the 10 regions of England. A research company was used to assist in questionnaire design, and interviewers were dispatched to pre-determined addresses to attain the relevant predefined quotas.

Participants used a laptop to enter questionnaire responses, so did not divulge information to the interviewer – this design minimises procedural and response bias, by ensuring confidentiality of data at the point of collection (Field, 2003). Results are presented appropriately in numerical and table format, and analysis involved the use of Stata 8.2. Data Protection is reported to be in line with the Data Protection Act 1998. Prevalence with 95% confidence interval was found to be 10% (n=1049). Most piercings were carried out in a specialist premise, with 20% carried out elsewhere, including self-piercing. As with other surveys, the self reported nature over the data makes it subject to response bias, and this is a limitation of this study (Kelley et al., 2003).

A study by Benjamins, Risser, Cromwell, Feldman, Bortot, Eissa and Nguyen (2006), focusing on body art among 997 minority high school athletes considers the issue of prevalence, identifying 8.6% (n=85) with tattoos and 8% (n=80) with piercings. It details the use of a cross sectional study between May and August 2004, in Houston, Texas, where inner city black and Hispanic students from 4 urban high schools participated through the completion of a self-administered questionnaire. Although, the researcher's note no one refused to participate, it is not clear if/how this translates to the notion of 'everyone' participating. As such, the numbers within the target population and the response rate are not clear. Resultantly, reporting bias may be a problem with this work, because it is impossible to determine how well the 997 respondents represent the target population, or how generalisable the results therefore are (Shuttleworth, 2009).

The introduction does however reflect the intent of the study and the purpose and rationale are both clearly stated. The literature review, while brief, is reflective of the study topic. The study method is detailed, although the intention and outcome of the pilot study is not reported. This would have indicated the validity and reliability of the tool used to collect data, without which measurement bias through use of a faulty scale could be a problem (Field, 2003). Verbal consent is reported in respect of ethics, but no indication is given of the relationship between participants and researchers or how consent was obtained.



Procedural and measurement bias may be problems in this research, due to the nature of the topic and where pressure could have been placed on the participants due to a power relationship. Furthermore, it is not evident if time was given to participants to reflect on their participation. Indication of a cooling off period would alleviate the concern of such procedural bias (O'Leary, 2004).

Descriptive statistics and use of Chi-square are reported in the analysis of results, with tables clearly identifying the findings and the level of statistical significance. The discussion reflects the results and the earlier literature, with application and implication for findings. The need to take account of researcher position and to accurately detail the response rate to avoid procedural bias are key lessons to be learned from appraisal of this research (Kelley et al., 2003; O'Leary, 2004), as is the limitation of a single approach to data collection to support a fuller understanding.

A 2007 survey by Cegolon, Mastrangelo, Mazzoleni, Majori, Baldovin and Xodo (2010) investigated prevalence of tattooing and body piercing in a group of Italian adolescent secondary school students from within the 7 provinces of the Veneto Region. This was part of a wider study to consider attitudes to assist in predicting future trends and inform the development of resources to support safe engagement. The intention was clearly outlined in the introduction to the study, with reference made to existing literature. Sampling involved selecting one of each of the six types of Italian public secondary school from across the seven provinces, totalling 42 schools. These were invited to participate, with 41 agreeing. From there, 4,524 students were randomly selected to participate from across 1<sup>st</sup>, 3<sup>rd</sup> and 5<sup>th</sup> year. The random selection at school level minimised the risk of sampling bias, but this could not be replicated at province level, where selection bias could have occurred. The authors evidence ethical approval. Piloting of the self-administered questionnaire used as the data collection tool is also reported. While the purpose of piloting the tool is to enhance validity and reliability, these concepts are not mentioned in the article (Field, 2003).

Measures were in place to inform students of the purpose of the survey, but with all 4,524 students returning the questionnaire, concern is raised over how it was administered and the freedom afforded to students not to complete (O'Leary, 2004). It was reported that only 95% (n=4524) were usable, and so this may have been a route for students to opt out. The prevalence of body piercing and tattooing were found to be 20% and 6% respectively, with earlobe piercing excluded for girls. The results, reported appropriately using tables and supported by statistical software and relevant tests, indicate approximately half of those tattooed/ pierced were 'underage'. No indication is given to how this was determined, nor are the implications of current measures to manage this explored. As such, there is a danger of reporting bias, with the researcher selectively choosing to address only some aspects of the findings. Subsequently, this has implications for the conclusions drawn (Hartman et al., 2002; Shuttleworth, 2009).

In summary, the studies of theme 1a provide evident that prevalence of tattooing and cosmetic body piercing has been the subject of research since the beginning of the 21<sup>st</sup> century. Methodologically, the quality of these studies has however been sub-optimal, with significant selection/sample bias in most research, impacting on measurement bias (Hartman et al., 2002). Equally response and reporting bias has implications for interpretation of both findings and conclusions (Shuttleworth, 2009). Of particular interest is the heavy reliance on survey methodology, where self-administered questionnaire is frequently used as the sole data collection tool. This is despite awareness of the limitations of self-reported behaviour, renowned for response bias, and often found to exceed objective rates compared to studies that have mixed or multiple methods of data collection (van de Mortel, 2008). The one mixed methods study within the review highlighted the value of multiple data sources to strengthen the quality of data collected and ultimately in better understanding the topic under study.

Also, comparison of findings across studies is difficult due to the range of definitions and inclusion criteria for tattooing and cosmetic body piercing. Such difficulties are further compounded by cultural differences and study biases.

This said, the findings suggest some growth of tattooing and cosmetic body piercing activity in western society's general population. Within sub-populations, the prevalence of tattooing and cosmetic body piercing of those within prisons and educational establishments is higher than national prevalence, but again the findings of studies over the past decade do not suggest an increasing prevalence – rather it appears relatively static. This suggests activity is now truly mainstream.

The prevalence of illegal activity is worthy of note – whether in those below the age of consent, those where activity is carried out by non-professionals or in illegal establishments such as prison. Reflecting upon this and the inherent risk of infection from any invasive procedure, the impact of illegal activity on legal/regulated practice requires exploration. Meantime, without evidence of hygienic tattooing and cosmetic body piercing as a causal risk factor for infection, it must be concluded that prevalence alone does not offer a robust rationale to justify regulatory intervention to manage risk to health.

#### *2.4.2 Theme 1b: Evidence to support need for tighter controls - infection*

Utilising the search terms “tattoo\*”, “pierc\*” and “infection” under Boolean principles, 770 results were returned, of which 730 were excluded from the review as they were not primary research or were related to blood borne virus risk factors, risk behaviour or healthcare associated infection. Some were opinion papers and not research. Of the remaining 40, 21 were duplicates, leaving 19 articles suitable for inclusion within the review of theme 1b - infection.

##### *Infection reported as causally linked to tattooing and cosmetic body piercing*

In 2004, Dubose and Pratt reported a case of endocarditis after oral piercing in an 18 year old woman. Having allowed a male friend to use the stud from her 4-day old tongue piercing to re-open his own, she re-inserted the stud into her own tongue without decontamination. She felt ill over the next 6 weeks with symptoms of fever, nausea, malaise and dyspnoea, and spent 35 days in hospital during which time she underwent mitral valve replacement.

The discussion in this case study focuses on increasing prevalence of piercing, highlighting the lack of client understanding of regulation and training within the industry and the risk it poses to health. No reference is made to woman's decision to 'share' the jewellery with a friend and the implications of such practice. The article is therefore considered to suffer from reporting bias (Shuttleworth, 2009).

Also in 2004, MacLeod and Adeniran reported a case study involving a 35 year old man who presented to the Plastic Surgery Department of a Plymouth Hospital in the UK with an extensive penile fistula, 12 months following the piercing of his glans penis. A detailed list of complications relating to the piercing process and to the persistent presence of the jewellery as a foreign body are supported by evidence. The case study does not draw any further conclusions as to the cause, but makes direct correlation between an increasing prevalence and the likelihood of increased complications – this is not supported by evidence, subjecting the paper to reporting bias (Shuttleworth, 2009).

Lopez-Jornet, Camacho-Alonso and Pons-Fuster (2005) provide a case study report on a lingual piercing that had become embedded. The paper introduces oral piercing and highlights potential complications through reference to other studies. The case study of a 28 year old male is then presented, with a time line offered of events from piercing to management of the embedded jewellery. Discussion then returns to the literature in the introduction. While clearly outlining the events to manage the embedded piercing, the case study does not address the effectiveness of the piercing practice, particularly in respect of the type of piercing. That the size of the piercing (bar or stud) is generally greater than the tongue thickness (to allow movement), this is of particular relevance in understanding the cause of the problem. In addition, no reflection is made on the two-month time delay between the male noting the upper ball becoming partially buried and seeking medical assistance, which would have impacted on the overall outcome in this case (Armstrong, 2005; Venta et al., 2005).

Reporting bias is an issue in this case study. As with any case study, it reflects one incident, and so selection/sampling bias is a further consideration when reviewing such research (Newell & Burnard, 2006).

Also in 2005, Lick, Edozie, Woodside and Conti presented a case study of a 27 year old man found to have *Streptococcus viridans* endocarditis following tongue piercing. The introduction is brief and offers no evidence from previous studies to support its claim of the medical complications that accompany piercing and tattooing. This can be considered reporting bias (Shuttleworth, 2009). The case study is detailed, but no discussion is given of how the tongue piercing six weeks prior to admission related to the study – this is particularly relevant in this study, given that *Streptococcus viridans* is a ubiquitous oral organism (Meurman & Uttamo, 2008). In addition, no reference is made to the man's heart murmur since childhood, which represents an underlying health problem. The self reporting of other associated factors such as intravenous drug use or dental activity introduces the risk of response bias (van de Mortel, 2008).

Hanif, Frosh, Marnane, Ghufloor, Rivron and Sandu (2005) published a paper including 3 case studies of perichondritis following piercing of the pinna. The first reports the presentation of a 16-year old to A&E two days after the insertion of jewellery into the left pinna. An auricular subperichondrial abscess was diagnosed and treated with antibiotic and pressure dressings. The second reports a 21-year old who presented to ENT with perichonritis of the right pinna one week following piercing. This was treated with intravenous antibiotics and pressure bandaging but resulted in an ear deformity. The third case involved a 23-year old woman who had multiple piercings of the right pinna 5 months earlier, and multiple lesions of the pinna. Jewellery had been removed after one month but the wounds never healed. Surgical drainage of the lesions was performed. The discussion paper focuses on the history of such complications in the local area (Rochdale, Greater Manchester), and the calls for government to act. No information is presented on the piercing aftercare advice given to these three recipients, nor of their actions to manage their piercings.

This could have influenced the outcome of each case (Armstrong, 2005; Venta et al., 2005), incurs reporting bias, and questions the appropriateness of the conclusions (Parahoo, 2006; Shuttleworth, 2009).

In 2006, Lopez-Jornet and Camacho-Alonso reported the findings of a study on the oral/dental complications of intra-oral piercing. The article begins by noting previous research associated with oral piercing complications. The study involved examination of 98 piercings in 97 volunteers between October 2004 and May 2005 at the University Dental Clinic Unit of Oral Medicine in Murcia Spain. These participants were recruited to the study through advertisement. Such volunteer sampling is not adequate in quantitative studies where statistical testing is undertaken (Parahoo, 2006), so sampling/selection bias is a problem, impacting on the generalisability of results. Results are presented in tables descriptively and inferentially (p-values are reported, and statistical significance highlighted despite the sampling bias) (Argyrous, 2005). While the results highlight gingival recession in only a quarter of the 98 oral piercings (which included 45 tongue piercings, 52 lip piercings and 1 cheek piercing), and mucosal problems noted in less than 10% of participants (n=9) , the discussion links these directly to piercing and no other possible causes have been explored. This contributes to reporting bias, and affects the overall quality of the research (Hartman et al., 2002; Shuttleworth, 2009).

A further case study reported in 2009 by Perez-Barrio, Gonzalez-Hermosa, Raton-Nieto and Diaz-Perez begins by outlining the association between tattooing and infection, citing previous research papers to support this claim. It continues by detailing the case of a 36-year old man who presented with umbilicated papules on an arm tattoo. The tattoo had been in situ for several years, but re-colouring had been undertaken, following which the lesions appeared. Biopsy identified molluscum bodies, diagnosed as molluscum contagiosum. Despite identifying molluscum contagiosum as very common, the authors attributed it to the tattoo due to its location. Despite the possibility of transmission via tattoo equipment or ink, no measures were taken to investigate this, and so no causal association between the virus and tattoo was confirmed (Donaldson & Donaldson, 2003).

The lack of follow up with the tattoo establishment means that procedural, measurement and reporting bias are issues affecting the quality of this case study (Hartman et al., 2002; Kelley et al., 2003; Shuttleworth, 2009).

In 2010, Ng, Clarkson and Hogg reported a case study of a 31-year old female who had presented with a right ala lesion, this being the site of a previous nose piercing. The lesion was diagnosed as a basal cell carcinoma. The article begins with reference to a similar case by Khundkar and Wilson (2009), and continues by outlining the case. With tumour-associated piercings rare, the authors pose the question as to whether the lesion was caused by the piercing, and highlight the existence of Marjolin's ulcers – associated with trauma and defined as “*skin malignancies arising from stable scar tissue or chronically unstable wounds or scars*” (Ng, Clarkson & Hogg, 2010: e153). This case study presents a balanced argument on the association between basal cell carcinoma and piercings, and offers differential diagnosis as possible explanation. It concludes by offering the recommendation that biopsy with histological assessment be undertaken when a patient presents with skin changes occur over a previous piercing.

Also in 2010, Callejo, Nacinovich, Prieto, Lambert, Vizzotti, Villar, Szejfman, Navia and Stamboulian presented a case study of a 34-year old female found to have *Moraxella lacunata* infective endocarditis following tattooing. The case study introduces the organism and presents a time line of events surrounding the admission of a female to the Cardiovascular Institute of Buenos Aires in Argentina with fever and dyspnoea. While extensive detail is offered on the microbiological investigation underpinning this case, the conclusion drawn that the “*infection was suspected to be at the site of the tattoo, which was placed 4 days before the patient became febrile*” (Callejo et al., 2010: 7) is not substantiated or followed up within the report. The title of this article highlights a reporting bias, as it is significantly out of alignment with the subsequent content/discussion.

### *Risk of infection from infection control practices*

Silverman, Sekhon, Saginaw, Wiedbrauk, Balasubramaniam and Gordon (2000), in a comparative survey of 212 18-55 year old patients presenting to emergency hospital services of an American hospital found no evidence of tattooing as a risk factor for chronic viral hepatitis. The 212 were allocated into two groups based on whether they had a tattoo or not, and as well as completing a questionnaire for viral hepatitis risk factors, had blood samples collected and tested for a range of hepatitis measures. The self-reported nature of the questionnaire on sensitive information such as risk factors may influence the responses given and so introduce response bias (Armstrong, 2005; Venta et al., 2005). In addition, while the groups were allocated on the basis of tattoo history, the representativeness is not determined and so sample size and selection are potential biases (Newell & Burnard, 2006). Statistical tests are appropriate, identifying p-values and presented in tabular form (Argyrous, 2005). That the participants were those presenting at emergency department, the opportunity to decline participation and appropriateness of inclusion under such circumstances present design and procedural bias. As a result, there are ethical implications in undertaking this study, which are not sufficiently detailed (Parahoo, 2006).

Keene, Markum and Samadpour (2004) clearly state the objective of their paper - to investigate reports of auricular chondritis following ear cartilage piercing. The report begins by outlining the context of initial cases presenting in Oregon in September 2000 with ear infections post-piercing from the same jewellery kiosk. The study design follows the process of investigating an outbreak of infection, and included cohort study of those pierced at the kiosk between August and September 2000 (using kiosk records), review of work practices, environmental sampling and molecular sub-typing of isolates. Confirmed and suspected cases were recorded.

This multi-data collection approach reflects the requirements of outbreak management (SEHD, 2003). Each of the 118 individuals pierced during that period were interviewed using a standardised questionnaire, from which 7 (4%) confirmed and 18 (10%) suspected cases of *Pseudomonas aeruginosa* infection were identified and treated.



A press release was used to support case findings. Practice review found a sub-optimal outcome from inspection 8 months earlier, and the inappropriate use of equipment and compliance with standard infection control precautions at that time. In addition, workers offered differing accounts of practice, and reported using equipment not designed or licensed for the purpose of cartilage piercing. *Pseudomonas aeruginosa* was cultured from two workers stool and hands. Finally, general review of Oregon's otolaryngologists found over three quarters had seen ear-piercing associated auricular chondritis. Concluding, the authors describe their study as "*an unfortunate natural experiment*" (Keene, Markum & Samadpour, 2004: 984), and highlight the sub-optimal practices which culminated in the outbreak. Overall the study highlights the value of multi-data collection to present a full understanding of events, and confirms the risk of infection from poor practice. One aspect of care not covered in this case is the aftercare of recipients which could have contributed to the cycle of events (Armstrong, 2005; Venta et al., 2005), and this is a missed factor that may contribute to measurement bias (Hartman et al., 2002).

To the contrary, the community outbreak discussed by Drage, Philips and Ecker (2009) does little to investigate the cause. They describe the investigation of a community outbreak investigation of 6 patients with skin infection reportedly caused by *Mycobacterium chelonae* after receiving tattoos. The report introduces the occurrence and modes of transmission of the organism, and the reporting and management of the index case. The investigation involved review of patient records between October 2007 and May 2008, with appropriate consents in place. Six persons with a similar diagnosis were found to have attended the same establishment for tattooing. The results presented in table form are reflective of the findings, and the discussion focuses on similar outbreaks. The conclusion to consider nontuberculous mycobacteria in patients presenting with a rash and a new tattoo appears appropriate, however the supposed outbreak is insufficiently investigated.

Given this organism is found in tap water (van Ingen, Blaak, de Beer, de Roda Husman & van Soolingen, 2010) the outbreak investigation should have extended to the collection and sampling of such – without this, causal association between the tattoo establishment and the infection is not established (Donaldson & Donaldson, 2003). Measurement and reporting bias are therefore considered significant in the reviewing of this paper (Hartman et al., 2002; Shuttleworth, 2009).

A mixed methods study in 2007 by Abiona, Balogun, Adefuve and Sloan (2010) considered the implications for transmission of blood borne virus from body art practices within prison. The study involved a cross-sectional survey of 1819 prisoners across 17 state prisons in Chicago, Illinois to determine prevalence, and focus group discussions with 47 ex-prisoners to identify factors and explore the context of body art practices in prison. Prisoners offered a range of reasons for engaging in tattooing and body piercing activities while in prison (symbol of experience, cultural, to pass time). Most activity took place in cells. While the extent of tattooing and piercing was reported as diminishing, opportunity to have tattoos/ piercing carried out in prisons by “professional” inmates was highlighted. However, equipment (which included a variety of materials) was often shared, with opportunity to decontaminate the equipment not always available.

The introduction to this paper offers a clear indication of the topic and rationale for the study, with the literature review making use of contemporary literature and focusing on blood borne virus transmission. It offers illegal tattooing and piercing activities in prison as a potential route for transmission, particularly between drug users and non-drug users. The mixed methods study design is clearly described, and the use of 47 ex-prisoners as a purposive sample is appropriate for the collection of qualitative data. There is however no mention of saturation, and so it is difficult to know if this was achieved, so risking the introduction of design bias (Parahoo, 2006).

Equally, the use of focus groups as opposed to one-to-one interviews has the potential to result in response bias (Kelley et al., 2003), where participants may not respond truthfully – the authors did however report this as a limitation in this study in terms of the potential for prisoners to report engagement as a means of showing off. The management of the qualitative data from the focus group discussions is clearly detailed, and NVivo 7 software used to support analysis. Data were summarised to support the pre-determined questions set by the researchers, and verbatim quotes utilised to represent these within the paper. No evidence is presented on how the data was validated, nor is there any reflexive statement to account for the potential inherent researcher bias (Parahoo, 2006). Both these design biases have implications for the study conclusions in terms of validity (Cho & Trent, 2006). Ethics is addressed and the conclusions drawn reflect the data gathered. The implications of the findings are developed into recommendations for future management of illegal tattooing and piercing in prisons.

A study by van Wijk, Kummer and Kon (2008) evaluated the extent of damage to ear cartilage using different piercing techniques. The rationale links the increasing popularity of ear piercing with increasing perichondritis, and damage of the cartilage increasing risk of infection. Twenty two cadaver ears were pierced using a range of equipment, and the extent of damage to the perichondrium and cartilage quantified. No significant difference was found in the extent of damage from the different piercing techniques employed in the study. The authors concluded that the findings contradicted assumptions in the literature. Furthermore they noted each technique as having the same risk for perichondritis, and advised focusing on hygiene and after care as methods of prevention.

The study introduction highlights, with use of literature, the increase in both piercing of the upper ear and perichondritis, and the suggestion that piercing technique is associated with excessive cartilage damage. The study method is clearly detailed, including account of the materials and equipment used, and measurement of damage (the results of which are presented in a table).

Analysis using statistical tests such as one-way ANOVA is detailed, although the small numbers in the sample incurs sample/selection bias, leading to measurement and reporting bias (Argyrous, 2005). This was not reported as a limitation of the study. Moreover, the inability of the cadaver to offer feedback on the experience was highlighted. The work was funded, with the source of funding identified and stated as not presenting any conflict of interest. The implications for practice are reported, and the need to focus on other factors contributing to perichondritis is stressed.

*Medical sequelae<sup>5</sup> reported by recipients of tattooing and cosmetic body piercing*

In 2001, Mayers et al. (2002) undertook a survey of 481 undergraduate students at Pace University in Pleasantville New York to determine prevalence and incidence of medical sequelae associated with body piercing and tattooing. The introduction focuses on prevalence, adding how the study would seek to determine the incidence of associated medical issues. The survey questionnaire used for data collection was piloted but no indication is given as to its validity and reliability as a result of this process. Ethical approval for the study was given by the University Institutional Review Board. The questionnaires were distributed between February and May 2001 on a voluntary basis during classes and university meetings.

The design of the questionnaire aimed to improve response rate by its brief and easy to complete nature. No indication is given however to why this is important (Field, 2003). In addition, the lack of robust approach to sampling in this quantitative work impacts on the overall quality of results obtained, and causes measurement bias (Hartman et al., 2002). The high response rate achieved leads to concern over procedural bias, given the route to administer the questionnaire was in the classroom. This, as well as having ethical implications in terms of power relationships (O'Leary, 2004), has implications for the quality of the responses and ultimately raises the issue of procedural, response, measurement and reporting bias (Hartman et al., 2002; Shuttleworth, 2009).

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<sup>5</sup> In this context, medical sequelae include physical (such as infection, allergy, bleeding or scarring) and psychological (such as disappointment, unhappiness or embarrassment) risks/ outcomes considered to have resulted from participation in tattooing and cosmetic body piercing activities.

The results are however presented appropriately for quantitative research, in tables predominantly, with p-values reflecting the statistical testing during analysis of results (Argyrous, 2005). In terms of medical complications, these were reported by 17% of the 229 students with piercings. Local trauma (3%, n=7), bleeding (4.5%, n=11) and bacterial infection (9%, n=21) were the most commonly reported problems. Of the 106 tattooed students, no medical complications were reported. The self-reported nature of this information is a limitation of this study, and likely to result in reporting bias (Armstrong, 2005). The sample and self reporting are both noted by the authors as limitations of the study.

A study by Gold, Schorzman, Murray, Downs and Tolentino (2005) looking at attitudes to piercing in adolescents reported common health problems as infection, allergy, bruising and keloid scarring. The study describes itself as an anonymous 32 item random convenience-sample survey, and was administered in 2000 to 225 12-21 year old adolescents attending a hospital clinic in Pittsburgh USA. The introduction includes a section on the literature relating to medical risks from piercing, but the rationale for including such materials (and indeed questions on medical complications) is not particularly clear. A pilot study for content validity and readability had been carried out, but little use was made of the results of self-reported medical complications in the analysis of attitudes and awareness of health problems. The approach to sampling and decision to use a convenience sample within quantitative research is inappropriate. Along with the self-reported nature of the data collected, this has implications for the use of statistical tests that convey significance. As such, the use of these tests within this work is also inappropriate (Argyrous, 2005), where sample bias has resulted in measurement bias, and ultimately reporting bias (Newell & Burnard, 2006).

Schorzman, Gold, Downs and Murray (2007) undertook an anonymous survey of 103 (from 105 invited participants) 17-25 year old college students' attitudes to body piercing practices. A 30-item self-administered questionnaire collected information on attitudes, including attitudes to adverse events from piercing between 2003-2004. Only 100 surveys were sufficiently completed to allow inclusion in the analysis.

The results showed 10% of the 103 participants (n=10) reported problems with their own piercing, including infection, allergy, bleeding and scarring. The sampling/selection approach impacts on representativeness and incurs selection/sample bias. This in turn affects the data collected and results in both measurement and reporting bias (Hartman et al., 2002; Shuttleworth, 2009). The conclusion that perception of health risk is based mainly on experiences of others is justified by the findings.

A survey in 2006 (Mayers and Chiffriller, 2008) of body piercing and tattooing medical complications begins by introducing the findings of a 2001 study (Mayers et al., 2002), making reference to other similar studies. The limitations and biases inherent within this study reflect those reported in the 2001 study (Mayers et al., 2002), highlighting the dangers of replication type studies. The study involved 661 students (18.8% of campus students) (response rate of 98.3%). The high response rate raises concern over the opportunity for students to decline involvement, with implications of procedural bias (O'Leary, 2004). The findings state that of the 334 pierced students, 63 medical complications were reported across 518 piercings. Excessive bleeding (5%, n=15), skin tearing (3.5%, n=12), bacterial infection (9%, n=30) and tooth injury (n=1) were the most common reported problems, with the rates reported reflecting the findings of the 2001 study. No medical complications were reported in the 142 tattooed students, also reflecting the previous findings from 2001. The self-reporting nature of responses introduces response and measurement bias to this work (van de Mortel, 2008).

As part of a prevalence study of body piercing in England carried out in January - March 2005, Bone et al. (2008) aimed to estimate the proportion of piercings resulting in complications and requiring medical attention. The approach to sampling is well detailed as a two stage process, firstly random sampling of geographical areas followed by quota sampling, stratified and proportional across the 10 regions of England. A research company was used to assist in questionnaire design. Interviewers were then dispatched to predetermined addresses to attain the relevant predefined quotas.

Participants used a laptop to enter their responses to the questions, and so did not divulge information to the interviewer – this design minimises procedural and response bias, by ensuring confidentiality of data at the point of collection (Parahoo, 2006). Results are presented appropriately in numerical and table format, and analysis involved the use of Stata 8.2. Data Protection is reported in line with the Data Protection Act 1998.

In terms of complications, 533 (27.5%) reported problems, 250 (12.9%) resulting in medical referral. Swelling, infection and bleeding were most commonly reported, with tongue, genital and nipple problems most frequent. Although not statistically significant, piercings by friends/relatives, non-specialist establishments and mobile piercers were more likely to be reported as resulting in complications. Generally the discussion and conclusion are reflective of the findings, and balanced in the recognition of most piercing problems being minor/self-limiting. Reporting bias is noted in the reference to concerns over transmission of blood borne virus, with limited evidence to support this (CDC, 2006; Parahoo, 2006). This is despite acknowledgement that the research was not designed to address such an issue.

In summary, the studies of theme 1b in relation to infection and tattooing/cosmetic body piercing have been subdivided into three groups for this review. First, there is case study evidence that purports to establish a link between individual cases of infection and either piercing or tattooing events. On review of this evidence it is clear that the reports reflect on the case but fail to establish a causal link in most instances. Most often the case studies involve one recipient, with no further evidence to implicate the practitioner or their practices as the cause of infection. At times, the research evidence clearly identifies other risk factors associated with infection risk, yet these are frequently not explored. That case studies report on individual cases presents significant measurement bias, and ultimately biases reporting (Hartman et al., 2002; Shuttleworth, 2009).

Secondly, the risk of infection from tattooing and cosmetic body piercing practices was explored through mixed methods approaches – either as research or as part of ‘natural experimentation’ during outbreak investigation.

It becomes clear that multiple methods of data collection are able to assist in better understanding of the cause of transmission, and are capable of demonstrating direct links between industry practice and infection. In reviewing the study on outbreak management by Keene, Markum and Samadpour (2004), it is worth re-iterating that the establishment investigated was known to officials, and had a history of poor practice. Equally, in reviewing the study by Abiona et al. (2010) in the prison setting, the risk of transmission is not so much related to tattooing and cosmetic body piercing – but rather to illegal/unhygienic tattooing and cosmetic body piercing, where there was makeshift equipment and limited opportunity for decontamination.

Thirdly, in reviewing the studies on medical sequelae/complications, the heavy reliance on survey methodology and self-reporting of responses limits the reliability and validity of the findings from these studies, by introducing response bias (Kelley et al., 2003). Overall, most of the studies reviewed raised concerns over sampling/selection bias, impacting on the quality of data collected and analysed. Despite this fundamental flaw, all made use of statistical tests which rely on appropriate sampling. The overall quality of these studies is compromised as a result, in terms of design, measurement and procedural bias (Hartman et al., 2002).

What becomes evident through the review of the studies within the theme – infection, is the absence of a robustly established causal relationship between tattooing and cosmetic piercing and infection in premises that are practicing under good hygienic conditions. Being known to the officials/enforcers of health and safety does not prevent poor practice, as seen in the study by Keene, Markum and Samadpour (2004). In terms of infection risk reduction however, the potential benefit specifically to the prison population and more generally to wider society in managing illegal/unhygienic tattooing and cosmetic body piercing activity can be seen from the findings of the study by Abiona et al. (2010).



#### *2.4.3 Theme 2: Professional and public opinion of the influence of regulation on health behaviour*

Utilising the search terms “attitude\*”, “(public) opinion”, “(government) regulation” and “(public) health (behaviour) (policy)” under Boolean principles, 671 articles were returned, of which 380 were excluded from the review as they were not primary research or were related to aspects of self-regulation, public opinion on aspects of social policy out with health. Of the remaining 291, 283 were duplicates, leaving 8 articles suitable for inclusion within the review within theme 2 – professional and public opinion of the influence of regulation on health behaviour.

##### *Focusing on public opinion*

Walsh, Paul, Tzelepis, Stojanovski and Tang (2008), in a wider study to assess community attitudes to a range of potential strategies to control tobacco, use compared public preferences to these approaches with governmental policies in the New South Wales population of Australia. This aim is clearly presented in the introduction, along with background information on Australian tobacco management, offering a sound rationale for undertaking the study. Through an anonymous computer assisted telephone survey of adults from randomly selected households in 2004, they assessed community attitudes towards smoking bans, tobacco availability, promotion and product regulation, tobacco industry donations to political parties, and government spending on tobacco control activities. Overall 49.1% (n=3506) of eligible subjects consented. Quotas and weighting were applied to increase representativeness of the sample, and from 12,000 invited to participate, 4859 were ineligible and 3506 (49.1%) eventually agreed to participate. These were randomly allocated into three sub-samples, one containing 1,191 and two containing 1,158 participants (representing 49.1% of the target population). With no explanation offered on the 4859 considered ineligible, nor how those who declined to participate (50.9%) impacted on the representativeness of the sample, sampling bias may have occurred. This has implications for the generalisability of results (Parahoo, 2006).

The study found the majority of participants supported smoking bans across the assessed settings - children's playgrounds (89%, n=3120), sports stadia (77%, n=2966), licensed premises (72%, n=2524), outdoor dining (69%, n=2419), beaches (55%, n=1928) and motor vehicles carrying children (55%, n=1928), and concluded that there was strong community support for additional government regulation mandating smoke-free provision. Analysis of results made use of Chi-square to compare responses between smokers and non-smokers, with outcomes of statistical testing reported in table format and using numbers and percentages. Confidence intervals are cited as 95%, specifying the probability of including the true value of the variable. Narrow confidence intervals can however be misleading if they arise from biased studies. As such, the study design must be adequately assessed before this can be fully interpreted (Davies & Crombie, 2009). The article concludes that support for state-controlled regulation is evident, and suggests the need for government action to bring the policies in line with this level of support.

The authors report the response rate as a limitation, alongside the time that passed between data collection and publication (4 years) and the potential for changes in views. The self reported nature of the data collected was also reported as a limitation, with the issue of social desirability recognised as potentially influencing respondents' answers. Finally, the ability of the scale to measure the views is reported as a limitation. Given the complexity of health behaviour, this is a real challenge with quantitative research, and could have been minimised by ensuring validity and reliability of the scales used (Field, 2003). Use of the scale as part of a national approach indicates the tool could have been previously validated. Equally, a mixed approach to data collection may have assisted in minimising these limitations.

A study by Wilson, Weerasekera, Blakely, Edwards, Thomson and Gifford (2010) also considered public opinion, examining smoker support for tobacco tax. The paper introduces the concept of tobacco tax, setting out its aim to study smoker support for current and dedicated tobacco taxes in New Zealand, using the International Tobacco Control Policy Evaluation Survey. This is a multi-country approach to evaluating tobacco control policy, so the validity of the tool adds to the quality of the study (Field, 2003).

Details of the research methodology/methods are alluded to in this paper, with reference made to additional papers for further information. In this paper, sampling is described as systematic boosted sampling, drawn from the participants of New Zealand Health Survey (NZHS). Eighty-five percent (n=2438) of adult smokers, aged 18-years and over, from the NZHS agreed to participate, with 1376 eventually completing a telephone questionnaire between March 2007 and February 2008, giving a response rate of 56.4%. Drawing the sample from a national survey in this way could have led to response bias (Kelley et al., 2003), and this is recognised as a study limitation by the authors. Ethical approval is reported. Results were weighted, with detail of the process referenced. Univariate analysis and multi-variate logistic regression analysis was conducted, appropriate statistical tests where there are independent variables, the results of which were presented in table format (Argyrous, 2005).

The results showed 68% (n=935) of respondents considered current tobacco tax levels too high, increasing with age. Despite this, the majority of respondents said they would support increasing this tax if the additional funds were used to support smokers to stop and to promote health. Amongst smokers, support for a tax increase was higher amongst those who did not smoke every day, those who supported advertising restrictions, those with greatest concern about the impact of smoking and those with greater intent to stop smoking. The discussion reflects the findings and draws on other contemporary literature to support its conclusions. Policy implications are offered. The response bias noted above has implication for the findings of this study and overall may have resulted in measurement and reporting biases (Hartman et al., 2002; Kelley et al., 2003; Shuttleworth, 2009).

Costa and Mossialos (2006) undertook a study within the general public to investigate determinants of smoking cessation and tobacco consumption, and in particular to examine the role of risk perception and anti-smoking regulation. The study introduces the risk to health from smoking and the debate surrounding which interventions best assist smokers to stop. The policy tools available in the EU are discussed as tax policies, regulation policies and anti-smoking policies.

From the anti-smoking analysed across the EU nations, the findings of this study suggest regulatory policies have an influence on smoking. Taxing and advertisement did not have a strong impact. Advertisement and anti-smoking campaigns were found to be strongly dependent upon population information levels at the time.

The findings from the large dataset led to complicated presentation of findings and analysis. Tables and graphs are utilised, and the use of statistical approaches to analysis are appropriate (Argyrous, 2005). Use of an international data set makes comparison across EU countries possible. The conclusions drawn reflect the findings and draw on contemporary literature to support them. Policy implications were offered, such as the need to target anti-smoking campaigns. That pricing did not seem to influence smoking habits, the role of regulation in smoking cessation as a result of constraining capacity to smoke freely were viewed as likely to continue.

Shwom, Bidwell, Dan and Dietz (2010) carried out a mail survey in 2004 to determine the public view of potential climate change policy in Michigan and Virginia USA. While the differences in climate and expected effects of climate change are reported as the reasons for selecting these two states, the authors note this as a limitation to the ability to relate findings to the general population of America. Sample/selection bias, measurement bias and reporting bias may impact on the findings of this study, and the ability of its conclusions to be generalised (Parahoo, 2006). Five hundred households from each were randomly selected from telephone listings, this again impacting on true random selection, where some residents may not have been listed.

The paper offers a detailed overview of climate and climate change management as an introduction and rationale for the study. Data collection was via mail shot, containing a letter of explanation, questionnaire (containing closed and open ended questions), consent form, pre-paid return envelope and a 'token of appreciation'. Three follow up packs of information were sent to aid response rate.

No indication is given as to the nature of the incentive, and while this is considered as an acceptable approach to improving response (Ruane, 2005), as is repeated issuing of the survey (Parahoo, 2006), it has ethical implications that do not appear to have been addressed in the paper, in terms of persuasion (Ruane, 2005). With some packs returned unopened, the overall response rate is stated as 38% (n=316). The authors note this as low compared to other similar studies and therefore as a limitation. Consideration has however been given to how representative the respondents were of the target population, which in part address the concerns with overall response.

The reasons for supporting or rejecting climate change policy were grouped into four categories – economic, political, technological and moral reasons, with results and analysis presented in text and tables. Statistical analysis using bivariate t-tests compared those who did support against those who did not, with p-values calculated to determine if the findings were of statistical significance (Davies & Crombie, 2009).

The inclusion of open-ended questions in the questionnaire provided opportunity to collect data rich in text, therefore assisting in more fully understanding the topic under study than would have been possible with just closed ended questions (O'Leary, 2004). The authors however highlight that around one third of respondents did not complete these questions, highlighting the difficulties of collecting qualitative data in this way. In addition, the authors note the content of the questionnaire did not capture all possible policies, and so content validity is questioned (Field, 2003). No indication is given of how the questionnaire was developed or piloted, which could have addressed these issues and enhanced content validity (Field, 2003). The findings identified those with greater concern of environmental protection were more likely to support policies on climate change. Those who focused on financial aspects of climate change had less support for such policies. The authors also note that values and beliefs were greater predictors of policy support than socio-demographic factors, this having implications for how policy is developed. In concluding, they suggest the need for greater participation by the public in policy development, reflecting on this in light of other available literature.

Van der Sar, Brouwers, van der Goor and Garretsen (2010) collected data in 2008 to explore the opinions of adolescents and adults on alcohol policy in the Netherlands, highlighting alcohol prevalence in the introduction as the rationale for the study. Cross-sectional survey methodology was employed, using the internet to collect data through a Dutch panel. This was based on a representative probability sample of Dutch household, developed by a central body, and consisted of 8280 panel members, aged 16 years and above. The age criterion is reflective of the legal age for drinking alcohol in the Netherlands and so is appropriate for this study. Availability, education and pricing were policy measures explored as dependent variables against socio-demographic factors as independent variables. A response rate of 67.2% (n=5568) was achieved, with 536 aged 16-22 years and 258 between 16-18 years. Results were subject to statistical testing and appropriately presented in tables, using t-tests and regression analysis to compare and predict respectively (Argyrous, 2005).

The study found 16-22 years olds were less in favour of restrictive measures when compared to adults, with alcohol consumption a strong predictor of opinion. The popularity of educational intervention over restrictive policy intervention in adolescents is reported as reflecting other literature on this topic, with implications for policy success. The self-reporting nature of responses is reported as a survey limitation, with selective non-response potentially biasing results (Kelley et al., 2003). The design of the scale used in the questionnaire is also reported as a limitation, where a middle category of "neither agree nor disagree" is considered to have potentially biased opinion scores. This is however a commonly used category in scales, offering respondents to select middle ground where they have no real opinion (Field, 2003). While Van der Sar et al. (2010) consider this a limitation, its value in gaining accurate reflection of opinion cannot be dismissed, so its biasing nature could be questioned. The short conclusion reflects accurately the findings of the study.

### *Professional and public opinion*

A study by Zheng, Fu and Li (2009) considers both professional and public opinion, surveying 242 workers, 284 customers and 46 restaurant owners in Shanghai to explore attitudes of second hand smoke and smoke free restaurants. The rationale for the study is provided in the introduction, and draws on literature from the global community on the impact of smoke and smoke free working environments on health. The research questions are clearly detailed. The researchers note in the introduction their hope that results from the study will provide evidence required to support banning smoking in restaurants in China. The need to ensure a neutral stance is important, with quantitative research demanding objectivity (Ruane, 2005), and so this inherent bias of the researchers at the outset of the study must be considered to have potentially biased the design, measurement and reporting of findings and conclusions (Hartman et al., 2002; Parahoo, 2006; Shuttleworth, 2009).

The study was carried out in May 2007, with three streets in Shanghai selected for participation due to the numbers of restaurants within them. Such approach to sampling is not random and may result in selection bias (Hartman et al., 2002; Newell & Burnard, 2006). Inclusion criteria (such as Chinese-only restaurants) further contribute to this bias, although the researchers report these account for the biggest proportion of Shanghai restaurants. Consideration of the other restaurants may have added a further cultural dimension to this study, and so the impact of measurement bias must be deemed as impacting on the generalisability of the study findings (Parahoo, 2006; Shuttleworth, 2009). The researchers describe random selection of 50% of eligible workers, but the non-random approach to identifying those eligible make this description somewhat false. Data collection involved a face-to-face interview with workers, managers and customers, although 6 managers from the 33 restaurants refused the researchers access to customers due to concern over disturbance – this further impacts on the sample. Questions were specific for each group, with workers asked about health, managers asked views on banning smoking and smoking levels of customers monitored.

Analyses of results were supported appropriately by SPSS with Fisher's exact test or Pearson Chi-square used to compare groups and logistic regression used to identify predictors, and presented appropriately in table format (Petrie & Sabin, 2000). The self reported status of workers health is acknowledged, and p-values used to report statistical significance.

The discussion of results and analyses relates closely to the findings from the study, reflecting on previous literature on this topic. In the absence of regulation, only one restaurant of the 33 had implemented a smoking ban, despite awareness by managers of health risks from second hand smoking. Fifty-six percent (n=26) of managers were concerned for the profitability of their business with any ban on smoking, despite customers stating they would continue to eat in restaurants if a ban was in place. In reporting the limitations of sampling, and despite the earlier bias of opinion, the researchers offer some relevant recommendations for policy, suggesting the need to instil confidence in managers/owners as part of any policy development to ban smoking in restaurants. The final conclusion that enforcement of 100% smoke free restaurants is feasible and acceptable is not reflected in the study findings and as such is unjustified.

#### *Focusing on professional opinion*

From a professional perspective, Grigg and Williams (2000) undertook an exploratory study in 1999 of Scotland's Trading Standards Officers' perceptions of legislation relating to weights and measures. The paper begins with an overview of the history and recommended changes to the laws governing weights and measures, aimed at simplifying the current approach. The aim of the research is clearly stated. Designed as an exploratory study in four stages, the first two stages as data collection stages (interviews followed by questionnaires), followed by two stages of analysis.

Six experienced Trading Standards Officers (TSOs) were involved in the interviews. While no detail is given of the approach to sampling, purposive sampling is an accepted practice in qualitative research, with 6-8 participants considered an acceptable number in a homogenous group (Parahoo, 2006).



Although themes are reported, no evidence is presented on how these were generated, introducing the risk of reporting bias as a result of design (Shuttleworth, 2009). This is important as the themes from these interviews were subsequently utilised to develop a 40-statement questionnaire for distribution across 32 Local Authority areas. Although a census survey is reported, the target population number is not identified. With 103 responses received from across 28 of the Local Authorities, a response rate of 54% is estimated. This estimation has implications for measurement bias and as such reporting bias. The response rate is however considered to be representative of Scottish officers and this is significant to the reporting of findings (Ruane, 2005).

Principal component analysis was used, this being an accepted approach in quantitative research to reduce the number of variables in the questionnaire to a more manageable number (Pallant, 2007). T-tests and correlation analysis was then performed on each variable to determine general support for the statements and the strength of their effect on the main response variable respectively. The findings showed that TSOs felt there were problems with existing legislation/enforcement, and supported the drive towards deregulation. Difficulties in prosecuting, resources, shifts in technology, skills of assessment/testing ability, difficulties understanding the legislation, out of date codes of practice, and burden of small traders were among the identified factors contributing to this view. The study concludes that review of the current approach to managing weights and measures is supported due to the problems understanding and enforcing the current legislation. This conclusion is in keeping with the findings from the study.

Also focusing on professional approaches to regulation, Gurau, Ranchhod and Gauzente (2003) undertook a study to explore and compare the privacy dimension of websites within the UK, USA and France. The rationale for the study related to concerns over privacy in the web and the protection of online privacy. Accounts of the legislative requirements for privacy were reported, taking cognisance of the different regulatory approaches and regimes in place across the three participating countries.

To assess the differences in regulatory regime, an observational survey was carried out (February - May 2003), with web sites randomly selected from across all sectors in the three participating countries. A total of 291 websites were accessed and studied. Trained researchers were used, this assisting in minimising measurement bias. The collected data were entered into SPSS for statistical analysis, with Chi-square used to assess the influence of nationality on privacy. Given the approach to sampling, Chi-square is an appropriate non-parametric test (Argyrous, 2005). In this study the approach to random selection has the potential for selection/sampling bias, however the sample has sufficient numbers from each country to enable comparison (Newell & Burnard, 2006). The decision to access from across all sectors however may make comparison difficult and lead to measurement bias (Hartman et al., 2002).

The results found that the French have a very clear emphasis on transaction based data request, while the US has a very intrusive approach. These results reflect the regulatory stance of the countries, where the USA expects companies to voluntarily implement a level of privacy with no clear governmental guidelines or standards. This reflects their more aggressive approach to the collection and use of customer data. The UK and France on the other hand have privacy levels set and enforced through European Directive or state law, with expectations on data use. This is reflected in the level of information provided to customers in terms of how their data is collected, used and secured. The study suggests future qualitative research to add to the understanding gained from this research, highlighting the value of multiple methods of data collection to aid better understanding of a topic (Creswell & Plano Clark, 2007).

From reviewing literature within the theme of professional and public opinion of regulation, it is evident that ascertaining public and professional opinion has relied heavily on the use of survey methodology alone. This quantitative approach requires an objective stance from the researcher and a robust approach to sampling if it is to produce valid results (Parahoo, 2006). In most of the studies, the sampling approach claimed to be random, but frequently involved a phased approach, beginning with purposive sampling.

This sampling bias has implications for the validity of findings and subsequent analysis and discussion (Ruane, 2005). A further lesson on the importance of objectivity in quantitative work can be learned from the potential bias introduced to the work of Zheng, Fu and Li (2009), who imply the outcome of their work in the introduction.

The reliance of survey methodology also highlights the limitation of self-reported information, as previously noted (van de Mortel, 2008). The importance of detailing the measures taken to maximise validity of findings is realised, along with the value of measures such as piloting of questionnaires and adequate sampling. Equally, being forthright about the limitations of self-reporting is now recognised as an essential feature of write-up where this approach to data collection has been used. While not utilised in the studies within this review, the utility of mixed methods in data collection to minimise the overall effect of self-reporting is also acknowledged (Creswell & Plano Clark, 2007). The introduction of open-ended questions to questionnaires does provide some qualitative data but this is also self-reported, and the study by Shworn et al. (2010) highlights how this is not always successful in obtaining the richness of data associated with qualitative approaches.

In summary, the studies within theme 2 span a range of topics. Despite the study limitations, the studies appear to suggest a general acceptance of regulation as a mechanism to affect health behaviour change in both the general public and associated professionals. The generalisability of findings across cultures and topics is difficult and no real cause and effect is determined by these studies. Equally, health behaviour change has been noted as complex, with many factors impacting on decision-making. The findings from the studies within this review are often underpinned by intent, yet it is well known that intent to change does not always translate into healthy behaviour change (IpsosMORI, 2007). If the effectiveness of regulation as an intervention to influence health behaviour is to be better understood, considering the findings from this review within the context of regulatory compliance becomes crucial.

Of particular interest is the diminished support for regulation when it has financial implication or impacts on personal choice, as seen by the findings of the work by Zheng, Fu and LI (2009). The type of support for regulation and how this translates into compliance with regulation is therefore worthy of further exploration.

#### *2.4.4 Theme 3: Evidence of the effect of regulation on compliance*

Utilising the search terms “compliance”, “(government) regulation” and “(environmental) health (behaviour)” under Boolean principles, 757 articles were returned, of which 745 were excluded from the review as they were not primary research papers or were related to treatment compliance, motivating factors or predictors of compliance with health behaviour or self-regulation. Of the remaining 12, 3 were duplicates, leaving 9 articles suitable for inclusion within the review within theme 3 – evidence of the effect of regulation on compliance.

##### *Public compliance with regulation*

Iribhogbe and Osime (2008) undertook a study to evaluate compliance with seat belt use in Benin City, Nigeria, the rationale for the study being the association between road traffic accidents/injuries and wearing a seat belt. A five-day, observational study was conducted in strategic locations in Benin City, assessing the compliance rates of seat belt use in 369 vehicles. Drivers, as well as front and rear seat passengers, were evaluated across a range of vehicles (172 private cars, 64 taxis, 114 buses, 15 trucks, and 4 other vehicles). The approach to sampling as a time period is not new, and can be effective if the 24-hour period is covered and issues of working week/weekends/holidays are considered to ensure representation (Oldfield, 2001). The times for data collection are not reported in the article, although the sites are identified as areas of high vehicle load and commonly experiencing traffic jams. It is not possible to gauge from the streets selected how representative these were of the roads in Benin City, so there is the potential for sample/selection bias, and measurement bias (Newell & Burnard, 2006).

As a limitation, the researchers noted the collection of data during the days before Christmas, when the road safety police had intensified their monitoring. This they suggest may have increased seat belt compliance, resulting in procedural and measurement bias in the study findings. Furthermore, as an observational study, the need to ensure inter-observer and intra-observer reliability is important to minimise procedural and measurement bias (Ruane, 2005). While the authors reviewed the collection of data following pre-test and orientation of the observers, they do not indicate the extent or purpose of this activity, and as such reliability cannot be assured. Measurement and reporting bias may therefore be a concern in this study (Hartman et al., 2002; Shuttleworth, 2009).

The study found that seat belt compliance rate for drivers was 52.3%, front seat passengers 18.4%, and rear seat passengers 6.1%, with drivers of all categories of vehicles more likely to use the seat belt compared to front and rear seat passengers. Drivers of private cars were more likely to use seat belts compared to taxi or bus drivers, front and rear seat passengers in private cars were more likely to use the seat belt compared to front or rear seat passengers in taxis or buses. Statistical testing assisted by a computer package examined the differences between drivers and passengers, and although no detail is given of the tests undertaken, p-values are recorded in the data, and presented in table format. The study conclusions reflect the study findings that compliance with seat belt use in Benin City is low. Contemporary literature was used to compare the findings with that of other countries. It makes appropriate recommendations on legislation, educational campaigns, and enforcement of seat belt use, also supported by previous research.

Also considering road safety, an earlier study by Goodwin, Wells, Foss and Williams (2006) assessed the use of increased enforcement (coupled with a campaign to highlight the enforcement) as an intervention to encourage compliance with graduated driver licensing restrictions and seat belt requirements in Guilford County, North Carolina. A comparison community was studied to assess whether changes over time could be reasonably attributed to the campaign.

The rationale for the study drew on literature associated with graduated driver license schemes designed to reduce the risk of accidents as novice drivers build up their driving experience. It is supported with statistics on crash/accident rates since the introduction of the scheme in North Carolina in 1997, alongside evidence of restriction violation from a recent study. The study was conducted as a phased mixed methods study in the summer of 2004. Four law enforcement agencies participated, representing all uniformed officers from within the county. These officers were trained on the graduated driver license programme and the campaign during routine training sessions. While this has the potential to minimise measurement bias, the effects of the training on inter and intra observer reliability were not checked (Ruane, 2005) and so this bias may still have occurred, with implications for findings.

Twelve schools were involved, 6 in the intervention community and 6 in the comparison community. The first phase of data collection involved interviews with young drivers and parents prior to the campaign, to determine self-reported violations of the restrictions. To examine seat belt use, 5694 observations of young drivers arriving and leaving school took place, followed by the introduction of a multi-event campaign involving press and schools in the intervention community, to raise the awareness of the increased enforcement. Thereafter the second phase of interviews was conducted. It is not clear from the article how representative the selection of participants through schools was of the wider population of young drivers, and so this could have resulted in selection bias (Newell & Burnard, 2006). Equally while the comparison community was used to test the effect of the increased enforcement and campaign, no indication was given of the potential contamination of this control group, nor of how well it matched the intervention group, these being factors which could have led to procedural bias, resulting in either over or under estimation of the value of the increased enforcement/campaign (Parahoo, 2006). In addition, the decision to interview a new sample in the second phase of interviews impacts on the ability of the study to offer before and after experiences – the use of the same participants would have supported this type of data collection and contributed to better understanding the impact of the enforcement/campaign (Parahoo, 2006).

To compare the two communities, Chi-square tests were carried out of the results, while linear regression analyses were undertaken to measure changes over time in the intervention community. While no indication is given as to the extent of normal distribution of the population, the authors report statistical tests were sufficiently robust and insensitive to violation of underlying assumptions, suggesting the tests as appropriate (Argyrous, 2005). The study found violation of the restrictions of the graduated driver license programme occurred, both with and without parental consent, but the extent of this was low. While the interview data was self-reported, the collection of data from both young driver and parent assisted in maximising the validity of findings. Overall the intervention resulted in only modest changes in compliance with graduate driver licensing restrictions. Again this has been associated with the high compliance with the restrictions pre-intervention. The study did however conclude that while the programme was able to produce changes in driver behaviour, these were insufficient to alter the behaviour of the minority of teenagers (and parents) who were not already complying with restrictions. The study also identified the negative impact that peer/family role modeling can have on behaviour, and highlights the complexity of behaviour change and compliance.

#### *Organisational compliance with regulation*

Beginning by introducing the evolution of tanning salons and the associated health risks as the rationale for this study, Forster, Lazovich, Hickie, Sorensen and Demierre (2006) describe their study to examine the business practices of tanning salons in Minnesota and Massachusetts in relation to compliance with sales restrictions for under 16-year olds. Of the 496 tanning businesses identified from telephone book and council official registers, eligibility for inclusion in the study was determined based on a series of set questions, businesses requiring to answer yes to each. The process was continued until 100 salons were recruited in each of the two areas. This is not true random sampling, as depending upon the order of the list, not all salons had equal chance of selection. Clearly, those further down the list having less chance (Parahoo, 2006), resulting in selection bias (Newell & Burnard, 2006).

Each business was visited twice during a two-week period by one of nine 15-year old recruited to the study as buyers. Following each visit, the buyer returned to the researcher to complete a questionnaire based on the experience. At the second visit, the researcher joined the buyer and asked the employee a series of questions relating to health and safety, to determine knowledge. This is considered covert observation, where the employee does not know they are part of a research study. Ethically, this is not considered sound as the employee has no opportunity to consent. It can however be justified as necessary in certain illicit/controversial settings (Ruane, 2005). Post-observation disclosure and de-briefing are considered necessary if covert observation is to be used, however more open approaches (such as informing participants of the broad research focus) are considered better options (Parahoo, 2006). In this study, a post observation interview was designed to address this issue, during which, demographic data on the business and employees was gathered with consent. Despite the covert observation, ethical approval was granted for this study.

The study reported results using tables and graphs and compared buyer success against business characteristics. Overall 81% (n=81) of businesses sold the buyer a tanning session on at least one occasion, with businesses in both areas equally likely to do so. Larger businesses and those dedicated to tanning activity were however less likely to do so. The design of the study has the potential to introduce bias due to buyers being instructed to tell the truth (Hartman et al., 2002). When asked their age therefore, they were honest. In reality the likelihood of such an approach is less and this may well impact on the outcome of such a visit. Under-estimation of compliance may therefore be a concern in this study.

Castel, Reed, Davenport, Harrison and Blythe (2007) undertook a survey of 32 college and university administrators in Maryland USA to determine the compliance with the law introduced 4 years previous, which mandated that students living on campus obtain meningococcal vaccination or sign a waiver refusing vaccination. This was based on research showing students of greater risk of meningococcal disease. The survey involved the use of a self-administered questionnaire to administrators.



All 62 institutions in Maryland were contacted and 32 identified with on-campus residences. The survey was therefore conducted as a census, and avoided the potential biases incurred through sampling (Parahoo, 2006). Student enrolment and on-campus student numbers were obtained through central record systems. Data were collected in September 2004 from the relevant administrator and returned in a pre-paid envelope. Telephone reminders were used to improve response rate to 88% (n=28). The ethical approval for this study is reported. Chi-square and ANOVA were used to assess statistical differences with p-values noted at 0.05. Compliance with six components of the law was assessed, finding only 7% (n=2) compliant with all aspects of the law. Ten (36%) were compliant with 4 components and 16 (57%) were compliant with 5 components. Recommendations on how to improve compliance are offered based on the findings of the study, including the introduction of multi-agency advice, support and education.

In 2008, Rossow, Karlsson and Raitasalo reported on the findings of a study on business compliance with alcohol purchase in Finland and Norway (where beer and alcopops are sold in privately owned and licensed outlets, whereas wine and spirits are only sold in government managed monopoly outlets). The article begins by outlining the legal position of alcohol sale in Finland and Norway. Outlining the issue of non-compliance with similar legislation found in other countries including the United States and Australia, the effects of strategies such as enforcement and education were reported as having mixed outcomes, justifying the need for further study to explore this issue. The study aimed to compare compliance with minimum age purchase of alcohol between monopoly outlets and other outlets, as part of a larger study on alcohol-related harm.

The study was experimental in design. Eight 18-year olds, considered to look like minors (4 boys and 4 girls) were recruited to act as buyers and instructed to buy beer from a range of outlets and other alcoholic drinks from the monopoly outlets. In Finland this was carried out Wednesday and Thursday evenings during October and November 2006 and in Norway, on Friday and Saturdays during January, February and April 2007 (where 10 buyers were recruited, and operated in pairs).

If asked for identification of age, they were advised to say they did not have it with them, and if refused sale, were advised to leave the premises. The researchers report watching the buyers attempts to purchase the alcohol but that this was not always possible in the Finnish component. There is therefore a risk of design bias, where some buying attempts may not have followed the agreed protocol (Shuttleworth, 2009). In experimental designs where comparison is to be made, it becomes important to ensure controls are in place and that experimental conditions are exact (Ruane, 2005). The different days for buying could have resulted in different outcomes due to different store pressures, and this could have resulted in measurement bias. In addition, the decision to operate in pairs in Norway may have introduced procedural and response bias (Kelley et al., 2003).

Sixty-six shops were selected from two regions, one in Finland and one in Norway, totalling 290 attempts by under-age minors to purchase alcohol (80% (n=232) in grocery stores, 13% (n=38) in gas stations and 7% in monopoly outlets (n=20)) in Finland and 170 purchase attempts in Norway. That each type of premise was not allocated the same number of attempts may have resulted in measurement bias, although this is dependent upon the total numbers of each and how this translated into a stratified sample (O'Leary, 2004). The article identified monopoly outlets constituting a minority of all outlets, so this approach appears justified. Bivariate analysis was conducted using cross tabulation and Chi-square statistical testing. The presentation of Norwegian results followed by combined results makes it difficult to interpret the text associated with the results and analyses; however the use of tables assists in the explanation. Overall, the results show that compliance with minimum legal age sale of alcohol is poor in both Finland and Norway, with rates of non-compliance reportedly higher or equivalent with those found in studies from other countries. The study also found monopoly outlets compliance to be better, but not sufficiently compliant to recommend all alcohol be sold from such outlets. The sample size is reported as a limitation and further research suggests repeat of the study with more test power.

In 2006, Quedley, Ng, Sapre, Blakiston, Crawford, Devadas, McLaren, Anand, Tipu, Dayal, Chandrasiri, Thomson and Edwards (2008) undertook an observational survey of 288 non-specialist tobacco retailers in the lower North Island of New Zealand to investigate retailer compliance with point-of-sale display legislation. The article introduced the changes to tobacco advertising through the introduction of restrictive legislation as part of wider policy to minimize health risk from smoking. Limited research on retailer compliance with point-of-sale legislation was reported as the rationale for this study, which hypothesised different levels of compliance across a range of socio-economic factors associated with the retailers.

All tobacco retailers in the Greater Wellington Regional Council area of lower North Island, New Zealand were surveyed, constituting approximately 10% of New Zealand's total population. While the authors reported this represented urban, suburban, small town and rural areas, no indication of how representative this is of the population of New Zealand is given, impacting on sample bias and limiting generalisability of findings. In addition, the use of the yellow pages to identify the retailers has the potential for further selection bias, where there is the assumption that all retailers are listed. Further measurement bias is introduced to the study through the researchers own judgement of which retailers were likely to sell tobacco and therefore suitable for inclusion (Newell & Burnard, 2006).

A pre-piloted checklist was used for data collection, developed in conjunction with enforcement officers involved in managing violation of the point-of-sale regulations. This approach to data collection tool development enhances tool content validity (Field, 2003). Ten observers were allocated to locations, visiting stores unannounced to judge compliance with the regulations against the tool. Inter-observer reliability was tested through repeat assessment by a different observer prior to commencement of data collection. Observer agreement ranged between 70-100%, enhancing the quality of data collected in the study (Ruane, 2005). Despite this, the authors identified observer error in the observation of 8 stores, highlighting the value and limitation of training. Ethical approval is also reported for the study.

The study found most common breaches of regulation were a failure to display a "Smoking Kills" sign, visibility of tobacco from outside the premises, and displaying tobacco less than 1metre from children's products. Compliance was significantly worse in dairies (small local general stores) and convenience stores. The use of logistic regression analyses was appropriate to support the identification of these predictors. Overall, a 64% rate of non-compliance led the researchers to conclude that the point-of-sale regulations were ineffective. That no license is required to sell tobacco, no accurate list of retailers is available and this makes enforcement difficult. This is highlighted as a limitation in terms of sampling/selection bias. Recommendations via two frameworks are proposed, one being to implement a complete ban on point-of-sale display. Without an accurate understanding of how well the study represents all retailers, this recommendation seems somewhat unjustified, and highlights the dangers of measurement and reporting bias (Hartman et al., 2002; Shuttleworth, 2009).

Whitmand and Harbison (2010) undertook a study to examine the extent of smoke free policies in general hospitals in Alabama, where restrictive policies on smoking are higher. This aimed to assist the management of high smoking rates previously identified from research. The study is described as a pilot, to study challenges faced when implementing smoking bans. The introduction provides a detailed account of the impact of smoke on health and the current patterns of smoking and smoking bans in Alabama. The research questions derive from this and are clear in their intent to identify policy and the challenges faced in implementing these. The target population included hospitals providing medical and surgical services in Alabama, totalling 101 within the state. A questionnaire was developed, based on the issues on smoking bans within the literature. This was sent to chief executive officers of each of the hospitals, to be returned anonymously. While the full census approach eliminated selection/sample bias, the lack of information on the piloting process of the data collection tool may impact on its validity and reliability (Field, 2003), leading to the potential from measurement and response bias (Hartman et al., 2002; Kelley et al., 2003).

A response rate of 48.5% (n=49) was achieved. This response rate may also incur response bias. SPSS was used to support collation and analysis of results, these being presented in tables and free text for open-ended questions within the questionnaire.

The study found that over a quarter (27.7%, n=13) had restrictive policies in place, applicable to staff, visitors and patients. All had encountered resistance from employees. Of those without such policies, backlash from employees and patients and costs to enforce were stated as barriers. Only a small percentage felt it was not a priority. One respondent noted that a policy had been implemented but had been abandoned after one year due to staff protest, while another reported frequent dissent and general staff discontent. Backlash and non-compliance were therefore the two main challenges identified. The study is recognised as having limited ability to generalise, hence the description as a pilot. It recommends conducting a larger scale study as follow up. In addition, while the chief executive officer was sent the questionnaire, there is no way of checking who completed it, and this is considered a limitation with potential for response bias (Kelley et al., 2003). This is accentuated by the anonymous nature of the study, so design bias is also a problem. The conclusion of the study reflects the findings and analyses, with suggestion that smoking bans be implemented incrementally to increase likelihood of success, involving employees and patients in the development.

Nimpitakpong and Kanokthed (2010) undertook a cross sectional survey of 8858 drug stores in Thailand in 2007, to examine the compliance with a 2006 smoke-free policy. Using stratified random sampling, 3600 drugstores were selected to participate, subdivided into two groups – those who participated in the smoke-free campaign in 2006 and those that did not. A self-administered questionnaire was issued to each drugstore to ascertain their compliance with the law. The tool was validated using experts in the field and piloted in 30 drugstores prior to use. While these are measures to improve the validity of the tool, the use of a questionnaire has implications for response bias due to self-reporting (van de Mortel, 2008). A response rate of 27.8% (n=1001) was returned, further contributing to this bias.

The results are presented descriptively and inferentially, with p-values cited where comparison across groups is made. The study found 63.3% (n=633) displayed no non-smoking signs, and no impact was reported on sales. Smoking inside stores was reported in 26.4% (n=264) drugstores. While this indicates non-compliance, actual rates could be over or under reported due to the self-reporting nature of the self-administered questionnaire. The study concludes that further action is required to promote compliance, with lack of enforcement and minor financial penalty for non-compliance noted as factors likely to contribute to the non-compliance.

Yapp and Fairman (2005; 2006) undertook an empirical study involving all local authority areas in England and Wales to examine compliance with food safety legislation within small and medium sized business enterprises (SME) and the effects of local authority intervention on compliance. The rationale for this study was the lack of existing research on the effectiveness of different enforcement approaches to compliance with food safety. The study was completed in two stages. The first stage involved interviews with personnel involved in food safety, to identify the problematic stages of compliance for SMEs. Eighty-five groups/businesses across England and Wales were contacted and full interviews held with 50, plus 2 focus groups (one with commercial food safety consultants, one with a group of butchers). This purposive approach to sampling is appropriate for collecting qualitative data (Parahoo, 2006).

Thereafter, multiple case studies were undertaken. Purposive sampling and selection of 8 local authorities across England and Wales tested the effects of different types of intervention on compliance. One hundred SMEs within each of these local authority areas were contacted by letter, aiming to recruit at least 10 from each of the 8 local authorities. 81 SMEs were recruited. Although the selection of the 100 SMEs per local authority is described as random, no indication is given of how this was carried out, therefore selection bias may have impacted on the findings of this work (Newell & Burnard, 2006). Data collection involved the taking of compliance case histories, semi-structured interviews with SME owners/proprietors and compliance assessment.

The interviewer was a qualified environmental health officer (EHO), and was used throughout the study to interview and make a professional judgement of compliance. While use of the same interviewer avoided the need to test for inter-rater reliability, no indication is given on the assessment of intra-rater reliability (Ruane, 2005). Equally, the position of the EHO is not made clear and so the inherent bias of the interviewer are not addressed, leading to risk of design, interview and measurement bias (Hartman et al., 2002). While the mixed methods approach to data collection may have minimised measurement bias (Creswell & Plano Clark, 2007), the purposive approach to sampling does not match with the description of the research as empirical (where a scientific approach is demanded across the research process) (Ruane, 2005), and this may have biased the outcome of the study (Parahoo, 2006).

Analysis of data involved the use of a theoretical compliance model. Enforcers and regulators were found to view compliance as involving a proactive, on-going process of evaluation and monitoring against the required standards, integral to the day-to-day running of the business. SMEs were found to view compliance in a very different way, the majority seeing compliance as a reactive process, carried out at a particular point in time, and as a means of carrying out everything they had been told to do during the inspection visit. Non-compliance was identified in over half the SMEs that stated they complied with food safety legislation. Despite having been informed of their non-compliance, most had not taken action. The researchers state the reasons for this as failure to understand the requirements and how they needed to be applied to their own business, or because they were unable to relate the requirements being made to general food safety principles, believing the issues could not be relevant to the food safety of their business. No indication is given to explain such conclusions, and this must be considered a significant reporting bias (Shuttleworth, 2009). Despite not taking action, the SMEs continued to perceive themselves to be compliant with the legislation.

Barriers to compliance were identified as lack of time; money; experience; knowledge; support; trust; and interest. The discussion interpreted the findings in relation to the three levels of compliance used by Kagan and Scholtz (1984), concluding that non-compliance most frequently fell within the category of organisationally incompetent, where lack of knowledge, trust, and organisational management were key contributing factors. On this basis Yapp and Fairman (2004; 2005; 2006) propose that compliance with regulation requires knowledge and understanding, willingness and ability. Additionally the prescriptive nature of regulation and understanding of compliance were considered to impact on achievement and motivation to exceed minimum compliance, and account for the reactive approach to achieving compliance. Reporting bias is evident (Shuttleworth, 2009), with little mention in the discussion of the SMEs concern over lack of consistency by EHOs.

Baiche, Walliman and Ogden (2006) undertook a study to determine the level of compliance with building regulations in England and Wales. Beginning by detailing key regulations and previous associated research findings, the study methodology is reported as a triangulated approach involving three methods of data collection – observation of 11 housing projects and inspection using survey protocols/ checklists; a questionnaire of 200 occupants within 8 recently completed housing developments in Oxfordshire and Gloucestershire; and semi-structured interviews with 6 building control inspectors. No indication is given as to how the developments or participants were selected, and so the potential for selection/sample bias exists. This in turn is a design bias, likely to impact on the validity of measurement and reporting (Hartman et al., 2002; Field, 2003; Shuttleworth, 2009).

The study found evidence of non-compliance with building regulations, these often associated with shortcomings in workmanship, lack of site organisation and insufficient checking procedures. The shortcomings were at times serious and difficult to rectify later in the building work. The survey of occupants then followed up on the previous observational survey work, to determine if any problems could be traced to earlier building regulation shortcomings.



Forty-three (21.5%) of questionnaires were returned, and via manual analysis identified a series of faults, these being presented in table format. No statistical testing was undertaken. This reflects the approach to the study sampling/selection. Indeed, the researchers note the study was not a systematic attempt to quantify issues, but rather to explore. Just less than half (n=18) reported no faults, with the remainder identifying cracks as the main problem, these being repaired. Through analysis, this was considered to reflect poor workmanship rather than non-compliance with building regulations, the faults being typical of most newly constructed houses.

The semi-structured interviews with six building inspectors found all agreeing that building regulations were not difficult or impractical to implement or enforce, with breaches not purposive in nature. Causes of non-compliance were considered to be poor workmanship, lack of knowledge of regulations by tradesmen, wrong material use, poor management, conflict and pressures to complete work. Improved training to achieve standards of workmanship and more consistent approaches to site management were recommended, in line with the findings. That poor workmanship was not considered a deliberate breach of building regulations does have the potential to introduce reporting bias into this study, and a detailed explanation of what constituted compliance in the introduction would have helped minimise this in the conclusions (Shuttleworth, 2009). The use of mixed methods of data collection does support better understanding of the compliance with these regulations than would have been achieved through a single approach to data collection (Creswell & Plano Clark, 2007). Despite this, the lack of robust sampling/selection does limit the ability to generalise the findings, making this a significant limitation of the study.

In summary, the studies of theme 3 have again highlighted the importance of adequate sampling/selection to ensure valid and reliable findings. In the case of these studies on compliance, observation has been the main method of data collection, avoiding the limitation of self-reported information.

Without adequate inter/intra-observer reliability however, the studies show how measurement bias can become an issue. This must therefore be considered in the design of any study using observation as a means of data collection (Ruane, 2005).

From the studies more generally, compliance with regulation was frequently found to be sub-optimal. Of particular interest is the limited impact organisational level regulation appears to have on individual behaviour, as found in the studies by Whitmand and Harbison (2010) and Braiche, Walliman and Ogden (2006). Indeed, the complexity of regulatory compliance is further emphasised through the different results of road traffic compliance studies by Iribhogbe and Osime (2008) and Goodwin et al. (2006). Unfortunately, most studies within the review have used observation in isolation, judging compliance on the basis of achieving standards. This design approach does not afford opportunity to further explore the motivations behind decisions to comply or not, and so compliance with collective goals of regulation are not examined (Yeung, 2004). This is a limitation of single data collection study designs, and as an area of compliance under-researched, clearly requires a mixed methods approach to data collection if it is to be more fully understood (Creswell & Plano Clark, 2007).

Finally in the review of this theme, the study by Quedley et al. (2008) demonstrates the danger of regulatory creep, where the solution to ineffective regulation may be to replace it with another (BRTF, 2004). In addition, this review has considered compliance with regulation across a range of topics, where the limitations of sampling/selection, measurement and reporting make it difficult to generalise across cultures and topic. Given the potential policy implications to derive from research, the studies within this theme demonstrate how the decision to include concept-associated literature must be balanced with the need for topic-specific literature.

#### *2.4.5 Theme 4: Evidence of compliance with infection control practice within healthcare*

Utilising the search terms “compliance”, “health(care)” and “(standard) infection (control) (precaution\*)” under Boolean principles, 1180 articles were returned, of which 1151 were excluded from the review as they were not primary research papers or were related to other aspects of healthcare, healthcare compliance, treatment compliance or motivating factors or predictors of general practice. Of the remaining 29, those considering compliance as part of a pre- post- intervention study were also excluded, along with those focusing on only one element of standard or transmission based precautions (such as hand hygiene, for example), leaving 7 articles suitable for inclusion within the review within theme 4 - evidence of compliance with infection control practice within healthcare.

Regina and Molassiotisb (2002) report the findings of a cross sectional survey of 450 randomly selected registered nurses, to investigate their knowledge and compliance with universal precautions in an acute hospital in Hong Kong. Introducing the concept and importance of universal precautions as a mechanism to minimise transmission of infection, and detailing literature on the sub-optimal use of these precautions from the findings of previous international research, the aim and rationale for the study is clear. Data collection was via a self-administered questionnaire devised for this research. That other similar research has been undertaken in this area, the opportunity to utilise a validated tool was missed. The content validity of the questionnaire was however assessed by experts and piloted for internal consistency. Reliability coefficient for compliance was tested using Cronbach alpha, scoring 0.72. Scores over 0.6 are considered as acceptable evidence of reliability (Pallant, 2007). Ethical approval for the study was gained prior to data collection. The decision to select the 450 nurses is not explained; therefore selection bias may be an inherent risk (Newell & Burnard, 2006; Parahoo, 2006).

The response rate was 70% (n=313), and while there is no standard acceptable response rate, published opinion suggests non-response may incur bias (Barclay et al., 2002). The results were summarised using frequencies, means and standard deviations, while relationships between knowledge and compliance scores were calculated using Pearson correlation co-efficient, this being an appropriate test to consider the relationship between two (often continuous) variables. One way analysis of variance tests were used to explore knowledge and compliance in relation to the demographic data collected. Quantitative findings are appropriately reported in tables and graphs (Koch, 2008). Overall the findings showed universal precautions to be practiced selectively, with low levels of understanding, reflecting the findings of previous studies (Pittet, 2001). Education is the suggested approach to managing this deficit. While education has been found in previous research to improve practice, its short-term impact makes reliance on this worthy of caution, and the issue of sustainability worthy of further exploration (Kretzer & Larson, 1998).

Similarly in 2002, Kermode, Jolley, Langkham, Thomas and Holmes (2005) undertook a cross sectional survey of 307 healthcare workers (of which 266 were returned, giving a response rate of 87%) in 7 rural north Indian health care settings (incorporating hospitals with community projects). The aim was to determine compliance with standard precautions, and concluded that knowledge and understanding of these precautions was only partial, with compliance sub-optimal. It is unclear how the sample was selected, and how representative it is of the general population of healthcare workers. This affects the generalisability of the findings (Parahoo, 2006). Again education was proposed as the route to improvement. This study also involved a self-administered questionnaire, making use of Likert scales to assess practice and determine compliance with standards. This study however utilised a previously validated questionnaire, testing it for internal consistency and reliability in this setting. The self-reported nature of responses is reported as a limitation of the study, impacting on responses and acknowledged as potentially overestimating compliance.

The authors highlight social desirability as a further factor affecting responses. Multiple regression analysis identified time in job, knowledge of transmission of infection, and positive perception of safety in the workplace as three predictors of compliance.

A further study by Qudeimat, Farrah and Owais (2006) considered compliance with infection control precautions as part of a wider study exploring knowledge and attitudes in dentists and dental nurses in Jordan's University of Science and Technology Dental Teaching Hospital, Israel in April 2002. The need to examine such practice was based on the lack of previous research specific to the Middle East. The study was designed as a survey, with self-administered questionnaires distributed to 48 dental staff and 28 dental nurses. No sampling approach is detailed, nor is the reason for selecting this site, and as such, the representativeness of the findings could be limited and difficult to generalise to the wider dental practices of the country (Parahoo, 2006).

Demographic data and detail on infection control practice was collected through the questionnaires, and the results input to SPSS for analysis including descriptive and inferential statistics. The authors report using Chi-square and Wilcoxon signed rank testing, where a p-value of  $< 0.05$  was appropriately considered statistically significant (Argyrous, 2005; Davies & Crombie, 2009). Response rate was 77% ( $n=37$ ) for dental staff and 82% ( $n=23$ ) for dental nurses. No indication of any measure to enhance the response rate is given, although these may not have been considered necessary given the good initial response (Parahoo, 2006). The results and analyses are reported in text, numbers and tables. The study concludes compliance with infection control precautions was poor, this also reflected in the findings. Education is considered the approach to address this problem, the limitations of this being previously highlighted (Kretzer & Larson, 1998).

Similarly, a study to investigate knowledge attitudes and practice to standard and transmission based precautions in operating room staff by Chan, Ho and Day (2007) used the same rationale and background as the previously noted studies to justify its need. The study focused on nurses and non-medical staff in January 2006. The participants were recruited from the operating theatre services of one main hospital in Hong Kong and included all grades of full time nursing staff including managers, totalling 142 participants. No reason was offered to explain the exclusion of students from the study, which could have impacted upon response bias (Kelley et al., 2003). The sample size was calculated electronically, the results suggesting the need for a sample of 103 to achieve a power of 80% and a 5% confidence interval. This indicates the range of possible effect sizes, but must be interpreted in conjunction with other study design issues, to avoid misinterpretation (Davies & Crombie, 2009). Ethical approval for the study was granted.

The study was designed as a self-reporting survey, with the data collection tool designed specifically for the study. This included demographic details, and questions to ascertain knowledge attitudes and infection control practices, using Likert scales to support responses. The validity (content and construct) and reliability (internal consistency) of the tool were tested. Participants were given two weeks to complete the questionnaire, allowing sufficient time to reflect on the decision to participate without pressure. With a 79.6% response rate, 113 questionnaires were returned. SPSS was utilised to support analysis of the data, first descriptively, then inferentially.

The use of Chi-square, Fisher's exact test and Mann-Whitney U test were used to test differences across various groups, and Spearman's correlation used to quantify relationships. The use of non-parametric tests in this study is appropriate as the authors note the results to be skewed and so violate the assumptions of normal distribution required in parametric testing (Argyrous, 2005). Results were considered significant at  $p < 0.05$ , and are presented appropriately in text and tables. The authors report the findings in conjunction with those from previous studies, concluding that compliance rates with standard and transmission based precautions varied and were associated with a range of factors.

Education is reported to exist, and so the authors suggest tailoring this to different target groups. The authors note the sampling frame as a study limitation and how this impacts on the ability to generalise findings, as does the self reported nature of the data collected. Further study on a more representative population is recommended.

Chiang, Wang, Chen, Chen, Yao, Wu, Ko, Yang, Tsai, Hsai, Su, Chen and Ma (2008) reported the findings of an observational study of compliance with infection control measures, undertaken between November 2005 and April 2006 in the emergency department of the National Taiwan University Hospital in Taipei, Taiwan. The initial 15 minutes of resuscitation for those with out-of-hospital cardiac arrest was filmed and recorded, excluding those aged 18-years and less. Although the study was granted ethical approval, no indication is given of how patients consented to their care being used in research, presenting ethical issues for this work. The films of 44 consecutive adult resuscitations were reviewed and infection control compliance evaluated. Criteria to determine compliance were well defined, but no indication is given on who collected the data or any measures to ensure inter and intra observer reliability, so there is the potential for measurement bias in the data collected (Hartman et al., 2002).

Results and analysis make use of a supporting statistical package and are presented appropriately in tables and graphs. In terms of compliance, the study found compliance with standard precautions to be unsatisfactory, with the use of personal protective equipment during the resuscitations ranging between 20-90% compliance. Lack of hand washing post-contamination was also found. The results are presented in the context of the busy emergency department, where the risk of transmission of infection is heightened due to the pace of activity. Immediate changes to special arrangement of staff and to the demarcation between clean and dirty areas are suggested as two immediate recommendations to aid compliance with precautions and reduce risk of transmission of infection. These recommendations reflect the findings of the wider study, and appear justified.

Harris and Nicolai (2010) undertook a study to estimate compliance with universal precautions, as part of a wider study considering knowledge and occupational exposure to blood and body fluids in Emergency Medical Services (EMS) in the pre-hospital environment in Virginia USA. The introduction to this study focuses on blood borne virus transmission via needlestick injury.

A convenience sample of 17 licensed EMS agencies in the greater Richmond area of Virginia was drawn from a list of all licensed EMS agencies in Virginia, selected on the basis of the high prevalence of HIV and AIDS found in that area. The study was designed as a cross sectional survey, with all 614 providers from across the 17 agencies issued with a questionnaire pack for self-administration and return via pre-addressed envelope. Six weeks were given to complete and return the questionnaire, with a response rate of 51% (n=311) achieved. Although the questionnaires were coded to identify the agency, the coding assured individual confidentiality, with resultant ethical approval reported. The development and piloting of the questionnaire provides evidence of validity (Field, 2003). Although the article identifies changes to the questionnaire as a result of piloting, no indication is given of these changes or why they were made.

Analysis of data involved the support of a statistical package, with descriptive statistics followed by correlations between variables using Pearson's and Spearman's correlation coefficients and Chi-square analyses of contingency tables. In terms of compliance with universal precautions, the study found that these were used inconsistently, although there was a strong relationship found between levels of training/knowledge and compliance. These results were considered in conjunction with previous similar studies. The self-reporting nature of data collection is a limitation of this study (van de Mortel, 2008), as is the decision to use a convenience sample, which introduces bias into measurement, and negates the validity of statistically significant results (Shuttleworth, 2009) Education is suggested as the route to improvement, despite the lack of evidence to support its ability to sustain change in practice (Kretzer & Larson, 1998).



The similarity in approach of the above studies is reflected in the international review of literature, which underpins the evidence for sub-optimal compliance with infection control precautions in healthcare practitioners by Gammon, Morgan-Samuel and Gould (2008). Based on awareness of the problematic and sub-optimal practice of infection control precautions, they aimed to evaluate the extent of compliance, factors affecting compliance, strategies utilised to affect behaviour change, and the impact of these. The literature review set date parameters of 1994-2006, and utilised recognised databases and clearly defined search terms. In addition, manual searching and secondary sourcing were utilised to extend the search, and following the application of inclusion/ exclusion criteria, resulted in 37 studies available for appraisal – 24 relating to compliance and 13 related to interventions associated with improving compliance.

The aim and design of the review are clearly detailed, demonstrating a systematic approach to reviewing the literature. Results are presented thematically within the discussion section and supported in a summary table. The review suggested compliance with infection control practice to be sub-optimal and generally described this as unacceptably low. Practice is also reported as selective rather than universal/standard. The review found the use of a range of interventions to improve compliance, with education either alone or in conjunction with another intervention (such as peer review, skills training, and computer assisted instruction) being the most common approaches. Of interest is the failure to identify any UK study, or to find studies addressing interventions over time – sustainability is therefore an aspect under-researched in terms of improving infection control compliance. The conclusion of the review reflects on the theory of behaviour change and how this has not been contextually applied. This connection implies a degree of complexity in understanding compliance, yet offers direction for future work to understand it. In addition, the identification of a shortage of studies on all aspects of standard precautions makes this an appealing inclusion when designing future studies to evaluate infection control compliance.

In summary, the studies of theme 4 clearly identify compliance as sub-optimal, despite evidence of interventional studies to improve compliance. That these have been found to produce short-term improvement highlights the need to explore views on sustainability of change and the factors that may impact on sustaining change. The heavy reliance on survey methodology and self-reported data may well be a significant factor in fully understanding infection control practice, and should be considered of limited value when used in isolation in future study designs (Creswell & Plano Clark, 2007).

Equally the limited ability of study findings to be generalised to wider healthcare populations due to sampling/selection and measurement biases highlights the need for robust sampling approaches to ensure representativeness (Newell & Burnard, 2006; Shuttleworth, 2009). Despite this, similar study designs are adopted, and there appears to have been little learning from previous studies to inform design of subsequent research studies. Future research design must be informed by not only the findings but also the limitations identified in this review.

Finally, the review identified healthcare practitioners as selective in their practice of standard precautions. This emphasises the need to assess all aspects of infection control practice. Although knowledge of standard precautions was explored in some studies, no study used this data to consider the extent of compliance with collective policy and regulatory goals – that being to reduce the risk of infection. The need to understand the extent of compliance through buy-in at this level remains very much under-researched yet worthy of exploration if a fuller understanding of compliance is to be achieved through research.

#### 2.4.6 *Theme 5: Evidence of compliance with infection control practice within the tattooing and cosmetic body piercing industry*

Utilising the search terms “tattoo\*”, “pierc\*”, “compliance” and (standard) infection (control) (precaution\*) under Boolean principles, 109 articles were returned, of which 104 were excluded from the review as they were not primary research or related to infection control compliance out with the tattooing and cosmetic body piercing industry. All 5 remaining studies have been reviewed within theme 5 - evidence of compliance with infection control practice within the tattooing and cosmetic body piercing industry. In addition, one study dated from 1994 (Goudey & Thompson, 1997a; 1997b) has been included within the review, due its particular relevance to the topic of study.

Goudey and Thompson (1997a; 1997b) undertook a cross-sectional survey of infection control in registered tattooing premises in Victoria, Australia in 1994. While the study is 15-years old, it continues to be of particular relevance, given the limited numbers of studies on this topic since then. Two papers report the findings of the study, these beginning with historical overviews of tattooing, its association with blood borne virus transmission, and the management of tattooing practices in Victoria Australia. Regulated standards have been in place since 1990, but having never been evaluated, offers a rationale for the study.

All registered tattooing premises in Victoria were identified (n=64), and then random stratified sampling was used to select 28 premises, of which 24 agreed to participate (13 metropolitan and 11 nonmetropolitan) to participate in the survey. This represented an 89% response rate, corresponding to 37% of the total premises. It included 37 tattooists, of which 35 agreed to participate. Reporting bias arises from the absence of definitions for the terms ‘metropolitan’ and ‘nonmetropolitan’. The claim that the study findings indicatively represent the views of registered tattooists in Victoria on the basis of random sampling and high participation rate is fair. Possible bias is however acknowledged by the authors, due to the level and commitment to participation by some.

The study involved self-administered questionnaires, inspection checklists and observation to collect data on knowledge attitudes and practices of the tattooists. This mixed approach to data collection is a strength of the study, for it enabled a breadth of data to more fully understand the topic of study (Creswell & Plano Clark, 2007).

The study found significant differences between self-reported and actual practice. Highlighting the limitations of self-reported data in isolation, 94% (n=33) reporting that their practices met all standards, while observation found practice fell below full compliance on most of the standards. One example is the use of razors, where all but one participant reported using disposable razors yet observation found that 73% of observed tattooists used reusable razors. No indication is given on the inter or intra observer reliability, and this could have biased the measurement and reporting of findings in this study (Parahoo, 2006). The authors also report, without quantifying, that a small number of tattooists declined the opportunity to be observed, and this would have potential to introduce response bias (Kelley et al., 2003).

The results are presented descriptively using text and number (in table format), reflecting the open and closed ended style of questions within the self-administered questionnaires. The use of open-ended questions is a strength of the study, able to elicit some rich data to better understand the views of those participating. The lack of opportunity to explore further is however a limitation in terms of study design, with some reflections from tattooists unsupported by evidence. So too is the lack of acknowledgement of personal biases that may have impacted on the reporting of findings from observation (Shuttleworth, 2009).

The study found that while participants saw themselves as wholly compliant, they were less confident in the practices of other tattooists and particularly critical of illegal practitioners. Subsequently, they were critical of Environmental Health Officers failure to deal with unregistered/illegal tattooing practices. This led to reports of feeling victimised and inconsistently treated.

Low levels of education and self-taught practices were considered in the discussion of this paper as possible reasons for the levels of compliance with infection control standards, although there was acknowledgement that the study identified a willingness to learn and to see the introduction of formal education to support practice. The recommendation to shift from critical to facilitative role in regulating practices is recommended in the study conclusion. The value of education and supportive enforcement appear to be justified, but are not supported by literature to demonstrate their effectiveness, particularly longer term.

Barnett, Ejidokun, Greaves, Harris, Vosper and Duncan (2003) reported their findings from audit of 10 tattooing and cosmetic body piercing premises in Gloucestershire between August and October 2002. This was instigated by the confirmation of a client developing hepatitis B post navel piercing, with no other risk factors for such infection in one premise in June of the same year. Although the study conclusion reports this work as offering a county-wide perspective, no detail is given on how the ten premises reflect the wider population in the area and beyond, and so selection/sample bias could yet be an issue in the study (Ruane, 2005).

Indeed, one limitation noted by the authors was the lack of access or ability to identify those working from home without registration, although the approach to audit did not identify this as an issue directly, nor did it present any evidence of this as a problem. The audit's aim was to identify areas of poor practice where subsequent intervention may be required in the interests of public safety. The audit tool used was based on a standardised tool used to audit standard infection control practice developed by Millward et al. (1993). The use of such a validated tool can be useful in terms of environmental audit, and will often include components requiring recipients of the audit to describe and demonstrate practice. This type of tool therefore adds an element of observation to what might otherwise be self-reporting, adding weight to the findings (Parahoo, 2006).

The local EHO and Health Protection Nurse (HPN) conducted the audit as part of an unannounced visit. While this is accepted practice in terms of health and safety and public health law, from a research perspective it does not lend itself to the attainment of informed consent, and so differentiates between audit and research (Fuller & Vassie, 2004). Using a structured questionnaire, participants agreeing to take part were interviewed by two members of the research team. It is not clear if both researchers were in attendance for each interview. Equally, no inter or intra observer reliability is discussed, and this procedural bias could have led to measurement and reporting bias (Hartman et al., 2002; Shuttleworth, 2009).

The study results are reported descriptively, using tables and graphs, and found all body piercers scored 60% and above across the 64 statements in the audit tool, with 2 scoring 80% and above compliance. Waste and sharps management were found to be particularly good, with decontamination, hand hygiene and use of personal protective equipment varied and often sub-optimal. The need for education and regulation is implied from the findings. Such significant policy implications highlight the need to ensure that studies presented as evidence of poor practice are methodologically robust (Titler, 2004).

Compliance with infection control practice was considered as part of a larger study on regulation of tattooing by Raymond, Halcon and Pirie (2003), and included investigation of practices through a cross-sectional survey using self-reporting and observation to collect data. Regulated and unregulated tattooists from across the seven counties of Minneapolis and St Paul, Minnesota, USA were eligible for inclusion, with participants recruited via unannounced visits to studios. While 75 tattooists across 32 businesses were identified as meeting the inclusion criteria, how this reflects the total population of tattooists in the target is unclear. This may have led to selection/sampling bias (Newell & Burnard, 2006). Sixty-one tattooists (81%) agreed to complete a questionnaire and 25 (33%) agreed to participate in the observation. This self-selection for observation could have added to this bias. The use of a trained observer will have supported intra-observer reliability (Ruane, 2005).

Results are presented in tables and graphs, with a statistical packaged used to support analysis. P-values are cited at  $<0.01$  for correlation outputs, declaring high statistical significance (Davies & Crombie, 2009). In terms of compliance with infection control standards, the study reported infection control practice scores ranging from 50-100%, highlighting the sub-optimal practice of some tattooists. These scores were higher in regulated tattooists and in those with positive attitudes to regulation. They were not positively associated with membership of a professional organisation. Observed infection control scores ranged from 45%-84%, highlighting the difference in self-reported and actual practice. This emphasises the significance of observational data to generate accurate understanding of infection control practice and again, the limits of self-reported data (van de Mortel, 2008).

Hellard, Aitken, Mackintosh, Ridge and Bowden (2003) also carried out a cross-sectional survey between July and October 2001 in Victoria Australia, making use of a questionnaire administered by local government EHOs, and collecting additional data via environmental swabbing. Ethical approval for the study was granted. The study examined the infection control practices of body piercing practitioners as part of wider work on knowledge/risk of transmission of hepatitis C.

Participation was voluntary, with 35 of the possible 60 establishments (58%) within the metropolitan and regional council areas of Victoria agreeing to participate. The voluntary nature of self-selection may have resulted in selection bias, where those with greater interest in infection control may have volunteered, skewing the results in favour of more positive outcomes (Argyrous, 2005).

Despite this potential bias, results found inefficient practices in decontamination, less than optimal knowledge and understanding of hepatitis C, and a general lack of understanding of infection control procedures. The environmental swabbing was completely negative, although the study recognised the limitation of small number. The study reflects a common trend of poor compliance with infection control practice, in this case, despite access to guidelines.

The study concludes a need for formal training, without evidencing its ability to effect change (Kretzer & Larson, 1998). This approach may limit the opportunities to identify interventions that are more effective in improving practice, and may be considered reporting bias.

A study carried out by Oberdorfer, Wiggers, Bowman and Lecathelinias (2003a) in 2002 to determine infection control practices among tattooists and body piercers in Sydney Australia, in the form of a cross-sectional observational study, involved examination of infection control practice. The target population was identified from telephone and business directories, and totalled 47 premises in Sydney. All were invited by letter to participate in the study, and were contacted two weeks later to determine their decision. Two environmental health officers were used to collect the data, with inter-rater reliability assessed prior to commencement of data collection. Knowledge, attitude, practice and inspection scores determined compliance. The questionnaire was developed for the study, but was based on previously developed guidelines. No indication of testing for validity or reliability is reported in the study, impacting upon measurement bias (Hartman et al., 2002; Shuttleworth, 2009). Statistical packages were used to support data analysis, with results presented descriptively and inferentially. Multi-variate analysis was conducted between a range of characteristics.

Forty-one of the eligible premises agreed to participate in the study (87% response rate). Results are presented in tables and text, with numbers and figures cited for the descriptive analysis, and odds ratios and p-value of <0.01 reported for inferential analysis. In terms of compliance, despite high levels of overall compliance, lower levels of compliance were found for attitude, structural and behavioural aspects of infection control practice, with only 5 of the 41 participants (12.2%) complying with all 20 premise and practice items inspected. Older and more experienced practitioners scored higher. The study concludes with the need for continued enforcement to enhance compliance with standards.



Stead, Williams, Williams and Robinson (2005) report the findings from their study into the practice of tongue piercing in Bristol and Bath in the south west of England, UK. While focusing on prevalence and complications, the study, designed as a cross-sectional survey of piercees (using a self-administered questionnaire) and piercers (through interview survey), also considered attitudes of workers to infection control. Ethical approval is reported. Both questionnaires were designed specifically for this study, and were piloted prior to use. No detail is offered on the approach or outcome of piloting and its ability to ensure validity and reliability of the tools (Parahoo, 2006). This has the potential for procedural and response bias (Kelley et al., 2003; Newell & Burnard, 2006).

The study intended to recruit participants from piercing establishments, identified through internet and telephone book searches, with permission then sought from managers to enter the premises and invite clients to participate. This proved ineffective in recruiting pierced participants, and the research team subsequently attended four events during the summer of 2003 where it was expected those with piercings would be. This approach to sampling/selection is not systematic, and has the potential to result in sample/selection bias. Issues of consent are addressed. Descriptive data analysis was supported by excel, with the results from each questionnaire analysed separately. For the piercees, 123/126 (98%) invited to participate did so. For the piercers, 34/63 premises (54%) did not meet the inclusion criteria of piercing tongues, and 7 declined participation, leaving 22 piercers across 22 premises agreeing to participate (76% response rate).

In terms of infection control practice, piercers were asked to describe their cross infection and hygiene practices. All reported having an autoclave, 82% (n=11) reported using disposable needles and half (n=11) reporting wearing latex gloves. In respect of these responses, the researchers describe the practices as “*commendable*” (Stead et al., 2005: 106). Such commendation could be considered as reporting bias, due to design, response and procedural bias, where self-reported information is the only means of data collection.

That sharps bins, surface disinfectant and ultrasound cleaner are only used in approximately half of the premises is somewhat concerning, although the lack of data collected in terms of practices limits the level of interpretation and conclusions that can be drawn. This highlights the limitations of self-reported data in isolation.

In summary, the studies of theme 5 collectively highlight the limited amount of research undertaken within this population. The heavy reliance on survey methodology is apparent, although the use of self-administered questionnaires in conjunction with observational data has been found more effective in understanding compliance with standard infection control practices that that achieved through single data collection approaches. Of note is the discrepancy between self-reported and actual practice, although no researcher has explored with practitioners the notion of what they are purporting to comply with.

Overall, the outcomes of these studies reflect the findings of healthcare research, where infection control practice is also sub-optimal (see theme 4, above). Equally, the inclination to suggest education and training as the solution is another common feature of these two themes within this literature review. Finally, the study by Goudey and Thompson (1997a; 1997b) highlights the issue of underground/illegal practices, and the potential for such to generate bad feeling among regulated/monitored practitioners. The risk of how this might impact on infection control practice has not been explored.

#### *2.4.7 Theme 6: The effectiveness of regulation and other interventions aimed at promoting compliance within the tattooing and cosmetic body piercing industry*

Utilising the search terms “tattoo\*”, “pierc\*”, “compliance”, “(standard) infection (control) (precaution\*)”, “intervention” and “(health) behaviour” under Boolean principles, 109 articles were returned, of which 104 were excluded from the review as they were not primary research or related to infection control compliance out with the tattooing and cosmetic body piercing industry.

All 5 remaining studies have been reviewed within theme 6 – effectiveness of regulation and other interventions aimed at promoting compliance within the tattooing and cosmetic body piercing industry. In addition, one study dated 1997 has been included within the review, due its relevance to the topic of study.

*Guidelines alone as an intervention*

A paper by Oberdorfer et al. (2003b) details the findings of a study undertaken in New South Wales Australia between March and May 2000. The study assessed the knowledge and attitudes of 874 owners/managers of commercial skin penetration premises regarding infection control, following the implementation of new infection control guidelines in July of the previous year (1999). It concluded commercial skin penetration premises lacked some essential knowledge in infection control, with the shortfall greatest among those who were not in receipt of the new guidelines on this topic. Barriers to improving compliance with the guidelines were related to daily operational issues and poor inspection skills by those enforcing the guidelines. The introduction to the study is heavily weighted in 'favour' of general statistics on blood borne virus transmission and associated costs, and relates little to the skin penetration industry. While brief consideration is given to data associating blood borne virus transmission to the industry infection control practices, the use of general statistics runs the risk of wrongly linking the industry with the staggering rise in BBV transmission over recent years. Such reporting bias (Shuttleworth, 2009) risks perpetuating the notion that there is strong evidence to associate the industry with BBV transmission, which there is not (see theme 1b above).

The study does give a detailed account of the research findings surrounding infection control practices within Australia, and makes appropriate links to the use of guidelines as a mechanism to improve such practice. Identification of poor outcome from studies considering the impact of interventions such as regulation and guidelines to improve infection control practice within this industry forms the basis of a sound rationale for this study. While there are no clear research questions or hypothesis, the aim of the study is very clear.

Use of the term “skin operator” suggests the study relates to those practising within the industry, however the sample includes owners and managers of premises, and these may not necessarily be practitioners. As a design bias, it has the potential to incur response bias (Kelley et al., 2003), by failing to accurately determine if those interviewed were indeed practitioners.

The methodology is clear, detailing the sampling method and data collection methods, including approaches to follow up. Ethical approval is confirmed, and some explanation given as to the development of the survey instrument, based on findings of previous research and recommendations within the new guidelines. Without a detailed understanding of the content of these guidelines, it is impossible to know if all aspects of the guidelines have been addressed. In addition, there is no mention of any validation of this instrument, and these factors could be a potential limitation to the study findings and generalisability (Parahoo, 2006). Given that previous research has suggested age and qualifications as two factors that influence knowledge and attitude to infection control, it seems relevant to include these within the section on demographic data.

The decision to use interviews as the method of data collection again limits the results to those self-reported by the participants, with response bias serving as an acknowledged limitation to the study. Sampling within this study is problematic generally, in that numbers of premises does not equate to number of practitioners, calling into question the validity of the statistics reported within the results section. Indeed, the use of the term ‘random’ within the sampling process is evidently inaccurate, given that, unlike the other groups of operators, all tattooists were chosen to participate. Furthermore, the inclusion of hairdressers, who only provided hairdressing services is also questionable (n=308) – this forms a large proportion of the overall sample (n=874), which does not appear to be justified given the topic under study. Measurement, response and reporting bias can occur from this selection/sample bias (Hartman et al., 2002; Newell & Burnard, 2006; Shuttleworth, 2009).

It also highlights the value of defining clearly and appropriately criteria for inclusion and exclusion within any study: Here, it is difficult to understand why hairdressers who only undertake hairdressing activity have been considered appropriate for inclusion.

Of the premises participating in the study, only 53% reported having received the guidelines. The analysis compares those who were/were not in receipt of the guidelines, and offers a clear indication of the value of guidelines in improving practice. Knowledge was better in those who had received the guidelines. Some analysis/comparison in knowledge and attitudes across the sub-groups is undertaken, but little of this type of analysis appears in the paper. This would have been valuable, and particularly important when one considers the findings, which shows tattooists' to have less concern over barriers to complying with guidelines. While some of the conclusions may be justified, the discussion, drawing on previous research findings, focuses on the negative findings in respect of knowledge and attitudes, and does little to discuss the positive findings. As such, this must be considered reporting bias (Shuttleworth, 2009). Moreover, the imbalanced reporting is evident in the small coverage of more positive responses across every outcome, for tattooists. A greater focus on this finding would have served to present a more balanced report of findings. While the conclusions and recommendations reflect the findings, the limitations identified are extensive and significant (particularly where owner/manager knowledge does not reflect operator knowledge). Resultantly, the findings, conclusions and recommendations of the work must be viewed with caution. It is fair to conclude that the recommendation for further research is therefore justified.

A further cross sectional observational study of tattooists and body piercers was conducted in Sydney Australia between January and February 2002 (Oberdorfer et al. 2003a) to examine the association between operator/premises characteristics and compliance with infection control practices, following the distribution of skin penetration guidelines. As noted above, sampling was via a computer-based telephone directory: 47 premises were identified for inclusion in the study, of which 41 agreed to participate.

The results of the study are reflected in text and tables, and demonstrate a high overall level of compliance. However, lower levels of compliance were reported for specific attitudes, suggesting a need for strategies to enhance current compliance.

In addition, the study found a lack of knowledge, particularly associated with poorer levels of education, again driving towards a conclusion of a need for strategies to increase knowledge. This study also reports high overall levels of compliance during the demonstrations and inspections, suggesting an increase in compliance over time. While this trend has been reported in other studies, it is difficult to compare these findings, given the different methodologies and potential for influence on practitioners practice as a result of the research itself. It does however draw attention to the need for sustainability in compliance, and while this is not addressed in this study, is worthy of further exploration.

The methodology details how informed consent was obtained from the owner/managers, but the nomination of one staff member by the owner/manager raises concern over voluntary participation, and the options available to staff who were not keen to participate. The possibility of coercion or pressure to participate questions the ethical foundations of this work, and has the potential for response bias (Kelley et al., 2003; Parahoo, 2006). Compliance was assessed on four domains (knowledge of guidelines, attitudes to infection control, demonstration of infection control procedures and assessment of physical infrastructure), and a variety of data collection methods utilised (self completed questionnaire, observation, and inspection). Such an approach offers the opportunity to understand compliance on a variety of levels and to enable corroboration of self-reported data with observed/inspected practices. This highlights the value of mixed methods data collection (Creswell & Plano Clark, 2007).

### *Regulations alone as an intervention*

Raymond, Halcon and Pirie (2003) undertook a study to investigate tattooists' attitudes to government regulation, and the relationships between regulation and infection control knowledge and practice. In a cross sectional study of 61 tattooists (both regulated and unregulated) in Minnesota, self-reported survey data were collected, along with observation of 25 of these practitioners. Attitudes to regulation were reported to be wholly positive, with most participants supporting inspection and training. The presence of regulation was not found to be associated with knowledge, but was associated with self-reported practices, concluding that tattooists in regulated areas may implement greater infection control practices than those unregulated, despite similar knowledge bases.

Raymond et al.'s (2003) study begins by introducing the growing nature of the tattooing industry in the USA, and the introduction of regulation to control the risk to health from blood borne virus (BBV) transmission. Highlighting the lack of (and need for) evaluative work to consider the impact of regulation on infection control practices, reference is made to previous work in Australia to support this claim. Methodologically, the study makes use of survey methodology with a self-administered/self-reporting questionnaire collecting demographic, knowledge and attitude, and self-reported practice data. In addition, for observational work, they modified a previously used checklist, highlighting the use of local standards within practice scores. It is not clear if this was the only modification to the previously validated tool, with no detail provided.

The sample population included all tattooists in businesses advertising tattooing services in Minneapolis and St Paul, with the exclusion of beauticians applying cosmetic tattoos. Recruitment was via unannounced visits to studios. With no discussion on ethical issues within the paper, the appropriateness of such an approach in terms of coercion and informed consent can be questioned. This is confounded by the authors' note that the researcher having arrived unannounced then waited for the questionnaire to be completed, with several studios requiring more than one visit to secure recruitment.

The risk of procedural and response bias is presented by such approaches (Kelley et al., 2003). Participation in the observational component of this study appears to be more ethically sound, where a trained observer obtained written consent prior to observing practices during one complete tattooing procedure on a pre-prepared checklist. 75 tattooists across 32 businesses were invited to participate, with 61 (81%) agreeing to undertake the survey, and 25 agreeing to the inspection/observational visit. Interestingly, involvement in the study was higher in the unregulated tattooists, demonstrating a willingness to participate. This is particularly reassuring when planning any future work with tattooists.

The results are reported in text tables and graphs, each component of data reflecting the others. Statistical significance is supported by appropriate  $p$ -values. The study concludes that while tattooists seem relatively knowledgeable on infection control and implement this into their practice, the increasing state regulation is justified because there is still improvement required, in both regulated and unregulated areas. Such findings support the notion that regulation alone is often insufficient to ensure risk to health is minimised, and that knowledge alone may not be the key indicator of effective practice. The study identifies self-reporting as a limitation to the study, as well as the low participation in the observational component, effectively limiting power (Parahoo, 2006). In addition, the enforcement of regulation was not explored. The recommendation to move towards more wide spread regulation across the USA is in itself not wholly justified from these results, but the suggestion that those areas with existing regulation should evaluate its effectiveness/effectiveness of enforcement would seem appropriate.



### *Regulation and guidelines as an intervention*

A study by Goudey and Thompson (1997b) considered registered tattooing premises in Victoria Australia, surveying self-reported compliance with infection control practice, as well as undertaking some observation of practice. The study of 36 respondents during 1994 found considerable discrepancy between self-reported and observed practices, with few tattooists understanding or implementing universal precautions or appropriate decontamination procedures. The authors concluded practice was a risk to clients and operators, and called for an urgent need to train tattooists as well as the staff who monitor them.

The paper begins with an introduction to tattooing and its health risks, making use of relevant research to support this claim, and to rationalise the need for tattooists to have adequate infection control practice. In addition, it outlines the process of regulation in 1990, and implementation of standards/guidelines to support tattooists in meeting regulatory requirements, rationalising the need for this research given that the effect of regulation had never been evaluated.

The study clearly cites its aim to “*evaluate current policy regarding infection control in tattooing in Victoria, and to provide information on the strengths and weaknesses of infection control practices in registered tattooing premises in Victoria*” (Goudey & Thompson, 1997b: 23). Methodologically, the study is appropriate in its design, making use of both a self-reported questionnaire and observation of practice. Such an approach ensures more robust data is collected (Creswell & Plano Clark, 2007). It does not identify who completed the observation, and this may be a limitation to the findings of this study, particularly if there was more than one observer, and no interrater reliability (Ruane, 2005).

Consent is discussed, but the issue of ethical approval is otherwise not mentioned. Sampling is reported as random, stratified by location from a total population of 65 registered premises. From 32 randomly selected premises, an overall sample size of 24 premises was eventually included in the study, and clear explanation was given for this.

It is unclear however, how the researchers came to agree on an original sample size of 32, and this could be a limitation to the findings (O'Leary, 2004). The results are predominantly detailed in text, with appropriate use of tables to support this text. While the development of instruments is not detailed in the paper, the systematic reporting of results appears to detail the responses to each question in a methodical way. The use of both numbers and percentages in the presentation of results are very clear and easy to understand.

The study acknowledges the limitations of observation, and equally of bias as a result of some practitioners declining to be observed. With this in mind, the conclusions are justifiable, highlighting the value and limitation of regulation and guidelines, and the important need to also consider education and training. In particular, the discrepancies between self-reported and observed practices highlights the value of these combined methods of data collection, and this must be considered in any proposed research in this field. Overall, the study highlights the need to evaluate infection control practice in registered premises following the implementation of regulation, reporting positively on tattooists' desire for better information, consistent standards, informed supervision, as well as education and training.

#### *Regulation and inspection as an intervention*

A paper by Worp, Boonstra, Coutinho and van der Hoek (2006) highlights the use of inspection of tattoo and body piercing studios in Amsterdam, since regulation was introduced in 1987, with unannounced access/visits to studios forming part of the regulatory requirements. The paper reports how inspections were not standardised until 2002, making it impossible to compare outcomes of these inspections, while highlighting the importance of consistency.

Since 2002, inspections have been standardised to include the using of a checklist, which considered instruments, materials and observed practice. This has enabled scoring to an equivalent 100%, and makes comparison of results possible.

Resultantly, from 2002 (15 studios with a mean score of 89.5%) to 2004 (22 studios with a mean score of 96.6%), an improvement in practices has been observed. The study concludes that written guidelines alone are insufficient to improve safety, and that regular inspection visits with verbal instruction is needed to support improvements in practice.

#### *Monitoring and education as an intervention*

A further study by Oberdorfer, Wiggers, Bowman, Burrows, Cockburn and Considine (2004), in the form of a randomised controlled trial (RCT) amongst 37 tattooing and body piercing premises in Sydney NSW Australia in 2002, evaluated the efficacy/acceptability of an educational feedback intervention. While there was no effect on knowledge, the experimental group had a significantly greater increase in perceived risk for non-compliance, and improvement in inspection scores. In addition, odds of compliance were greater in the experimental group for some demonstration and observed practices. The authors concluded “*effectiveness of regulation is dependent upon effective enforcement*” (Oberdorfer et al., 2004: 152). The study highlights the supplementary deterrent effect educational programmes can produce.

The paper itself begins by outlining the efforts being made to reduce the health risk from these practices through regulation, guidelines and inspection visits following legislative processes. There is recognition, with evidence from other research, to support the claim that these measures are often insufficient to ensure compliance, acknowledging the limited data on the most effective interventions. This introduction sets the scene for the research, rationalising the need to evaluate an educational intervention designed to improve tattooists’ and body piercers’ knowledge and attitudes towards infection control. While no question is identified, the aim is clear, the population identified and the intervention detailed.

In the study, premises formed the basis of population/sampling, with one owner/manager and one staff member asked to participate from the 47 eligible premises identified. As in previous research, the use of premises does not accurately reflect numbers of practitioners/operators, and this is a limitation to generalisability of findings (Parahoo, 2006). The methodology (RCT) offered an opportunity to evaluate the outcome of an educational intervention against a control group. Allocation to groups is well detailed, involving randomly allocating pairs from a list ordered by baseline inspection scores. While not wholly random, it ensured balance between the groups. It is unclear who undertook this allocation, and so the issue of blinding cannot be assured, and may have implications for observer bias (Hartman et al., 2002). The intervention involved provision of an educational feedback session by a trained EHO to participants in the experimental group two months post-baseline data collection. The control group received no intervention.

Two weeks later the premises were contacted and the owner/manager interviewed to determine receipt/acceptability. A further two months on, follow up data was collected from both the experimental and control groups, and inspections made by a trained EHO, this time clearly blinded to the groups' status. All data collection and follow up was collected in the same way, so avoiding any performance bias. From the initial group of participants, all drop-out was accounted for and explained. No power calculation is available to minimise the play of chance, however all analyses appropriately use finite population correction to adjust the variance estimates, given the small population size (Agyrous, 2005).

The findings indicate no significant difference among groups. In terms of attitudes however, there was a significantly greater increase in the experimental group compared to the control when considering risk of non-compliance. In addition, the experimental group had significantly greater increases in score relating to some infection control practices, and non-significant trends towards greater mean change in inspection score. This suggests the measure of any educational intervention must go beyond measurement of knowledge, with wider impact appearing to translate into practice.

In summary, the literature reviewed within theme 6 highlights the limited amount of research undertaken within this population, as well as the heavy reliance on survey methodology. While randomised control trial enables comparison of interventional groups, it is time consuming and costly, and has found similar results to previous studies. The limited impact of interventions in isolation is evident from these studies. Conversely, the value of inspection and enforcement in promoting and enhancing compliance, at least in the short term, has been demonstrated.

## **2.5 Synthesising the findings from literature review**

The findings from theme 1 identified the lack of an established causal link between infection and tattooing/cosmetic body piercing in most of the studies reviewed. When coupled with the apparent static prevalence levels, it can be concluded that infection and prevalence per se do not offer robust rationale to justify regulatory intervention to manage risk to health. The lack of methodological rigour and limited numbers of studies indicates a gap in existing literature and a need for further research in the field of tattooing and cosmetic body piercing. In particular, there is a need for research to understand how this lack of evidence influences commitment to regulatory goals, this having implications for regulatory effectiveness.

Focusing specifically on the findings of the study by Abiona et al. (2010) within theme 1b, the potential impact on health from illegal/unhygienic tattooing and cosmetic body piercing practices requires further exploration. The lack of research on this aspect of practice in the general population suggests a gap in the literature. Furthermore is the need to better understand the management of such activity out with the prison environment, along with the impact of such activity on the attitudes and compliance behaviours of licensed practitioners.

Reflecting on the outbreak management investigation which confirmed poor practice as the most likely cause of transmission of infection (Keene, Markum & Samadpour (2004) (theme 1b) and the findings from themes 5 and 6, limited evidence exists to demonstrate the ability of regulation, either in isolation or in conjunction with other interventions, to assure practice and/or levels of compliance that effectively minimise risk to health from tattooing and cosmetic body piercing. The evidence within themes 3 and 4 shows this limitation is not isolated to the tattooing and cosmetic body piercing industry. Compliance with practices designed to minimise risk of infection within healthcare settings; to ensure safe construct of buildings; to manage food safety; or to minimise risk of injury on the road are all shown to be sub-optimal. The need for more research to understand the issue of compliance is therefore necessary.

Focusing specifically on the work by Yapp and Fairman (2004; 2005: 2006), the particular problems faced by food-related SMEs in complying with regulation makes compliance with regulation in other types of SME worthy of study. It also highlights compliance with regulation requires knowledge, understanding, willingness and ability. Despite the concerns of inconsistent enforcement practice highlighted by SMEs in this study, these requirements were targeted solely at the SME. With little or no work to explore the role of the EHO in compliance, this is a gap in the literature that would benefit from further study.

From the evidence within theme 2, the general support for regulation suggests improving compliance should not be difficult. Reflecting upon the findings of Zheng, Fu and Li (2009) (where support for regulation to ban smoking was tempered with the concern that such a ban would impact on the profitability of their business), the need for further research to explore how support for regulation translates into compliance with regulation is required. Understanding how and why people respond to regulation as they do should in turn support greater understanding of regulatory compliance.

## **2.6 Purpose statement**

Synthesis of the literature review has identified a need for further research to address content and/or methodological design gaps in the existing evidence-base associated with state-controlled regulation, compliance, infection control practice and the tattooing and cosmetic body piercing industry. To ascertain which of these gaps this research study plans to address, a purpose statement has been developed. This outlines the intention and reasoning for this study and its proposed design/methods. Succinctly written and derived from identified gaps in existing literature, Creswell (2009: 11) argues the purpose statement's clarity and specificity make it "*the most important statement in the entire study*".

The purpose statement for this study is:

It is the intent of this study to determine the extent of regulatory compliance with the Order in Scotland's tattooing and cosmetic body piercing industry. A mixed methods concurrent design will be used, a type of design in which different but complementary data will be collected on the same topic (Creswell & Plano Clark, 2007). A semi-structured questionnaire, qualitative focused interviews and non-participant observation will be used to determine the extent of compliance by concurrently exploring and explaining users' experiences to the Order. The reason for collecting both quantitative and qualitative data is to bring together the strengths of both forms of research to more fully understand regulatory compliance with the Civic Government (Scotland) Act 1982 (Licensing of skin piercing and tattooing) Order 2006 within Scotland's tattooing and cosmetic body piercing industry than could have been achieved through a single approach.

## **2.7 Rationale for my research study**

A broad justification for this study's topic selection and need have been presented in Chapters 1 and 2. Most simply, the writing within these chapters highlight how very little literature currently exists on regulatory compliance in the tattooing and cosmetic body piercing industry globally, none of which is specific to Scotland. Furthermore, much of this existing literature was shown to contain methodological biases.

In offering a more substantial justification of need, reference is made to the writing of Yeung (2004: 31) that *“the essential purpose of regulation is to fulfil the collective goals justifying regulation”*. It may be debated that the process of regulatory enforcement negates such a need for the proposed research, but here it is argued that regulatory enforcement serves only to ensure compliance with the regulatory standards and fails to extend sufficiently to address collective goals. This argument, based on the research evidence appraised within themes 3, 4 and 5 of the literature review, contends that, to date, no literature exists on the ‘extent’ of compliance with the requirements of the Order in Scotland’s tattooing and cosmetic body piercing industry, neither addressing its ability to meet regulatory standards nor fulfil its collective goal to minimise risk to health. This study will therefore fill this gap in existing knowledge. Moreover, by focusing the topic of this study on extent of regulatory compliance, it is proposed this work will offer a significant contribution to new knowledge, by providing a novel approach to determining regulatory compliance.

Themes 3, 4 and 5 of the literature review suggest that, from across a range of disciplines and in relation to environmental, health and social policy issues, most research to date has adopted survey and observational methodologies to determine compliance against a set of standards. Only two studies have considered the concept of compliance beyond achieving practice standards. In the study by Oberdorfer et al. (2003a) compliance is considered across four domains - knowledge, attitude, practice and inspection. The study by Yapp and Fairman (2004; 2005; 2006) considered knowledge, attitudes and behaviour and linked this to categories of behaviour/ attitudes, based on the work of Kagan and Scholtz (1984). Neither of these studies formally incorporate these wider activities into a definition of regulatory compliance.

This research will build on the work of work of Oberdorfer (2003a), Fairman and Yapp (2004) and Yapp and Fairman (2005; 2006), utilising the work of Yeung (2004) to formally define regulatory compliance. It will offer a significant contribution to new knowledge by utilising compliance definitions to determine ‘extent’ of regulatory compliance with the Order.



In this context, the extent of regulatory compliance will relate not only to achievement of regulatory standards but will also be based on knowledge and support (determined through attitudes and behaviour) for the collective goal of this regulation. For the purpose of this study, the extent of regulatory compliance therefore encompasses both rule compliance (compliance with regulatory compliance) and substantive compliance (compliance with collective goals) (Yeung, 2004). The new knowledge derived from this study will have implications for many other disciplines across environmental, health and social sectors, where regulatory compliance is frequently considered sub-optimal, and where research recommendations (such as education and training) are often unsubstantiated.

The findings from studying the extent of regulatory compliance should highlight opportunities to improve regulatory design and maximise regulatory compliance. These findings can then be utilised in other settings as a means to improve current compliance rates. As well as offering this substantial contribution to new knowledge, this study will also be able to address identified gaps in knowledge: Firstly, given that review of the literature with themes 1a – ‘prevalence’ and 1b – ‘infection’ both concluded that alone they did not offer a robust rationale to justify regulatory intervention to manage risk to health, this study will contribute to understanding of how users perceived risk to health from tattooing and cosmetic skin piercing activities, exploring if and how they consider regulation has contributed to minimising this risk.

Secondly, this study will provide an opportunity to explore how users perceive illegal tattooing and cosmetic body piercing in Scotland, and its potential to impact on regulatory compliance. While the work of Abiona et al. (2010) explored illegal tattooing and cosmetic body piercing activity in the prison setting, and the study by Goudey and Thompson (1997a; 1997b) identified illegal activity as a concern for legal practitioners, no further work in this area has been published.

Given the link between illegal activity and unhygienic practice identified in the work of Abiona et al. (2010), the opportunity to explore the impact of illegal/unhygienic practice on regulatory compliance is particularly pertinent to this work, given the assertion by Walters (2001: 52) noted in Chapter 1 that regulation “*should be effective in minimising health risks...by ensuring that only those practitioners willing and able to practise safely remain in practice*”.

Thirdly, the research by Yapp and Fairman (2005; 2006) identified concerns of inconsistency in regulatory enforcement practices, which were not subsequently explored or discussed. In addition, the outbreak investigation by Keene, Markum and Samadpour (2004) demonstrated how being known to officials is insufficient to ensure safe practice. By considering users of the Order to include both practitioners of the tattooing and cosmetic body piercing industry and regulatory enforcers, this study will provide an opportunity to better understand the role and influence of the enforcer of regulation on the extent of regulatory compliance.

Finally, appraisal of professional and public opinion of regulation in theme 2 of the literature review highlighted general acceptance of and support for regulation as a mechanism to promote health behaviour/health behaviour change. However, Zheng, Fu and Li's (2009) findings, where support for anti-smoking laws is tempered by the potential impact on business profits, highlights the complexity of predicting behaviour change. This is supported by the findings of a survey by Ipsos MORI (2007) that new regulation can be challenging to integrate into practice. That study also recognised how ongoing monitoring and evaluation of practices can aid the embedding of new regulation into day-to-day practices (Ipsos MORI, 2007). As such, this study serves as a valuable step in that ongoing process, so justifying its need.

## 2.8 Chapter 2 summary

Chapter 2 began by considering my planned methods for searching; assessing and synthesising the literature. It continued by reflecting on how best to organise the literature review, stating the options available, rationalising the choice made, and outlining the broad content of the review. Thereafter it progressed to systematically reviewing the literature, adopting a thematic approach to appraising the literature in terms of methodological quality. Conclusions were drawn following synthesis and interpretation of the findings.

From background discussion in Chapter 1 and appraisal of the literature in this chapter, the purpose statement for this study was developed, detailing the study intent and outlining its methodology. Subsequently the rationale for this study was presented, justifying topic selection and research need. In justifying the topic and need for this study, its ability to fill gaps in existing knowledge have been shown. Most importantly, by focusing this study on 'extent' of regulatory compliance with the Order, emphasis has been given to the significant contribution this study will make to new knowledge and understanding of regulatory compliance. Before drawing this chapter to a close, this study's research questions, objectives and scope study are provided.

### 2.8.1 *Research questions and study objectives*

The primary research question for this study is:

1. To what extent has regulatory compliance with the Civic Government (Scotland) Act (Licensing of skin piercing and tattooing) Order 2006 in Scotland's tattooing and cosmetic body piercing industry been achieved?

The secondary research questions for this study are:

1. What has been the response of users of the Order to the implementation of the Order within the tattooing and cosmetic body piercing industry in Scotland?
2. Why have users of the Order within the tattooing and cosmetic body piercing industry in Scotland responded to the implementation of the Order in the way they have?

3. How has the collection of mixed methods data on the response of users to the Civic Government (Scotland) Act (Licensing of skin piercing and tattooing) Order 2006 contributed to a fuller understanding of regulatory compliance?

To assist in answering these questions, the objectives of this study are:

1. To explore users' experience of regulatory implementation, and within this:
  - a. To explore users' knowledge, attitudes and behaviours towards the design of the Order
  - b. To explore users' knowledge, attitudes and behaviours towards the standards within the Order
  - c. To explore users' knowledge, attitudes and behaviours towards the monitoring and enforcement of the Order
2. To explain users' experiences of regulatory implementation
3. To determine the extent of regulatory compliance arising from the understanding of users' response to regulatory implementation

#### *2.8.2 Scope of study*

Although the Civic Government (Scotland) Act 1984 (Licensing of skin piercing and tattooing) Order 2006 considers skin piercing to include acupuncture, cosmetic body piercing and electrolysis, and tattooing (both permanent and semi-permanent) to include micro-pigmentation (See Appendix 1), my study focuses on the activities of Scotland's tattooing and cosmetic body piercing industries only. This decision was based on the complete absence of any professional regulation within these elements of the skin piercing and tattooing industry prior to the implementation of the Order. As such, this avoids the issue of previous regulation as a confounding variable (Pallant, 2007), and the potential to influence compliance.

# Chapter 3

## Conceptual framework

### **3.1 Introduction and overview**

Parahoo (2006) differentiates between a 'theoretical framework' (research underpinned by one theory), and a 'conceptual framework', which draws on concepts from a range of models, definitions, theories, and research findings to guide a study. In practice such clear distinction is not always obvious, with these terms often used interchangeably. While Parahoo (2006; 157) notes frameworks "*may or may not be stated*", the benefit of explicitly offering account of the theoretical underpinning of any study becomes apparent through its ability to link to the research questions, and to the research context (McGaghie, Bordage & Shea, 2001). On this basis, making explicit a study's theoretical underpinning and formally linking this to all aspects of the research process is deemed paramount. Moreover, such an approach will add meaning and value to the overall study and its contribution to both academia and industry.

### **3.2 Background**

Within Chapter 1, I introduced the concepts of regulation and regulatory compliance in the context of the tattooing and cosmetic body piercing industry in Scotland. In Chapter 2, I appraised the literature associated with regulatory and infection control compliance within the tattooing and cosmetic body industry, synthesising this in conjunction with literature on regulatory compliance across wider environmental health associated industries and infection control compliance within healthcare. From six themed reviews, I identified regulatory and infection control compliance to be frequently sub-optimal, concluding further research is required to better understand how and why people respond to regulation as they do. In turn, I supposed that determining the extent of regulatory compliance with the Order in Scotland's tattooing and cosmetic body piercing industry would contribute to a greater understanding of regulatory compliance.

In this chapter, I present the development of the conceptual framework underpinning my study. Beginning by exploring the evolution of compliance process models (Henson & Heasman, 1998; Fairman & Yapp, 2004), I will show how the model by Fairman and Yapp (2004) has been utilised as the core component of my conceptual framework, providing a base from which I can systematically explore users' response to the implementation of the Order in Scotland's tattooing and cosmetic body piercing industry. To assist in transforming the compliance process model into a conceptual framework, I will review and appraise compliance related literature. From this, the conceptual framework underpinning my study to determine extent of regulatory compliance will become apparent.

I continue the chapter by relating my conceptual framework to my study objectives, research questions and overall study intent. By demonstrating its integration across these aspects of the research process, the beneficial use of a conceptual framework to systematically explore and explain users' response to the implementation of the Civic Government (Scotland) 1982 (Licensing of skin piercing and tattooing) Order 2006 will be highlighted. In addition, how it supports the determination of the extent of regulatory compliance in Scotland's tattooing and cosmetic body piercing industry will be emphasised.

### **3.3 Evolution of the compliance process model**

Henson and Heasman (1998) cited numerous attempts to construct models of compliance/compliance decisions (such as the compliance decision tree by Cole & Sommers (1981) and Sproull's (1981) organisational framework), noting the limited emphasis placed on the process by which decisions are made as rationale for their exploration of the process of compliance within the food industry. While finding specific differences in the way businesses comply with food safety regulations, they reported the occurrence of a distinct and common series of actions as businesses decide whether or not to comply (See Figure 3.1), creating a model of the compliance process to reflect this.

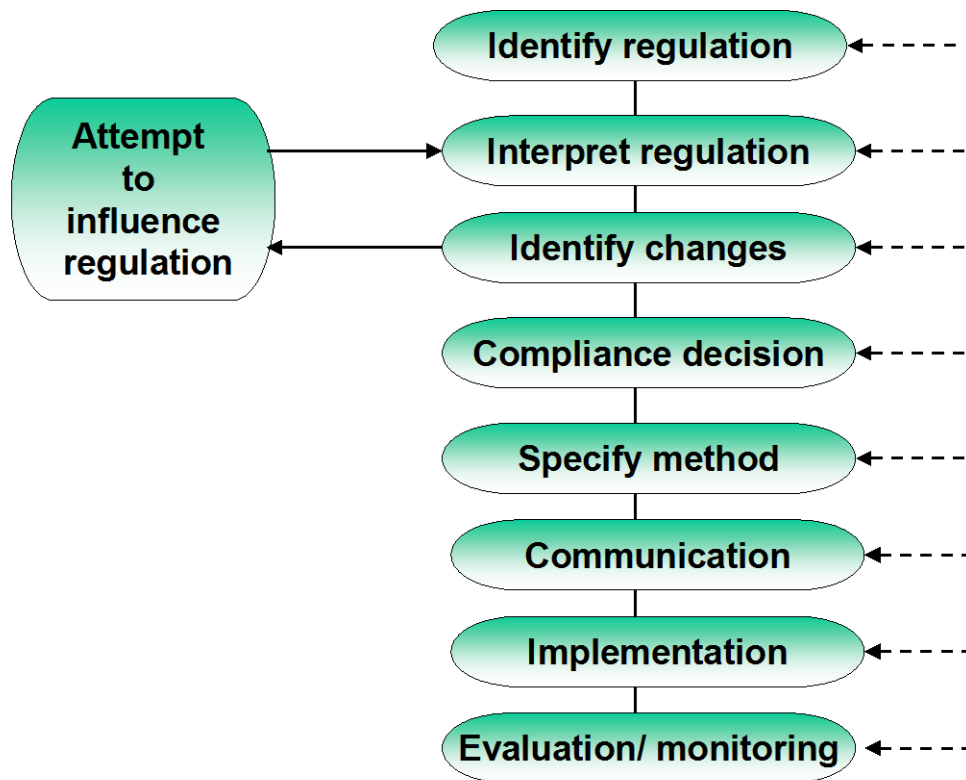


Figure 3.1: Compliance process model, by Henson and Heasman (1998)

Henson and Heasman's (1998) compliance process model describes the decision-making process carried out within a business when faced with legislative requirement. The key features of the model are its assertions that the process of compliance is a cycle of eight distinct stages, ordered sequentially.

In 2004, Fairman and Yapp examined the applicability of the model to medium, small and micro businesses (SME)<sup>6</sup>. From their findings they adapted this model specifically for such businesses (See Figure 3.2). Identifying key persons and types of enforcement interventions, Fairman and Yapp (2004) also noted three main differences between their model and that of Henson and Heasman 's (1998).

<sup>6</sup> Medium, small and micro sized businesses are defined by the number of staff and annual financial turn-over. A medium sized business = <250 staff, not exceeding annual turn-over of EUR 50 million. A small business = <50 staff, not exceeding annual turn-over of EUR 10 million. A micro business = <10 staff, not exceeding annual turnover of EUR 2 million



Firstly, they found no evidence to support the identification and interpretation of regulation as two distinct steps and so merged these into one. Secondly, their findings suggested that making a decision to comply followed the specification of how to comply, and so these steps were order reversed. Finally, they noted that formal communication was not always utilised, and finding no reason to maintain this as a separate step, instead incorporated it into the implementation stage.

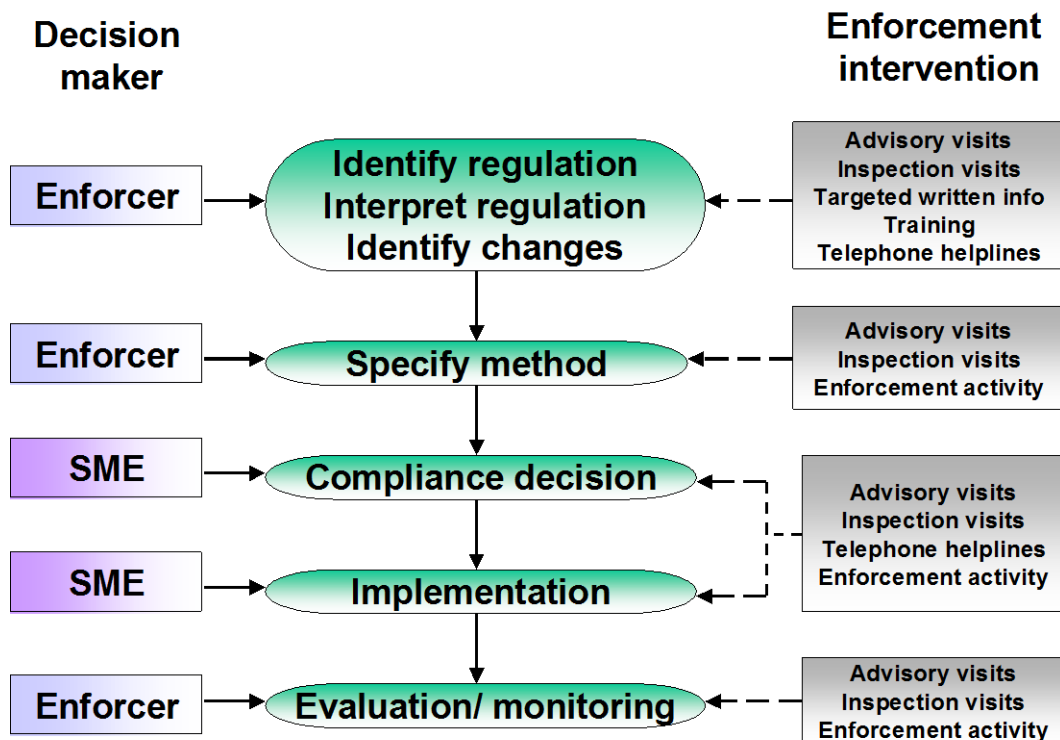


Figure 3.2: SME-specific compliance process model, by Fairman and Yapp (2004)

### 3.4 From theoretical model to conceptual framework

To offer a conceptual framework from which to determine the extent of regulatory compliance with the Order in Scotland's tattooing and cosmetic body piercing industry, the SME-specific compliance process model (Fairman & Yapp, 2004) was considered in conjunction with literature on compliance choice; motivations/inclination to comply, judging compliance and securing compliance (Hutter, 1997; Henson & Heasman, 1998; Baldwin & Cave, 1999; Yeung, 2004). Regulatory design was also examined (BRTF, 2005; Better Regulation Commission, 2006).

### 3.4.1 Compliance choice

Henson and Heasman (1998) argue that compliance decision does not simply require a 'yes' or 'no' answer. Instead they contest that a range of choice is open to those contemplating how to respond to regulation, from deciding to fully comply through to the option to cease practice (See Figure 3.3).

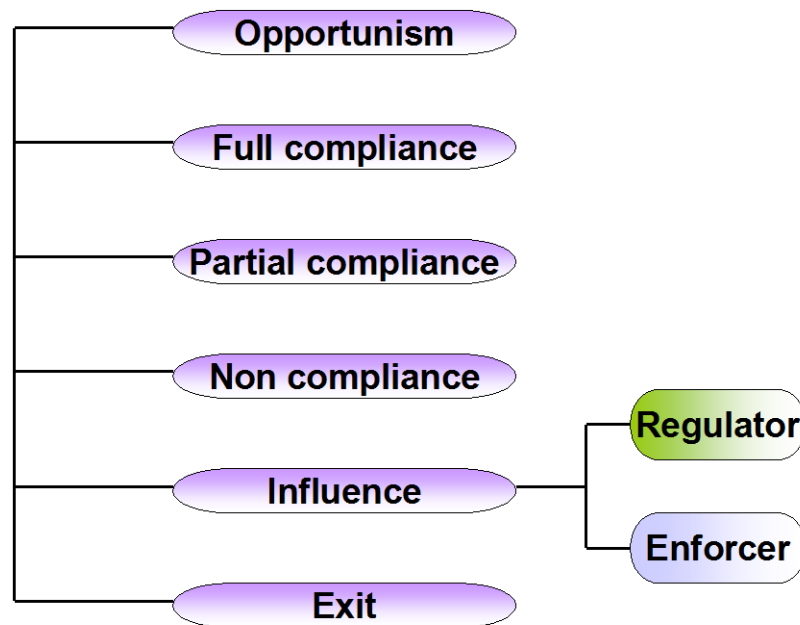


Figure 3.3: Compliance decision tree (Henson & Heasman, 1998)

Subsequently, authors have reported differences in how choice affects decision-making. On the one hand, businesses adopt a mix of approaches, shifting through the branches of the tree dependent upon the regulation (Marcus, 1984). Others adopt a compliance culture, resulting in one dominant approach to regulatory compliance decision-making, reflective of the culture (Henson & Heasman, 1998).

The concept of levels of compliance may be useful in understanding extent of compliance, but the major limitation of this strand of compliance work is its lack of definition of compliance, and indeed the lack of detail on the impact of each level in relation to outcome (Chatterjee, 2006).

### 3.4.2 *Motivation/ inclination to comply*

Many factors have been found to affect inclination to comply with regulation including self-interest, corporate responsibility and protection of reputation. In formulating the conceptual framework for this study, attitudes have therefore been considered a factor associated with compliance. As such, thought has been given to the various classifications used to determine motivation/ inclination behind compliance decision-making.

Kagan and Scholz's (1984) categorisation of attitudes of non-compliant businesses in terms of regulatory compliance (reproduced in Yapp & Fairman, 2006) identified three categories - the amoral calculator (motivated by profit, and non-compliance decision determined by cost-benefit calculation); the political citizen (generally motivated to comply, but non-compliant due to lack of support/ disagreement with the regulation); and the organisationally incompetent (where lack of knowledge, leadership or organisational management leads to non-compliance). Hawkins (1984) focused on key stakeholders in business compliance, presenting a four-fold classification of those considered socially responsible, unfortunate, careless or malicious. Socially responsible stakeholders approached compliance with regulation from a moral stance, endeavouring to comply on principle. This work is elaborated by Hutter (1997) who offers poor; reasonable; fairly good; responsible; very good; and exemplary as finer categories to distinguish compliance level. Collectively, these works highlight the dichotomous views of businesses, and their approach to regulation (and compliance with it) (Gunningham & Kagan, 2005; Pautz, 2009a). Baldwin and Cave's (1999) matrix approach to understanding compliance motivation considers two further dimensions - intention and familiarity. From this, four categories of compliance type emerge (See Figure 3.4). Intention in this matrix relates to the willingness to comply, while familiarity focuses on information level required to comply.

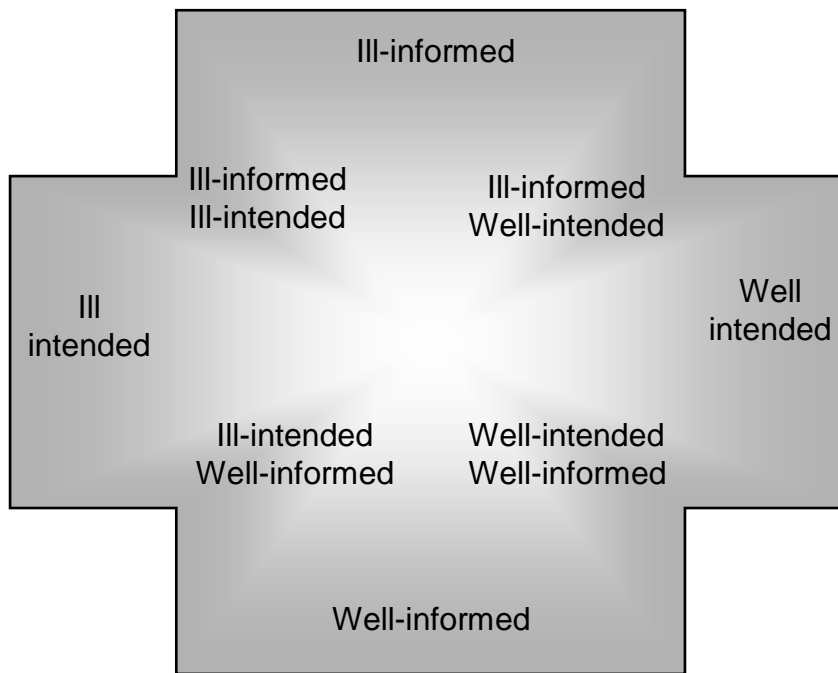


Figure 3.4: Compliance types, by Baldwin and Cave (1999)

While different in definition, each of these classifications delineates between those who deliberately fail to comply and those who fail to comply unintentionally (for example, due to lack of awareness or knowledge). This differentiation is supported by May (2004; 2005) who suggests motivation to comply with regulation is driven by deterrence/fear of consequence; moral responsibility/sense of civic duty; and social pressure. Such categorisations are useful in isolation, but they do not necessarily reflect the context and wider interactions and interdependences associated with achieving compliance. Indeed, Pautz (2009b) notes that the multiplicity of personnel involved in compliance decision-making make such concise characterisation easier said than done.

### 3.4.3 *Judging and securing compliance*

Hutter (1997) notes that judging compliance can occur at different levels such as organisational and individual levels, arguing compliance is judged according to a range of criteria such as commitment to regulatory objectives, attitude, ability and compliance history. Literature on securing compliance has identified it as the role of the enforcer, with a range of factors influencing their ability to secure compliance (Baldwin, Hutter & Rothstein, no date).

These factors include issues such as the specificity of the legal framework; legal powers and rights; the strength of sanction; the perception of risk and its consequence; interaction and relationships; motivation of the regulated; political influence; and capability and capacity of the regulating institution and its personnel.

The work of Yeung (2004: 11) addresses a more fundamental issue in securing compliance by asking “*with what must compliance be secured?*” While the factors associated with judging and securing compliance are relevant to better understanding compliance and non-compliance, determining the extent of compliance requires an answer to this question. Yeung (2004) contends regulatory theorists use the phrase ‘securing compliance’ inconsistently, interchanging its reference between ‘compliance with collective goals’ and ‘compliance with regulatory standards’. Serving to bring clarity to this situation, Yeung (2004) offers specific terminology to clarify and define regulatory compliance (See Table 3.1).

ACTION	DEFINITION	OUTCOME
Regulatory implementation	Action taken with the aim of securing compliance with the collective goal(s) of a regulatory scheme	Substantive compliance
Regulatory enforcement	Action taken with the aim of securing compliance with the regulatory standards embodied within a regulatory scheme	Rule compliance

Table 3.1: Defining compliance (Yeung, 2004)

Differentiating between substantive compliance and rule compliance in this way, it is possible to comprehend the potential to achieve rule compliance without securing substantive compliance. This has been termed ‘creative compliance’ (Parker, 2000; Yeung, 2004).

Parker (2000) purports that work to avoid creative compliance and maximise compliance with the collective goal(s) of any regulation ought to begin at the regulatory design stage, by developing an understanding of the practices to be regulated within the context in which the regulation will be applied. From this perspective, regulatory implementation becomes a process rather than an event, incorporating institutional design, standard setting, monitoring and enforcement of regulatory standards (See Figure 3.5).

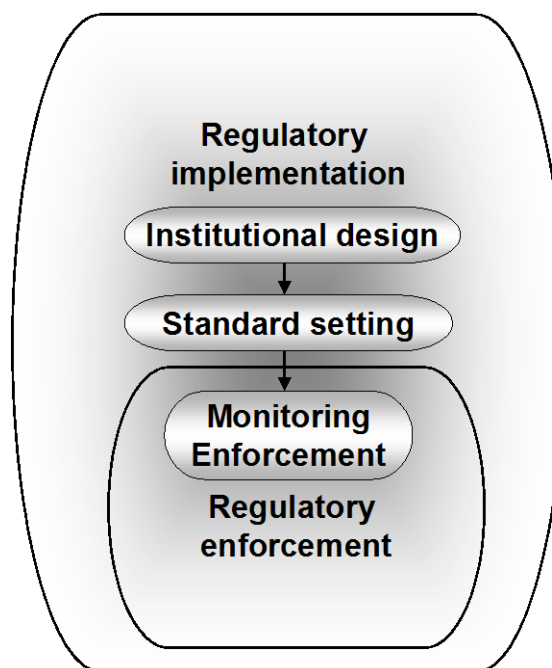


Figure 3.5: The process of regulatory implementation (adapted from Yeung, 2004)

#### 3.4.4 *Regulatory design*

In designing new regulation, the principles of good regulation provide the basis tenets from which to determine fitness for purpose (BRTF, 2000; 2005). Moreover, these principles should be applied not just in the design stage but also throughout the implementation process (See Figure 3.5). The principles include proportionality; accountability; consistency; transparency; and targeting (See Appendix 3). Corroboration of regulatory appropriateness/effectiveness should take cognisance of the five principles of good regulation, which incorporate efficiency; clarity and predictability; and flexibility, responsiveness and timeliness (Baldwin & Cave, 1999; BRTF, 2000).

### 3.4.5 Conceptual framework

The conceptual framework for this study is derived from the compliance process model (Henson & Heasman, 1998), coupled with synthesis of literature on compliance choice, motivations/ inclination to comply, judgement of compliance, securing compliance and regulatory design, where determining the extent of regulatory compliance is considered dependent upon clearly defining compliance (See Figure 3.6).

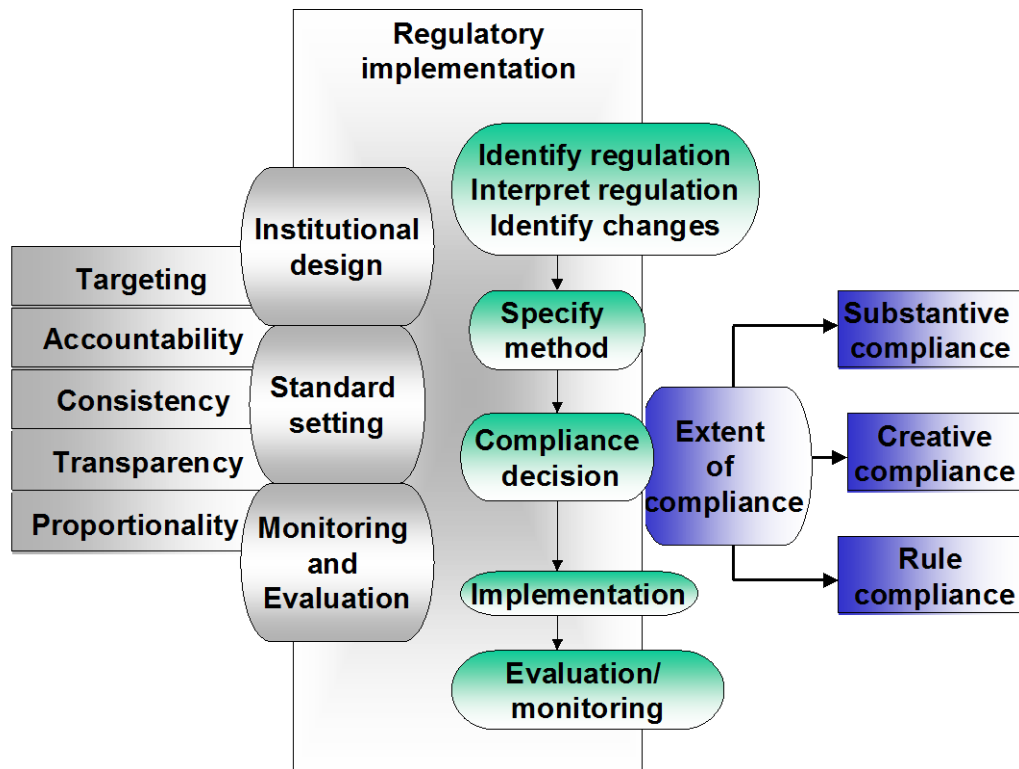


Figure 3.6: Conceptual framework underpinning this study

The work of Yeung (2004) has been incorporated into the conceptual framework to support systematic exploration of users' response to the Order. In determining the extent of compliance, this ensures clarity of compliance definition, while facilitating exploration of the phenomena 'rule compliance', 'substantive compliance' and 'creative compliance'. This is particularly relevant to any study of risk regulation, where the possibility of achieving compliance with regulatory standards without the intended reduction in underlying risk has implications for health. Without such clear definition, the positive association between compliance and risk reduction is tenuous.

Moreover, the framework design reinforces the notion that within each of the three defined phenomena, no levels of compliance exist (Chatterjee, 2006). In short, compliance (substantive or creative or rule) will be deemed achieved or not. In addition, the tenets of good regulation have been incorporated into the conceptual framework, providing established criteria from which to explore regulatory implementation (See Figure 3.6). Consequently, this will inform the extent of compliance with the collective goal of the Civic Government (Scotland) Order 1982 (Licensing of skin piercing and tattooing) Order 2006.

### **3.5 Chapter 3 summary**

Chapter 3 began by exploring the evolution of the compliance process model (Henson & Heasman, 1998; Fairman & Yapp, 2004). From review and synthesis of this literature alongside the body of literature on compliance choice, motivation/ inclination to comply, judgement of compliance, securing compliance and regulatory design, the conceptual framework underpinning this work emerged.



# Chapter 4

## Study design and methodology

#### **4.1 Introduction and overview**

Considered to be “*based on philosophical assumptions and derive(d) from different historical traditions*” (Lacey, 2006: 21), “*methodology*” refers to the philosophical framework and fundamental assumptions of research. As the choice of philosophical framework influences procedures of research, methodology can acceptably be interpreted as the overarching term for the plans and procedures for research. Such decisions are made from and include philosophical assumptions and concepts underpinning the research (Creswell, 2009).

#### **4.2 Background**

Building on the findings from Chapter 2 – ‘Literature review’ and utilising the conceptual framework devised in Chapter 3 – ‘Conceptual framework’, Chapter 4 of my thesis provides detail of the study design and methodology for my study, where the intent is to determine the extent of regulatory compliance with the Order within the tattooing and cosmetic body piercing industry in Scotland.

I begin the chapter by giving consideration to my own beliefs and values, and how these have influenced my decision to use a mixed methods approach underpinned by pragmatism as the worldview in the design of my study. As a personal reflection, this section has been written in the first person.

I continue the chapter by clarifying the definition of methodology utilised within my thesis, appraising the three main methodological approaches (qualitative, quantitative and mixed methods) and rationalising the decision to design my study as concurrent mixed methods. Thereafter, I provide a detailed review of pragmatism as the philosophical worldview underpinning my study. Defining the basic tenets of pragmatism, I explore how pragmatism as a worldview fits with my decision to utilise a mixed methods study design. Therein, an examination of the design and research methods is reported, incorporating my study intent and research questions.

### **4.3 The researcher's lens**

As a registered general nurse with district nursing, tissue viability, infection control and teaching experience, I came to this research with a working lifetime in healthcare - acute and primary care experienced, clinically and academically skilled. It is a career pathway commencing in the early 80s, in higher education, when I was first exposed, as an undergraduate nursing student to nursing debates between theory and practice, art and science, profession and trade. I did not know it at the time, but it was a period of change: The medical model approach of the 60s and 70s had seen public health, health promotion, health education and disease prevention focus on behavioural approaches (encapsulated in the ideology that health problems were the result of lifestyle, and placing the onus on individuals). Into the 80s came the re-emergence and recognition of wider issues affecting public health and the need for measures that would address social, economic and environmental determinants of health (Townsend & Davidson, 1982).

I held, and have continued to hold the belief that while the medical model has endured as the dominant way of thinking about health in western societies, nursing has evolved beyond this one-dimensional perspective on health and illness, to actively engage with wider factors. In working to measure health/needs assessment, nurses utilise both objective and subjective measurement of health, and use behavioural and structural approaches to promote public health/health promotion. This ability to function within a profession of both art and science is evident in the concept of holistic care, whose underpinning principle dictates that health and health behaviour cannot be separated from its social context (Brooker & Waugh, 2007).

Despite my views on the 'domination' of the medical model, it has been important for me to recognise and acknowledge the shift from a focus on individual ill-health to a focus on health and whole populations. Society has been charged with a collective responsibility. I agree with Jochelson's view that this change in focus has brought with it some contentious debate about governmental involvement in public health (Jochelson, 2005), and that this in turn has affected society's aspirations and expectation of the role of government in public health.

As a lay-person as well as a healthcare professional and academic, I realise my social, environmental and political perspectives have played their part in the way I functioned as a nurse, teacher and how I now function as a researcher within the wider social, community and public health arena. In turn, these perspectives have influenced how I approached this work, the data I chose to collect and the way I chose to analyse, synthesise and interpret the findings.

Recognising research can be conducted in many different ways, my research lens has mirrored what I consider to be my real world perspective – seeing the world as a global entity, increasingly integrated and interdependent. To me therefore, it has made sense that in an ever-progressing world, which embraces both art and science as tools to facilitate advancement of knowledge and understanding, research requires to do so too. It also made sense to me that in nursing, teaching and researching, to do the best for our patients, clients, students, participants and populations, requires looking beyond the dichotomies that we are exposed to. I came to this work believing that to do what is best required practical thinking, practical activity. That to be pragmatic about the decisions we made would deliver the best quality and safest care, engage students in the best and most effective teaching and learning – and produce the best research.

#### **4.4 Study design**

In designing this study, use has been made of Creswell and Plano Clark's (2007:4) framework for research design, in which they define methodology (and use it interchangeably with the concepts of research design or approach) as *"the framework that relates to the entire process of research"*. While acknowledging and embracing research methodology as a framework relating to the entire research process, the interchange between the terms methodology and design has been avoided by replacing Creswell and Plano-Clark's (2007) term 'strategies of enquiry' with 'design'.

As such, in this study, it is the interplay between philosophical worldview (such as positivist/ post-positivist, constructivist, advocacy-participatory, pragmatist), design (such as case study; phenomenology; grounded theory; ethnography; observational studies; randomised controlled trial; sequential; concurrent; or transformative) and methods (to collect, analyse and interpret data) that has provided the framework for research methodology (qualitative, quantitative or mixed methods) (see Figure 4.1).

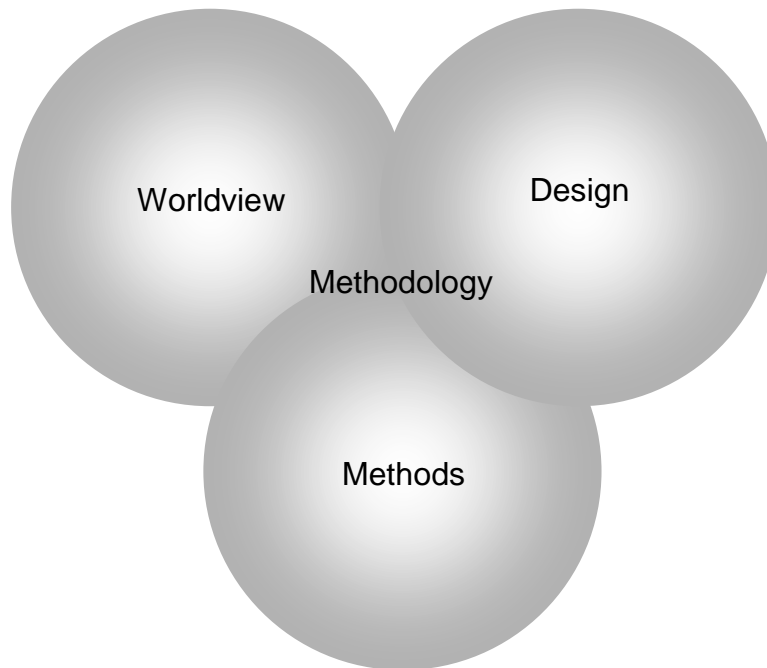


Figure 4.1: A framework for research design (adapted from Creswell, 2009)

The categorisation of research methodology into three main types (quantitative, qualitative or mixed methods) is commonplace in social and behavioural research (Creswell, 2009). Quantitative research collects, analyses, interprets and presents numerical information, where data are typically gathered using instruments so that they can be subject to statistical analysis. It acts as a mechanism for testing objective theories, examining relationships amongst variables, and as such will often have a hypothesis or statement that can be tested. Qualitative research uses narrative, words, documents or graphical material and analyse such materials to identify themes, relationships, and concepts, or to develop theory.

It acts as a mechanism to explore and understand the meaning of phenomena such as experience, culture or situations, doing so in depth to take account of context and complexity. Mixed methods research combines components, in varying degrees, from both qualitative and quantitative methodologies (Creswell, 2009; Teddlie & Tashakkori, 2009).

Such distinct categorisation however serves to signal broad differences between quantitative and qualitative research, heightening the deceptive notion of dichotomous camps (Muncey, 2009). Overdrawing differences, this portrays a rift wider than is in fact present. Reflecting upon Creswell and Plano-Clark's (2007) definition of methodology, it is considered more relevant to view research methodology as a continuum, with qualitative and quantitative situated at different ends and mixed methods tending towards the middle. From this perspective, come opportunities to explore philosophical worldviews, design and methods across this continuum (See Tables 4.1 & 4.2).

	Qualitative		Mixed methods		Quantitative
<b>Worldview</b>	<b>Constructivism</b>	<b>Advocacy/ participatory</b>	<b>Pragmatism</b>	<b>Positivism/ post-positivism</b>	
<b>Key elements of worldview</b>	<ul style="list-style-type: none"> <li>○ Understanding</li> <li>○ Multiple participant meanings</li> <li>○ Social and historical construction</li> <li>○ Theory generation</li> </ul>	<ul style="list-style-type: none"> <li>○ Political</li> <li>○ Empowerment issue-orientated</li> <li>○ Collaborative</li> <li>○ Change-orientated</li> </ul>	<ul style="list-style-type: none"> <li>○ Consequences of actions</li> <li>○ Problem centred</li> <li>○ Pluralistic</li> <li>○ Real-world practice orientated</li> </ul>	<ul style="list-style-type: none"> <li>○ Determination</li> <li>○ Reductionism</li> <li>○ Empirical observation and measurement</li> <li>○ Theory verification</li> </ul>	
<b>Ontology (reality)</b>	Multiple realities	Political reality	Singular and multiple realities	Singular reality	
<b>Epistemology (knowledge)</b>	Closeness	Collaboration	Practicality	Distance and impartiality	
<b>Axiology (values)</b>	Biased	Biased and negotiated	Multiple stances	Unbiased	
<b>Methodology</b>	Inductive	Participatory	Combining	Deductive	
<b>Rhetoric (language)</b>	Informal	Advocacy and change	Formal and informal	Formal	
	Qualitative		Mixed methods		Quantitative
<b>Design</b>	Narrative research Phenomenology Ethnography Grounded theory Case study		Sequential Concurrent Transformative		Experiments Surveys

Table 4.1: Worldviews and designs along a research methodology continuum (Adapted from Creswell & Plano Clark, 2007)

	Qualitative	Mixed methods	Quantitative
<b>Researcher</b>	Identifies personal stance		Remains in background
<b>Research intent</b>	Understand meaning individuals give to a phenomenon inductively		Test a theory deductively To support or refute it
<b>Literature</b>	Minor role Justifies problem Underpins arguments and research questions		Major role Justifies problem Identifies questions and hypotheses
<b>Data collection</b>	Open-ended Understand complexity of a single phenomenon Words and images Few participants		Closed-ended Test specific variables that form hypotheses/ questions Numbers Many participants
<b>Data analysis</b>	Themes Patterns Generalisations		Numerical Descriptive Inferential
<b>Data validation</b>	Procedures that rely on participants, researcher or the reader		Procedures based on external standards

Table 4.2: Methods along a research methodology continuum (adapted from Creswell & Plano Clark, 2007)

#### 4.5 Worldview

For this study, use of the term ‘worldview’ as a way of describing underpinning philosophical assumptions has drawn from the work of Guba (1990: 17), who defines it as “*a basic set of beliefs that guide action*”, and Creswell (2009: 6) who considers it to be “*a general orientation about the world and the nature of research that a researcher holds*”. In this context, worldview is shaped by past experiences, often leading researchers to develop a preference to a particular methodology.



Table 4.1 outlines four worldviews, with associated issues of epistemology, ontology, axiology, methodology and rhetoric. Epistemology is the philosophy of knowledge, how we come to know what kinds of knowledge are legitimate and consider the relationship between the researcher and that being researched. Ontology is the philosophy of reality, the study of being/existence. Axiology considers the role of values, while methodology in this context considers the identification of practices used to attain knowledge. Rhetoric considers the language of research. Research design provides specific direction for procedures within a research study (Creswell & Plano Clark, 2007).

#### 4.5.1 *Positivism/ Post-positivism as a worldview at the quantitative end of the research continuum* (See Table 4.1)

Positivism (coined by Comte (1798-1857) in the 1820s) and post-positivism were the dominant/prevaling worldview of the western world for much of the 20<sup>th</sup> century, and the basis of western science (Teddlie & Tashakkori, 2009). They have their philosophical assumptions based in traditional forms of research, where observation and reason are the means of understanding human behaviour. This is sometimes referred to as scientific research or empirical science. These assumptions hold true more for quantitative research than qualitative research. Holding that truth is waiting to be discovered, and that true knowledge can be obtained by observation and experiment, positivists adopt scientific methods as a means of seeking to predict causal relationships between key variables, and ultimately as a way of generating knowledge – although it is argued that causation was not feature of the original philosophy (Laudan, 1971).

That facts exist independently of theories and observation, reality is deemed to be objective, and truth is considered definite and ascertainable. In short, positivism assumes that social phenomena can be measured objectively and as such can be analysed following principles of scientific method. The important feature of this approach is the ‘systematic’ nature of process, aiming to minimise any contamination through the application of rigour (including reliability and validity) to ensure and enhance accuracy of the research process.

The positivistic worldview therefore makes use of quantification as a mechanism to enhance precision in the systematic process of knowledge generation, and relies on the principles/assumptions of science – these being determinism (events caused by other circumstances/causal links required for control/ prediction); empiricism (collecting verifiable/empirical evidence to support/ refute theories/hypotheses); parsimony (most economical way to explain phenomena); and generality (process of generalising observed phenomena to a wider population) (Creswell & Plano Clark, 2007).

Positivists argue that natural and human sciences share common logical and methodological principles, both of which operate within a strict set of laws to be discovered through empirical inquiry (Gray, 2004). This has been criticised by Kuhn (1922-1996), who highlighted the constraining culture of research communities and the limits these place on developing new ways to look at problems, and by Popper (1902-1994) who philosophically questioned the validity of many of the assumptions inherent in scientific enquiry, examining the ‘provisional’ nature of knowledge/truth and contesting that research should be about challenging hypotheses rather than trying to prove them (Teddlie & Tashakkori, 2009). More recently, Phillips & Burbules (2000) challenged the traditional notion of absolute truth, contesting one cannot be positive about claims of knowledge when studying humans.

To address such challenges, post-positivism emerged. While maintaining an emphasis on quantitative methods, post-positivists assume that absolute truth can never be found, but in seeking to understand, reflects the need to identify and assess the causes that influence outcomes (Creswell, 2009). Post-positivists therefore hold a deterministic philosophy in which causes most likely determine effect, and where understanding the world requires the testing, verification and refining of governing laws and theories.

The dominance of positivism has also been challenged by alternative traditions, namely interpretive constructivism and critical postmodernism. From these positions, it can be argued that the processes involved in the development of quantifiable measures of phenomena remove context from meanings, exclude participants' meanings and interpretations from collected data, and make use of statistical samples which do not allow for generalisation to, or understanding of, individuals. While positivists strive to determine truth and fact using experimental and survey methods, interpretivists/constructivists argue these methods impose a worldview, rather than understanding a worldview (Gray, 2004; Creswell, 2009).

#### *4.5.2 Constructivism as a worldview at the qualitative end of the research design continuum (See Table 4.1)*

Constructivism (or social constructivism, and often combined with interpretivism) as a worldview is typically seen as an approach to qualitative research and holding the assumption that individuals seek to build understanding of the world in which they live. By developing subjective meanings of experiences (which can be multiple and varied), truth is built/constructed within the minds of individuals through ongoing processes of negotiation, re-evaluation and refinement. As such, constructivists argue that the nature of truth, and inquiry into that truth, is problematic in that it does not reflect any external realities. Rather, it is reliant upon convention (agreed/generally accepted social norms and customs), human perception and social experience. Constructivists look for the complexity of these views. The focus is on constructed reality, where the definitions of knowledge and truth are based on inter-subjectivity rather than objectivity, and viability as opposed to truth (Gray, 2004; Creswell, 2009).

#### *4.5.3 The advocacy/ participatory approach as an additional worldview to be found along the research design continuum (See Table 4.1)*

The advocacy/participatory worldview arose from those who felt post-positivist assumptions imposed laws and theories, which failed to address social injustices. Moreover, they felt the constructivist worldview did not sufficiently advocate for marginalised people.

This worldview holds the assumption that research must be entwined with politics and political agendas, contain an action agenda for reform, and address issues such as empowerment, inequality, oppression, suppression, domination and alienation. Such research focuses on the needs of the marginalised, dictates collaboration, and provides a united voice for participants through which their lives can be improved. Aiming to create political debate and discussion so as to produce change, theoretical perspectives such as feminism, racialised discourses and critical theory can be integrated within this philosophical assumption (Creswell, 2009).

#### 4.5.4 *A further worldview situated in the middle ground of the research designs continuum – pragmatism (See Table 4.1)*

The roots of pragmatism can be traced back to Peirce, James, Mead and Dewey (Maxcy, 2003), thereafter associated with Kaplan, Rorty, Bernstein, West and Cherryholmes (Maxcy, 2003; Talisse & Aikin, 2008). As a worldview, it considers the nature of reality (ontology) as both singular and multiple, with practicality the overriding determinant in the relationship between research and researcher. In terms of truth, pragmatism is concerned with 'what works at the time' and 'solutions to problems'. Multiple stances, both biased and unbiased perspectives are considered acceptable in determining the role of values and value of roles (axiology). The focus is on methods, with an emphasis placed on the research problem.

As such, combining methodologies and designs, and collecting both qualitative and quantitative data and mixing them are considered appropriate processes of research. From such a perspective, the language of research (rhetoric) can be both formal and informal, where researchers working within this paradigm may use both first and third person approaches to writing. Not committed to any one system of philosophy, and drawing from both qualitative and quantitative assumptions, pragmatism has become a philosophy for underpinning mixed methods studies. Researchers subscribing to this philosophy have the freedom to choose the design and methods best suited to the needs and purposes of the subject under study, benefiting from pluralistic approaches to derive new knowledge (Morgan, 2007; Creswell, 2009).

#### 4.5.5 *Mixed methods research – and its fit with pragmatism*

Mixed methods as a research approach is now recognised as part of the research continuum, sitting between quantitative and qualitative approaches, and combining components, in varying degrees, from both (Creswell, 2009; Teddlie & Tashakkori, 2009). The notion of a continuum as opposed to discrete approaches is supported within the worldview of pragmatism, considering qualitative and quantitative methods as compatible, and as such, affords the use of both within a single research study. Subsequently, five practical reasons for ‘co-existence’ between quantitative and qualitative methodologies/designs and their underlying worldviews have been proposed – (1) Both have been used for many years; (2) Many researchers have advocated using both; (3) Funding agencies have supported research involving both; (4) Both have influenced policy; (5) Much has been taught by both (Creswell, Plano Clark, Gutmann & Hanson, 2003).

While pragmatism as a worldview allows for the use of mixed methods within social/behavioural research (Creswell & Plano Clark, 2007), mixed methods is not without its critics. Such critics concern themselves with the incongruity between the positivist position of objective truth and the claims of no single reality found within the constructivist tradition (Silverman, 1985; Johnson, Long & White, 2001). Other arguments consider the compounding of errors (Armitage & Hodgson, 2004) and the judging of quality when competing traditions are used in the same study (Mays & Pope, 2000). Indeed, proponents of mixed methods research are not currently in complete consensus as to the philosophical underpinning or meaning of ‘mixed methods’: Some consider it broadly as a methodology (Teddlie & Tashakkori, 2009), while others have an emphasis more focused upon research methods (Creswell, 2009; Greene, 2007). Three broad stances have emerged from the literature on mixed methods.

Firstly there is the view that builds upon the notion and earlier discussion above of pragmatism as a worldview, allowing the use of mixed methods (Creswell, 2009). Tashakkori and Teddlie (2003) developed this notion to consider pragmatism as the worldview that best provides a foundation for mixed methods research, formally linking pragmatism and mixed methods research. Indeed they suggested many different authors embrace pragmatism as the worldview for mixed methods research, and argue against the forced choice dichotomy between post-positivism and constructivism. More recently, Creswell (2009) reviewed the ongoing development of mixed methods research to find many researchers across a range of fields now adopting and using mixed methods research underpinned by pragmatism.

Secondly, is the dialectical perspective (Greene & Caracelli, 2003) that claims researchers can use multiple worldviews in mixed methods research. Emphasising the use of more than one worldview within a study, it is an approach that recognises the emerging contradictions and arguments as features to be honoured but which cannot be reconciled. Rather, these contradictory ideas, oppositions and tensions are acknowledged as reflections of the different ways in which we come to know about the world, and must simply be used explicitly. In arguing that research can and does use aspects of more than one worldview, care is required to ensure that where worldviews are mixed, they remain true to their underlying premises.

Thirdly, is the perspective that considers mixed methods research as a method in its own right. From this perspective, the worldview relates to the type of design, varying with the type of design chosen. It allows the use of a variety of worldviews, advocating different worldviews be honoured in application (Creswell et al., 2003). To this end, and derived from core assumptions identified by Morgan (1998) – that designs vary by sequence of data collection and weighting of such; Tashakkori and Teddlie (1998) – that data integration occurs at different places in the research process; and Greene and Caracelli (1997) - that some designs include a transformational value- or action-orientated dimension, four criteria have been identified as implicit within research designs - implementation/sequence of data collection, priority, stage of integration, and theoretical perspectives.

These four implicit criteria have been used to form a matrix to aid decision-making around research design and methods configuration to best address the research intent/questions (see Table 4.3).

Implicit criteria				
Research design type	Implementation	Priority	Stage of integration	Theoretical perspective
Sequential Explanatory	Quantitative followed by qualitative	Usually quantitative; can be qualitative or equal	Interpretation phase	May be present
Sequential Exploratory	Qualitative followed by quantitative	Usually qualitative; can be quantitative or equal	Interpretation phase	May be present
Sequential transformative	Either quantitative followed by qualitative or qualitative followed by quantitative	Quantitative, qualitative or equal	Interpretation phase	Definitely present
Concurrent Triangulation	Concurrent data collection of quantitative and qualitative data	Preferably equal; can be quantitative or qualitative	Interpretation phase or analysis phase	May be present
Concurrent Nested	Concurrent data collection of quantitative and qualitative data	Quantitative or qualitative	Analysis phase	May be present
Concurrent transformative	Concurrent data collection of quantitative and qualitative data	Quantitative, qualitative or equal	Usually analysis phase; can be during interpretation phase	Definitely present

Table 4.3: Mixed methods designs (Creswell et al., 2003: 224)

It is argued that affording a mixed methods study a mixed methods name and characteristics in this way conveys rigour (Creswell et al, 2003). Ultimately, the intention is to clarify the mix, while appreciating the blending of worldview, design and methods (Maudsley, 2011).

#### **4.6 Purpose statement, research intent, questions and objectives**

The purpose statement for this study (Chapter 2, 2.6) has characterised this study as a mixed methods concurrent design. Different but complementary data are collected on the same topic (Creswell & Plano Clark, 2007), using a semi-structured questionnaire, qualitative focused interviews and non-participant observation. The reason for collecting both quantitative and qualitative data in this study has been cited within the purpose statement as bringing together the strengths of both forms of research to more fully understand regulatory compliance within the Order in Scotland's tattooing and cosmetic body piercing industry than could be achieved through a single approach. In turn this also addresses the design limitations of previous research.

##### **4.6.1 Intent**

The purpose statement also indicated this study's intent to determine the extent of regulatory compliance with the Order in Scotland's tattooing and cosmetic body piercing industry, making clear what this study is about (Parahoo, 2006). In formulating this mixed methods study intent, the expected neutrality has also been respected, through avoidance of action verbs affiliated to either qualitative or quantitative research (Creswell & Plano Clark, 2007).



#### 4.6.2 *Research questions*

Creswell and Tashakkori (2007: 207) propose in their exploration of the nature of research questions in mixed methods research that a “*strong mixed methods study starts with a strong mixed methods question or objective*”. Mixed methodologists have adopted different approaches to the design of research questions for mixed methods studies: Some opt for one overarching mixed question (Mertens, 2007), some adopt specific questions for the stage of study, and others combine both these approaches through separate qualitative and quantitative questions followed by an explicit mixed methods question (Creswell & Plano-Clark, 2007). All give consideration to the study design. In formulating the research questions for this study, cognisance was taken of the study’s intent to bring together the strengths from both forms of research to more fully understand the topic of study, and the use of a concurrent design to achieve this.

The research questions for this study (Chapter 2, 2.8.1) were therefore based on distinct qualitative and quantitative questions, with integrating mixed methods questions to bring both aspects together. This reflected the position posited by Woolley (2009: 21) that integrated research questions are capable of ensuring “*each method contributes by addressing an aspect of the same substantive issue*”. The use of mixed methods research questions served as a tool to explicitly demonstrate the relationship between quantitative and qualitative study components. Moreover, it facilitated overall integration of study findings. Bryman (2007) and Yin (2006) support this approach, purporting how integration occurs at various stages of the research process including the procedure of writing research questions.

#### 4.6.3 *Research objectives*

Research objectives support the research intent, by explaining in further detail the achievements expected from the study (Parahoo, 2006). This study’s research objectives (Chapter 2, 2.8.1) will therefore assist in answering the study’s research questions.

#### 4.7 The study's concurrent design

In this study, the decision to adopt a concurrent design was clarified in purpose as collecting complementary data for the purpose of completeness – that is to more fully understand the topic under study (See Table 4.3). This provided opportunity to acceptably make use of the array of data collection methods. This facilitated the gathering of more comprehensive evidence to answer questions that could not be answered by one or other approaches in isolation. Careful attention to study design was however required if the integrity of each approach was to be maintained, and as such, explicit description of the approaches to data collection and analysis were crucial to the overall credibility of study findings and outcomes.

Using both quantitative and qualitative data collection and analysis to address the research questions, this mixed methods study was based on a concurrent design. Both qualitative and quantitative data were collected from across the target population at roughly the same time, thereafter integrating this data within and across the sub-groups (practitioners and enforcers) in the analysis and interpretation of the overall results. The description of the design as 'concurrent', as well as reflecting current thinking in mixed methods design, avoided the difficulties and confusion now associated with the term triangulation (Halcomb & Andrew, 2005; Adami & Kiger, 2005; Woolley, 2009; Casey & Murphy, 2009). The research design did however continue to make use of the principle of triangulation, using more than one method of data collection to strengthen a design and increase ability to interpret findings (Thurmond, 2001).

No explicit use of the term prevented any emerging confusion of its purpose, given that triangulation is now recognised for two distinct purposes – confirmation and completeness: First introduced into research by Campbell and Fiske in 1959 and developed by Webb in 1966 (Jick, 1979), the purpose of triangulation was to confirm data by enhancing validity and confidence in findings. Halcomb and Andrew (2005: 73) noted how Fielding and Fielding (1986) introduced a second purpose, that of "*completeness of understanding of the concept under investigation*".

Arguing the rare use of triangulation to achieve convergent validity alone, but rather to disclose the scope and range of the topic under study (Breitmayer, Ayres & Knafl, 1993; Begley, 1996; Coyle and Williams, 2000), 'completeness' was considered to exist at both a paradigmatic and/or methods level within a study.

The practicalities of collecting all data for a mixed methods study concurrently is acknowledged in the variation in terms used to describe approaches to timing of data collection. Indeed terms such as 'simultaneous' (Morse, 1991; 2003) and 'parallel' (Teddlie & Tashakkori, 2009) have also been used to describe the type of implementation associated with concurrent mixed methods design. Teddlie and Tashakkori (2009) suggest that simultaneous/concurrent implies the collection of data at exactly the same time and recommend the use of what they describe as the more inclusive term 'parallel'. This recognises that in reality, a researcher cannot collect all data at the same time. In this study the term concurrent was retained, on the basis that it reflected a period 'of' time as opposed to a period 'in' time.

The concurrent flow of work also emphasised how it was not the intention to build upon the findings from one sub-group or type of data to develop the next. It is however recognised with concurrent designs that some informal 'cross talk' may occur as knowledge of one set of data/analysis shapes the analysis of another, leading to convergence, consistency and corroboration, or indeed divergence and dissonance (Teddlie & Tashakkori, 2009). Iteratively, the gradual interpretation of information as a researcher moves through data collection and analysis does have the potential to inform data analysis and interpretation within a study. The concurrent approach to data collection was additionally beneficial to this study, allowing the forms of data collection to be described from the outset. This facilitated the securing of ethical approval for the whole study (See Appendices 4-6).

Generally with this design, forms of data are deemed independent of each other, with weighting of quantitative and qualitative data collection as equal is possible. However, within this study there was however an element of the embedded design (See Table 4) across the aspects of data collection, due to the nesting of some closed questions within the interviews and the inclusion of open-ended questions within the questionnaires. The main types of data were therefore considered independent of each other at data collection stage. The amalgamation of characteristics from both the concurrent and embedded designs reflected the scope of the underlying pragmatic worldview of this study, taking a 'what works' approach to answer the research questions. Designed to ensure both qualitative and quantitative data could be collectively compared and contrasted in one overall interpretation, it was an approach that would ultimately provide a comprehensive analysis and well-substantiated conclusions - overall a better understanding of the topic, and a total outcome greater than the sum of the parts (Jick, 1979; Morse, 1991; Yin, 2006; Woolley, 2009; Creswell, 2009).

#### 4.7.1 *Visualising the study design framework*

A study design framework was developed to describe the research design diagrammatically (See Figure 4.2), respecting the guidelines offered by authorities such as Steckler, McLeroy, Goodman, Bird and McCormick (1992), Creswell et al. (2003) and Ivankova, Creswell & Stick (2006) on the use of such diagrams. Additionally, the use of notation gave indication of the importance of the methods of data collection within this study. Applying current convention (Morse, 1991), the primary method of data collection was indicated by use of uppercase letters and the secondary method indicated by the use of lowercase letters, with the use of brackets indicated the embedding of one method within another.

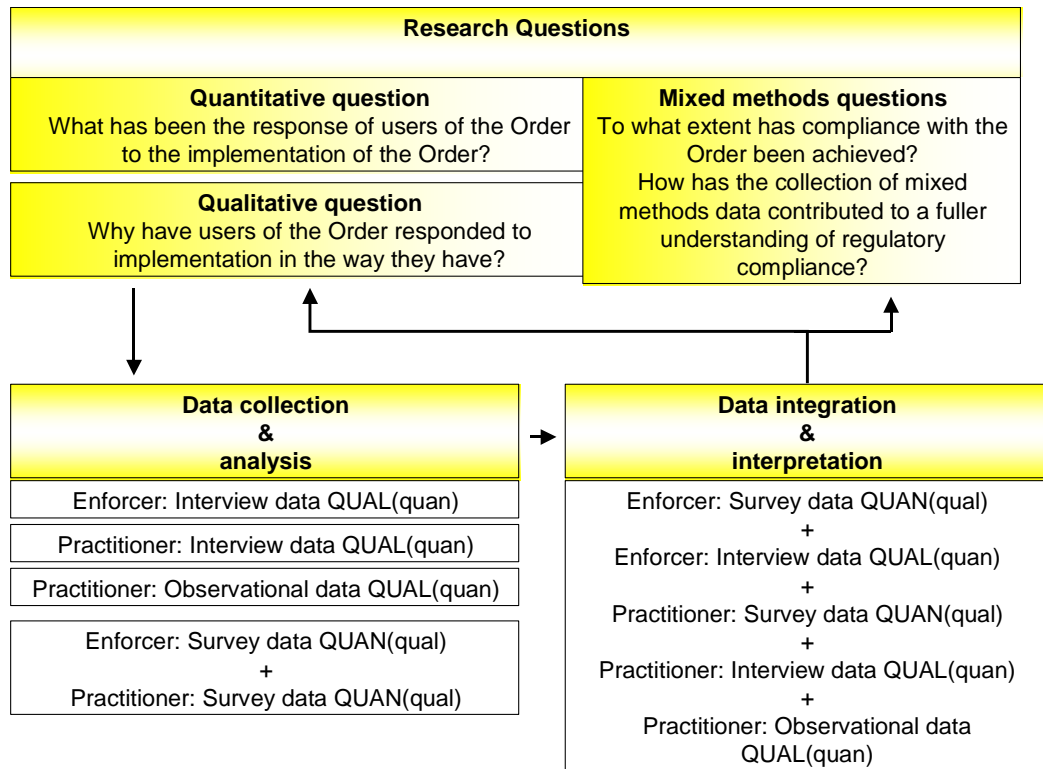


Figure 4.2: Study design framework

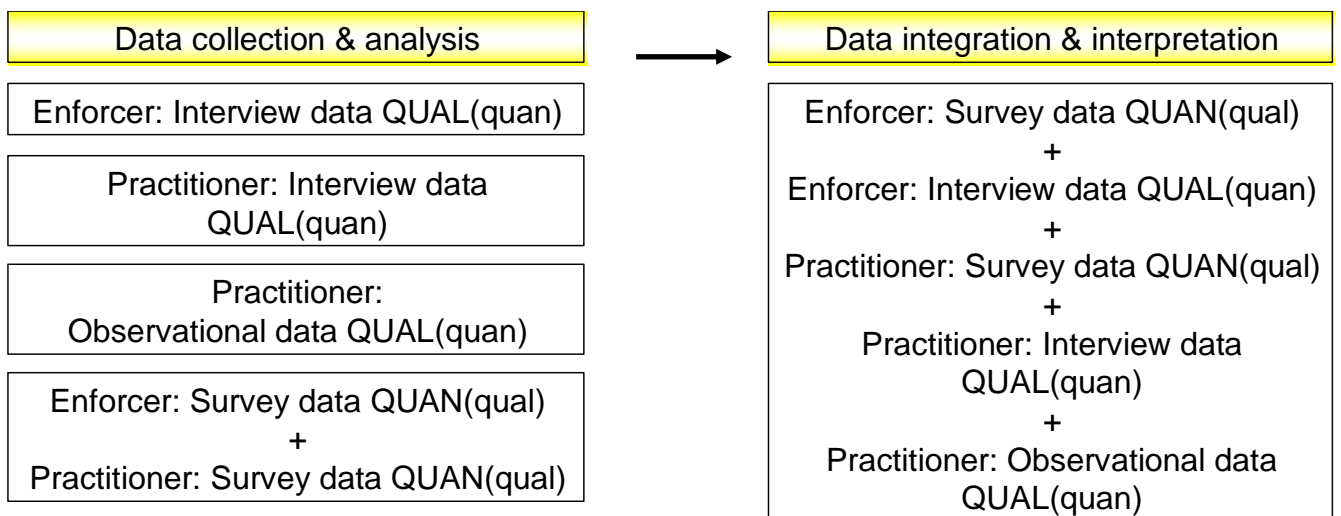
The study’s design framework also served to highlight the data collection sub-groups: Environmental Health Officers (‘enforcers’) and license holders (‘practitioners’). While there is no clear consensus on whether the same or different individuals should be selected to participate in the qualitative and quantitative components of a mixed methods study, the decision to use the same population for each aspect of data collection in this study was informed by Creswell and Plano Clark (2007). They suggest it is common practice to select the same individuals for both, to ease data comparison, and improve validity. Furthermore, this decision concurs with the view of Woolley (2009), who supports the use of ‘subsamples’ (samples from within samples) as evidence of efforts to maximise integration in a mixed methods study. In addition, it accords with Yin (2006: 42), who purports that *“the more that a single study integrates mixed methods...the more that mixed methods research, as opposed to multiple studies, is taking place”*. Such a decision therefore affords this study the ability to evidence integration at more than one point of the study. In turn, this is consistent with the production of findings greater than the sum of the parts.

#### 4.7.2 *Integrating the study and conceptual frameworks*

To promote integration across the research process, the study's design was then positioned within the study's conceptual framework (See Figure 4.3). This was viewed as an important part of this study's development, for it contributed to the legitimacy of description as mixed methods research (Yin, 2006). By demonstrating integration across these aspects of the research process, the potential to produce a fuller understanding of regulatory compliance was maximised (Woolley, 2009).

Research Questions	
<p>Quantitative question</p> <p>What has been the response of users of the Order to the implementation of the Order?</p>	<p>Mixed methods questions</p> <p>To what extent has compliance with the Order been achieved?</p> <p>How has the collection of mixed methods data contributed to a fuller understanding of regulatory compliance?</p>
<p>Qualitative question</p> <p>Why have users of the Order responded to implementation in the way they have?</p>	

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#### **4.8 The worldview underpinning this mixed methods study**

In planning this study, the influence of pre-existing philosophical assumptions on design and methods were considered (Chapter 4, 4.3). Making explicit the worldview underpinning any study, Creswell (2009) argues the choices to adopt a design and methods can also be explained. Hence, the association with rigour previously noted.

Of the four worldviews considered above, the concept of this study as mixed methods design was linked with the worldview of pragmatism. Pragmatism as the 'one best worldview' to fit with mixed methods research was highlighted as one of three stances within the debate surrounding the relationship between worldview and mixed methods research (Creswell & Plano Clark, 2007). Drawing on many ideas, and applying a 'what works at the time or in the context' philosophy to the process of research, pragmatism was deemed the most appropriate worldview to underpin this research study.

To determine the extent of regulatory compliance through exploration and explanation of users' response to the Order within the tattooing and cosmetic body piercing industry in Scotland, the adoption of a concurrent design was also considered most appropriate. By collecting qualitative and quantitative data from two sub-groups of the target population, it was felt these data could be integrated within and across each approach to data collection and again in the interpretation of the overall results. Thus, such design provided scope to maximise the use of quantitative and qualitative data to best address the research questions. The research design, while not necessarily easy or straightforward to implement, brought together the differing strengths and non-overlapping weaknesses of qualitative research methods with those of quantitative methods (Creswell & Plano Clark, 2007), thereby creating opportunity to generate well-substantiated conclusions about regulatory compliance.



As well as placing a heavy focus on the topic under study, it is argued that this research design also “*makes intuitive sense*” (Creswell & Plano Clark, 2007:66), for it has been able to collect all data, irrespective of type, at roughly the same time, limiting delays for ethical approval and shortening data collection time. This design also supported separate collection and analysis of data, using conventions associated with the data type. Although carried out by a lone researcher, this study’s design also supports inclusion of experts from separate fields of specialist study, providing opportunities for mentoring of novice researchers who may lack expertise in certain methods.

Within these parameters, it becomes evident that pragmatism has indeed been the most appropriate worldview to underpin this work. Both mixed methods research and pragmatism draw on more than one system of philosophy to value the use of qualitative and quantitative data and its synthesis. This research study took cognisance of context, a concept which pragmatists agree is essential. From a pragmatist worldview, researchers have freedom of choice. Such choice has been evident within this study through the autonomy afforded in the selection of design and methods to best address the research questions and meet the needs and purposes of the study. The study clearly made use of a variety of data collection methods, concurring with the view of pragmatists who do not see the world as an absolute entity, and who consider qualitative and quantitative methods to be compatible (Tashakkori & Teddlie, 1998). Of key relevance in the decision to consider pragmatism as the most appropriate underpinning worldview was the very practical and applicable nature of the research design, which enabled and supported a very focused view of the intent of the study, and the questions to be answered.

## **4.9 Ethical considerations**

Within any research work, ethical principles dictate that research should benefit both the participating individuals and society in general, should not cause harm, and should be fair and truthful. The rights of those participating include the right not to be harmed; the right of full disclosure; the right of self-determination and the right of privacy, anonymity and confidentiality (Parahoo 2006). To protect these rights/interests, research projects are subject to scrutiny by relevant ethics committees, the key aspects for consideration including consent, confidentiality and anonymity.

### *4.9.1 Consent*

Consent should be informed, ideally in writing, and requested only after potential participants have been given written information about the research and what it will involve. In particular, information should be given in relation to benefits to them and the wider community; any risks; and the relevant processes and procedures. Additionally, any consent must consider access to the research site (Parahoo, 2006).

In a mixed methods research study such as this, consideration to gaining informed consent should take cognisance of both the quantitative and qualitative approaches to data collection. Gaining informed consent for quantitative data collection should be planned and managed at the start of a study. For qualitative components, informed consent should be viewed as more of a process than a one-off event, given the inability to predict the course of an interview or observation (Parahoo, 2006). The need to balance harm and benefit in all forms of data collection should be central to the complex issue of ethical research behaviour, and as a researcher it is paramount that the need to collect data does not take priority over the rights of the participants.

Making use of the principles of both written and implied consent, informed consent was obtained prior to each data collection in this study. Time was given for potential participants to reflect on the information given and consider fully their possible involvement. Edinburgh Napier University Ethics Committee had previously considered the consent forms.

Having reviewed these forms as part of wider review of the ethics of this study, they had granted approval for all three data collection approaches used within the study design (See Appendices 4-6). In addition, negotiation with Local Authority personnel had secured permission to enter local authority premises to undertake data collection associated with enforcers. Access to practitioners operating from private business premises within the tattooing and cosmetic body piercing industry was determined through written agreements with those individuals who agreed to participate in this study.

#### 4.9.2 Confidentiality and anonymity

Preserving confidentiality and anonymity are important aspects of any research work. As a researcher, there is a requirement to give assurances of how these will be respected. Anonymity describes circumstances where the participants will remain unknown to the researcher, while confidentiality means that information shared during research is not identifiable to that participant (Newell & Burnard, 2006)

In a mixed methods study such as this, anonymity could be assured when data collection tools such as questionnaires, which do not ask participants to give their name, were used. This was further enhanced through postal distribution and return (O'Leary, 2004). Anonymity was not possible when data are collected using interviews or observation, so appropriate handling of collected data became crucial to preserving the privacy of participants. In these situations, collecting and presenting data in ways that avoided identifying the participant was essential to assuring confidentiality. It is argued however that this is "*easier to promise than to fulfil*" (Parahoo 2006: 311), and at times it is practically very difficult (Mander 1992). With the non-participant observational data collection, avoiding any direct reference to individuals or settings within field notes supported the maintenance of confidentiality. For the interview data, care was taken to use verbatim quotes sensitively in the reporting of findings to further promote confidentiality. To support this, pseudonyms were allocated to each participant to preserve their real identity (See Table 4.4). In this study, the selection of names for pseudonyms reflected the mix of males and females across the study components, but not specifically the gender of the participant.

Furthermore, in the reporting of findings, care was taken with colloquialisms when documenting verbatim quotes, to avoid identifying an area or person.

Practitioner code	Practitioner pseudonym	Enforcer code	Enforcer pseudonym
		E1	Andy
Interviews		E2	Bob
P1	Ade	E3	Carol
P2	Ben	E4	David
P3	Colin	E5	Ellen
P4	Dan	E6	Fiona
P5	Ed	E7	Graeme
P6	Frances	E8	Harry
P7	Gavin	E9	Ian
P8	Hugh	E10	Jim
P9	Izzy	E11	Karl
		E12	Lisa
Observations		E13	Michael
P1	Ade	E14	Neil
P2	Ben	E15	Ollie
P7	Gavin	E16	Peter
P9	Izzy	E17	Quentin
P10	Jackie	E18	Rita
P11	Karen	E19	Sean
P12	Lee	E20	Taylor
P13	Mark	E21	Una
		E22	Vic
		E23	William
		E24	Wilma
		E25	Yvonne
		E26	Zak

Table 4.4: Allocation of pseudonyms to respondents

Preserving confidentiality was further supported by appropriate data storage. All data (whether in hard copy/paper or electronic format) required secure storage (Parahoo, 2006). As such, tape recordings and paper copies of transcriptions from interviews, along with completed copies of questionnaires were stored in a locked cabinet, while electronic records/files were held on a secure computer, and backed up on a separate data stick (which was also stored in the locked cabinet). The backing up of electronic data and use of metal cabinets for storage, as well as ensuring confidentiality, served also to protect the data from damage. While the Data Protection Act (1998) does not specify data retention, retaining data did form part of the research participation agreement in this study.

This agreement stipulates study data are to be held for the duration of this research study only. In this instance, the period was considered to reflect the duration of PhD study. Thereafter all data will be destroyed as confidential waste.

#### 4.9.3 *Funding*

While opportunities to gain financial support for specific projects may be many, for the novice researcher, there is often no 'quick win'. Individuals require to build research credibility by working and learning from experienced researchers, and from research publication. Thereby "*a reputation sufficient to enable grants to be awarded on the basis of sound proposals*" is developed (Bond & Lacey, 2006: 49). At times however, research capacity building organisations make available small grants to local researchers, and this has been the case with this research study.

Following the submission of a proposal, a large NHS Board granted £10,000 to support the study's interview data collection, noting its fit with the existing local and national priority for research around blood borne virus transmission, and in particular the transmission of hepatitis C (Scottish Executive, 2006). Accepting this funding acknowledged the researchers' right to align them self to such sponsorship. With such a right came the responsibility to maintain a sound ethical position. This has required the researcher to make clear such allegiance. Hence the funding associated with this research has been declared in the writing of this thesis. This approach has allowed for consideration of research biases (Shuttleworth, 2009). To avoid such bias, care was taken to set clear boundaries on the associated requirements of this funding. This stipulated no changes could be made to the submitted proposal, given its process through Edinburgh Napier University's Research Ethics Committee. Moreover, no restrictions could be placed on the use of the collected data and subsequent analysis. There has been no experience of coercion from the funding body in this instance, but these clarifications have served to avoid any conflict of interest or concerns over bias. This is important, for it is recognised that corporate funders can be extremely influential, dictating the direction and scope of research studies and setting terms and conditions for the publication of findings (Ruane, 2005).

#### **4.10 Populations, sampling and access**

The selection of a target population, and approaches to sampling vary in qualitative and quantitative research. As both have similarities and differences, mixed methods research designs must make transparent the decision-making surrounding those invited to participate and how these relate to the overall intent of the study (Brannen & Halcomb, 2009).

##### *4.10.1 The theoretical population*

Identifying a theoretical population – that is “*the total number of units from which data can potentially be collected*” (Parahoo, 2006: 256) (where units may be individuals, organisations, events or artefacts), is generally considered to be an early and crucial step within research design. Inclusion and exclusion criteria may be set to refine the theoretical population and subsequently define the target/study population, from which a sample can be drawn and from whom data can potentially be collected. The decision to set inclusion/exclusion criteria depends upon the topic under study, and is directed by the need to answer the research questions.

In this study the theoretical population was considered to consist of all users of the Civic Government (Scotland) Act 1982 (Licensing of skin piercing and tattooing) Order 2006, which applies to skin piercing, tattooing, acupuncture and electrolysis. Order. Drawing from this theoretical population to create a target population, those involved in electrolysis, acupuncture and micro-pigmentation were excluded. Local Authority staff involved solely in the issuing of a license, or those contributing to the decision to grant a license based on disclosure procedures (such as police) were also excluded, as were clients of the industry. These decisions were made on the basis of the study intent, where the scope of this study focused on tattooing and cosmetic body piercing.

Although clients were excluded, it was anticipated their response to the infection control behaviour/practices would be observed and noted during non-participant observation, and incorporated indirectly into the findings of the study. This is discussed in greater detail later in this chapter, as are the arrangements for client consent on this basis. Having stipulated the exclusion criteria, the target population was now delineated from the theoretical population.

#### 4.10.2 *The target population*

The target population for this study was now clearly identified as those from the theoretical population who use the Order to *officially* and *directly* manage practices within Scotland's tattooing and cosmetic body piercing industry. Everyone covered under a license to operate as a tattoo artist or cosmetic body piercer (or apprentice of tattooing or cosmetic body piercing) in Scotland, within the bounds of the Order, were considered part of the target population (henceforth, this sub-group of the target population are described as 'the practitioners'). In addition, those actively engaged in the control and monitoring of infection control practices within the tattooing and cosmetic body piercing industry in Scotland (as part of a Local Authority EHO enforcement role) formed part of the target population (henceforth, this sub-group of the theoretical population are described as 'the enforcers').

Although the target population was clearly defined, the numbers and locations of those within it were unknown. This phenomenon is described in the literature as rare groups, hard-to-reach groups or hidden populations. Two key characteristics of such "*hidden populations*" are described. Firstly is the absence of a sampling frame "*so the size and boundaries of the population are unknown*", and secondly is the existence of "*strong privacy...often resulting in individual refusing to co-operate*" (Dawood, 2008: 35). To study hidden populations, innovative approaches to sampling have been developed and utilised. In the case of this study, some ingenuity was called for to quantify both theoretical and target populations.

Avoiding the temptation to use a convenience sample (due to the inadequacy for making estimates (Sudman & Kalton, 1986)), the use of snowballing was employed to identify those Local Authority staff meeting the study inclusion criteria. This decision was made in the knowledge that pure snowball sampling does not adhere to the principles of random sampling, is unable to guarantee representativeness, and is subject to selection bias (Kish, 1991; Lee, 1993; Atkinson & Flint, 2001). It is however recognised as a useful approach to sampling hidden populations, capable of finding potential participants through initial contacts who then act as informants or intermediaries to other members of the target population (Sudman & Kalton, 1986; Watters & Biernacki, 1989; Faugier & Sargeant, 1997).

Pragmatically and practically, this approach was considered appropriate for this study. Primarily, it created an otherwise unheard voice for those who use the Order to *officially* and *directly* manage infection control practices within Scotland's tattooing and cosmetic body piercing industry. Concurring with the views of Dawood (2008) on the importance of balancing the issue of representation and practicality, and reflecting on the principles of pragmatism as the worldview underpinning this study, the lack of representation as a result of sampling technique was viewed as a potential yet acceptable consequence. To minimise limitations from snowball sampling, and maximise opportunity to produce a sampling frame that fully represented the target population, pure snowball sampling was rejected in favour of a snowballing technique. In this case, key Local Authority contacts were utilised to identify all EHO staff meeting the study inclusion criteria. Thereafter, in the knowledge that each key contact had access to a list of licensed practitioners within their local authority area, access to these was requested via an individual Freedom of Information request to each of Scotland's 32 Local Authorities. By applying the study inclusion/exclusion criteria to each list, those skin piercing and tattooing practitioners who met the inclusion criteria were identified (See Figure 4.4).



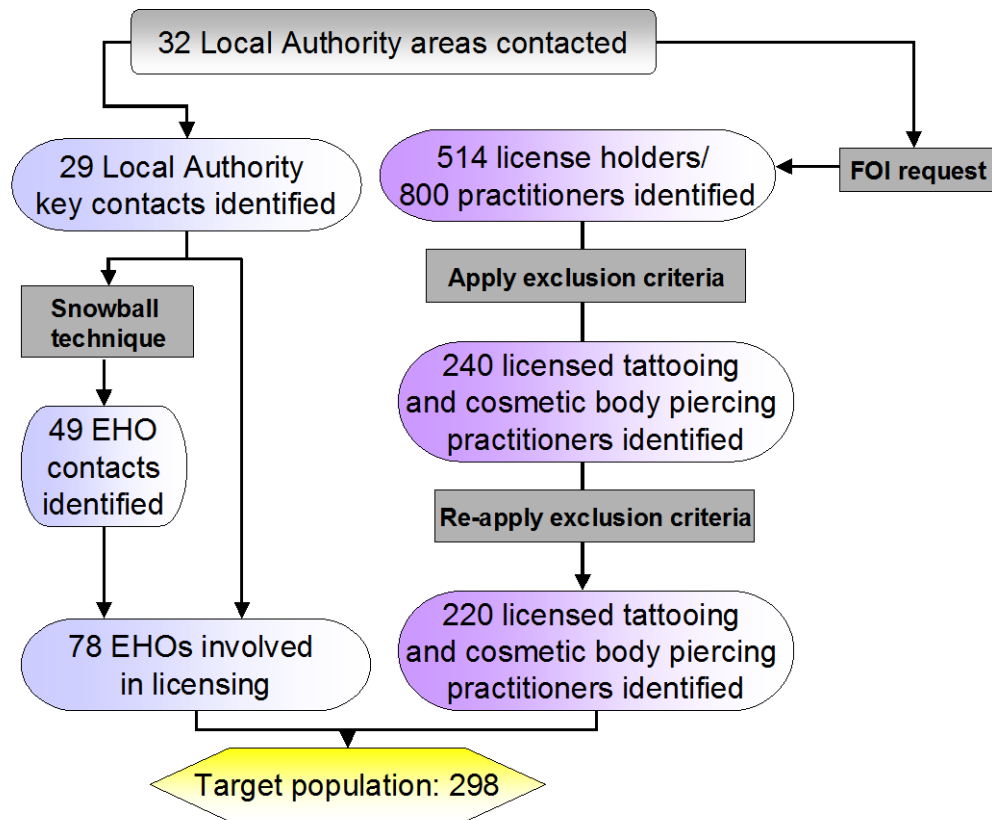


Figure 4.4: Identifying the theoretical and target populations

This approach supported the production of a robust sampling frame, considered fully inclusive of all relevant members of the initially hidden target populations. Concerns over representativeness and selection bias at this juncture were therefore alleviated.

#### 4.10.3 Sampling

Sampling is a strategy, which involves selecting participants from the target population to “*maximise the researcher’s ability to answer research questions set forth in a study*” (Teddlie & Tashakkori, 2009: 169). Generally, the decision to sample is made when the target population is too large to study in its entirety, where it is impracticable to carry out a census, or indeed where it is unnecessary or unethical to sample the whole population in terms of answering the research question. A sample is therefore a proportion/subset of the target population from whom data is gathered, rather than involving all of the target population.

Where the total population is of a manageable number, full population sampling (or census) can be utilised in accordance with the chosen methodology. Two basic types of sampling are probability (also known as scientific, random or quantitative) and non-probability (also known as purposive, non-random or qualitative) sampling. Both types have the overall purpose of generating a sample capable of addressing the research questions. Although both seek a form of generalisability, probability sampling strives to assure external validity, defined as “*the validity of inferences about whether causal relationship holds over variations in persons, setting, treatment variables, and measurement variables*” (Shadish, Cook & Campbell, 2002: 507), while non-probability sampling aims for transferability of inferences across settings/context (Teddlie & Tashakkori, 2009). In probability samples, selecting participants is based on cases collectively representative of the population, the focus becoming breadth of information. On the other hand, non-probability sampling selects cases are considered most suitable and/or informative with regard to exploring the research questions, and are typically small, focusing on depth of information.

With probability sampling, sample selection is undertaken before the study begins, with every person in the target population having a greater than zero chance of being selected. On the other hand, non-probability sampling occurs before and/or during the study using expert (although subjective) judgement, with the sample made up of persons whose chances of selection are not known in advance. Non-probability sampling cannot therefore depend upon the rationale of probability theory to determine the likelihood of the sample representing the population of study well. This does not however mean non-probability samples are not representative of the target population, rather it is difficult to know how well sampling has achieved this (Teddlie & Tashakkori, 2009). While the decision to sample is often made when the study population is too large to study, the purpose of the research should also play a significant part in the overall sampling strategy.

If the purpose of the research is to contribute to understanding of phenomena, non-probability sampling facilitates selection of a sample from those most informed and able to contribute towards understanding about the given phenomena. The emphasis is to ascertain different perspectives and reveal phenomena in all of its aspects. If however the purpose of the research is to examine relationships and make generalisations, then probability sampling is considered the preferred strategy (Parahoo, 2006; Teddlie & Tashakkori, 2009).

Conscious that creative use of sampling techniques is deemed one of the defining characteristics of mixed methods research, the sampling strategy of this study was designed with capacity to gather both breadth and depth of data across and within the study's target population and data collection approaches. Taking cognisance of the research questions and concurrent study design, alongside the need to remain true to the principles of the methodological approach, independent sampling procedures were devised to ensure external validity/representativeness for those quantitative aspects of the study and transferability/richness of information in the qualitatively focused aspects.

In the absence of consensus on the most appropriate method of sampling in mixed methods research, this study adopted a pragmatic approach, taking the principles of sampling from qualitative and quantitative research and applying these across the quantitative and qualitative elements of this mixed methods study (Teddlie & Tashakkori, 2009). Reflecting on the issue of sampling, the decision was made to administer the questionnaire through a full population census survey approach (n=298). This avoided potential sample bias, maximised representativeness and supported generalisation of findings (Parker, 2010). It was however recognised that even well designed census surveys can incur non-response bias if invited participants decide not to participate or to withdraw (Teddlie & Tashakkori, 2009). In this study therefore, attention was paid to maximising the response rate. Parahoo (2006; 279) identifies that "*it is difficult to define an acceptable response rate*".

In the 'Results and analysis' chapter of this work, the common approach of comparing this study's response rate to that of other similar studies has been exploited, but perhaps more importantly has been the "*attempt to explain non-responses and their possible implications for the data*" (Parahoo, 2006: 279).

Although the sampling frame was well defined in this study, non-probability purposive sampling was considered appropriate for gathering the study's qualitative data. This enabled inclusion of participants from the target population, with key experience of the topic under study (Endacott & Botti, 2007). With all 298 members of the target population deemed to have key experiences through their use the Order to *officially* and *directly* manage infection control practices within Scotland's tattooing and cosmetic body piercing industry, each was invited to participate in interviews. Thirty-five members of the target population responded positively to the invitation, so making up the purposive sample. The purposive sample included 26 enforcers and 9 practitioners from across Scotland, including representation from urban and rural settings and from those working alone or as part of a team/studio. This supported maximum variation across the heterogeneous sample (Endacott & Botti, 2007). Creswell & Plano Clark (2007) contest that collecting qualitative data from as many participants has the potential to sacrifice detail. In this study, robust methods of analysis were considered to negate this concern, while supporting meaningful data interpretation. With direct involvement in infection control practice, all practitioners (n=220) were also invited to participate in the non-participation observational component of the study, with 8 agreeing to support observation of practice (4 of whom were involved also in interviews) (See Figure 4.5).

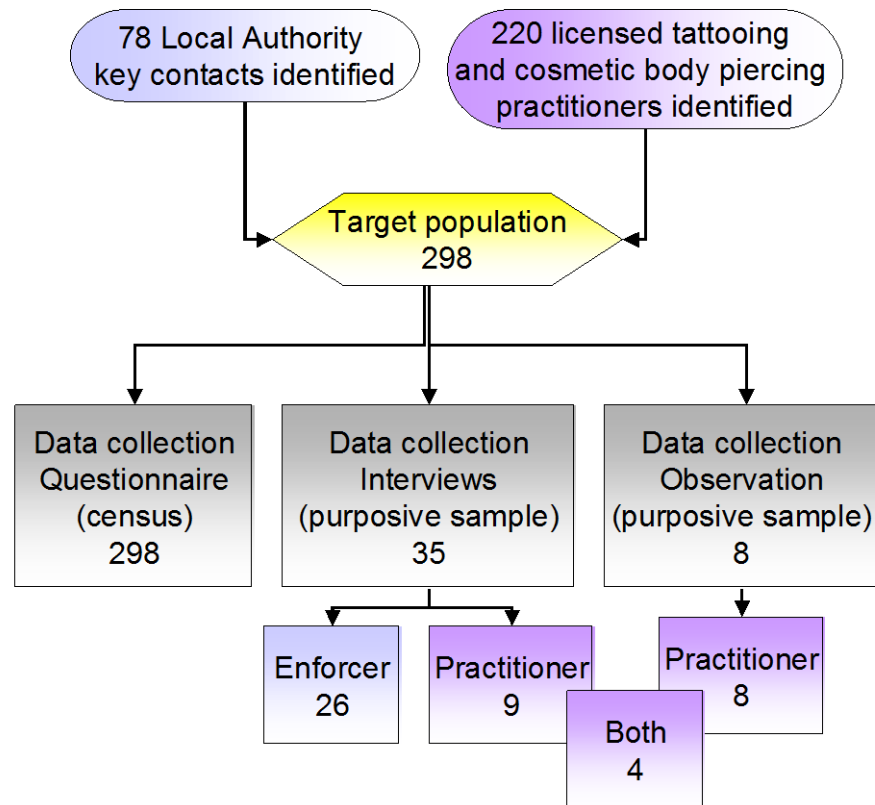


Figure 4.5 Study participants, by data collection approach

The approach to sampling in this study included the decision to adopt an integrated approach. By drawing a non-probability sample from a probability/full population sample, the use of overlapping participants within the study’s qualitative and quantitative aspects served to ease comparison of data (Teddlie & Yu, 2007). Moreover, it supported overall integration of findings within this mixed methods study (Yin, 2006; Creswell & Plano Clark, 2007; Woolley, 2009).

#### 4.10.4 Data quality across the datasets

One of the challenges to conducting mixed methods research is to ensure the data from the qualitative and quantitative strands are valid and credible. When this is done successfully, the mixed methods study is said to have high overall data quality (Teddlie and Tashakkori, 2009). Data quality in mixed methods research is determined by the quality of the separate qualitative and quantitative data within the overall study, with two sets of standards used for assessing data quality.

For quantitative data quality assurance, validity (whether the data represent the constructs they were assumed to capture) and reliability (whether the data consistently and accurately represent the constructs under study) are the measures evaluated. Internal validity (justification for making causal inferences) can be threatened by a number of factors recognised as biases and confounders (such as history, maturation, testing, instrumentation, selection or mortality). External validity (the degree to which generalisability can be considered) can be threatened mainly from the selection and allocation of the sample (Parahoo, 2006). In this study, appropriate sampling approaches and thorough design of data collection tools limited the impact of these threats.

Within this mixed methods study design, the approaches to data collection and analysis showed awareness and management of a further set of issues surrounding measurement validity. These included face validity, content validity (the extent to which an instrument measures what it is supposed to), criterion-related validity (the comparison of similar findings on the same topic, such as a standard or previous test scores by other methods) and construct validity (the ability to measure an intended construct) (Johnson & Turner, 2003).

In the qualitative strands, credibility (whether the interpretations are credible to the participants under study) and dependability/trustworthiness (the extent to which variation can be explained consistently) were considered analogous to the quantitative concepts of validity and reliability. As research participants are possibly the only people who can determine credibility, validation of this study's findings and interpretations through member-checking supported credibility. In addition, the use of a personal reflexive journal to record the reciprocal impact/influence of the researcher and the research ensured reflexivity – *“the continuous process of reflection by the researcher on her own values, preconceptions, behaviour or presence and those of the respondents, which can affect the interpretation of responses”* (Parahoo, 2006: 327). This was considered to contribute positively to validity, recording the potential influence of the researcher on the research and the impact of the research on the researcher.

Moreover, such approach reflected Willig's (2001) wider concept of reflexivity, involving both personal and epistemological reflexivity, and encompassing how, as researchers and people, research affects/changes individuals. Use of reflexivity as a mechanism for improving data reliability reflected its use by other researchers (Jootun, McGhee & Marland, 2009), contributed to minimising bias, and increased researcher truthfulness (Golafshani, 2003).

Some mixed methods researchers have taken a pragmatic and inclusive approach to the variations in terminology associated with research quality across methodologies. New 'shared' terminology has been coined and adopted by some researchers, using the term "*valid research*" to refer to the "*conduct of high quality research*". In turn they consider the term valid to be synonymous with the term trustworthiness (used to refer to the "*measures taken to persuade an audience that the research findings are worth attention*") (Johnson & Turner, 2003: 300). This stance reflects that of Johnson & Christensen (2000, cited in Johnson & Turner, 2003: 300) who describe valid research as "*plausible, credible, trustworthy, and therefore defensible*". Although addressed separately, the approaches taken in this study to ensure validity, reliability, credibility and trustworthiness are considered to have collectively embodied the attributes of valid research.

#### 4.10.5 Approaches to data collection

Data collection strategies are those techniques utilised by researchers to gather information (Johnson & Turner, 2003). Of the major methods of data collection, questionnaires, interviews and observation are utilised in this mixed methods study. Reflecting the importance of instrumentation and data collection to maximise integration within a single study (Yin, 2006) the development of the study's data collection tools was viewed as an anthology of integrated tools, addressing the same broad topic, and with capacity to produce overlapping datasets. Also facilitating integration during data analysis and interpretation (Woolley, 2009), the use of both qualitative and quantitative data collection tools replicated the fundamental principle of this study design.

That is, methods were mixed so the strengths were complementary and the weaknesses limited, to produce the most complete and precise portrayal of the phenomenon under study (Tashakkori & Teddlie 1998). Given the extensive data collection involved in this study, a schedule of data collection was recorded on a gantt chart (Appendix 7).

On the basis that no relevant validated tool existed (Field, 2003), a semi-structured questionnaire data collection tool was developed and piloted, informed by the research intent, research questions and the literature on the topic of infection control regulation and practice within the tattooing and cosmetic body piercing industry. Its design facilitated postal administration, whereby dictating the need for research participants to self-complete. Postal administration also supported distribution to the 298 members of the target population at low cost, over the geographical area of Scotland. Unfortunately, good response rates are notoriously difficult to achieve with this approach, due to difficulties ensuring participants complete them (Parahoo, 2006). To this end, and to support ethical requirements of informed consent, a covering letter/information sheet was produced and issued with each questionnaire, aiming to improve rate of return (Williams, 2003) (See Appendix 8). Written consent was not requested as part of the survey. Instead, returned questionnaires were deemed as indicating implied consent<sup>7</sup>. Questions within the questionnaire were both open-ended and closed, with a range of response styles for closed questions (such as yes/no choice, tick boxes and Likert scales). Where appropriate, “don’t know” and “not applicable” were included to prevent guessing. Inclusion of open-ended questions provided the opportunity to give comments throughout (Teddlie & Tashakorri, 2009).

Designing a good questionnaire is considered to involve three key tests: acceptability, validity and reliability (Field, 2003), each of which was addressed during questionnaire design and piloting stages. To test acceptability, an informal pre-pilot of the questionnaire was undertaken with the research supervisory team, and then with two groups, each of 5 academic nursing staff.

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<sup>7</sup> With implied consent, consent is presumed on the basis of the respondents’ actions – in this instance, the action of completing and returning the questionnaire



Amendments to the questionnaire were made after each pre-pilot, until there was confidence in the appropriateness of the questions and layout. The questionnaire was then piloted for validity and reliability, prior to agreeing the final version for use (See Appendix 9).

To test for validity, the questionnaire was examined to ensure it measured what it aimed to. Efforts were made to promote face validity, content validity and construct validity during questionnaire design, and these efforts were then tested: By drawing the content of the questionnaire from literature on the topics of regulation and infection control practice in the tattooing and cosmetic body piercing, the use of relevant language from these fields supported attainment of face validity. As non-experts within these fields, the research supervisory team and 10 academic nursing staff utilised in the acceptability testing were invited to comment on whether the tool appeared capable of identifying users' views. Similarly, to test content validity (the adequacy of items in the scale) health protection staff with an awareness of regulatory implementation within the tattooing and cosmetic body piercing industry across Scotland were invited to review the content for completeness.

These approaches to establishing validity are somewhat limited in that those assessing face validity had no expert knowledge of the topic under consideration. Equally, in assessing content validity, the similarity in views/beliefs of the health protection experts and the researcher asserted an improbable likelihood of being severely challenged (Kember & Leung, 2008). This potential measurement bias is considered within the discussion on study limitations.

Construct validity is concerned with the degree to which a scale measures the construct it is designed to measure. Although difficult to achieve in a newly constructed questionnaire, Murphy-Black (2006: 375) suggests *"increasing the number of different questions will increase construct validity"*. As such, 15-items were included in the scale to ascertain users' views of the effectiveness of regulatory implementation, and a significant number of questions on the topics of regulation and infection control practice made up the final version of the questionnaire.

Reliability refers to the ability of a scale to produce the same results if used repeatedly with the same group under the same conditions – that is, how free it is from random error. Test-retest and internal consistency are two frequently used indicators of the reliability of a scale (Pallant, 2007). To determine reliability of the questionnaire's 15-point scale (intended to measure users' views of the effectiveness of regulatory implementation), a pre-selected sample of 20 ear piercers were invited to complete the questionnaire prior to it being administered to the target population as a census survey. Two weeks later, the same group of ear piercers were asked to complete the same questionnaire again. The results were compared, and high test-retest correlation was noted. The scale was also assessed for internal consistency using Cronbach's coefficient alpha (as a measure of the degree to which the items in the scale measure the same underlying construct). In the pilot study of 20 ear piercers, the Cronbach alpha coefficient was found to be 0.819. An alpha coefficient of more than 0.7 is considered acceptable (but above 0.8 is preferable), and so this scale was considered to have good internal consistency. From these combined results, the scale was considered reliable (Pallant, 2007).

Extract from reflexive journal, 12 December 2008

*Cronbach alpha is 0.819...but the inter-item correlation matrix from the reliability output contains negative values for three items? All relevant items are correctly reverse scored, so I think there is a possibility that some items on the scale are not measuring the same construct? Low corrected item-total correlation values for the same items (less than 0.3) and higher alpha if deleted items indicate the same. I know I want to ask all the questions – its potentially the impact of small pilot numbers - leave all items in the questionnaire and re-run check for reliability of the 15-point scale (and possibly on an amended 12-point scale) when all survey responses are available...*

The development of the study's qualitative interviewing data collection tool was informed by Patton's (2002) continuum. Including informal conversational interviews, the interview guide approach and standardised open-ended interviewing, this continuum highlights a decreasingly qualitative approach to interviews, from the completely unstructured interview where questions arise spontaneously from conversation, through to those with open- and/or closed-ended questions delivered from an interview protocol using the same wording and sequence for each participant. While the latter type of interview is described as an example of mixed interviewing (Johnston & Turner, 2003), the decision was made to select the interview guide approach for the conduct of interviews in this study. This offered scope to use a pre-specified/listed topics (informed by the research intent and research questions, and mirroring those of the questionnaire) from an interview protocol (See Appendix 10), but with flexibility to reword or re-order the deliver of the questions. This, it was felt, supported a more conversational approach to the interview. In turn, it was anticipated this would generate a greater depth of information from the interviews. The interviews, described as qualitative focused interviews, aimed to elicit users' experiences and views of the Order within the tattooing and cosmetic body piercing industry in Scotland. All 298 members of the target population were invited to participate in the interviews (See Appendix 11). Data from the 35 focused interviews were recorded on digital audio-tape for later transcription.

Non-participant observation data collection aimed to provide additional information on the behaviour of the sub-group of practitioners from within the target population. All 220 practitioners were invited to participate in the observation of practice (See Appendix 12). Due to the potential for clients to be indirectly involved in the observation of practice, client information and consent forms were made available to those practitioners agreeing to participate (Appendix 13).

Given the proffered association between regulation and risk to health/infection (Walters, 2001), it was felt structured observation (utilising a previously validated audit tools to determine compliance with standard infection control practice) would focus solely on infection control practice during tattooing and cosmetic body piercing procedures, restricting observation to within the confines of the audit tool, and missing opportunities to observe wider activity and interactions (Parahoo, 2006). To this end, unstructured observations were considered. This offered greater flexibility and an accumulation of wider information on tattooing and cosmetic body piercing practices associated with the implementation of the Order. In planning to carry out unstructured observation of practice, the issue of how to manage recognised procedures/techniques in infection control practice was considered an issue.

To establish a more complete understanding of the extent of regulatory compliance while managing the infection control elements of practice, it was decided that semi-structured non-participant observation were the best approach, where data would be collected as field notes. Use of the term 'semi-structured observation' aimed to highlight the observation was not completely without focus. Rather, observation was undertaken with a degree of structure – particularly associated with the observation of standard infection control practice, such as hand hygiene, where there is, for example, recognised technique. It was anticipated early observations would be broadly scoped, becoming more focused over time. Such an approach reflected the views of Mulhall (2003) who noted researchers as having ideas that change as observational data are gathered, and Parahoo (2006) who commented how unstructured observation increases in structure as researchers focus on ideas or issues as the observations progress.

Jotted notes initially served as an aide memoire from the semi-structured observations, these being utilised immediately following the observational period to produce more comprehensive field notes. It is contested that novices to this type of data collection need to be aware of the danger of failing to take adequate notes (or indeed, not note at all). Hence, a decision was made to write up field notes immediately following observation sessions.

In preparation for this method of data collection, two simulated infection control related procedures were planned, with the researcher observing these alongside a fellow infection control expert (believed to bring the same limitations to the semi-structured observation process as the researcher, in terms of risk in being selective in what to focus on) (Parahoo, 2006). Notes from these observations were compared. Serving as a pilot to data collection, it assisted in comprehending the level of note taking required before, during and after the procedures, and enabled reflection on the wider aspects of the observational experience beyond standard infection control practice. This 'pilot/training' contributed to the management of bias. Seeing what one wants to see is known to impact on observational findings (Brown, 2010), so this helped minimise the risk of researcher bias during study data collection.

The effects of 'Hawthorne' are a recognised limitation of observational data collection. However, Mulhall (2003) argues this is over-emphasised, given the difficulty in maintaining changes to normal behaviour over long periods. Additionally, spending sufficient time in the observation areas is considered to diminish its effects (Parahoo, 2006). As such, to support fading into the background, whole days were spent in observation areas during semi-structured non-participant observation data collection. To further assist this process, casual clothing similar to those of most practitioners (black hoodie/t-shirt, denims and trainers) were worn during periods of observation.

Finally, in terms of the observational component of this study, the issue of safety was considered. In delineating between the role as a researcher and the role as a nurse/infection control practitioner/lecturer, decisions were made on how and when to intervene in observational events considered 'unsafe practice' (Nursing and Midwifery Council (NMC), 2008). Barnett (2009) in an article on the ethical conduct of observational research highlights the dilemma and debate surrounding such intervention. While some researchers argue the distinction between observation and experimental manipulation, others maintain "*observational studies cannot observe high risk behaviours without a plan to intervene when exposures are potentially unsafe*" (Barnett, 2009: 356).

In discussion with fellow nursing professionals in relation to the nursing professional code (NMC, 2008), it was agreed at the outset with each practitioner to intervene in the event of inappropriate re-use of equipment that required decontamination or disposal (such as needle re-use and ink sharing). No intervention was to occur for issues such as poor hand hygiene techniques or lack of use of personal protective equipment. In addition, it was decided that no intervention would take place for issues considered by the researcher as breaches of aseptic technique, where the risk assessment for the area indicated approval of such practice by the EHO (such as the use of cling film to dress a tattoo).

Over 200 hours of non-participation observation were undertaken within 4 studios in 4 Local Authority areas, and across the practice of 8 practitioners. During this time, 27 occurrences of tattooing and/or cosmetic body piercing were observed. No client declined indirect involvement in the study, although 3 further procedures of a sensitive nature were not observed at the request of the practitioner.

Overall, in planning and implementing the approaches to data collection, the research intent and research questions dictated the need to collect data using a range of data collection. As well as providing better results than each dataset in isolation (Creswell, 2009), the production and use of a connected set of data collection tools generated an overall dataset to support synthesis of findings at the point of analysis and interpretation (Woolley, 2009). Moreover, this further supported genuine integration across the research process, which in turn is demonstration of the existence of mixed methods research (Yin, 2006; Bryman, 2007; Maudsley, 2011).

#### *4.10.6 Approaches to data analysis*

Onwuegbuzie and Teddlie (2003) highlight that while concurrent designs collect quantitative and qualitative data at the same time, data analysis often occurs after all data have been collected. The rationale is to ensure analyses are legitimate and representative of all data collected. Analysis in this study was undertaken on the range of data collected, based on the research questions and focused by the study's conceptual framework. This reflects the view purported by Onwuegbuzie and Teddlie (2003) that mixed methods analysis offers a more comprehensive analytical technique than either qualitative or quantitative analysis alone, using the strengths of each to better understand the phenomena under study.

As a tool for legitimisation, analysis within this mixed methods study strived to legitimise its findings by intertwining the qualitative and quantitative findings to generate more meaningful interpretation and conclusions. The primary intention of this study's analyses was therefore to utilise the results from the different but complementary methods of data collection, to achieve expansion and completeness, leading ultimately to a greater understanding than would have been achieved through one source of data collection in isolation.

Data analysis began with the conversion of raw data into useful forms. For the quantitative data, SPSS 15.0 for Windows was utilised to manage and organise. The categorical questionnaire data were coded by assigning a numerical coding for each option. Exploring the data followed in a simplistic way, conducting descriptive analysis to determine trends and normal/non-normal distribution, and selecting appropriate statistical tests for further analysis. The quantitative data was then subjected to statistical analysis to address the research questions, proceeding from descriptive analysis (including frequencies, percentages, minimum and maximum values, mean and standard deviation) to inferential analysis (including non-parametric statistical tests such as Chi-square test for independence, Mann-Whitney U test and Wilcoxon Signed Rank test). Again, this was supported by use of SPSS 15.0 for Windows (Pallant, 2007).

The qualitative data from the 35 focused interviews were transcribed verbatim. Exploration of responses to the broad open-ended questions from the focused interviews began with thorough reading and re-reading of the texts, recording initial thoughts in memos in the transcript margins and in a reflexive diary. The semi-structured non-participant observation data was managed similarly, achieving immersion in the data through repeated reading of field notes (Parahoo, 2006). The approach to opening up the data and searching for groups of statements/phrases that may form themes was based on the principles of framework analysis, utilising the thematic network technique described by Attride-Stirling (2001) (See Appendix 14). As a method of analysis, this framework approach was inductive and therefore capable of reflecting the phenomena under study. Initially however it was deductive, deriving codes at the beginning of data collection linked to pre-set aims and objectives (Pope, Ziebland & Mays, 2000). In this study, these codes were derived from the study's conceptual framework, and were associated with common issues from literature associated with regulatory compliance. Pope, Ziebland and Mays (2000) suggest this framework approach is particularly suited to more structured qualitative data collection and is now becoming a popular approach to analysis in applied qualitative research, where there is often linkage of qualitative data to quantitative findings. As such it was an approach well suited to this mixed methods study, where the analytical process had been heavily informed by a priori reasoning.

Generating codes from the data at the beginning of the analysis firstly involved devising a coding framework and breaking down the text into segments that were manageable and meaningful. The development of a coding framework can be done in more than one way – it can be derived from the research questions and associated theoretical interests or it can be based on issues arising directly from the text. In this instance, the coding framework was based on the study's conceptual framework (See Figure 3.6, page 150). Thereafter, text was broken down using the coding framework into extracts of text.



Breaking down of text reflected the process of thematic analysis data reduction used by other researchers (Miles & Huberman, 1994). In this study however, it was structured so as to support integration of qualitative and quantitative data explicitly, this being an important aspect of mixed methods research (Yin, 2006).

Once coded, systematising the abstraction of basic, organising and global themes involved reading the text segments within each code, extracting common themes from the coded segments, refining by reading and re-reading the themes until the themes were considered discrete yet representative of the text segments from which they had been derived. Following theme identification, the thematic network was constructed by first ordering the themes into groups on similar topics, thereafter re-naming these as basic themes. Groups of basic themes were then re-arranged into clusters, which shared common underlying concepts, these being described as 'organising themes'. Global themes were then deduced from summarising the main topic of the organising themes (Attride-Stirling, 2001) (See Figure 4.6).

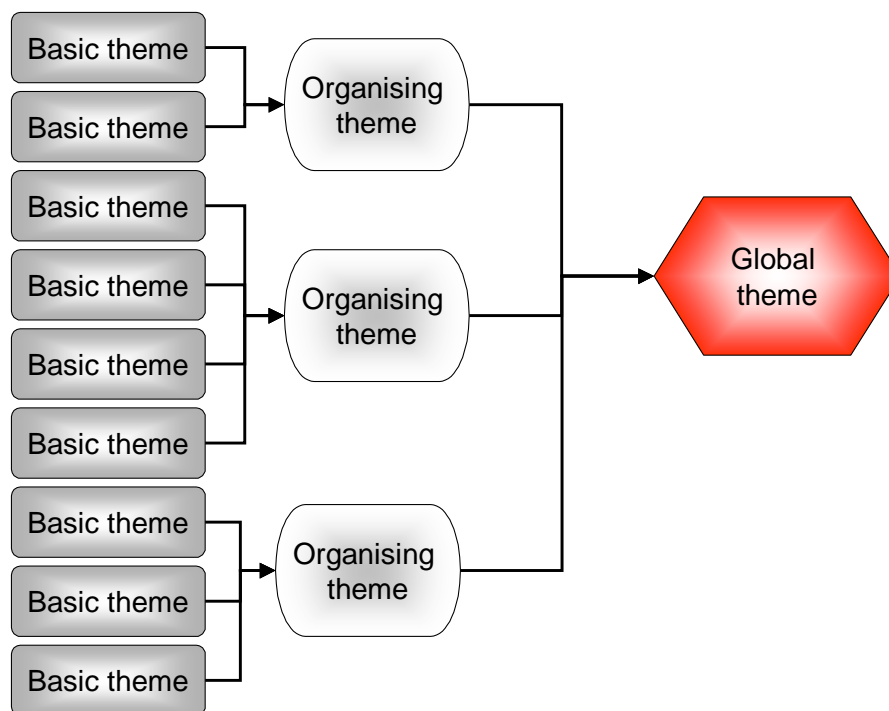


Figure 4.6: Structure of a thematic network (adapted from Attride-Stirling, 2001: 388)

Thematic networks draw on the common features of hermeneutic qualitative analysis and the principles of argumentation theory, aiming to explore understanding of an issue. In the context of research, thematic network analysis is a way to organise a thematic analysis of qualitative data. While the thematic analysis strives to elicit themes, the thematic network serves as a tool to facilitate web-like structuring of these themes, starting with the generation of 'basic themes' (derived from the text of the transcripts). In this study, the transcripts from practitioners, the transcripts from the enforcers and the observational field notes were explored individually to elicit basic themes. These basic themes were then grouped by similarity of idea into clusters called 'organising themes' to reveal meaning from the text. Finally, the organising themes were grouped into global themes that collectively offered a view on an issue relating to compliance with regulation in the tattooing and cosmetic body piercing industry in Scotland. Resultantly, each global theme became situated in the centre of a thematic network, as depicted in Figure 4.6, above. The process of data analysis may generate more than one global theme (Attride-Stirling, 2001), and in this study, generated thematic networks from more than one perspective.

Repeated reading of transcripts/field notes identified practices and how these contributed to regulatory compliance. Conscious that such identification was personal interpretation, verification of interpretation by those interviewed/observed was requested. Although this is a contentious issue for some researchers in terms of the ability of participants to understand the interpretations (Sandelowski, 1998), it did offer an element of confirmability. The keeping of a reflexive journal, recounting how personal interpretation might have influenced this study also added credibility to the findings. As such, potential biases were transparent at the outset. Such an approach is derived from the principles of Heideggerian phenomenology, where there is recognition that personal interpretation cannot be separated from description of phenomena (Lowes & Prowse, 2001). Its use in this study highlighted how research underpinned by pragmatism can draw from differing philosophies to assist in achieving its intention (Maudsley, 2011).

Initially, the analyses of the individual datasets (questionnaire data, interview data, observational data) did not build on each other. Instead each separate analysis was based on Tashakkori and Teddlie's (1998) parallel mixed analysis approach. This concurred with the view that different methods of data collection require distinct approaches to analysis (Yin, 2006). Yin also stresses the importance of an integrated analysis if integrated findings are to be considered greater than the sum of their individual parts, and for this reason, counterpart analyses were designed and carried out in this study (See Figure 4.3, page 175). These analyses incorporated elements of survey responses, interviews and non-participant field notes, and ensured all three approaches to data collection were synthesised and amalgamated to assist in answering this study's research questions.

#### **4.11 Chapter 4 summary**

Beginning by offering a personal account of my beliefs and values, the influence these have had on my decision to use a mixed methods approach underpinned by pragmatism as the worldview in the design of this study was noted. Chapter 4 – 'Study design and methodology' developed from the findings from Chapter 2 – 'Literature review' and utilised the conceptual framework devised in Chapter 3 – 'Conceptual framework', to provide a detailed account of the design of this research.

I continued the chapter by clarifying the definition of methodology utilised within this thesis. Having considered the three main methodological approaches (qualitative, quantitative and mixed methods), I rationalised the decision to adopt a mixed methods design for this study, underpinned by the worldview of pragmatism. Thereafter I detailed the strategies of inquiry and research methods, supported by evidence. The detailed implementation of the planned design was appraised, demonstrating the conduct of valid mixed methods research, capable of producing connected qualitative and quantitative data, the findings from which can be integrated to become greater than the sum of their parts (Woolley, 2009). The results and individual analyses of this data are presented in the following chapter.

# Chapter 5

## Results and individual analyses

## **5.1 Introduction and overview**

Data and its analysis are said to lie at the heart of the research process (Greene, 2007). In a mixed methods study, the research design helps determine how best to present results and analysis. Two main models have emerged (Creswell & Plano-Clark, 2007) – the ‘merging of results’ model or the ‘reporting of results in sequence’ model. It is common in a concurrent design, such as this study, to separately report qualitative and quantitative results, followed by merging of data in a subsequent discussion section.

## **5.2 Background**

Building from the findings from Chapter 2 – ‘Literature review’ and utilising the conceptual framework devised in Chapter 3 – ‘Conceptual framework’, I gave an account of the design/methodology underpinning this research in Chapter 4 of my thesis. Designed to ensure the conduct of high quality/valid research, my three approaches to data collection have produced connected qualitative and quantitative data. Chapter 5 – ‘Results and individual analyses’ and Chapter 6 – ‘Integrative analysis and interpretation’, will collectively support the individual and integrative analyses of these study data.

This chapter focuses on the individual analyses of the qualitative and quantitative data generated during this study and how each contribute to determining the extent of regulatory compliance with the Order in Scotland’s tattooing and cosmetic body piercing industry. Addressing each type of data sequentially, I will detail the analytical processes undertaken to prepare and explore each dataset, giving account of the outputs separately. From qualitative interview and observational data analyses, the basic, organising and global themes emerging from the use of thematic network technique for coding and systematic extraction of textual evidence (Attride-Stirling, 2001) will be presented in text and diagrammatic formats. Thereafter, utilising SPSS, I will provide detail of outputs from quantitative data analysis. Proceeding from descriptive to inferential analysis, these data shall be presented as figures, graphs and tables, supported by explanatory text.

### **5.3 Qualitative data analysis**

#### *5.3.1 Preparing the qualitative data*

Creswell and Plano-Clark (2007) consider data preparation to involve the conversion of raw data to a form useful for analysis. In this study, preparing the qualitative data involved verbatim transcription of the taped interview and observational field note data to a word-processor, checking for accuracy during the process. Coding of themes was undertaken manually, and as such, no use was made of qualitative data analysis software. The conceptual framework (See Figure 3.6, p175) was utilised to develop a coding framework (Attride-Stirling, 2001), from which codes could be added/removed as the thematic analysis progressed. The initial coding framework included 15 key words derived from the conceptual framework, each associated with regulatory compliance:

1. Proportionality
2. Accountability
3. Consistency
4. Transparency
5. Targeting
6. Design
7. Standards
8. Monitoring/ enforcement
9. Implementation
10. Identification
11. Interpretation
12. Changes
13. Methods
14. Decision-making
15. Compliance

#### *5.3.2 Exploring the qualitative data*

Having transcribed the qualitative data to word-processor and developed a coding framework, the thematic network analysis continued with preliminary exploration of the data (Creswell & Plano-Clark, 2007). This involved reading and re-reading the data from the interviews and observation, and recording initial thoughts as notes in the margins of the transcripts/field notes. The aim of this process was to become knowledgeable of the data by becoming immersed within it (Newell & Burnard, 2006).

As such, the generation of these early notes was a key step in the thematic analysis process, serving as a crosscheck of the data against the coding framework (Creswell & Plano-Clark, 2007). From this preliminary exploration, 'risk' was added as a code to the coding framework.

Using the coding framework, reduction of the individual texts from practitioner interviews, enforcer interviews and non-participant observational field notes was undertaken by segmenting the text, drawing out salient quotes from sentences and paragraphs, and placing these segments into one (or more) of the codes from within the coding framework. This approach of breaking up the data under codes from the coding framework reflected the 'charting' component of framework analysis, where data were broken down, lifted from their original context and re-arranged into themes. Once coded, review of the sentences and paragraphs within each of the codes of the coding framework supported the extraction of salient themes from a reconstructed view of the text. While Attride-Stirling (2001) encourages the refinement of these themes to ensure they are discrete and non-repetitive, in this study, it was deemed more important to ensure the data reduction retained an overall representation of the original text. Review of this study's practitioner interview data yielded 29 themes, the enforcer interview data yielded 28 themes, and 25 themes were extracted from the observational field notes.

It was at this stage of analysis that the thematic networks were constructed. Themes derived from the text were grouped together by topic and considered as 'basic themes'. Although this shift from 'themes' to 'basic themes' is considered little more than a re-naming process, Attride-Stirling (2001; 391) advocates that it helps to delineate between "*the identification of themes and the creation of the thematic network*". The basic themes were then re-visited and grouped into clusters of similar topic – these clusters were re-named as 'organising themes'. Through reflection of the organising themes, the global themes emerged.

Attride-Stirling (2001) advises that each global theme produces one thematic network, but in this study, nine global themes have been represented across three networks. This approach has enabled the creation of one network per dataset, supporting the collective presentation of associated global themes for each of the three datasets (interviews with practitioner; interviews with enforcers; and observational field notes) (See Figures 5.1, 5.2 & 5.3).



<b>Codes</b>	<b>Themes (Basic)</b>	<b>Organising</b>	<b>Global</b>
Proportionality	Awareness of need to manage inherent risk		
Accountability	Need for change		
Consistency	Possibility of regulation	Awareness	
Transparency	Persistence of underground activity		
Targeting	Historical inaction of industry	Experience	There has been support for regulation
	Tension/ frustration with authority		
	Lack of choice		
Design/ Standards	Confusion due to regulatory interpretations	Reputation	Compliance decision-making was underpinned by business preservation
	Natural evolution		
Monitor/ Enforce	Changing standards	Competence	There are challenges to sustaining and enhancing compliance
Identification/interpretation	There has been lack of communication		
	Poor engagement as an industry collectively	Expectation	
Change	Industry knowledge base of the regulation	Responsibility	
Methods	Enforcer knowledge of the industry		
Decision-making	Existence of a range of standards and skills	Relationships	
Implementation	Opportunity for industry development		
Compliance	Ability of legal and illegal practitioners		
Risk	Predictability/ consistency		
	Explanation for changes		
	Lack of options		
	Eradication of illegal practice		
	Hope of influencing public opinion		
	Follow up through enforcement		
	Compliance for survival		
	Industry role in enforcement		
	Support for practitioners		
	Power base of enforcers		
	Flexibility to negotiate		
	Tripartite arrangements		

Figure 5.1: Thematic analysis networks – Practitioner interview data

<b>Codes</b>	<b>Themes (Basic)</b>	<b>Organising</b>	<b>Global</b>
Proportionality	Becoming aware of regulation by chance		
Accountability	No national picture		
Consistency	Lack of infection link		
Transparency	Activity was going on in people's homes		
	Home activity was difficult to address		
	Regulation made activity cost-prohibitive		
	There was no enforcement	Awareness	
	There was a perceived risk		
Targeting	The conditions led to consistency	Experience	Greater control through regulation to promote compliance
	Some scope for interpretation		
Design/ Standards	Knowledge without understanding		The industry presented no imminent risk to health
	A willingness to comply	Competence	
Monitor/ Enforce	Practitioners actioned advice		Sustaining/ enhancing compliance remains a challenge
	Complaints were not infection related		
Identification/interpretation	The industry was low priority	Expectation	
	Regulation would bring increased control		
Change	License equated with good practice		
	Similar to other industry management		
Methods	Everyone working to conditions/guidance	Relationships	
	Them and us/ divided		
Decision-making	Supportive		
	At odds		
Implementation	Resignation/ Power		
	Challenged		
Compliance	Opportunity to update skills and knowledge		
	Gaps in own knowledge		
Risk	Telling of the rules		
	Assessing standards		

Figure 5.2: Thematic network analysis - Enforcer interview data

<b>Codes</b>	<b>Themes (Basic)</b>	<b>Organising</b>	<b>Global</b>
Proportionality	Room for improvement		
	How to enhance now		
Accountability	Missed chance to develop practice		
	Make lean/ promote profit		
Consistency	Doing what is asked	Competence	
	Rote		
Transparency	Knowledge and / or understanding		
	Process/ procedure/ task driven	Risk	
Targeting	Over practice		Processes designed to promote good practice
Design/ Standards	Ownership/ responsibility for own space	Expectation	Scope to enhance compliance
	Asepsis		
Monitor/ Enforce	Undisturbed procedures		
	Simple vs. complex task		Challenges to sustaining/ enhancing compliance
Identification/interpretation	Processes habitual	Relationships	
	Lack of learning		
	Complacency		
Change	No evidence of client concern	Opportunity	
	Returning clients		
Methods	Clients acceptance		
	Client disinterest in process		
Decision-making	Friendships/ collegiality		
	Lack of leadership		
Implementation	Isolation		
	Support		
Compliance	Learning		
Risk			

Figure 5.3: Thematic network analysis - Observational field note data

Having constructed the thematic networks, the next step was to analyse and appraise each global theme separately, in the context of its organising and basic themes. The original text was re-visited. Rather than reading linearly though, reading, description and interpretation of themes was guided by the research questions (Lathlean, 2006), and supported with text segments (Attride-Stirling, 2001). The detail of these activities has been reported within:

- 5.3.3 Analysis of practitioner interview data
- 5.3.4 Analysis of enforcer interview data
- 5.3.5 Analysis of observational field notes

### *5.3.3 Analysis of practitioner interview data*

The three global themes to emerge from analysis of the qualitative practitioner interview data were identified in Figure 5.1 as:

- There has been support for regulation
- Compliance decision-making was underpinned by business preservation
- There are challenges to sustaining and enhancing compliance

#### There has been support for regulation

'Support for regulation' emerged as a global theme derived from the organising themes of reputation, awareness, expectation and competence (See Figure 5.4).

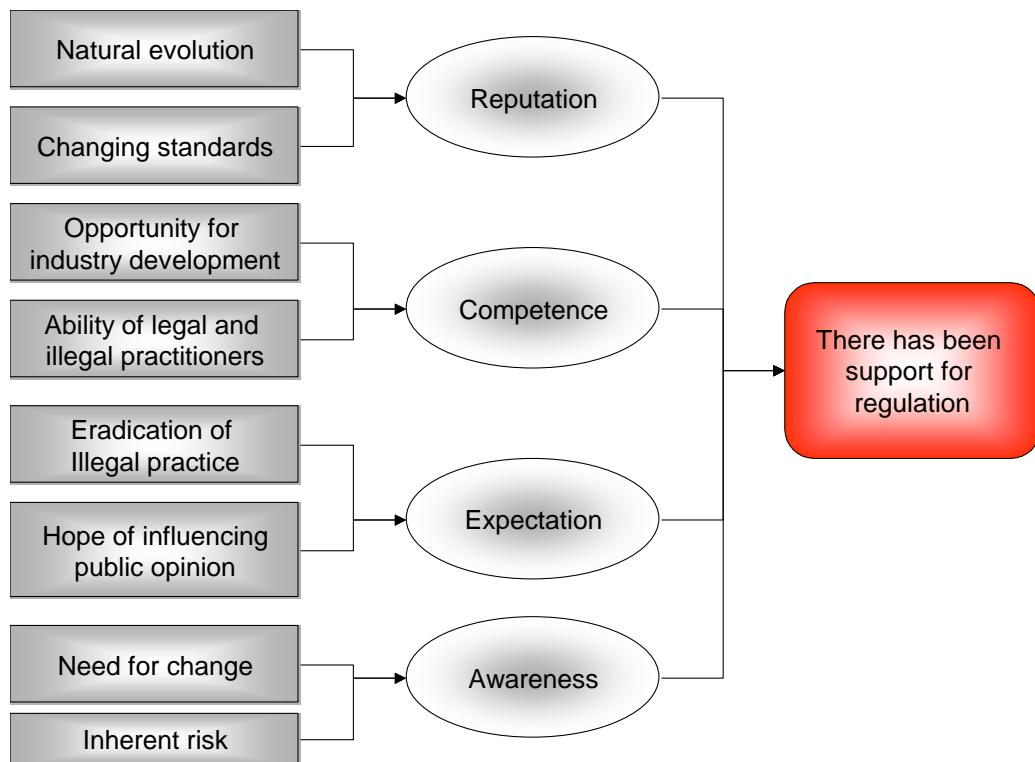


Figure 5.4: Thematic network - 'There has been support for regulation'

The findings identified industry practitioners as very conscious of their historical background, and the reputation this had created. Rather than dismiss or deny this, regulation had become an extension of their historical journey. Past reputation was cited openly within the context of a natural evolution of the industry. Changes to practice were associated with advancing knowledge and updating of practice:

*“.....They used to have a kind o block of almost like Vaseline....and they would take the needles out and just stick them into this block...how many times these things had been used I’ve no idea...20 years ago. Coming forward maybe 10 years it was using like sealed and sterilised packets....chances are the guys would only have ...four machines...four grips so whether they used fresh needles or not it wouldn’t make any difference you’d still have these grips that have got inks running through them and a mixture of the blood and the ink. So it’s kind of moved forward to all these things being individual for each person, and I mean, it has come on a long way”*

(Ben, page 2, line 26)

*“Personally speaking, in the last 20 years the whole industry has totally flipped and it...the majority o’ the flip is to the good side, its for the good of the art, its for the good of the client, its for the greater good of the artists because the more talented new individuals coming into the business, the more it makes the existing studios, that do actually take it seriously, want to push their limits you know”*  
(Ben, page 2: line 4)

*“I mean, it used to be very sort of it was underworld, it was, you know all underground. It was about body shock. Now it’s more about aesthetics and certainly you get very few people now with multiple facial piercings.... They are not looking for what it used to be, sort of, the old cannula in the back of a tattoo shop by the hairy biker. They are looking for something they feel secure with”*  
(Colin, page 1, line 27)

Through these commentaries on the shift in practice, practitioners highlighted their awareness of the inherent risk of infection from their practices:

*“Ye always will get, ye always will get ye know, like cross contamination and aseptic technique...you can read that in any medical journal”*  
(Ed, page 11, line 16)

*“You have to say there is a risk, you would be a liar and a fool to say, to say to anyone a piercing is without risk”*  
(Frances, page 5, line 1)

*“...at the end of the day it is an invasive procedure, every time you break someone’s skin you’re running the risk of causing them a problem of some description...just by the nature of this”*  
(Colin, page 10, line 12)

While practitioners indicated support for regulation, this was co-dependent upon the attainment of practitioner’s expectations. Firstly, was an expectation poor practice would be addressed either by the industry practitioners themselves realising the need to act, or via the licensing process per se:

*“...what we expected would be that you know, a lot of them would be eh ..the fact that legislation was coming is a kind of wake up call and either get your shit together or move on out”*  
(Dan, page 4, line 26)

*“if you don’t have a license, then all they’ll do is come down and shut the doors”*  
(Ben, page 8, line 22)

In turn, there was an expectation public attitude and approach to tattooing and cosmetic body piercing would be influenced with the introduction of regulation:

*“I would say what we honestly expected was that it would be a kind of return to the old days, for you know, this groundswell of opinion...which would see people, I suppose you could say voluntarily through better knowledge, movin’ away fae the poorer operators and getting better work”* (Dan, page 4, line 19)

Furthermore, support for regulation was found to be very much driven by the underlying perceptions that existing competence would ensure ability to comply:

*“up until the guidelines coming in, I was pretty much almost there, you know”* (Colin, page 4, line 24)

*“..there’s been no changes in, in the way we operate, we’ve operated the way we’ve operated for well almost a decade and a half now...the only change is that we’ve updated the way we operate you know, we’ve introduced different ointments”* (Dan, page 3, line 21)

These findings evidenced practitioner support for regulation. Reflecting upon the findings of previous studies (See Chapter 2, 2.4.2), it could be argued that such support was liable to have enhanced the likelihood and extent of regulatory compliance. Previous research such as that of Zheng, Fu and Li (2009) has however demonstrated how support for regulation can quickly diminish if impacting upon factors such as business profit. Equally a study by IpsosMORI (2007) identified how support for regulation did not always translate into regulatory compliance.

Amidst the inherent risk associated with industry practices, practitioners’ awareness of their historical evolution may be construed as a positively influencing compliance factor. As members of a negatively stereotyped identity group however (Denton, 2001; Mason, 2004), the threat of identity devaluation may have impacted on practitioners’ abilities to create a positive professional image.

Such negative attributions are recognised as undermining perceptions of group competence, character, or commitment (Morgan Roberts, 2005), and in turn, this may have negatively influenced regulatory compliance.

Compliance decision-making was underpinned by business preservation

The global theme of ‘compliance decision-making underpinned by the need to ensure business preservation’ was derived from the organising themes of experience, awareness and responsibility (See Figure 5.5).

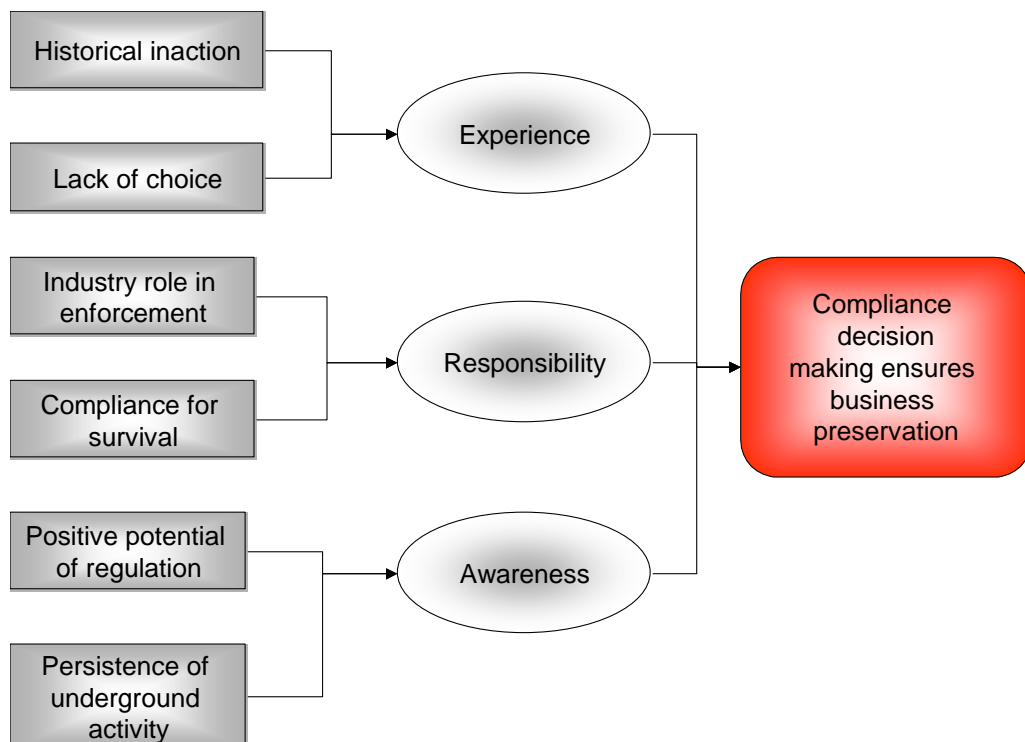


Figure 5.5: Thematic network - ‘Compliance decision-making ensures business preservation’

In terms of experience, practitioners recognised themselves as historically inactive, slow at times to make necessary changes to practice. Regulation had acted as a catalyst for change:

*“I think it human nature...its just a case of some people need that sudden boot in the...it might simply be down to the fact that its human nature to be lazy....people do prioritise”*

(Dan, page 14, line 3)



*"I don't think the people who made the big shift hadn't made the shift previously because they (a) didn't care or (b) weren't bothered. I think it was simply a case of it would either be eh finances itself or quite simply life getting in the way"*

(Ed, page 14, line 18)

*"I know one colleague in particular who hadn't done it until that point....just hadn't got around to it. When it came to the crunch these guys and these women stepped up to the mark, really they chose to step up to the mark..."*

(Frances, page 15, line 25)

*"I suppose ultimately just by human nature we all like a bit of guidance, we need to be poked in the right direction"*

(Colin, page 18, line 11)

When asked about the decision-making process towards compliance, their experience had not been influenced/informed by the issue of 'risk to health'. Instead, practitioners were very clear their decision-making had been purely business related, simply believing they had no choice but to comply if they wanted to continue practicing/operating their business:

*"You can't work unless you do it...that's pretty much it, that's pretty much it"*

(Gavin, page 13, line 29)

*"..the bottom line of it is if you're a business person, the regulation can....you can lose your business very very quickly, lose your income stream very very quickly...there's probably a lot of people more worried about losing their income than anything else"*

(Frances, page 9, line 20)

*"If they didn't, they wouldn't be allowed to do it, it's that simple"*

(Colin, page 18, line 20)

*"You'd just lose your livelihood, don't you? If we don't have a license then all they'll do is come down and shut the doors"*

(Ben, page 8, line 22)

*"Because it's the law and if we don't do it we'll no' be allowed to do it. Its for....went through that list n' went 'oh f\*\*\*, right we need to bring that in, you need that, oh that's gonna cost a fortune...'is it gonna be worth it...are we bringing in enough already to cover that...what are we gonna do?"*

(Ed, page 10, line 6)

Although lack of choice was a dominant feature in the decision-making experience, this was coupled with an awareness of the potential positive benefit to the industry from regulation. This awareness focused on the guarantee of regulation to create a consistent and level standard to which everyone would work, this being of positive benefit to industry progression:

*“...it’s down in black and white and we’re all singing from the same hymn sheet”*  
(Hugh, page 11, line 1)

*“...if it brings us all up to the same bar, great....they’re definitely going in the right direction....”*  
(Ed, page 10, line 24)

*“We need regulation. We need a sort of continuity to the industry. It is a must if we’re gonna progress”*  
(Colin, page 10, line 9)

*“Regulation is an even playing field ye know, if I have to have an autoclave as a vacuum, everybody should have one”*  
(Dan, page 13, line 18)

Since implementation however, this positive perception of ‘a level playing field’ had been tinged by a growing awareness of the persisting presence of unlicensed/ illegal/ underground activity:

*“...we know a lot of people that do it from home, know of them. The illegal underground scene in Scotland is huge, it’s a lot bigger than what’s going on legally, a lot bigger”*  
(Ade, page 14, line 6)

Despite this awareness of unlicensed and concerning practices, the practitioners felt it was not their responsibility to act on such intelligence. Instead, they felt it was the client’s responsibility to report any wrong-doing:

*“the only way to catch these people is for, is for their customer to know its illegal and for their customers to want to prosecute them”*  
(Gavin, page 16, line 15)

*“....unless people report it themselves, there isn’t anything that can be done”*  
(Ben, page 13, line 28)

*“We’re no’ here to police either the industry or the idiots who are like takin’ people’s health and riskin’ it”*  
(Dan, page 16, line 19)

Furthermore, practitioners felt the extent of their responsibility lay solely with addressing their own compliance requirements, so ensuring their own business survival:

*“...I think a lot of people...the first thing ...is cost, no’ how its gonna affect their clients or how its gonna make them safer”*

(Ed, page 10, line 20)

Some examples were however given where practitioners had taken on the responsibility of reporting unlicensed activity. In these instances, they perceived the outcome as no more effective than that of their fellow practitioners’ inaction:

*“..you can complain and drop hints and send e-mails but can’t really impact on it (underground piercing) and I understand where the environmental health officer is coming from...they need hard facts...generally they need complaints before they can act”*

(Frances, page 12, line 6)

*“...we’ve actually given their name to environmental health three times and still nothing has been done about it...and still they’re tattooing...you kind of give up after a while...because the council just say that there’s nothing they can do about it”*

(Ade, page 14, line 14)

*"Anytime where I had seen something bad, I was on the phone to my EHO saying this is happening, blah, blah, blah. He’d say we cannae dae anythin’ about it unless the actual client makes a personal complaint themselves”*

(Ed, page 4, line 5)

Collectively, these findings demonstrated the rationality of practitioners’ behaviour. Reflecting the theory of rational choice, their decisions were shown to materialise from very logical cost-benefit assessment, culminating in the selection of the option judged to maximise benefit (Conner & Norman, 2005). The responses identified this option was to comply with regulation, to opt out or to operate underground. The findings also demonstrated how this had the potential to negatively influence regulatory compliance: Perceived persistence of unmanaged underground activity may alter the perception of cost-benefit in those originally opting to comply, and in turn, negatively impact on their behavioural intention (Conner & Sparks, 2005).

### There are challenges to sustaining and enhancing compliance

The global theme of challenges to sustaining and enhancing compliance was derived from the organising themes of reputation, experience, competence and relationships (See Figure 5.6).

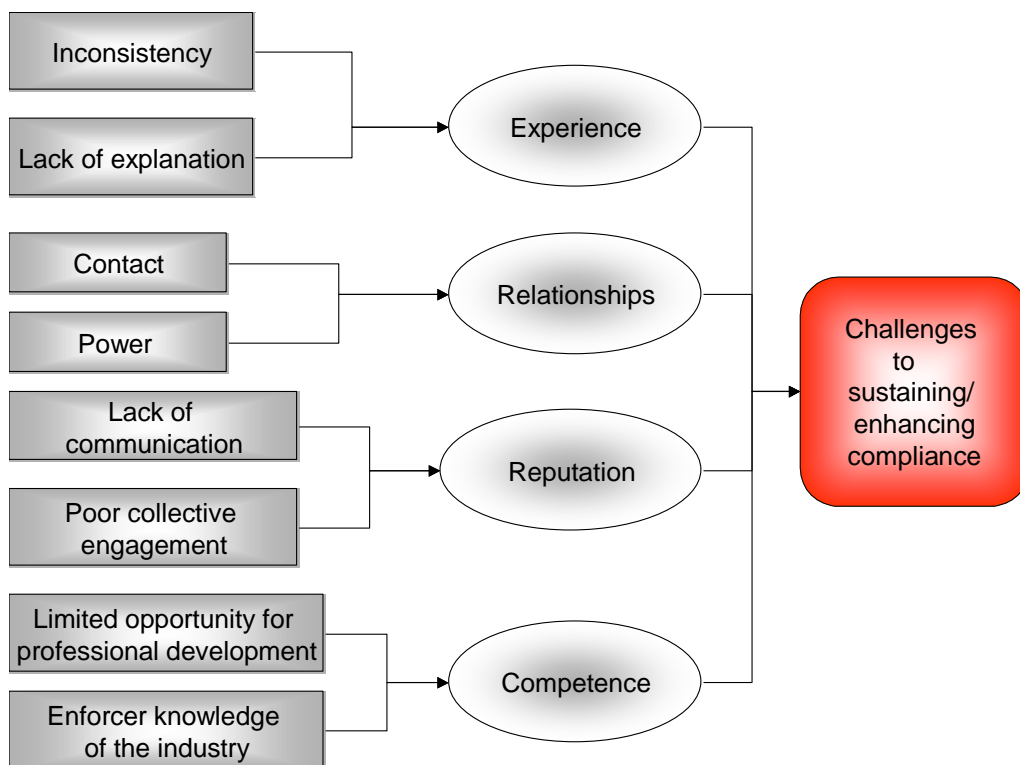


Figure 5.6: Thematic network for 'Practitioner challenges to sustaining/enhancing compliance'

From these findings came evidence of the industry's reputation for poor communication and engagement networks, concurring with Armstrong (2005). The lack of sharing of ideas and experiences and the inward focus of some practitioners serving was evidence of the challenges faced by the industry in sustaining and enhancing compliance:

*"..The tattoo world is quite arrogant...it's like...people don't like other tattooists"*  
(Ade, page 24, line 16)

*"..It's very dog eat dog, very closeted...you know, everyone wants to stay a step ahead"*  
(Ed, page 28, line 16)

*"The guys I keep in touch with tend not to talk shop....I'm not interested to be honest in what anybody else is doing. All I'm interested in is what we're doing in here"*  
(Ben, page 5, line 15)

Some evidence was found of communication emerging from the implementation of regulation. Through this supporting, sharing and learning from others' experiences of regulation, practitioners reported an awareness of what they described as 'inconsistent implementation'. With many factors known to influence motivation/inclination to comply with regulation (Hawkins, 1984; Hutter, 1997; Baldwin & Cave, 1999), these findings have evidenced the existence of frustration. This had the potential to impact negatively on compliance, and indeed the sustainability of changes. Furthermore, such frustration could have diminished support for the regulation, so limiting the scope to achieve substantive compliance:

*"It's different in every council...two completely different sets of rules for these shops. Why's it different? That frustrates me..."*  
(Ed, page 4, line 28)

*"If the legislation is Scotland wide, why isn't the licence fee the same everywhere. I'm £(amount), one of my mates is £(amount). Now where is the parity in that?"*  
(Dan, page 3, line 18)

*"...there was differences between the different environmental health authorities like down in (place name) compared to up here as to the stuff that they have...how they have interpreted the legislation"*  
(Gavin, page 9, line 28)

In addition, some practitioners reported experiencing the need to make changes without adequate explanation. This lack of understanding as a result threatened the ability of practitioners to make the necessary adjustment to achieve rule compliance:

*"We would have had a far better result...if education had been at the core of the health inspector's visit rather than actively looking for things they could punish you with..."*  
(Dan, page 6, line 6)

*"...the floor to ceiling divide thing...I spoke to environmental health in (place name) and I spoke to environmental health up here, just asking why – not because I didn't want to do it...its like fine, its in the rules, I'll do it no problem...no-one would give me an answer, it was just 'it's in the legislation that's why you've got to do it..."*  
(Gavin, page 5, line 14)

This lack of explanation led practitioners to challenge the competence of the enforcer, questioning their knowledge and understanding of the industry. This risked collapse of both rule and substantive compliance (Baldwin, Hutter & Rothstein, no date):

*“the lassie we’ve got ...she’s asking us more questions cos’ she’s no’ too sure herself...they’ve no’ got anybody that’s trained in it”*  
(Ed, page 6, line 26)

*“What they need to do is, if they’re serious about it at all, is to start to listen to the people in the industry because (pause) quite frankly ...they know nothing about this industry”*  
(Dan, page 18, line 2)

*“The people in the environmental health department....the two of us were on a real learning curve”*  
(Colin, page 12, line 5)

The competence of practitioners was also affected by the implementation of regulation. The practitioners report differences in the available opportunities to learn and develop their knowledge, understanding and skill. Given the reputation highlighted above, such loss of occasion to engage in continuous professional development threatened practitioners’ ability to achieve and sustain compliance:

*“Tattoo conventions....do they want one licence to cover the whole building...or are all these artists got to pay for a licence just for the week-end. So that’s the fear that we’ve got, that it’s gonna become impossible”*  
(Ade, page 22, line 3)

*“You’re trying to take it to an art level...like you would do such as exhibitions...but you’re getting held back a bit”*  
(Ben, page 23, line 7)

*“Those amateur tattooers usually either..either they carry on doing it...or they go professional you know...more often they open their own shop. I think the legislation is stopping those people from opening a shop..”*  
(Gavin, page 16, line 6)

Furthermore, enforcer engagement with the industry for training purposes augmented this notion of incompetence:

*“It sounds a bit big headed, but they always come to us for help. If anybody’s got any questions or anything, they always phone us and say ‘right I’ve been faced with blah, blah, blah, what would happen if that happened and I’m telling and that’d be it. So we’ve always got the support fae them...”*

(Ed, page 7, line 6)

*...we have environmental health coming in here...anybody that’s never had a studio to deal with, they send them down here to us so they can have a walk round, we talk them through everything, ask loads of questions about the way we do things...”*

(Ben, page 5, line 21)

*“...we’ve got a very, very excellent relationship with the local environmental health department, in fact, so much so that they bring people here who are training as environmental health officers, they bring them in here and they let them practice on us a wee bit...we tell them what they need to know as students”*

(Frances, page 7, line 20)

In turn, this influenced the relationships between practitioner and enforcer, altering the level of contact and potentially the nature of compliance. More generally, the overall level of contact influenced practitioner perception of the need to maintain standards of compliance. Sustained rule compliance was therefore a concern:

*“We’ve been kind of put down as the standard for best practice in this area. So we’ve had about (number) environmental health officers through here in the past three years”*

(Ben, page 5, line 24)

*“We’ve had a license visit and I don’t think we’ve had another visit since, so we could be doing anything here...”*

(Ben, page 23, line 5)

*“Our experience has been that there is no enforcement...It really seems to simply be a case o’ ‘gees yer money, see ye in a couple of years’....”*

(Dan, page 17, line 20)

While forging working relationships is considered key to effective regulation, these findings have identified the potential influence of the enforcer on the effectiveness of this regulation, due to the loss of credibility and risk of impartiality (Walshe, 2002).

In contrast, the willingness of both enforcers and practitioners to engage in such relationships highlight an element of trust, concurring with the work of Pautz (2009a; 2009b). These very much reflect the motivations and inclinations to comply with regulation identified in Chapter 3 – ‘Conceptual framework’. These findings also raised concern over the ability of this regulation to fulfil the requirements of ‘good regulation’ (BRTF, 2000), particularly in terms of transparency, accountability, and consistency. The findings have shown regulation may not in fact be as ‘black and white’ in nature as professed in the literature (Baldwin & Cave, 1999), with discrepancy and contradiction having threatened understanding of regulatory requirements. In turn, this has potentially influenced the extent of both rule and substantive compliance.

#### *5.3.4 Analysis of enforcer interview data*

Three global themes emerged from analysis of the qualitative enforcer interview data (See Figure 5.2):

- Greater control through regulation to promote compliance
- The industry presented no imminent risk to health
- Sustaining/ enhancing compliance remains a challenge

##### Greater control through regulation to promote compliance

The global theme of regulation as a mechanism that offered greater control was derived from the organising themes of expectation, experience and relationships (See Figure 5.7).



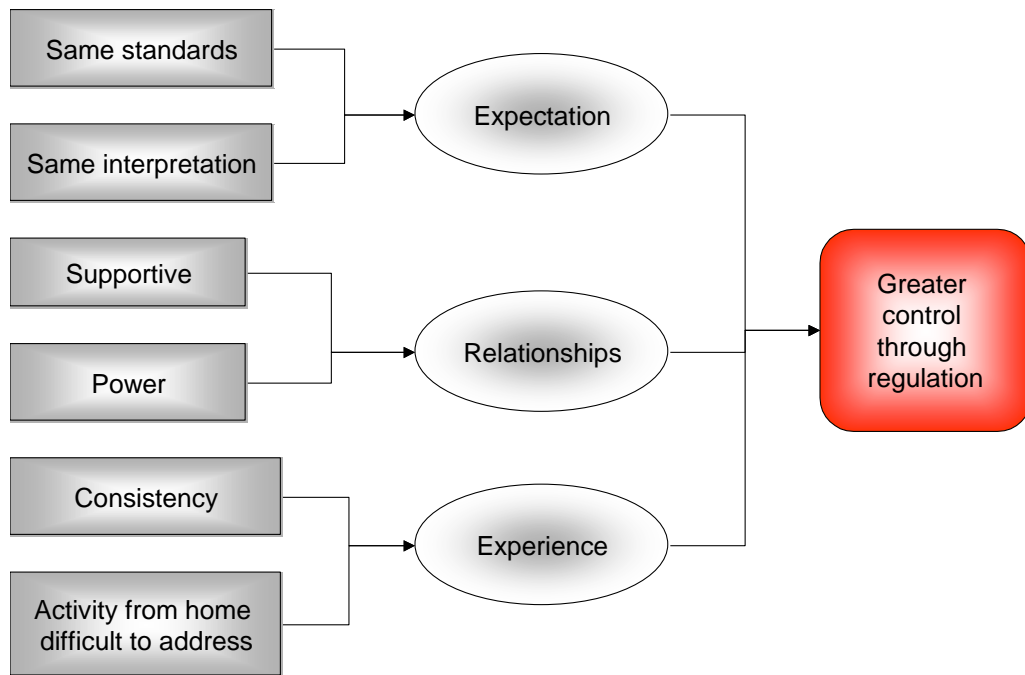


Figure 5.7: Thematic network – ‘Greater control through regulation’

From this data, the enforcers expected regulation to offer greater control through use of the same standards and same interpretation of the regulatory requirements:

*“..exercising proper controls in a consistent uniform way... licensing is one of the most attractive options in order to do that ...if you brought in a voluntary code of practice for example, we’ve found over the years that it just doesn’t work. You need that legislative lever.”*  
 (Ian, page 4, line 10)

*“I think regulation has been good about making it black and white in terms of your structure...I think the legislation makes it black and white. You must have this, you must have this.”*  
 (Carol, page 10, line 6)

*“I just say...its in black and white in the legislation...says it there...floor to wall partition...it must be...no room for compromise”*  
 (Graeme, page 26, line 28)

While in some cases the benefit appeared to favour the enforcer, others suggested the benefit was to the practitioner:

*“I used to have businesses say to me ‘what are the piercing regulations? What are the tattooing regulations?’. They almost expected that there would be regulation....they would say ‘what exactly do you want me to do?’ They wanted specific direction and I think they thought regulation would give them that. And a more level playing field among the businesses....They have this perception of regulation offering a level playing field, and amongst health and safety practitioners, we also have this perception that regulation confers better control. Licensing in particular confers better control.”* (David, page 2, line 16)

*“...it was much more cut and dried...black and white. When you’re reading from the guidance notes and things they accept it much more...We wouldn’t have achieved the same level of detail that we were able to achieve as a result of the licensing conditions”* (Ian, page 7, line 29)

From the interviews, enforcers reported consistent experiences of regulatory implementation. Indeed, enforcers collectively held a strong view that regulation had been applied consistently across the country:

*“Nationally...generally, my impression across the country is we probably do things fairly similarly”* (Fiona, page 11, line 27)

*“I haven’t seen any evidence to the contrary. Nobody has said in (council area) that they don’t do that in (council area) or (council area) – I haven’t heard any problems like that...”* (Ian, page 25, line 15)

*“...with the guidance produced, everyone is working to that. There might be some interpretational lee-way but in essence it should be minor...and everyone is working with the same format so that makes it more consistent across the board”* (Ellen, page 19, line 24)

There was also a distinct feeling that neither the practitioners nor enforcers would have applied the level of control within the legislation without licensing:

*“we wouldn’t have done it if it wasn’t mandatory”* (Andy, page 11, line 10)

*“I don’t think they would have done it on their own”* (Carol, page 12, line 6)

Relationships were found to have played a significant part in the securing and enhancing of control. Firstly, a supportive approach to the relationship appeared to operate:

*“I’m a bit soft...you don’t want to be in a position where they think no that’s it closed down, you’re finished’. So we’ve tried to work with them....to see a gradual improvement...get them on your side...explain to them why you want things done, don’t give them hundreds of things to do at once, try and bring them up to a minimum...then get to start with and then we can work with them after that”* (Graeme, page 9, line 31)

*“I think the fact we were able to put in the effort to work with them to ensure they were compliant before the licensing came in...so they didn’t need to do anything...they were made aware quite quickly...”* (Andy, page 13, line 10)

*“I always push that they come to me for advice...that’s just part of education”* (David, page 13, line 15)

The relationships also involved an element of power:

*“.....we would have struggled to get him to attend (training) otherwise...it happened to be on the day that the licenses were being issued...if they didn’t turn up...it would have been harder if the license wasn’t dependent upon them going to the training day”* (Andy, page 12, line 11)

*“ when I first went they kept asking what happens if we don’t get a license. When I tried to explain – well you will be reported to the procurator fiscal –end up in court”* (Carol, page 10, line 23)

*“I remember having an argument because they wanted to (activity).....and I thought ‘after all I have spoken to you about...”* (Carol, page 8, line 19)

Often, both approaches were encompassed within the working relationship:

*“I don’t go in as the font of all knowledge. I probably know more than they think I might know...I ask things like ‘what do you cut your black ink with to make a grey wash?’ and they think ‘I think he might know something about this’....I caw-cannied...and say something that made him realise that I did know a wee bit without being pretentious or condescending about it...but I let them know if they are not doing something right...”* (David, page 7, line16)

*“I think there was a desire to comply with legislation definitely and I think our...the way we went about enforcing it was done, was done in a, you know, an educational advisory way. It wasn't too heavy handed but it was made clear that if you don't do that work then you wont get your license. As far as were concerned, we will object to the licensing committee and they will accept that”*  
 (Ian, page 19, line 2)

These findings reflect the range of paradigms from which enforcers are known to work within to secure compliance, including the deterrence paradigm, the compliance paradigm and a combination of both (Walshe, 2002; Fairman & Yapp, 2004). From these findings, the clear account of regulatory requirements was capable of promoting rule compliance. With this the absolute focus, no evidence was found of efforts to fulfil the collective goals that justified regulatory implementation. As such, it must be contested that achievement of substantive compliance was compromised at this juncture (Yeung, 2004).

The industry presented no imminent risk to health

The global theme that the industry presented no imminent risk to health was derived from the organising themes of awareness, experience and competence (See Figure 5.8).

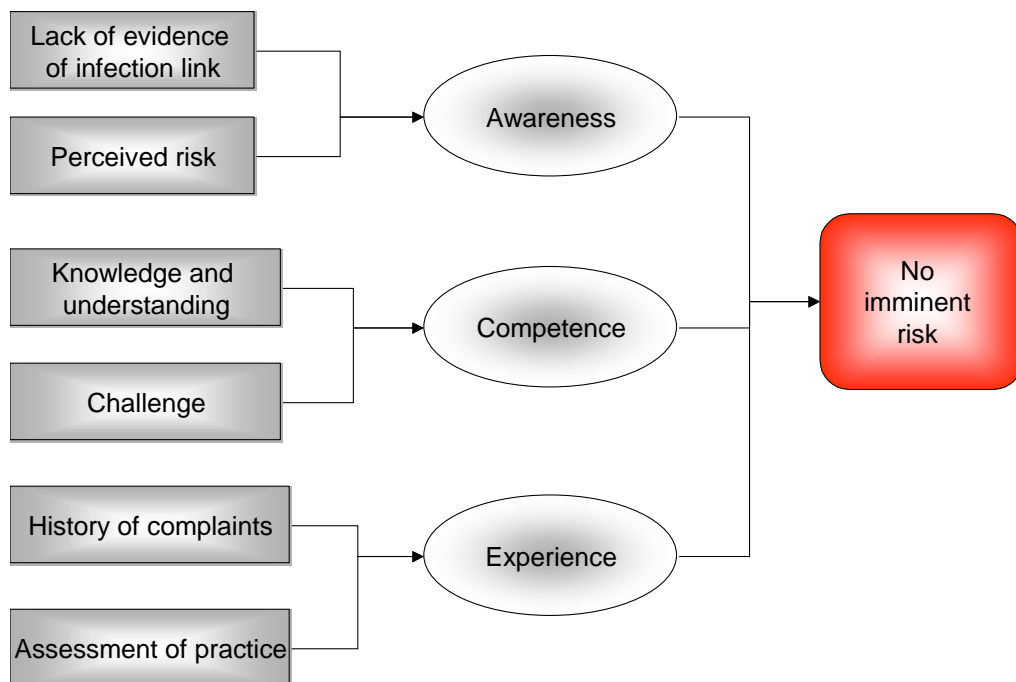


Figure 5.8: Thematic network for ‘No imminent risk’

Enforcers were aware of the inherent risk from tattooing and cosmetic body piercing activities, but had not been exposed to evidence of actual risk:

*“...if you’re cutting someone’s skin, you’re open to infection”*  
(Harry, page 3, line 33)

*“Yeh, there is a risk to the members of the public...the potential risk is hard to fathom...we don’t get information so the risk is maybe not as high as.... But again, it was creating an open wound, so it would be considered a risk”*  
(Ellen, page 5, line 27)

*“...without there being any real documented evidence, its hard to say..whether the risk was real is hard to say...”*  
(David, page 3, line 7)

The interviews with the enforcers established that, in their experiences of dealing with complaints prior to regulation and assessing practices as part of health and safety legislation, there was no imminent risk to health as a result of practitioners’ practices:

*“...personal opinion...waste of time and money, especially when it comes to....I mean, we didn’t really have a problem with people walking out of claires accessories and dropping dead because of infection problems...”*  
(Fiona, page 3, line 12)

*“I would say I’ve been round a few of them myself and I’ve been pleasantly impressed by the standards I’ve seen..”*  
(Ian, page 25, line 1)

*“Put it this way, since licensing, I don’t think that a huge lot has changed...I don’t think we had any great concerns...they themselves are very often tattooed and pierced so they are very aware from their own point of view that they’re not wanting AIDS or hepatitis from somebody else”*  
(Fiona, page 2, line 31)

*“Most of them are not too bad actually...they might have needed a bit of tweaking here and there.”*  
(David, page 7, line 13)

In addition, enforcers were confident in the competence of practitioners, having assessed practitioners’ knowledge and understanding. This reduced enforcers’ concern of risk to health as a result of practices:

*“...everyone doing ear piercing has been trained by the manufacturer of the guns...they seemed to know what they were doing”*  
(Andy, page 8, line 16)

*“I think we are fortunate that we are able to get out there and assess the competency by knowing these people....we have been able to spend time talking about the new regulation. Its not as if you’ve got 5 staff and are only speaking to the manager and have no idea what everybody else is doing”*

(Andy, page 9, line 18)

*“They do follow procedures that need to be followed...”*

(Carol, page 9, line 22)

While these findings indicated confidence in infection control practices within the industry, the lack of evidence of actual risk to health prior to implementation questioned the essential purpose of this regulation. Substantiating the argument posited above, it questioned the basis upon which to promote and achieve substantive compliance, given the absence of concern over health risk. The findings also served as evidence of good practice, where enforcers reported minimal change to practice with/ since the implementation of regulation. While these findings were suggestive of rule compliance (Yeung, 2004) (Chapter 3, Table 3.1), they did not necessarily relate to the implementation of regulation. This recognises that while differences in practice may be detected following an intervention, it cannot always be concluded that the intervention caused to difference (Donaldson & Donaldson, 2003; Pallant, 2007).

#### Sustaining/ enhancing compliance remains a challenge

The global theme of sustaining/enhancing compliance remaining a challenge was derived from the organising themes of awareness, experience, relationships and competence (See Figure 5.9).

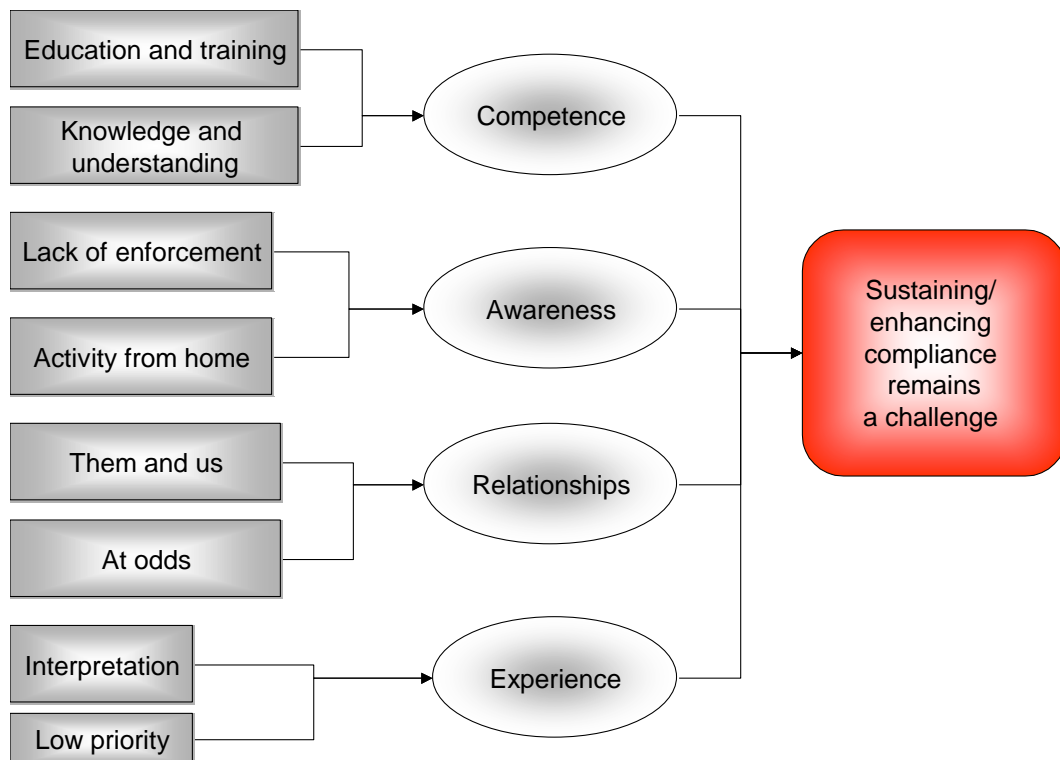


Figure 5.9: Thematic network for ‘Enforcer challenges to sustaining/enhancing compliance’

Awareness of lack of enforcement presented a challenge to the sustainability/ enhancement of current compliance:

*“We have no-one in our licensing section who is prepared to go and enforce that so there are issues with the licensing section as opposed to the EH section....it makes a laughing stock of the licensing system if the licensing rules are not getting enforced by anybody else...so what’s the point of the license in the first place”*  
 (Fiona, page 5, line 14)

*“The council is not actively enforcing. That was a problem with publicising and we haven’t ever been told what to do with the ones that are not licensed. The enforcement is a bit that has still not been dealt with properly”*  
 (David, page 6, line 20)

*“still some people don’t know about the legislation....”*  
 (Ellen, page 20, line 1)

Equally, was an awareness of how unlicensed activity had the potential to impact on the overall success of licensing to improve practice, and how this had affected regulatory compliance:

*“Every now and again you hear on the grapevine somebody’s doing some ear piercing somewhere...you never take that much....unless you get a proper allegation there is not much you can do”*  
(Andy, page 4, line 9)

*“There are a couple of people whom I strongly suspect are tattooing from home but its quite difficult to get to ”*  
(Carol, page 4, line 3)

*“There is a definite danger from the people we don’t know about – there is no getting away from that, but we are never going to be able to properly regulate that because unless you know where they are, you cant regulate them”*  
(Fiona, page 12, line 23)

*“...our great concern was the people we didn’t know about who were doing it in houses and that’s still exactly the same issue to be honest”*  
(Fiona, page 3, line 4)

From enforcer experiences, despite reporting consistent application of the regulation, the issue of interpretation raised concern over the sustainability and enhancement of compliance:

*“...I wasn’t aware of any particular qualifications that they could have got.... think that is a critical element that should have been included in the Order. It doesn’t put the detail in...in what they are actually looking for...so I’m unclear as to what we should be looking for when we ask for instruction or training before they start”*  
(Bob, page 8, line 7)

*“I think the idea was right but the actual follow through in terms of the licensing procedure has been somewhat cumbersome and messy because there’s so many conditions to be fulfilled and there’s 3 sets...there’s the legislation itself...there’s the conditions, and there’s the enforcement guidance and they all get mixed up...I’m sure there are still enforcement consistency issues.”*  
(Ian, page 5, line 3)



*“...I would have thought we were doing things consistently but then you notice in the forum afterwards...I mean we adopted the national conditions thinking everybody will but I don't know if that's the case...But from a tattooists I'm told 'they don't do that and so-and-so don't do that' or 'were getting made to do this and they don't have to do that'...so I get the feeling that maybe it's not – I don't know”* (Carol, page 13, line 10)

In addition, enforcers experienced implementation and enforcement as low priority. This had the potential to impact on compliance as time passed following introduction of regulation in 2006 (Baldwin, Hutter and Rothstein, no date):

*“It does appear to have fallen a little bit flat I must say. I don't think we're proactive enough about chasing up licenses that have expired...”* (Ian, page 22, line 27)

*“I think in terms of health and safety, because after the initial licensing, providing there are no major problems, these aren't going to be heavily regulated”* (Bob, page 10, line 19)

*“...to be fair to them, as a council we haven't really pushed a lot of publicity about the requirements. So they probably could get away with saying they didn't know they have to be licensed and what standards are expected...”* (Carol, page 4, line 2)

Analysis of the interview data (above) highlighted how efforts to enhance control involved two types of relationships – supportive and power-based, and at times used these in combination. This reflected current approaches to enforcement (Walshe, 2002). The issue of relationships were also presented as a potential factor in sustaining and enhancing compliance. At times the enforcers and practitioners appeared to be at odds with each other:

*“They still have a really 'them and us' attitude. You know, they say 'you don't know how to do a tattoo so why are you in here telling us what to do'. I explained I don't know how to change a tyre but I can inspect KwikFit. That's the way it is. We're regulators...”* (Carol, page 9, line 4)

*“there was an element of 'why is this happening to us anyway?' because if they were already probably doing the best they could because they are professional....I think, again a lot of legislation is brought in to regulate the rogue element and it penalises to a degree the ones who have always done it OK”* (Andy, page 6, line 12)

*“I think from the point of view of people...practitioners...don't like people coming in and telling them what to do and how things could be done...Taking regulation out of the picture, I don't know...because I think you need the carrot and the stick”*  
(Carol, page 3, line 12)

*“I'd like to think I had a good relationship with them I don't know what they say behind my back but they are nice to my face”*  
(Carol, page 9, line 9)

Interviews with enforcers also highlighted the tenuous relationships that exist within the industry and between practitioners, which raised concerns over the industry's ability to work together to enhance and sustain compliance over time:

*“They complain about one another...at one stage they did talk about forming a piercing and tattooing association in (place name)...but no there were too many people who didn't get on with each other for that to happen I think...”*  
(Ian, page 15, line 25)

*“You know yourself when you go to any even...the people who are there are already engaged with positive practice. Its not that group you are trying to target...and that's the same in all walks of life...the people who are interested are going to be there.”*  
(Bob, page 12, line 5)

*“I think you will have exceptionally good practice and I think you will have exceptionally bad practice. How much you have in between, I'm not really sure”*  
(Bob, page 6, line 1)

Finally, competence emerged as a factor that could challenge the sustainability and enhancement of regulatory compliance:

*“Even in subsequent visits trying to get the message home to them about the difference between a disinfectant and a detergent was quite a hard message...trying to get them to think more clinically about what they were doing...its really difficult....”*  
(Carol, page 8, line 9)

From the interviews with enforcers, the competence of themselves as enforcers was a particular issue:

*“...the lack of training was an issue for us...and we did have to go and search for help”*  
(Andy, page 12, line 5)

*“We were quite lucky, we could pick up the phone and say ‘ we don’t understand what happens with...tattooing...can you explain it to us?’ ...”*  
(Andy, page 14, line 5)

*“I think my infection control knowledge is a basic level...I don’t say my infection control knowledge is great. If I’m being honest, I think these regulations ... made myself and other EHOs get back into the roots of what our profession are because I think maybe that was a wee bit drifting away”*  
(Carol, page 14, line 12)

These findings have identified a significant number of factors, which may have impacted on compliance and its sustainability across this industry, these very much reflecting the motivations and inclinations to comply with regulation previously identified (Chapter 3, 3.4.2). In particular, recognition that not all practitioners know of the regulation, the inability to effectively tackle illegal activity and the low priority status given to enforcement must all be considered as negatively impacting on the inability of this regulation to achieve rule compliance.

#### 5.3.5 *Analysis of observational field notes*

Three global themes emerged from analysis of the qualitative observational field notes (See Figure 5.3):

- Processes designed to promote good practice
- Scope to enhance compliance
- Challenges to sustaining/ enhancing compliance

##### Processes designed to promote good practice

The global theme that design of processes promoted good practice was derived from the organising themes of risk, expectation, relationships and competence (See Figure 5.10).

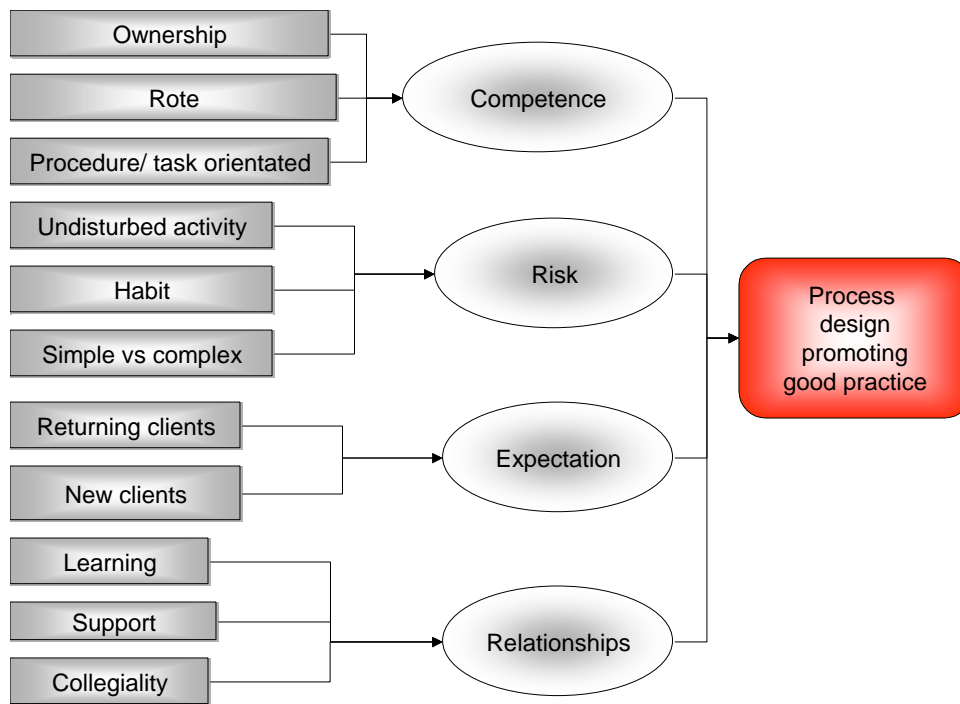


Figure 5.10: Thematic network - 'Process design promoting good practice'

In terms of risk (to health), it became apparent that much of the practice within studios, irrespective of size or numbers of staff, was habitual. Equally, the simplicity of the work activity was considered to impact positively on risk, as did the generally undisturbed nature of activity:

*"It strikes me, just one day into the scheduled observational work just how different this is to healthcare activity. Already the simplicity – not in terms of the art of tattooing, or indeed the procedure to ensure asepsis....but rather the single task activity that the practitioners work involves. There really is no multi-tasking, and that must surely impact on the level of risk generated?"*

(Extract from observational fieldnotes, 5<sup>th</sup> September 2009)

*"The tattooists work very methodically and systematically...their process for setting up is almost ritualistic. Each artist I have seen to date has a slight variation, but as I watch each one over a period of a day, I can begin to pre-empt their next move in terms of procedure....the order they place on their setting up procedure for example, is absolutely habitual – this could be a factor capable of minimising risk, promoting good practice, or just the opposite. From what I have seen across six practitioners now, it appears to be serving to promote good practice..."*

(Extract from observational fieldnotes, 11<sup>th</sup> December 2009)

*“The telephone rings, and Gavin doesn’t stop...this is interesting in terms of business preservation in a single-practitioner studio....but then the answer machine comes on and a message is left....so potentially no business lost and practice goes on undisturbed. How healthcare could potentially benefit from such ordered activity – I suppose I can think of efforts to work like this...the ‘do not disturb me’ aprons worn during medicine rounds.....but not sure they are implemented so rigorously”*

(Extract from observational fieldnotes, 7<sup>th</sup> May 2010)

Also promoting good practice was the expectation of both new and returning clients. Dialogue between the artist and the client served to expose these expectations, from the desires of the new client through to the past experience of the returning client:

*“...it felt quite odd to sit on the boundary of a conversation and just to listen in... like prying almost, but so enlightening in terms of understanding what someone being tattooed expected from their experience. That new client, let Jackie know very clearly that she had not experienced this before and that she was scared – but it didn’t stop her letting Jackie know that the place she proposed to put the tattoo was not exactly to her liking – and so Jackie removed the transfer and tried again – no messing, no debate, just acceptance of the client need”*

(Extract from observational fieldnotes, 10<sup>th</sup> December 2009)

*“...he didn’t want the piercing there...up a bit...and over. So Ben re-did the spotting and the client was happy to proceed. Two ear piercings later, the client sat up and inspected these in the mirror – and nodded with approval...”*

(Extract from observational fieldnotes, 9<sup>th</sup> December 2009)

*“...clearly a returning client...already heavily tattooed, he shared the story of how he had gotten on since his last visit. No problems he remarks...but quickly adds that Lee had said he would touch up a few bits, and he pointed these out...Lee nodded in agreement and the conversation continued with the sharing of how this might be done....a lot of time spent before moving on...quite impressive to be able to spend so much time making sure everything was OK!”*

(Extract from observational fieldnotes, 5<sup>th</sup> November 2009)

*“...the stencil was all ready....but his girlfriend didn't like skulls. Your choice Izzy told him....he went off on the telephone and Izzy waited – patiently? It seemed like she was patient. It seemed like a while but actually it was only a few minutes had passed and he came back – could he see it on....so the stencil was placed...he liked it, but his girlfriend hated skulls he said repeatedly...‘why not get the roses done first...think about it...and if you want later we can add them in...or something different?’ Izzy paused. That was the solution...after 25 minutes...As the tattooing commenced, the conversation over ‘needing to be sure as this was permanent’ continued. Impressive.”*

(Extract from observational fieldnotes, 4<sup>th</sup> September 2009)

Relationships formed part of the process design that promoted good practice, with a sense of teamwork visible both within and across staff working together, and also during practitioner-client engagement:

*“In this studio there is clearly a sense of collegiality...they look at each others designs, and talk amongst themselves about their plans. I will be interested to see the difference in a studio where the staff work together but are self-employed as opposed to employees. The opportunity for sharing of good practice and learning from each other definitely feels as if it positively promotes practice.”*

(Extract from observational fieldnotes, 14<sup>th</sup> December 2009)

*“Mark tells the client how to take care of the tattoo, and provides an aftercare sheet...‘important to learn to care to promote healing’, he says..”*

(Extract from observational fieldnotes, 11<sup>th</sup> December 2009)

*“Lee looks up to see Karen (receptionist staff) leaning over the booth – they talk for a few minutes about the size of the impending tattoo – Lee is working on a stencil that is almost three feet – its going to cover a whole leg and buttock – so they get into conversation about how best to manage it around the groin...Lee invites Karen to assist in placing the stencil when the client comes in....and they have a laugh and a joke bet about whether the dragon's head will be in the wrong place....I hope I am around when the client arrives, just to see what they were referring to. Who knows – this is when it is disadvantageous to be a non-participant observer!”*

(Extract from observational fieldnotes, 9<sup>th</sup> November 2009)

*“The client asks when he should take off the cling film...‘after a few hours’ is the reply...along with the assurance that he would get some written instruction before he leaves...The client nods.”*

(Extract from observational fieldnotes, 5<sup>th</sup> May 2010)

Linked in part to the theme of risk, competence was a theme that contributed to the notion that process design promoted good practice:

*“Gavin owns the studio, so he takes great care in keeping it tidy – keeping it free from clutter – clearing his station at the end of each procedure and before the next client arrives...very orderly, very systematic, but with pride....”*

(Extract from observational fieldnotes, 11<sup>th</sup> December 2009)

*“In calling this simple...I need to reflect on the difficulty of the procedure. Maybe what I can see is what might be described in healthcare as task-orientation. The act of tattooing or piercing, from what I have seen to date, is very much task orientated. The visible ‘competence’ of the practitioners is possibly dependent upon the ability to focus solely on one task at a time – one tattoo, one piercing....Either way, the rote way that activity is taught, learned, practiced can help – or possibly hinder – good practice. I will see...”*

(Extract from observational fieldnotes, 14<sup>th</sup> December 2009)

*“Each practitioner stocks their own trolley. I saw Ade checking and filling the trolley, just the same way as Lee and Jackie and Mark did. It seems to be a normal part of activity – no-one seems to expect anyone else to clear up after them...its all part of the process, they all seem to just get on with it, no questions ...”*

(Extract from observational fieldnotes, 7<sup>th</sup> May 2010)

These findings demonstrated how the task-orientated nature of the work within this industry, coupled with local ownership – of premises, of work stations, of clients, for example all contributed to the opportunity to achieve technical compliance with standards, and so promoted rule compliance (Yeung, 2004).

### Scope to enhance compliance

Scope to enhance practice as a global theme was derived from the organising themes of opportunity, competence and relationships (See Figure 5.11).

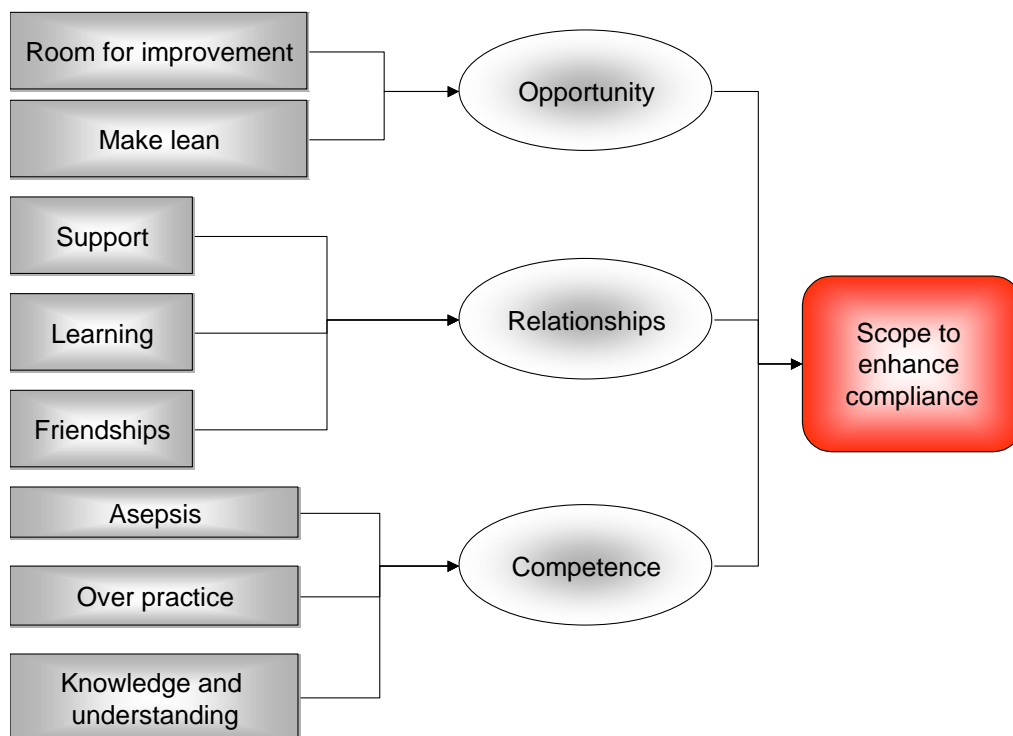


Figure 5.11: Thematic network - ‘Scope to enhance compliance’

From analysis of observational field notes, the opportunity to enhance practice through improvement or by making procedures lean/ leaner was noted:

*“In dismantling the tattooing machine, the needle was placed first in a cup, then carried across to the sharps bin (by Jackie) – this is a practice that could be made leaner – and safer - by placing directly into the sharps bin. I wonder if this is old habits dying hard...from the days when needles were re-used....but it presents a danger and an opportunity to improve practice...”*

(Extract from observational fieldnotes, 14<sup>th</sup> December 2009)

*“The lone nature of practice makes it difficult to make the re-stocking of ink...there is room for improvement here, especially given the multiple numbers of workers here...not so easy in single practice studios, but definitely room to make use of colleagues to support better practice..avoid taking off gloves, washing hands, re-filling ink....why not use a colleague to help?”*

(Extract from observational fieldnotes, 5<sup>th</sup> November 2009)



Competence was linked as an organising theme associated with enhancing practice:

*“Over-practice – changing gloves three times during the setting up for a piercing - calls into question knowledge and understanding of infection control, and the use of gloves as part of standard infection control practice...”*

(Extract from observational fieldnotes, 14<sup>th</sup> December 2009)

*“I am conscious that I am observing what has been audited as acceptable practice by enforcers – so I am not about to jump in and stop activity such as this – but I do wonder how and why the use of cling film has persisted here...it makes me wonder about everyone’s knowledge and understanding of asepsis, and whether this has been a marker for standards – the Order would appear to reflect its need. I think this shows there is scope for improvement....”*

(Extract from observational fieldnotes, 7<sup>th</sup> September 2009)

*“It wouldn’t take much to introduce a sterile field....It strikes me that the issue of asepsis and its understanding/ promotion is an issue for both practitioners and enforcers...has this come about because of understanding of asepsis (or lack of understanding)..or lack of understanding of the practice of tattooing/ piercing?”*

(Extract from observational fieldnotes, 3<sup>rd</sup> November 2009)

Relationships offered scope to improve practice, where learning, support and friendship all served as vehicles to facilitate improvement:

*“There is a distinct willingness to learn and share with each other. There is no hiding of skill or practice – its all very open, very visible”*

(Extract from observational fieldnotes, 12<sup>th</sup> December 2009)

*“There are books and journals in the reception area – this is evident in each studio so far – to me, this is a sign of keeping in touch with the wider industry practices. Yes, sometimes the books are used for ideas etc, but access to up-to-date equipment, supplies, etc are also sourced through these books/ journals....resources and opportunity to learn and enhance practice...”*

(Extract from observational fieldnotes, 8<sup>th</sup> May 2010)

At a local level, the collegiality and open communication offered scope to share ideas, learn and enhance practice, and to promote substantive and rule compliance.

### Challenges to sustaining/ enhancing compliance

The global theme of challenges to sustaining and enhancing compliance was derived from the organising themes of risk, expectation, relationships and opportunity (See Figure 5.12).

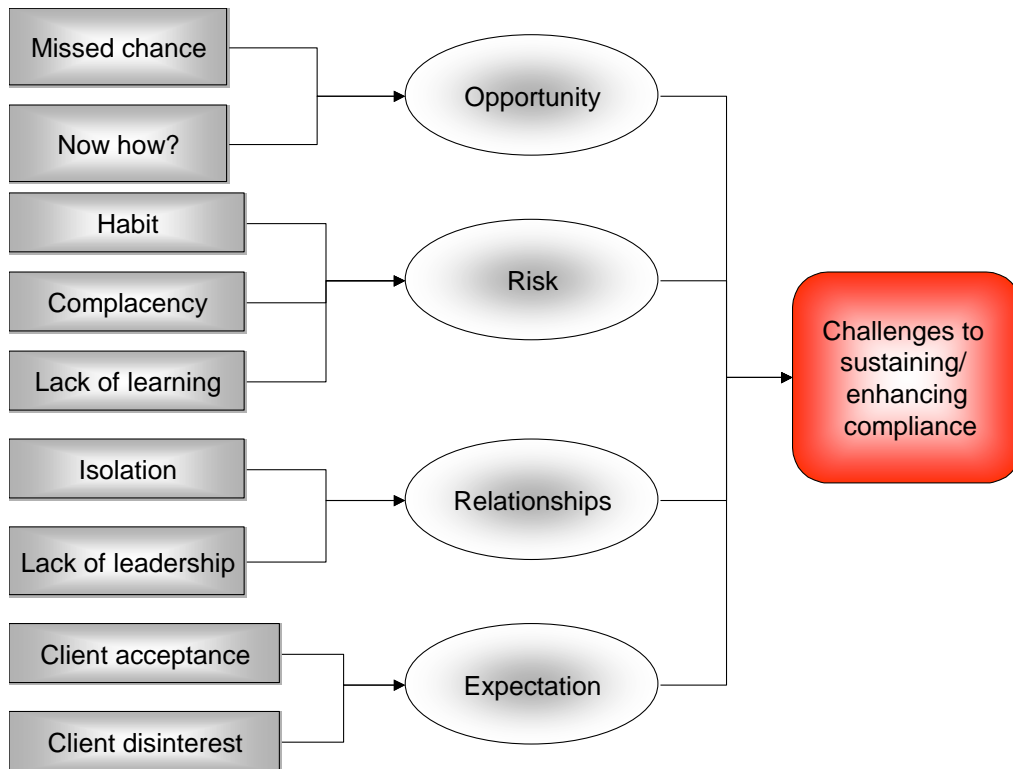


Figure 5.12: Thematic network 'Challenges to sustaining/ enhancing compliance'

Reflection on the overall experience of observation and review of field-notes generated from these sessions identified challenges to sustaining and enhancing practice:

*“Many of the factors/features of practice as well as being positive – I mean, they have been highlighted as promoting good practice – also have the potential to present as challenges to sustaining or enhancing good practice/compliance with regulatory requirements. This is a risk...”*

(Extract from observational fieldnotes, 11<sup>th</sup> May 2010)

There was a distinct risk that habitual practice, complacency and a lack of learning from opportunity could all challenge the sustainability of compliance:

*“There is a bit of drifting around...with cups of tea in hand...some eating going on...some juice lying around...where might this stop?”*

(Extract from observational fieldnotes, 6<sup>th</sup> November 2009)

*“H used 4 pairs of gloves during the decontamination of her station – somewhat excessive...over-practice, not risking infection, but certainly eating into profits.. It makes me question the habitual practice...or the lack of learning to emerge from the risk assessments undertaken by the EHO – by now watching the practice, it is clear that it does not truly reflect the risk assessment - who now watches this and tries to do something about it? Who helps by saying...‘could there be a better way to do this – could we look at this and see if we can cut down the glove use here? No-one....”*

(Extract from observational fieldnotes, 11<sup>th</sup> May 2010)

*“I can’t see any real set time for more general cleaning – maybe that’s because I’m not here long enough...but I didn’t see it elsewhere...when does the clutter get cleared? Where is the cleaning schedule? How can best use be made of the routine? There is a risk that this builds to a danger point...things become invisible, and the opportunity for risk increases. This flies in the face of the ownership and pride with individual stations....”*

(Extract from observational fieldnotes, 11<sup>th</sup> December 2009)

Expectation also presented a challenge to sustaining and enhancing compliance/ good practice, where client disinterest and client acceptance played a significant role:

*“That’s three clients I’ve watched today, who do not seem to be watching what is going on as the practitioners set up the equipment – too busy on their telephones telling pals they are getting a tattoo...or arranging their night out...or getting the shopping sorted out....making plans, but not watching to see if they are happy with the set up and the equipment about to be used. If the client isn’t interested, there is a danger that the practitioner becomes disinterested....”*

(Extract from observational fieldnotes, 7<sup>th</sup> December 2009)

*“Another studio, another town...but the same disinterest...is it because they are returning clients, confident in the process/procedure? Not sure, but even so...surely we should watch each time – just to keep staff on their toes? How will practitioners ever review what they do, if clients don’t challenge their practice?”*

(Extract from observational fieldnotes, 8<sup>th</sup> May 2010)

*“...they nod in approval, yes that’s fine is what they are indicating to the closed needle packaging...but they lack eye contact and look away sharply....’just get on – I don’t want to see’ they say.... This ‘just do it’ approach is very common...”*

(Extract from observational fieldnotes, 11<sup>th</sup> December 2009)

While relationships have been considered as a facilitator of good practice, there was also a danger that these challenged sustainability and enhancement of compliance:

*“..working in total isolation...no-one to keep a check on his standards other than himself. It is a vulnerable practice. I think back to days as a District Nursing Sister, and the times I had opportunity to cut corners...to provide sub-optimal care...and how professionalism, desire to do right by the patient kept me above such activity. Yet that sense of vulnerability was there. I don’t question the practitioners’ responsibility to offer good service, but the risk is there....when the only relationship you have beyond the client is with yourself...”*

(Extract from observational fieldnotes, 8<sup>th</sup> May 2010)

*“... relationships also present a danger – who is the leader? When does leadership become visible? How do you shift from friend to manager? Boss? Its not impossible – I know I have been both managed by a friend and managed a friend – but I know that with this comes a different degree of flexibility....of acceptance...are these close friendships a danger to sustainable compliance?”*

(Extract from observational fieldnotes, 12<sup>th</sup> December 2009)

Finally, opportunity - or more accurately ‘missed’ opportunity – was a theme that emerged from the field-note data, and which contributed to the global theme of challenges to sustainable/ enhanced compliance:

*“I struggle to reconcile the use of cling film as a base for setting up, but realise from the risk assessment procedures within the two studios I have been in so far, that this is clearly identified in the practices, and has subsequently been endorsed...This has been a missed opportunity to take the practice to an acceptable level of asepsis...”*

(Extract from observational fieldnotes, 7<sup>th</sup> November 2009)

*“Having spent over 200 hours with practitioners now, I am aware that cling film is a commonly used covering for a tattoo. This does not seem to be a rare and unusual aspect of practice. Why did the EHO not stop this practice at the point of audit?”*

(Extract from observational fieldnotes, 8<sup>th</sup> May 2010)

These findings identified a significant number of factors, which could have impacted on compliance and its sustainability across this industry. These however are less related to the motivations and inclinations to comply with regulation identified in Chapter 3 (3.4.2). Rather, they were more associated with knowledge and understanding. Yapp and Fairman (2005; 2006) proposed that regulatory compliance requires knowledge and understanding, willingness and ability. Moreover, Fishbein et al. (2001) highlighted skills as a variable necessary for behaviour. Although the Order clearly sets out the requirements of the licensing authority to have regard for knowledge, skill, training and experience in determining whether an applicant is fit to hold a license (SEHD, 2006), the shift from artist-customer (Armstrong & Kelly, 2001) to enforcer-practitioner regulated business has not served to fully enhance knowledge and skills – for example, in the management of asepsis (McLane, Chenelly, Sylwestrak & Kirchhoff, 1983) or in wound care (Hudspith & Rayatt, 2004; Benson & Dickson, 2006). This must be viewed as having negatively impacted upon the extent of rule compliance achieved through regulation.

## **5.4 Quantitative data analysis**

### *5.4.1 Preparing the quantitative data*

Questionnaire responses were entered into the data file set up in SPSS 15.0 for Windows. Thereafter the data were screened for errors made during data entry, checking for variables out with the possible value range and returning to the original raw questionnaire data to support correction (Pallant, 2007). Variables were checked for valid coding and missing cases, of which there were none.

### *5.4.2 Exploring the quantitative data – descriptive analysis*

Exploration of the responses from the questionnaires commenced the descriptive phase of data analysis (Pallant, 2007). It began by appraising the survey response rate and describing demographic characteristics. Thereafter, knowledge/ awareness, attitudes and self-reported behaviours of survey respondents in relation to the implementation of the Order were considered.

### Demographic characteristics from survey responses

Figure 4.4 (Chapter 4, 4.9.2) identified the target population of 298 (220 practitioners and 78 enforcers). In carrying out census survey, 107 questionnaires were returned, all of which were complete. This gave a response rate of 36%. The response rates across the two sub-groups of the study's target population (practitioners and enforcers) were noted (See Table 5.1).

Profession	Number in target population	Number of responses	Percentage response
Practitioner	220	62	28%
Enforcer	78	45	58%
Total	298	107	36%

Table 5.1: Survey response rate, by profession

Despite issuing questionnaires by postal administrations twice to practitioners in an effort to improve responses, the overall response rate for this sub-group of the target population remained low. While disappointing, it did reflect the response rate of similar studies adopting a postal administration approach to data collection (See Chapter 2 – 'Literature Review'). Specifically, it well exceeded the response rate of 27% (n=111) achieved by the consultation survey on regulation of skin piercing (Walters, 2001), in which only 7% (n=32) represented the skin piercing industry. Given the credence placed on the findings from consultation and significant outcome to emerge from it, the response rate for this study must be considered more than acceptable and its findings considered equally if not more credible.

Many issues are suggested as contributing to the response rate of questionnaires/surveys. These include the quality of the covering letter; the length and style of questions within the questionnaire; the questionnaire layout; the administration and the follow up process (O'Leary, 2004).

In this study, assisted administration by the EHOs may have contributed to the higher response rate in this sub-group of the target population (Newell & Burnard, 2006). Securing their co-operation was more straightforward because of the opportunity afforded to meet with Lead EHOs in each of the 32 Local Authority councils of Scotland.

While the covering letter issued with the questionnaire provided information on the benefits of this study, and a contact name and number to discuss the study, the absence of any collective tattooing and cosmetic body piercing industry forum limited the opportunity to further discuss this study's worth in terms of their time and effort (O'Leary, 2004; Ruane, 2005). Taking account of the industry's historical reputation of disengagement with authority, and its hidden population status, the practitioner response rate must be considered acceptable (Heckathorn, 1997). EHOs did offer to act as administrator of the questionnaire to the industry practitioners. Given the study topic and existing practitioner-enforcer working relationship, the risk of introducing social desirability bias (Ruane, 2005) was considered too great, and so this offer was turned down in favour of maintaining a neutral researcher stance.

Extract from reflexive journal, 18 September 2010

*Having reflected on the events of this week's supervision session, and the discussion on response rate, it is perhaps too simplistic to suggest that the better the response rate, the more representative the findings will be of the target population (and vice versa). This is commonly cited in research books....but I will clearly need to consider response rate in a wider context, looking to the representativeness of responses in terms of the demographic nature of the target population. I can make use of the demographic data collected within the questionnaires for this purpose.*

Ruane (2005) also identifies that while it is not uncommon for a questionnaire to generate a low response rate (considered to be a return of less than 30%), the impact must be acknowledged as a measure of response bias. As such, it is recognised that those who responded may have differed from the majority who did not, and that self-selection bias may have undermined the generalisability of this study's findings. It is however anticipated that this limitation has been mitigated by the study's mixed methods approach to data collection and analysis.

It is also important to recognise that the representativeness of the responses can be considered in other ways beyond response rate: For example, in this study, the practitioner respondents represented both tattooing and cosmetic body piercing, while urban and rural areas of Scotland are well represented across both enforcer and practitioner responses (See Table 5.2). In taking this wider view, any potential bias from low response rate has also been limited.

Profession	Local Authority type		Total (n/ %)
	Urban (n/%)	Rural (n/%)	
Enforcer	12 (26.7%)	33 (73.3%)	45 (100%)
Practitioner (tattooing)	15 (48.4%)	16 (51.6%)	31 (100%)
Practitioner (piercing)	12 (38.7%)	19 (61.3%)	31 (100%)
Total (n/ %)	39 (36.4%)	68 (63.6%)	107 (100%)

Table 5.2: Survey responses, by profession and area

The number of respondents in these two sub-groups (enforcers and practitioners) was reviewed for sufficiency, given the inappropriateness of running some statistical tests where group sizes are small. To overcome the problem of small numbers in some age categories (See Table 5.3), age categories were combined to manage the extremes (See Table 5.4). This facilitated use of these data during subsequent inferential analysis (Pallant, 2007).

Age (years)	Frequency (n)	Percentage (%)
18-30 years	6	5.6%
31-40 years	42	39.3%
41-50 years	41	38.3%
51-60 years	17	15.9%
61+ years	1	0.9%
Total	107	100%

Table 5.3: Respondents, by 5 age variables



Profession	Age (years) (n/%)		Total (n/%)
	18-40 years	41+years	
Enforcer	19 (42.2%)	26 (57.8%)	45 (100%)
Practitioner	29 (46.8%)	33 (53.2%)	62 (100%)
Total	48 (44.9%)	59 (55.1%)	107 (100%)

Table 5.4: Respondents, by profession and 2 age variables

In terms of experience, just under half of the enforcers had more than 5 years experience (n=22, 49%), while most practitioners had more than 5 years experience (n=54, 87%) (See Table 5.5).

Profession	Years of experience			Total (n/%)
	< 5 years	5-10 years	> 10 years	
Enforcer	23 (51.1%)	12 (26.7%)	10 (22.2%)	45 (100%)
Practitioner	8 (12.9%)	19 (30.6%)	35 (56.5%)	62 (100%)
Total	31 (29%)	31 (29%)	45 (42%)	107 (100%)

Table 5.5: Respondents, by profession and years of experience

#### Respondents' knowledge/awareness of industry practice

From a 7-point Likert scale, respondents identified lack of national knowledge/ awareness of infection control practice within the tattooing and cosmetic body piercing industry both pre- and post- regulation, with 41% (n=44) and 43% (n=46) respectively reporting simply to 'not know' (See Figure 5.13).

By profession, the findings indicated both practitioners and enforcers equally unaware of national level practices. For industry practitioners, the underpinning rationale for such findings could be the historical association with marginalisation and closed secrecy (Denton, 2001). Alternatively, it might be purported that the findings expose the limited ability of existing industry forums/networks and professional journals to promote effective communication of industry practices to the industry they claim to serve. Either way, these data alone offered insufficient evidence to substantiate such suggestions.

Furthermore, these findings suggest the recognised networks of communication at local, national and international levels, used by enforcers to share information have also been ineffective in the sharing of knowledge on tattooing and cosmetic body piercing activities. Again, it does not explain why this would be the case.

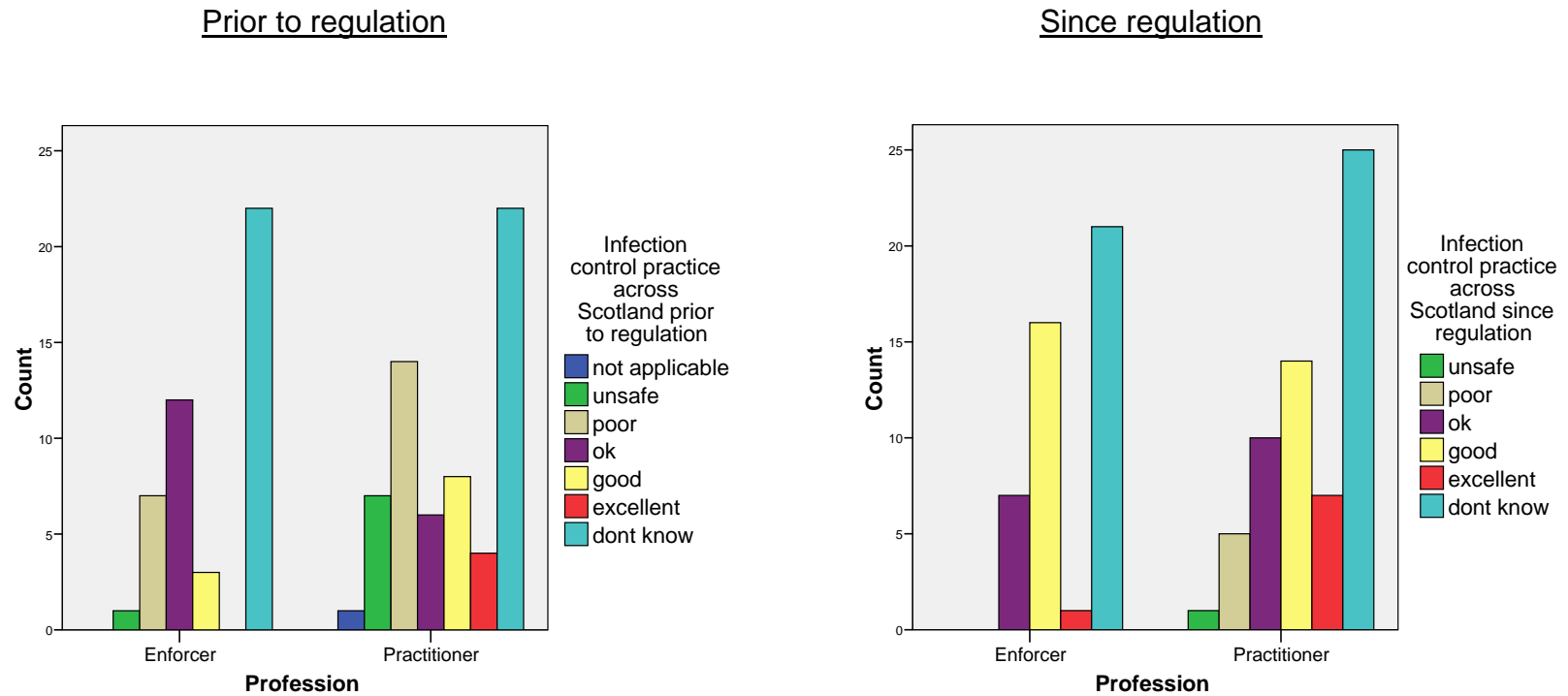


Figure 5.13: Awareness of infection control practices within the tattooing and cosmetic body piercing industry across Scotland, prior to and since the implementation of regulation, by profession

Despite this evidence of lack of knowledge/ awareness of industry practices post-regulatory implementation, a number of respondents reported a positive shift in knowledge/ awareness of infection control practices nationally (See Figure 5.13). Where such newfound knowledge emerged from remained unexplained by the quantitative data alone. Reflecting on the reviewed literature in Chapter 2 (2.4.2) professionals and public are recognised as viewing regulation as a mechanism to positively affect behaviour. From this basis, the shift in knowledge/awareness in this study may simply have been assumed. In this study, the absence of any new information sources to emerge with the implementation of regulation makes this a possibility.

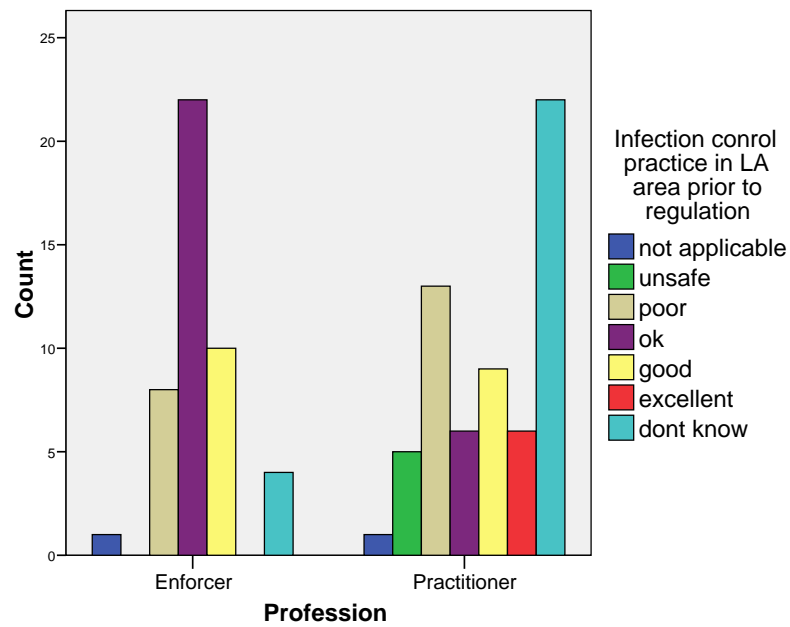
More practitioners (34%, n=21) than enforcers (18%, n=8) cited the existence of poor/ unsafe infection control practice nationally prior to regulation. Indeed, 10% (n=6) practitioners also reported its persistence post-regulation. This did not correlate with the finding on attitude to the need for improvements in industry practices, where 82% (n=88) of all respondents reported a need for improvement (82% (n=37) of enforcers and 82% (n=51) of practitioners). Likewise, while 80% of respondents (n=86) held the attitude that regulation was introduced to minimise risk to health, only 38% (n=33) of all respondents felt the introduction of regulation was because of poor practice (including only 23% (n=14) of practitioners). These findings highlighted the tenuous links made by enforcers and practitioners between 'risk to health', 'poor practice' and 'regulatory implementation'. Such incongruity may have had implications for the achievement of both rule and substantive compliance (Yeung, 2004).

A different picture emerged from analysis of data on self-reported knowledge/ awareness of infection control practice at local authority level (See Figure 5.14). While practitioners reported a lack of awareness within their local authority area, enforcers were much more confident at this level. This could be explained through the findings associated with monitoring of industry practices: Seventy three percent of respondents (n=78) acknowledged the existence of monitoring since the implementation of regulation. From the findings of other studies, such awareness has been found to positively impact on rule compliance (Goudey & Thompson, 1997a; 1997b; Raymond, Halcon & Pirie, 2003; Oberdorfer et al., 2003a).

Conversely, 16% (n=17) of respondents reported to their knowledge, no monitoring of infection control practice was taking place since regulatory implementation, while the remaining 12 (11%) respondents did not know. Reflecting on the previous research studies above, this may have posed a risk to successful regulatory implementation, including regulatory compliance, with negative implications for rule compliance (Yeung, 2004).

To generate the findings on respondents' knowledge of systems for monitoring practices numerically, the responses from open-ended questions on monitoring (See Appendix 9) were 'quantitised', making the data suitable for use in quantitative (descriptive and inferential) analysis (Teddlie & Tashakkori, 2003). The use of such terminology to describe transformation of qualitative data to numerical states, or vice versa (described as 'qualitising' of data), is unique to mixed methods research, having been used consistently by a number of researchers (Miles and Huberman, 1994; Tashakkori & Teddlie, 1998; Sandelowski, 2003). Quantitatively, these data identified EHO visits/programmed health and safety inspection as the key processes for monitoring both prior to and since the implementation of regulation. This explained enforcers' awareness of monitoring practices at Local Authority level.

Prior to regulation



Since regulation

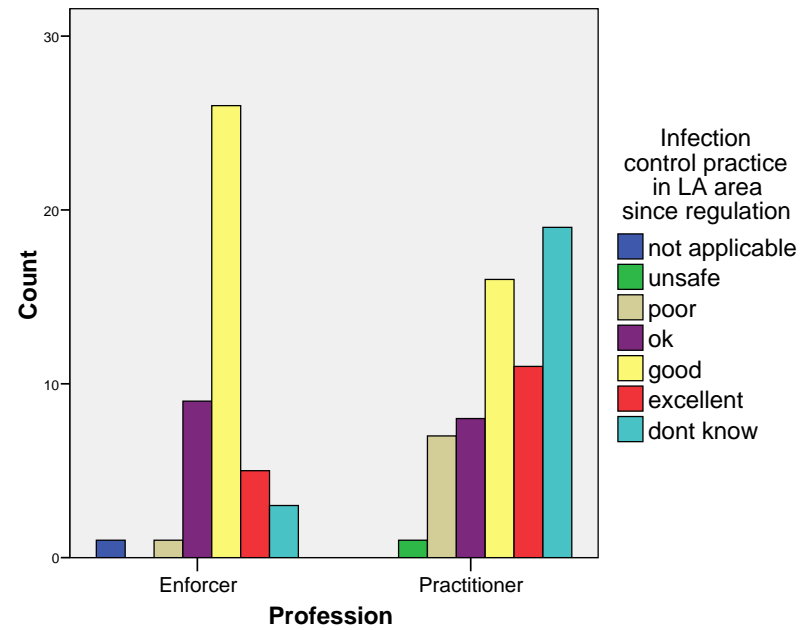


Figure 5.14: Awareness of infection control practices within the tattooing and cosmetic body piercing industry across Local Authority area, prior to and since the implementation of regulation, by profession

### Respondents' attitudes to regulation

To best understanding respondents' attitude to regulation, consideration was given to making the vast amount of data on the 15-item 'attitude to regulation' scale more manageable. Firstly, the reliability of the 15-item attitude scale was re-checked, using Cronbach's alpha co-efficient as a measure of internal consistency. This test had already been carried out during the piloting of the questionnaire to determine if all items on the scale were measuring the same underlying construct (Pallant, 2007). Although a high Cronbach alpha score was attained at that time, the inter-item correlation matrix contained some negative scores. Given the small sample size of 20 during piloting, consideration was given to the possibility that sampling error produced the negative correlation (Nichols, 1999), and so these items had been retained within the final version of the questionnaire.

In re-running the test using the study data, the presence of negative values on the inter-item correlation matrix re-affirmed the possibility that all items were not measuring the same construct. Individual items were therefore removed from the scale and the test re-run, until a combination of 12 items produced an all-positive inter-item correlation matrix (See Table 5.6). This new 12-item scale (See Appendix 15) had a Cronbach alpha score of 0.872, confirming the scale as having good internal consistency.

	Regulation was best way to achieve improvement	Regulation was required to minimise risk to health	Regulation has resulted in improvement	Regulation was the only way to improve practices	Aim of minimising risk has been achieved through regulation	Regulation has been applied consistently	Regulation makes clear the requirements	Time was given to comply	Support was given to aid compliance	Regulation has done little	Change is likely to be short term	Change will be difficult to sustain
Regulation was best way to achieve improvement	1.000	.699	.465	.480	.351	.239	.308	.212	.228	.403	.434	.126
Regulation was required to minimise risk to health	.699	1.000	.437	.440	.225	.067	.271	.309	.196	.335	.316	.029
Regulation has resulted in improvement	.465	.437	1.000	.725	.526	.424	.387	.251	.454	.586	.418	.228
Regulation was the only way to improve practices	.480	.440	.725	1.000	.565	.429	.426	.288	.399	.532	.357	.205
Aim of minimising risk has been achieved through regulation	.351	.225	.526	.565	1.000	.580	.391	.198	.287	.553	.368	.160
Regulation has been applied consistently	.239	.067	.424	.429	.580	1.000	.431	.313	.399	.456	.354	.319
Regulation makes clear the requirements	.308	.271	.387	.426	.391	.431	1.000	.482	.619	.303	.199	.212
Time was given to comply	.212	.309	.251	.288	.198	.313	.482	1.000	.559	.328	.190	.043
Support was given to aid compliance	.228	.196	.454	.399	.287	.399	.619	.559	1.000	.357	.206	.269
Regulation has done little	.403	.335	.586	.532	.553	.456	.303	.328	.357	1.000	.680	.400
Change is likely to be short term	.434	.316	.418	.357	.368	.354	.199	.190	.206	.680	1.000	.499
Change will be difficult to sustain	.126	.029	.228	.205	.160	.319	.212	.043	.269	.400	.499	1.000

Table 5.6: Inter-Item Correlation Matrix



To facilitate use of the attitudinal data across the variables of the new 12-item ‘attitude to regulation’ scale, categories were collapsed from 5 to 3 within the ordinal variables (combining disagree with strongly disagree to create a negative attitude to regulation category, and combining agree with strongly agree to create a positive attitude to regulation category). A total ‘attitude to regulation’ score was calculated for each respondent, and from this, a mean ‘attitude to regulation’ score, by profession, was then determined (See Table 5.7).

	Total number	Mean	Standard deviation
Enforcer	45	44	5.598
Practitioner	62	40	7.917
All	107	42	7.291

\* With possible scores ranging from 12-60, mean ‘attitude to regulation’ scores above 36 indicated an overall positive attitude to regulation

Table 5.7: Mean ‘attitude to regulation’ score, by profession

The analysis therefore demonstrated a positive attitude to regulation in both enforcers and practitioners. This general acceptance of regulation concurred with findings from previous studies (Walsh et. al., 2008; Wilson et. al., 2010), although it could not be assumed that this positive attitude to regulation equated with compliance with the regulation, given the findings of a study by IpsosMORI (2007).

Having established the reliability of the 12-item attitude scale, and determined the respondents to hold a generally positive attitude to regulation, factor analysis with principal component analysis method of variable extraction was employed to explore the possibility of reducing the variables in the scale. Although the sample size (n=107) was considered small for the purpose of factor analysis (Pallant, 2007), inspection of the correlation matrix showed few coefficients of less than 0.3. This indicated factor analysis was considered appropriate. This was further supported by the Kaiser-Meyer-Olkin measure of sampling adequacy (KMO) value of 0.818 (above the recommended 0.6). Moreover Bartlett’s test of sphericity was significant ( $p < 0.05$ ) further verifying the suitability of the dataset for factor analysis.

To determine how many factors to extract from the dataset, consideration was first given to factors with eigenvalue of 1 or more (Pallant, 2007). From review of the total variance (See Table 5.8), the first three factors had eigenvalues above 1, and accounted for a total of 66% of the variance. This suggested the retention of three factors.

Factors	Initial Eigenvalues		
	Total	% of variance	Cumulative %
1	5.102	42.516	42.516
2	1.441	12.006	54.523
3	1.390	11.579	66.102
4	0.996	8.303	74.405
5	0.666	5.552	79.957
6	0.599	4.996	84.952
7	0.414	3.449	88.401
8	0.359	2.991	91.392
9	0.313	2.608	94.000
10	0.271	2.255	96.255
11	0.237	1.972	98.227
12	0.213	1.773	100.000

Extraction method: Principal Component Analysis

Table 5.8: Total variance explained

Secondly, a scree plot was produced and reviewed. This indicated a break/ elbow between component 3 and 4, and showed the first three factors as contributing most to the explanation of variance. This again supported the retention of three factors (Catell, 1966) (See Figure 5.15).

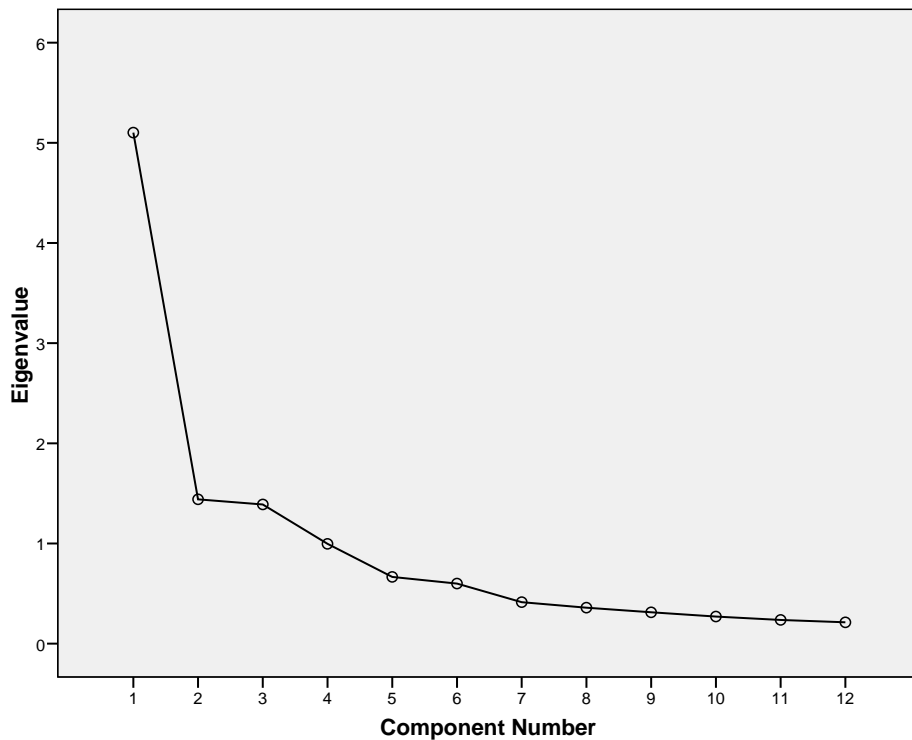


Figure 5.15: Scree plot

From the rotated component matrix (See Table 5.9), all items loaded on to the first three components. This further supported the appropriateness of a three-factor solution, where items with loadings greater than 0.55 were considered to load onto a particular factor. The dark shading on Table 5.9 indicates how the variables from the 12-item scale loaded onto each of the three new factors. These three new factors represented the underlying relationship among groups of variables from the 12-item attitude scale. As they reflected closely the elements of good regulation identified in Chapter 3 (BRTF, 200; Baldwin & Cave, 1999), they were re-named:

- Factor 1 = Attitude to efficiency of regulation
- Factor 2 = Attitude to clarity/ predictability of regulation
- Factor 3 = Attitude to responsiveness/ timeliness of regulation

	Component		
	1	2	3
Regulation was best way to achieve improvement	0.186	0.101	0.837
Regulation was required to minimise risk to health	-0.025	0.128	0.888
Regulation has resulted in improvement	0.462	0.350	0.551
Regulation was the only way to improve practices	0.406	0.382	0.564
Aim of minimising risk has been achieved through regulation	0.550	0.329	0.307
Regulation has been applied consistently	0.603	0.491	0.008
Regulation makes clear the requirements	0.170	0.789	0.174
Time was given to comply	-0.017	0.759	0.192
Support was given to aid compliance	0.208	0.822	0.082
Regulation has done little	0.725	0.211	0.382
Change is likely to be short term	0.751	-0.030	0.351
Change will be difficult to sustain	0.749	0.041	-0.121

Extraction Method: Principal Component Analysis.  
Rotation Method: Varimax with Kaiser Normalization.

Table 5.9: Rotated component matrix

To summarise the volume of data across these new factors, the mean and standard deviation were calculated from the individual component outputs for each of the three new factors (See Tables 5.10, 5.11 and 5.12).

	Total number	Mean	Standard deviation
Enforcer	45	17.89	2.269
Practitioner	62	14.98	3.615
All	107	16.21	3.425

\*With 5 variables within this factor (See Table 5.9), the possible attitude to efficiency score ranges between 5-25. Scores greater than 15 would be considered to indicate a positive attitude

Table 5.10: Mean 'attitude to efficiency of regulation' score, by profession

	Total number	Mean	Standard deviation
Enforcer	45	10.96	2.276
Practitioner	62	10.31	2.558
All	107	10.58	2.453

\*With 3 variables within this factor (Se Table 5.9), the possible attitude to clarity/ predictability score ranges between 5-15. Scores greater than 9 would be considered to indicate a positive attitude

Table 5.11: Mean 'attitude to clarity/predictability of regulation' score, by profession

	Total number	Mean	Standard deviation
Enforcer	45	15.42	2.624
Practitioner	62	14.90	3.268
All	107	15.12	3.012

\*With 4 variables within this factor (See Table 5.9), the possible attitude to responsiveness/ timeliness score ranges between 5-20. Scores greater than 12 would be considered to indicate a positive attitude

Table 5.12: Mean 'attitude to responsiveness/timeliness of regulation' score, by profession

Descriptively these data indicated that attitudes to the efficiency of regulation were generally positive across all respondents. However, enforcers held more positive attitudes than practitioners, who were undecided. For attitudes to clarity/predictability of regulation and responsiveness/ timeliness of regulation, both enforcers and practitioners were found to hold positive attitudes. Although difficult to offer any further explanation of these findings, it was again considered that timing of data collection might have played a part. With regulation in place for one year only, insufficient time may have passed to enable practitioners to form concrete opinions on the efficiency of regulatory implementation.

Practitioner indecision was also reflected in their views on practitioners operating poor practice despite the implementation of regulation (See Figure 5.16).

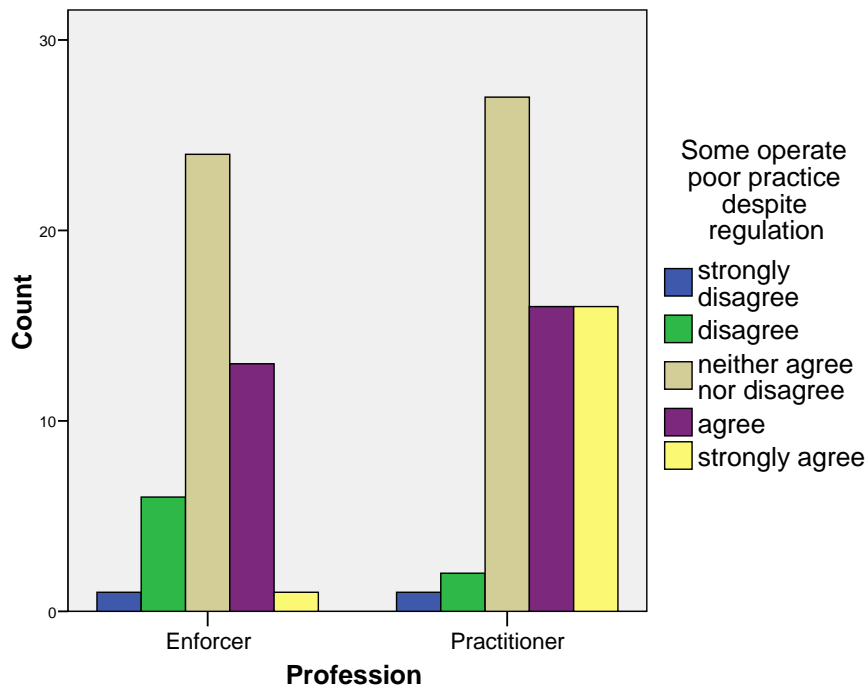


Figure 5.16: Respondents attitude to the statement 'Some operate poor practice despite regulation'

While this data in isolation did not explain why practitioners were undecided, these findings did concur with those of previous studies, where concern over sustainable compliance has been reported (Goudey & Thompson, 1997a; 1997b; Worp et al., 2006; Oberdorfer et al., 2004) (See Chapter 2, 2.4.6). Given the established links between motivation/inclination to comply and securing of compliance (Hawkins, 1984; Hutter, 1997; Baldwin & Cave, 1999), this indecision may have impacted on the desire of practitioners to achieve compliance, as well as the enforcers' ability to secure compliance.

Self-reported behaviour associated with infection control practice

To determine the infection control practice, the data associated with practitioners' views of their individual infection control practices pre- and post-regulation was reviewed. From this, it became clear that all practitioners rated each of the six identified elements (hand hygiene, use of personal protective equipment, sharps management, waste management, environmental decontamination and food hygiene) equally. With no obvious benefit to be gained from individual analysis of each element, the data was utilised to calculate a total 'standard infection control practice' score for each respondent (based on a possible score between 0 and 30).

Collectively, this score represented a view of infection control practices pre- and post- regulation, based on the assumption that each of the six elements of infection control practice held equal weighting. These data were then converted to generate a mean 'standard infection control practice' rating (based on a six point Likert scale including not applicable, unsafe, poor, OK, good and excellent). The inclusion of a 'not applicable' option aimed to address those not practicing within the industry prior to the implementation of regulation (n=2).

Based on the mean 'standard infection control practice' ratings, large numbers of respondents viewed their infection control practice positively both pre- and post-regulation (See Figure 5.17). This reflected the findings of previous studies, both within this industry and across wider healthcare environments, where self-reported practice of standard infection control precautions has frequently been reported as good/very good/excellent (Regina & Molassiotisb, 2002; Barnett et al., 2003; Hellard et al., 2003; Kermode et al., 2005; Qudeimat, Farrah & Owais, 2006; Chiang et al., 2008; Harris & Nicolai, 2010). In isolation, these findings may be likened to rule compliance. Such a link is however tenuous, when considered in conjunction with the study designs, many of which offer self-reported data. In such studies, dichotomy between self-reported and actual practice has been reported, with actual practice frequently cited as sub-optimal. As such, in isolation, the self-reported nature of these data made it impossible to conclude that rule compliance had been achieved (van de Mortel, 2008).

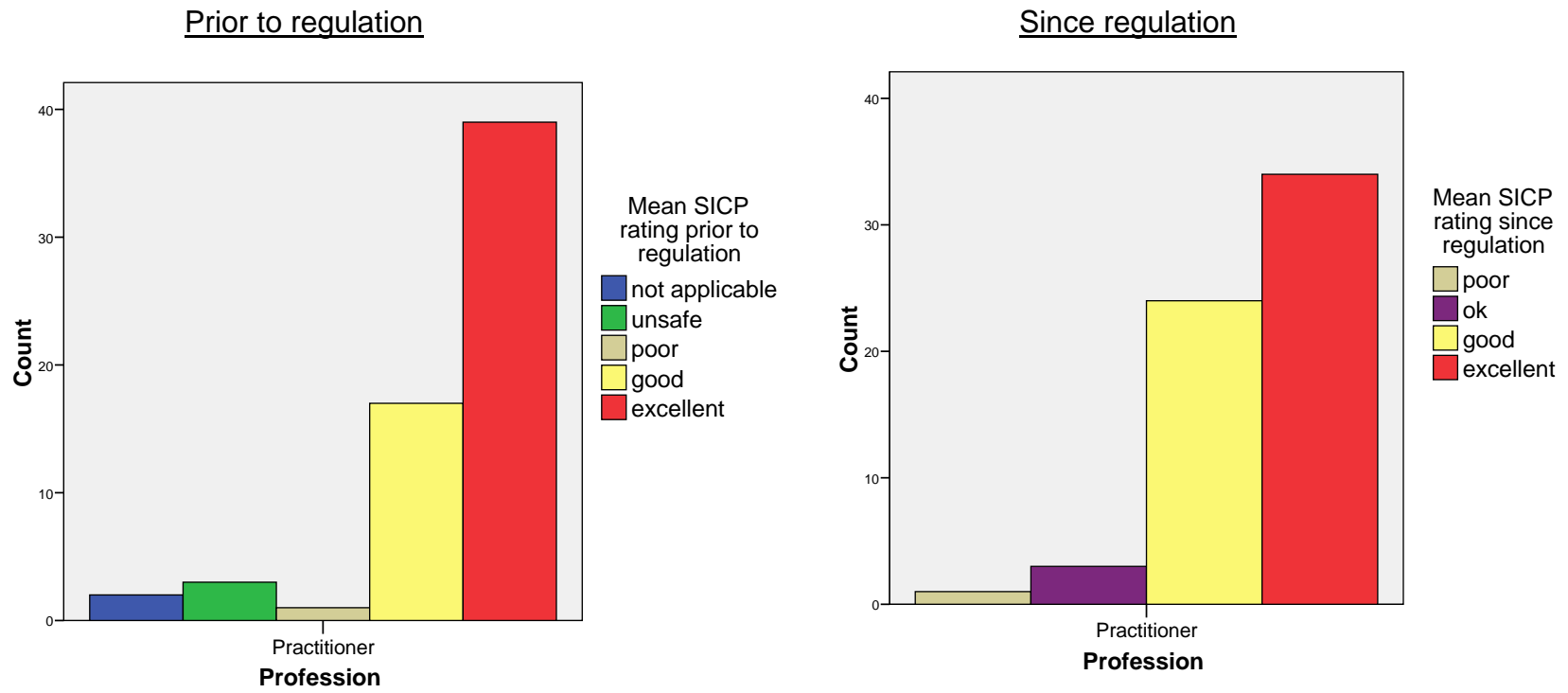


Figure 5.17: Mean 'standard infection control practice' rating, pre-regulation and post-regulation



On further review, the reported change to standard infection control practice pre- and post- regulation was minimal (See Figure 5.17). Although the evidence base for risk to health has been cited previously as weak (See Chapter 2, 2.4.1), the negligible change in self-reported standard infection control practice could have done little to influence the risk to health implied during regulatory design and implementation. This had implications for the ability of regulation to achieve substantive compliance.

#### 5.4.3 *Exploring the quantitative data – inferential analysis*

Having prepared and explored the quantitative data through descriptive analysis and manipulation of data into more useful forms, quantitative data analysis continued with the use of inferential statistics to explore relationships between variables and to compare groups. Non-parametric techniques were utilised. Although less sensitive than parametric equivalents, these were particularly suited to the study data, which consisted mainly of categorical and ordinal variables (Pallant, 2007). Moreover, the non-parametric techniques did not make any distribution assumptions of the data (such as normality) as parametric tests would have, hence their description as ‘distribution-free tests’. Despite the less stringent requirements of non-parametric tests, the data in this study have however met the general assumptions of random sampling and independent observation (where each person is counted only once) (Pallant, 2007).

#### Demographic characteristics and attitude to regulation

Chi-square tests for independence were used to explore the relationship between gender and attitude to regulation; age and attitude to regulation; years of experience and attitude to regulation; and profession and attitude to regulation. In these tests, and based on a cross-tabulation table, comparison was made between *observed frequencies* of cases occurring in each category and the value that would be expected if there was no association between the two variables being measured (Argyrous, 2005; Pallant, 2007). In order for the test to be valid, the collapsing of variables noted previously ensured no more than 20% of expected values were less than 5 and none were less than 1. As a result, the analyses within this study data were based on 2x2 or 3x2 cross tabulation tables.

The Chi-square tests for independence indicated no significant association between age and attitude to regulation ( $\chi^2=0.005$ ,  $p=0.946$ ), gender and attitude to regulation ( $\chi^2= 0.003$ ,  $p=0.955$ ) or years of experience and attitude to regulation ( $\chi^2=0.955$ ,  $p=0.620$ ). The Chi-square test for independence did however indicate a significant relationship between profession and attitude to regulation ( $\chi^2=4.426$ ,  $p=0.035$ ), where practitioners were found statistically more likely to have a negative/ neutral attitude to regulation than enforcers. The established link between positive attitude and good practice in previous studies (Yapp & Fairman, 2005; 2006; Raymond, Halcon & Pirie, 2003) suggested this finding had implications for practitioners' achievement of both rule and substantive compliance. Again, the self-reported nature of the data did however mean that such finding be treated cautiously (van de Mortel, 2008).

#### Enforcers and practitioners – a comparison

To better understand the relationship between profession and attitude to regulation, the Mann-Whitney U test (the non-parametric alternative to the t-test for independent samples, which evaluates the mean rank of two groups) was used to test for differences between enforcers and practitioners in terms of overall attitude to regulation. The 'total attitude to regulation' score (where the possible scores ranged from 12, indicating the most negative attitude to regulation, through to 60, indicating the most positive attitude to regulation) was used (Pallant, 2007).

The Mann-Whitney U test revealed significant differences in the 'total attitude to regulation' scores. Although both groups demonstrated a positive attitude to regulation, the test found enforcers (Mean rank=64.04, Median=45, n=45) to have a significantly higher 'total attitude to regulation' score than practitioners (Mean rank=46.70, Median=40 n=62), indicating a more positive attitude to regulation ( $p=0.004$ ). Having represented these findings in boxplots, this more positive attitude was further highlighted by the distribution of scores, the position of the box, and the median value for enforcers. Moreover, the boxplots highlight greater variation in the practitioners' attitudes to regulation when compared to those of enforcers', demonstrated by practitioners very low as well as very high scores (See Figure 5.18).

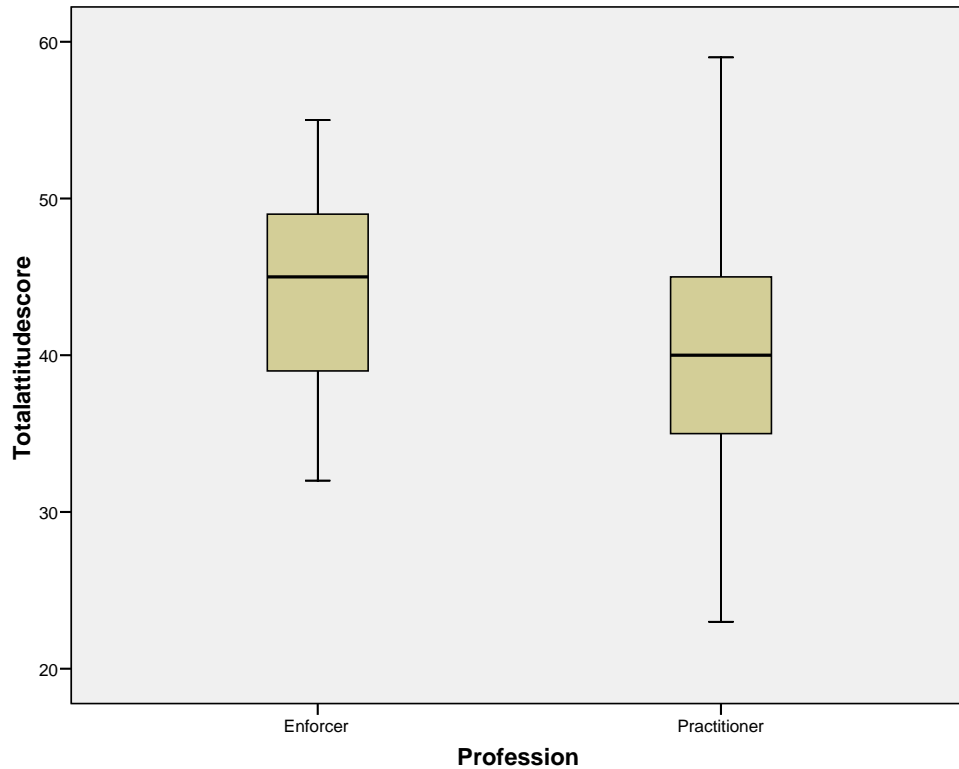


Figure 5.18: Box plot representation of 'Total attitude to regulation' score, by profession

In considering the 12-item attitude scale in its 3-factor format ('attitude to efficiency of regulation'; 'attitude to clarity/predictability of regulation'; and 'attitude to responsiveness/timeliness of regulation') (See Chapter 5, 5.4.2), the Mann-Whitney U test revealed enforcers (Mean rank=69.87, Median=18, n=45) had a significantly higher 'attitude to efficiency of regulation' score than practitioners (Mean rank=42.48, Median=14.5, n=62), which indicated a more positive attitude to the efficiency of regulation ( $p < 0.001$ ). Again, this was illustrated through score distribution using boxplots (See Figure 5.19).

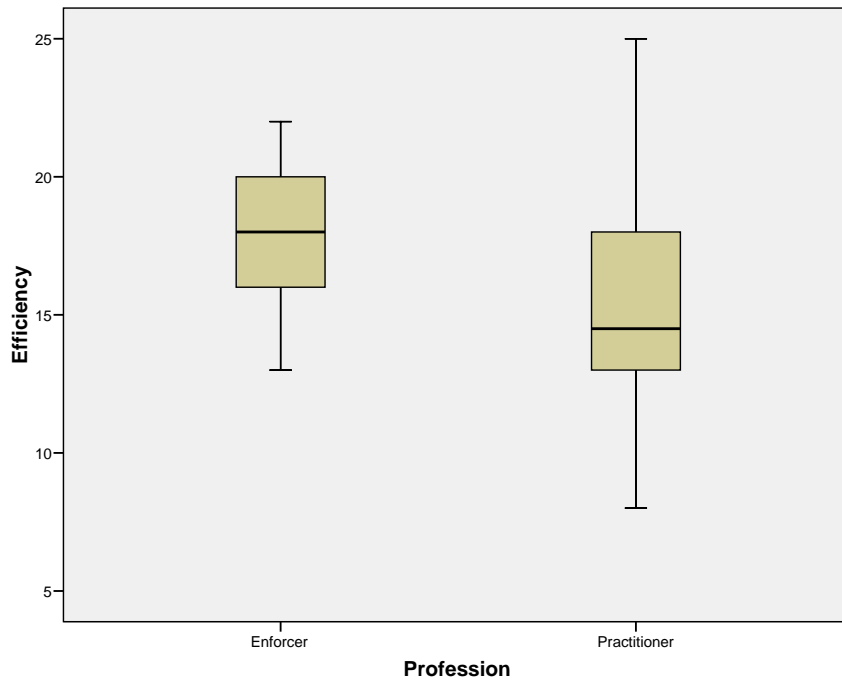


Figure 5.19: Box plot representation of 'Attitude to efficiency of regulation' score, by profession

The Mann-Whitney U test however revealed no significant difference in the 'attitude to clarity/predictability of regulation' scores between the enforcers (Mean rank=59.69, Median=12, n=45) and practitioners (Mean rank=49.87, Median=10, n=62) ( $p=0.099$ ), nor in the 'attitude to responsiveness/timeliness of regulation' scores between enforcers (Mean rank=56.79, Median=16, n=45) and practitioners (Mean rank=51.98, Median=15, n=62) ( $p=0.426$ ). Again, the distributions of scores were illustrated by the use of boxplots (See Figures 5.20 & 5.21).

These findings help to better understand attitude to regulation. With attitude to regulatory efficiency inconsistent across the two professions, this factor must be considered the most influential in terms of achieving and/or securing regulatory compliance.

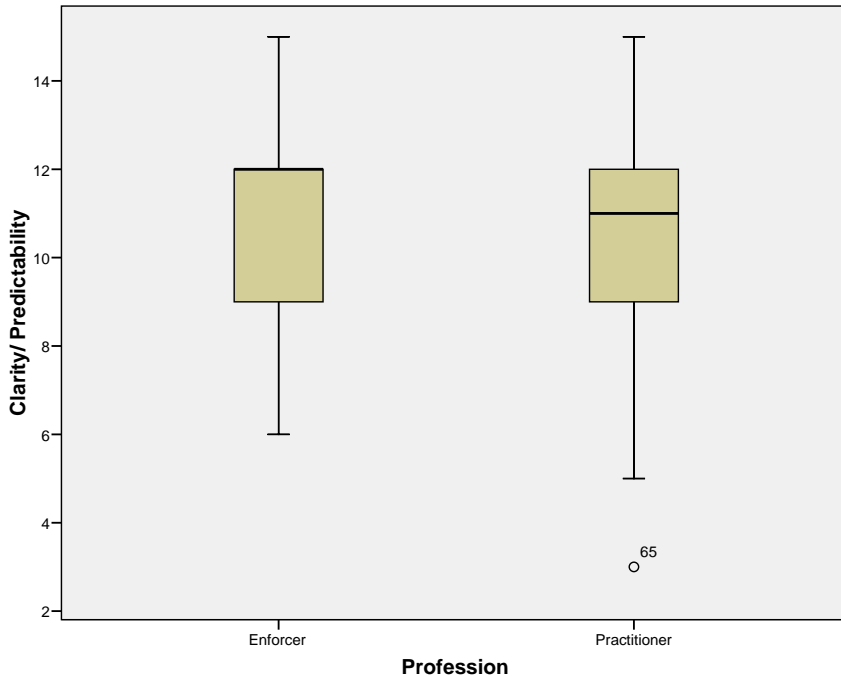


Figure 5.20: Box plot representation of 'Attitude to clarity/predictability of regulation' score, by profession

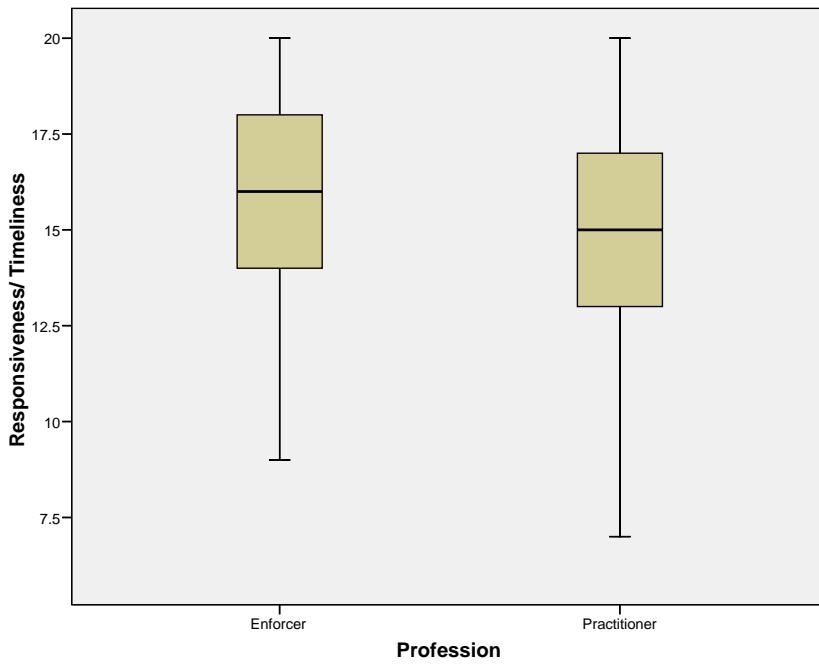


Figure 5.21: Box plot representation of 'Attitude to responsiveness/timeliness of regulation' score, by profession

### Regulation and self-reported practice

To more fully understand the findings presented in Figure 5.17, a Wilcoxon Signed Rank test was used to compare the practitioners' 'total standard infection control practice' scores from before and after the implementation of regulation. Designed for use with paired samples, this test was chosen as the non-parametric alternative to paired samples t-test, converting scores to ranks (as opposed to comparing means) and comparing them across time (Argyrous, 2005; Pallant, 2007). Only data from 60 of the 62 practitioners were included in this test, with data from 2 practitioners excluded due to the absence of a prior to regulation score (reported as not applicable, and explained as not working in the industry prior to the implementation of regulation).

The Wilcoxon Signed Rank test revealed a statistically significant difference between 'standard infection control practice' scores prior to and since implementation of regulation ( $p < 0.001$ ). Although the median 'standard infection control practice' score was unchanged from prior to regulation (Median=30) to since regulation (Median=30), and increased for those practitioners in the 25<sup>th</sup> percentile range (Median prior to regulation=28, Median since regulation=29), the median score for practitioners in the 75<sup>th</sup> percentile decreased from prior to regulation (Median=35) to since regulation (Median=30).

Previously (5.4.1), the change in practitioners' standard infection control practice had been described as negligible. Further analysis has clarified this shift as 50% of scores unchanged, 25% increased and 25% decreased. This would appear to conflict with previous research, which has found regulation to support improved practice (Raymond, Halcon & Pirie, 2003) (See Chapter 2, 2.4.5 and 2.4.6) and from this perspective would be considered as negatively impacting upon rule compliance (Yeung, 2004).

Alternatively, and challenging the frequently cited limitation of self-reported information from questionnaires and its failure to reflect actual practice (Goudey & Thompson, 1997a; 1997b; van de Mortel, 2008), it is posited that as a result of regulatory implementation, practitioners may have become more aware of the standard of their infection control practice, and post-regulation, rather than dropping in standard, have instead recorded this more accurately. Offering this alternative explanation was to realise that the significant difference in scores prior to and since regulation might not have been *caused* by the implementation in regulation. Other confounding/contaminating factors may have influenced the shift in scores, or simply the passage of time or change in attitude (Pallant, 2007). While the use of a control group (similar to the participants, but not exposed to the intervention) could have provided a mechanism to rule out such confounding factors and improve this study's findings, no sufficiently similar group was available. Instead, the use of a mixed methods approach to data collection and analysis was adopted, with which integrative analysis and interpretation of mixed methods data is expected to address this issue.

## **5.5 Chapter 5 summary**

I have used Chapter 5 to initiate analysis of the findings from this study. The principles of framework analysis were utilised to individually analyse the qualitative data. Adopting a thematic network technique (Attride-Stirling, 2001), I systematically extracted themes from the interview and observational data. Thereafter, these themes were explored in conjunction with original text.

Additionally, descriptive and inferential analysis has been undertaken to describe the characteristics of the respondents, explain the response rate, and explore respondents' experiences of regulatory implementation, as reported within the quantitative data. I calculated frequencies, mean, median and standard deviation, where appropriate. Furthermore, I utilised Chi-square tests for independence, the Mann-Whitney U test, and Wilcoxon Signed Rank test to explore relationships between variables and compare groups.

Through individual exploration and explanation, I have identified, from practitioners' and enforcers' responses to the regulation, knowledge/awareness, attitudinal and behavioural factors likely to have contributed, both positively and/or negatively, to the achievement of compliance with the Civic Government (Scotland) Act 1982 (Licensing of skin piercing and tattooing) Order 2006. These factors included issues such as support; motivations; systems and processes; relationships; competence; expectation and experience, and reflected existing literature on regulatory compliance (Baldwin, Hutter & Rothstein, no date). Exploration of practitioners' self-reported infection control practice showed a shift in how practitioners rated their self-reported practice, and highlighted the ease with which 'self-reporting' can be used as a rationale. As a multi-directional shift however, the need to reflect on the possibility of confounding factors was considered, with integration and interpretation of the data proposed as one direction to resolve such 'paradox'.

As such, I will utilise Chapter 6 to integrate and further interpret these data, concurrently appraising the findings of both my qualitative and quantitative data to more fully understand users' response to the Order, and determine the extent of regulatory compliance with the Order in Scotland's tattooing and cosmetic body piercing industry.



# Chapter 6

## Integrative analysis and interpretation

## **6.1 Introduction and overview**

Mixed methods research generates qualitative and quantitative data, which requires collective consideration as mixed methods data (Sale & Brazil, 2002; Morse, 2003). Amidst the debates on the timing of integration within a mixed methods study (Creswell, 2009; Yin, 2006; O’Caithin, Murphy & Nicholl, 2007; Woolley, 2009), Maxwell and Loomis (2003) argue that the study intent and research questions should underpin any decisions associated with strategies for analysis, integration and interpretation.

## **6.2 Background**

Building from the study background in Chapter 1 and literature review in Chapter 2, I identified the intention of my study to determine the extent of regulatory compliance with the Civic Government (Scotland) Act 1982 (Licensing of skin piercing and tattooing) Order 2006 in Scotland’s tattooing and cosmetic body piercing industry. The primary research question for my study was noted as:

1. To what extent has regulatory compliance with the Civic Government (Scotland) Act (Licensing of skin piercing and tattooing) Order 2006 in Scotland’s tattooing and cosmetic body piercing industry been achieved?

The secondary research questions for my study were:

1. What has been the response of users of the Order to the implementation of the Order within the tattooing and cosmetic body piercing industry in Scotland?
2. Why have users of the Order within the tattooing and cosmetic body piercing industry in Scotland responded to the implementation of the Order in the way they have?
3. How has the collection of mixed methods data on the response of users to the Civic Government (Scotland) Act (Licensing of skin piercing and tattooing) Order 2006 contributed to a fuller understanding of regulatory compliance?

In Chapter 3 – ‘Conceptual framework’, I appraised the theory of regulatory compliance, making use of existing compliance process models (Henson & Heasman, 1998; Fairman & Yapp, 2004) to develop a conceptual framework to underpin this study. Subsequently, I utilised my conceptual framework to plan and execute a systematic exploration and explanation of users’ response to the implementation of the Order in Scotland’s tattooing and cosmetic body piercing industry, anticipating the outcome would assist in answering my research questions and achieve my study intent.

To this end, in Chapter 4 – ‘Study design and methodology’, I considered the worldviews, designs and methods available to researchers. In turn, this informed the development of my concurrent mixed method study. Stressing the importance of integration as a key feature in legitimising the description of this study as mixed methods research (Yin, 2006), I explicitly integrated my study intent, research questions and conceptual framework (Chapter 4, Figure 4.3).

I commenced the process of data analysis in Chapter 5 – ‘Results and individual analyses’, individually manipulating the raw data from my distinct qualitative and quantitative datasets in preparation for its subsequent use as mixed methods data. So far, these separate analyses have established practitioners’ and enforcers’ responses to the implementation of this regulation, and identified factors likely to contribute to and influence regulatory compliance.

In this chapter, I integrate and further interpret these data to determine the extent of regulatory compliance with the Order in Scotland’s tattooing and cosmetic body piercing industry. By concurrently appraising my findings, a fuller understanding of users’ response to the Order than that which resulted from analysis of single data sources in Chapter 5 will be achieved. Moreover, this study’s contribution to new knowledge is evidenced.

### **6.3 Recap of the theory underpinning this study's conceptual framework**

The conceptual framework for this study (Chapter 3, Figure 3.6) was build around the compliance process model. Designed originally by Henson and Heasman (1998) and later adapted specifically for use in small and medium sized enterprises (SME) by Fairman and Yapp (2004), it currently explains the process of working towards compliance with regulation from a food-related business context. In this study, the SME-specific compliance model (Chapter 3, Figure 3.2) formed the core of the conceptual framework, analogous with the small, micro and indeed sole trader structure of tattooing and cosmetic body piercing businesses in Scotland.

Fairman and Yapp's (2004) 5-step model considers the identification and interpretation of regulation as driven by the enforcer, also considered responsible for identifying changes and specifying the method(s) to support such changes. Only once these steps have been completed, does the model designate the practitioner (or SME) as decision maker. Informed by enforcement interventions (such as advisory/inspection visits and verbal/written information), compliance decision-making is undertaken. Implementation of change follows, led by the practitioner (or SME). Thereafter, and completing the first sequence of what is documented as a cyclical process, the enforcer is once again pronounced decision maker during monitoring and evaluation.

Given the study intent and ongoing debate on the nature of compliance (Hutter & Rothstein, no date; Edelman et al. 1991; Lange, 1999), the need for a well-defined definition of compliance was considered an essential element of this study. To this end, Yeung's (2004) work on compliance was incorporated into the evolving conceptual framework. In deciding to choose Yeung's (2004) multiple definition(s) of regulatory compliance, it followed that the concept of regulatory implementation be viewed more broadly than that described within the SME-specific compliance process model of Fairman and Yapp (2004). Subsequently, the concept of regulatory implementation was widened to embody design and standard setting as well implementation of standards/ rules and monitoring/enforcement (Yeung, 2004), and was built into the conceptual framework.

To complete the conceptual framework, the principles of good regulation (proportionality; accountability; consistency; transparency and targeting) were incorporated as the basic tenets from which to determine regulation's fitness for purpose across regulatory implementation (BRTF, 2000; Cave & Baldwin, 1999).

#### **6.4 Integration and interpretation of the study data**

Reflecting on Maxwell and Loomis' (2003) suggestion that any decisions associated with integrative analysis and interpretation of data in a mixed methods study should be underpinned by the study intent and research questions, explicit use was made of this study's conceptual framework (Chapter 3) to focus the integrative analysis and interpretation of the data. This approach was judged to elevate the qualitative and quantitative data to the status of 'mixed methods data'. Greater than the sum of their individual qualitative and quantitative parts (Yin, 2006), these mixed methods data resultantly exceeded the "*mutually illuminating*" status required as a minimum in reporting the analysis and interpretation of mixed methods research (Bryman, 2007: 8).

As well as providing opportunity to achieve the study intent and comprehensively answer each of the research questions, re-visiting the quantitative and qualitative data as mixed methods data provided an opportunity to address the final stage of Attride-Stirling's (2001) thematic network analysis process – integration of exploration (See Appendix 14), where it is expected that key conceptual findings are synthesised and related both to the theoretical underpinning of the research and to the research questions. Providing further evidence of how this study was designed to promote integration across the research process, it maximised the study's potential to be viewed not only as a mixed methods study, but moreover as a 'high quality' mixed methods study (Bryman, 2007; O'Caithin, Murphy & Nicholl, 2007).

## 6.5 Understanding users' experiences of regulatory implementation

In accordance with the study objectives, integrative analysis and interpretation of this study's mixed methods data involved critical appraisal of respondents' experiences of regulatory implementation. Through in-depth review of how these experiences correlated with the regulatory implementation process identified in the study's conceptual framework, and judicious evaluation of their influence on the achievement of compliance, the extent of compliance was determined.

### 6.5.1 Regulatory design (including standard setting)

The design of the Civic Government (Scotland) Act 1982 (Licensing of skin piercing and tattooing) Order 2006 (incorporating standard setting) began back in 2001 through public consultation on the regulation of skin piercing (SEHD, 2001). Appraisal of the quantitative data from this study failed to identify any respondent (n=107), either practitioner or enforcer, who had engaged in the consultation. This was subsequently corroborated through the findings from interview data:

*"I don't remember a consultation...."*  
(Carol – Enforcer, page 5, line 16)

*"Honestly, I cannae remember...."*  
(Ed – Practitioner, page 7, line 18)

*"We weren't really aware of the initial consultation...2001...most people said no-one really saw it"*  
(Ellen - Enforcer, page 10, line 22)

Moreover, review of the quantitative data did not identify any respondent (n=107), either practitioner or enforcer, who had been involved in the design/standard setting element of the regulation. Again this lack of involvement was substantiated by interview data:

*"...all I remember at the time was (EHO name) phoned up and said 'this should be starting in the next couple of months, we'll gie ye a 'phone when there's a visit due..."*  
(Ed – Practitioner, page 7, line 18)

*“I think what most people said was ‘who was involved in the drafting of the legislation because the legislation came out but no-one was consulted.... There is a lot of supposition that they were talking to tattooists and maybe not everyone else they wrote into it. As far as we are aware, we haven’t found any EHO who says they were involved.”*

(Ellen – Enforcer, page 10, line 23)

For practitioners, these findings concurred with evidence from Henson and Heasman (1998), who claim that while large businesses are generally aware of regulation at the proposal stage, smaller businesses more often become aware of new regulation at a later stage, usually at the point of implementation. To better understand the impact of such findings on compliance within this study, reference was made to the work of Parker (2000).

Parker (2000) contests the need to develop, at regulatory design stage, an understanding of the ‘practices to be regulated’ and the ‘context’ within which the regulation will be applied, if compliance with collective goal(s) is to be maximised. In this study, ‘practices to be regulated’ were identified within the content of the Order (SEHD, 2006a), National Conditions (SLSPTWG, 2006) and Local Authority Implementation Guide (SLSPTWG, 2007). Evidence of a developed understanding of these documents during regulatory design would have served as evidence of substantive compliance in this study. Having demonstrated the distinct lack of involvement in regulatory design, it can be deduced that practitioners’ and enforcers’ were unable to develop an understanding of the practices to be regulated. From this, it was reasoned that the ability to maximise substantive compliance had been compromised.

This reasoning was substantiated through interview data. These data broadly evidenced how lack of involvement negatively influenced motivation to comply:

*“I feel I kind of ambushed them a bit. I came in one day and said ‘your premises in this condition won’t satisfy the licensing requirements....if there had been more involvement from the grass roots people maybe it would be more accepting for us coming”*

(Carol - Enforcer, page 17, line 2)

Similarly, lack of understanding of industry practices was evidenced in a quote, cited previously within the practitioner network 'Challenges to sustaining/ enhancing compliance':

*“What they need to do is, if they’re serious about it at all, is to start to listen to the people in the industry because (pause) quite frankly ...they know nothing about this industry”*

(Dan – Practitioner, page 18, line 2)

While the time delay between consultation (2001) and implementation (2006) may conceivably have played a part in these findings associated with lack of involvement in with consultation/ design, the quantitative data refuted this suggestion. These data showed around half of enforcers (49%, n=22) and over four fifths of practitioners (87%, n=54) had five or more years of experience. Working within their respective disciplines during this period, they should have been exposed to the consultation. Despite documented evidence of a consultation process, these findings suggested inadequate consultation. Such a conclusion can be justified, in light of the lack of a robust sampling frame and dissemination strategy associated with consultation. This has implications for the transparency and accountability of this regulation, in terms of the principles of good regulation (BRTF, 2000; 2005).

Despite the lack of involvement in regulatory design, this study’s quantitative survey data found 80% (n=86) of respondents agreed/ strongly agreed regulation was required to minimise risk to health (See Figure 6.1). A Chi-square test for independence indicated no significant association between profession and this attitude ( $\chi^2=5.396$ ,  $p=0.249$ ). From this finding, it was deduced that substantive compliance could be secured.



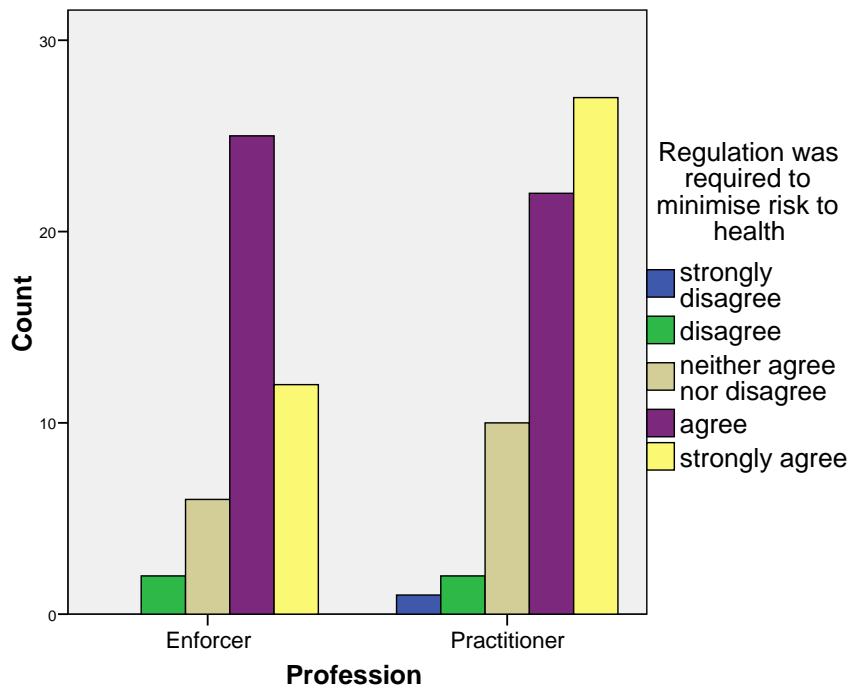


Figure 6.1: Respondents' attitude to the statement 'Regulation was required to minimise risk to health', by profession

Parker's (2000) notion of 'context' was then critically reviewed. As discussed in Chapter 1 (1.3.3), the 'context' of regulation within the tattooing and body piercing industry was embodied in the documents associated with consultation. These documents identified the underpinning need for regulation as risk to health. Use of regulation would, it was purported, strengthen existing controls to minimise such risk (SEHD, 2001; Walters, 2001) Understanding this context was therefore viewed as a key element in achieving substantive compliance.

Integrative appraisal of the practitioner network 'There has been support for regulation' and the enforcer network 'No imminent risk' (Chapter 5, 5.3.4 & 5.3.5) showed how respondents, irrespective of profession, recognised and acknowledged the inherent risk to health from tattooing and cosmetic body piercing activities. This concurred with the quantitative findings above on the need for regulation to minimise risk to health, and appeared to demonstrate respondents understanding of the context from which regulation was introduced. However, these same networks highlighted respondents' inability to cite evidence of actual risk to health from tattooing and/ or cosmetic body piercing activities.

While reflecting the lack of robust evidence of an established causal link between tattooing and cosmetic body piercing activities and infection noted in Chapter 2 (2.4.1), it also disputed the degree of contextual understanding. Moreover, opinions on what prompted the introduction of regulation were varied. Some respondents associated this with the inherent risk noted above, while others (predominantly practitioners) disassociated it from the issue of health. Instead they believed it to be politically and/ or financially driven:

*...I think as an EHO you wouldn't say it isn't a priority because of risk to health, but as a council...I'm not sure how high up it would be on the agenda now." (Carol – Enforcer, page 6, line 4)*

*"I think it's because tattooing over the last five years has just continued to get bigger and bigger all the time"*  
(Hugh – Practitioner, page 4, line 13)

*"A way of making money...its become a bigger industry, there's money in the industry, the government want some of that..."*  
(Ben – Practitioner, page 6, line 11)

*"Some people must have thought it was a bigger issue...MPs maybe..."*  
(Fiona – Enforcer, page 3, line 9)

*"I've absolutely no idea....the only thing I can think of is more popular"*  
(Graeme – Enforcer, page 4, line 8)

These findings further questioned the extent to which the context of this regulation was understood, and therefore questioned the extent to which substantive compliance could have been achieved. Reflecting upon the documentation associated with the introduction of regulation, risks purported to arise from skin and body piercing were identified and cited as:

- *Transmission of serious infections like hepatitis B or C*
- *The potential transmission of HIV infection*
- *Localised bacterial wound infections, particularly those of the nose and upper ear*
- *Consequent deformity of the upper cartilaginous part of the ear*
- *Scarring*
- *Bleeding*
- *Jewellery embedding in the skin*
- *Allergic reactions to jewellery metal and antiseptics*
- *Tooth damage from biting on tongue jewellery*
- *Risks arising from administration of local anaesthetics*

(Walters, 2001: 4)

Considering how these risks had been documented, use of the word “*potential*” suggested HIV transmission was a perceived risk. This mirrored, somewhat discretely, the evidence that no proven cases of HIV transmission linked to tattooing/ cosmetic body piercing had to date been found (Braverman, 2006). To the contrary, the phrase “*transmission of serious infections like hepatitis B or C*” suggested actual risk – doing so rather subjectively through inclusion of the word “*serious*”. At the time, this conflicted with the Center for Disease Control, who continue to advocate transmission of blood-borne virus from tattooing and cosmetic body piercing activities as a perceived risk (CDC, 2006; 2010). Types of risk were undefined for the remaining factors.

With no obvious distinction made between actual risks (based on reality, and evidenced from actual incidents/ cases) and perceived risks (considered to reflect belief), for most risk factors, exposure to the documents associated with consultation was considered unlikely to have addressed respondents’ deficit in understanding of risk and risk to health from tattooing and cosmetic body piercing. Nor would it have clarified the reason for introducing regulation. It was therefore concluded that at regulatory design stage, substantive compliance was not achievable (See Figure 6.2).

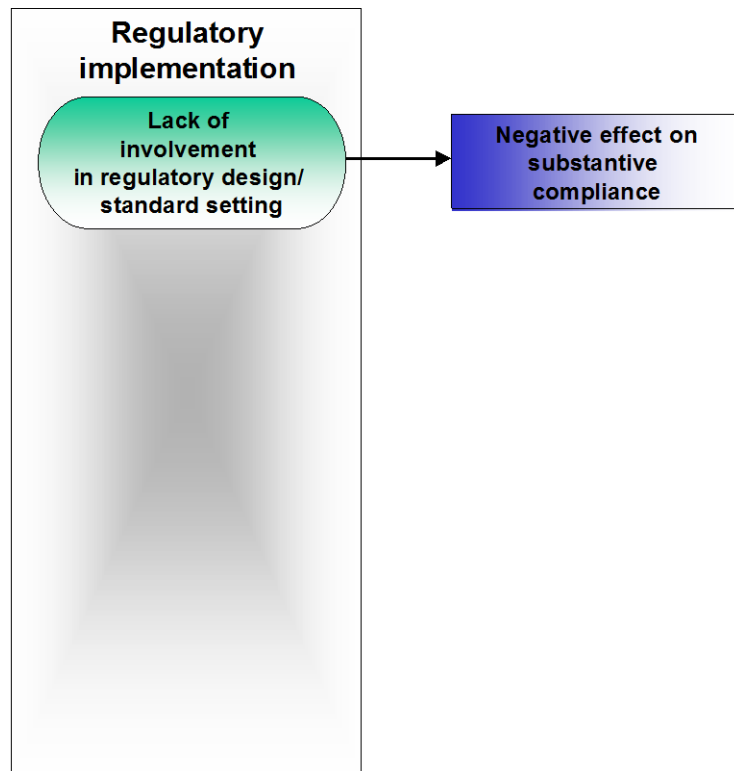


Figure 6.2: Regulatory design/ standard setting as part of regulatory implementation

### 6.5.2 Identification of regulation

Enforcers and practitioners were found to have shared in the identification of this regulation. For some however, its arrival was anticipated, while for others it was unexpected:

*“Honestly I canny remember...I just remember...all I remember at the time was (EHO name) phoned up and say ‘this should be starting in the next couple of months*

*(Ed - Practitioner, page 7, line 18)*

*“...we knew it was coming...”*

*(Hugh - Practitioner, page 9, line 18)*

*“The only difficulty was not being told it was coming in April 2006...we only learned about it November / December the year before...or January was it? (Andy - Enforcer, page 6, line 7)*

*“....I remember when the regulation came out we were all a bit shocked because they seemed to just appear one day...one Monday morning...oh look, there’s new regulation for skin piercing..... it just suddenly appeared and everything had to be put in motion after that....” (Carol - Enforcer, page 5, line 16)*

*“It came as a complete surprise to everybody when in 2006 it just arrived out of the blue...” (Bob - Enforcer, page 2, line 27)*

For the practitioners, operating predominantly as micro-businesses and sole traders, this finding reflected earlier findings by Henson and Heasman (1998), who purported that smaller businesses more often become aware of new regulation at a later stage. While Henson and Heasman (1998) suggest this is generally post-implementation, the interview data indicated the presence of pro-active practitioners:

*“We opened here in October 2005...maybe 6 months later ...It must have been the start of 2006, quite close to the start and then we found out it was being regulated so I spoke to (EHO name) a few times and (EHO name) sent me draft copies of things and we kind of looked through it just to see how much work we actually had to do...we were probably aware, were really aware of it...of the licensing coming in....from a friend that’s got a studio in (place name) ...”*

(Ben - Practitioner, page 1, line 25)

*“The real interesting thing with the regulations when they were set up was that the local licensing department and environmental health officers didn’t know the regulations were coming in (laugh) so it was quite incredible...I’d been on the internet and the first draft regulation had been published.....so the day was looming for the regulations to be you know brought into practice....phoned the local license department ‘look, what’s happening with this?’...‘what’s happening with what?’....‘body piercing’... exact words ‘Mr (surname), there is no regulation covering body piercing...”*

(Frances - Practitioner, page 6, line 29)

This conflicted with the finding of Fairman and Yapp (2004). Fairman and Yapp (2004) assert small businesses feel little responsibility to actively lead on the identification of regulation, instead relying on others such as environmental health officers and professional bodies for information and guidance.

Reviewing these findings in conjunction with the qualitative evidence contained within the enforcer network ‘There has been support for regulation’ (Figure 5.4), the ongoing journey of this industry towards its own professional identity (Chalmers, 2009b) was deemed to best explain these findings. This did not however explain the late identification of the regulation by enforcers.

Indeed, as members of large governmental business organisations, these findings conflicted with those of Henson and Heasman (1998), who argue larger businesses are generally aware of regulation at the proposal stage. Henson and Heasman (1998) relate this awareness to negotiation and manipulation of regulation to serve their own needs. As such, the public service function of Local Authorities in this instance, with no such underlying motive, may have contributed to the late identification by enforcers. Arguably however, the low priority given to this industry, evidenced within enforcer interview data, was viewed as more accurately explaining this phenomenon:

*“...it wasn't a big issue for us...”*

(Ellen - Enforcer, page 2, line20)

*“Personal opinion...waste of time and money. I mean, we didn't really have a problem with people walking out of (business name) and dropping down dead because of infection...”*

(Fiona - Enforcer, page 3, line 12)

Late identification of the regulation by enforcers was reflected in the timing of production of National Conditions and Local Authority Implementation Guide. Both were launched in February 2007, almost one year after the regulation was implemented. Given the use of these documents collectively to define and apply regulatory standards, their absence during this first year was deemed to have negatively influenced rule compliance. Moreover, the late identification of this regulation had implications for the application of the principles of good regulation (BRTF, 2000), in respect of ensuring transparency, demonstrating accountability and promoting consistency (See Figure 6.3).

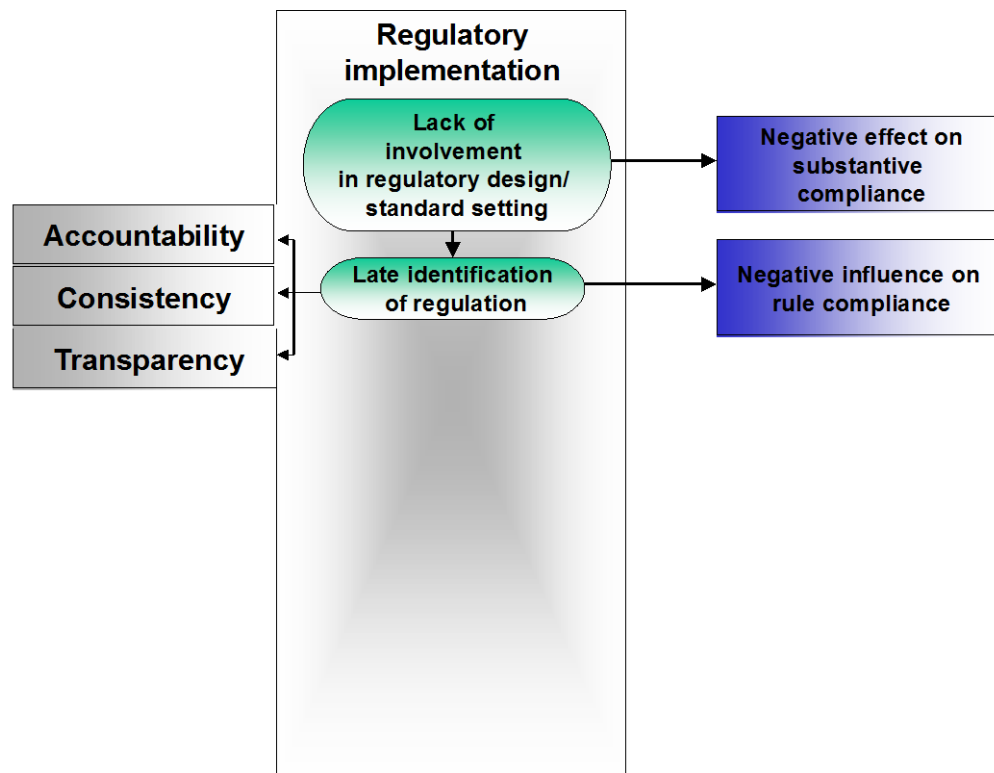


Figure 6.3: Regulatory design/ standard setting as part of regulatory implementation, with implications for principles of good regulation

In this study, the decision to classify ‘identification of regulation’ as a discrete step within the regulatory implementation process was considered to more accurately mirror the experiences of study respondents. This echoed the work of Henson and Heasman (1998) but contrasted with that of Fairman and Yapp (2004) (See Figures 3.1 and 3.2). Despite concurrence with Henson and Heasman (1998) at this stage, findings from this study did not wholly reflect the subsequent steps from either their research, or that of Fairman and Yapp (2004).

### 6.5.3 Continuation decision-making

In this study, following regulatory identification, respondents became involved in ‘continuation decision-making’. This decision-making was undertaken without the interpretation of regulatory requirements or consideration of need for change, as posited by both Fairman and Yapp (2004) or Henson and Heasman (1998). Moreover, in this study, respondents’ continuation decision was directly related to business preservation. This was evidenced through the practitioner network ‘Compliance decision-making ensures business preservation’.

Furthermore, it was corroborated through enforcer interview data, where the impact of cost of the licensing fee on the decision to continue was highlighted:

*“We did find we had people who...mainly because of the cost said they were ear piercing...have said they are no longer ear piercing”*  
(Carol - Enforcer, page 7, line 1)

*“Most people we expected of doing electrolysis and ear piercing we wrote to and told them they needed a license and they wrote to say if its going to cost that much we are going to stop doing it.”*  
(Ellen - Enforcer, page 10, line 8)

*“I think they’d be one or two of the smaller beauty salons...one or two people ear piercing which wasn’t a very big part of business said it was too expensive to apply for a license.”*  
(Andy - Enforcer, page 12, line 29)

Equally, this step was determined as different from the ‘compliance decision-making’ proposed by Fairman and Yapp (2004). Indeed, reference to this step as ‘continuation’ decision-making served to disengage it from the concept of compliance. This was justified by the straightforward yes-no decision-making outcomes of ‘continuation decision-making’, differentiating it from the more complex decision-making associated with compliance (Henson & Heasman, 1998).

From this perspective, and dependent upon the decision made, this part of the regulatory implementation process had the potential to contribute to the achievement of regulatory compliance. For example, it became clear that those who opted not to continue with regulatory implementation found themselves facing a further decision around the continuation of tattooing and/or cosmetic body piercing activities. Representing the continuation decision-making process diagrammatically (See Figure 6.4<sup>8</sup>) has served to illustrate how this secondary decision sat outside the regulatory implementation process.

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<sup>8</sup> The use of a dotted line represents an associated element of activity which sits outside the regulatory implementation process



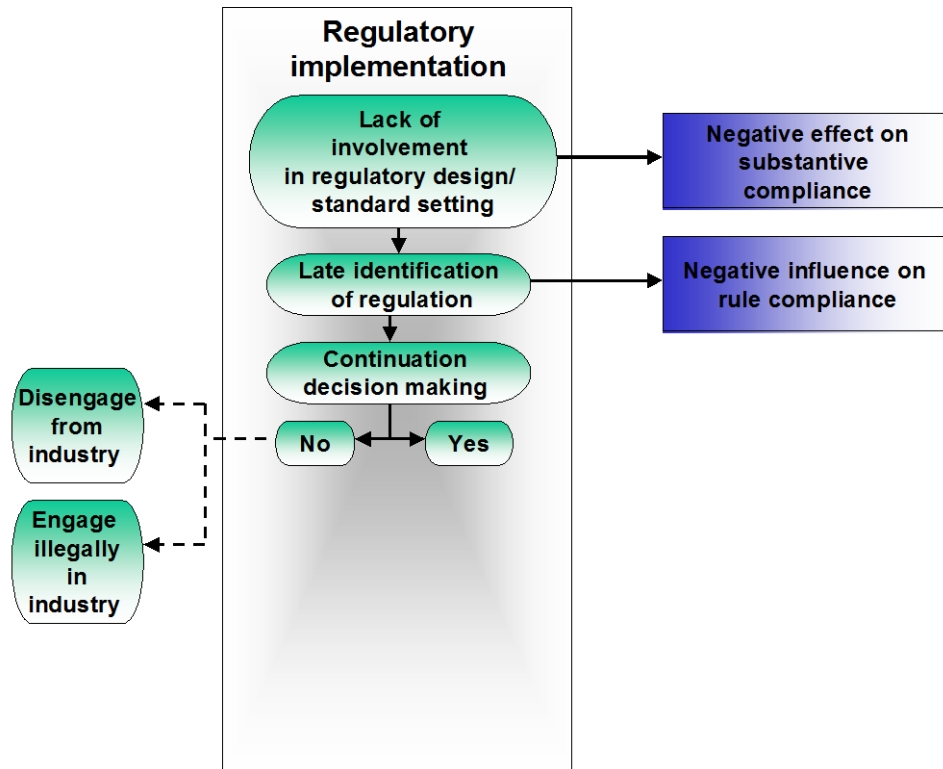


Figure 6.4: Continuation decision-making as part of regulatory implementation

Evidence of such unregulated (and therefore illegal) activity was identified in both enforcer and practitioner interview data (See Figures 5.5 & 5.9):

*“I know of at least two in this town and it’s a small town...that aren’t licensed. One of them is a tattooer who’s been tattooing for a very long time...he used to tattoo professionally in town like ten years ago and now he works in his house...”*

(Gavin - Practitioner, page 15, line 7)

*“...you can get a rogue trader at any time....”*

(Ian - Enforcer, page 18, line 28)

*“There’s loads o’ people runnin’ without a bloody license or they’ve been forced underground...the only effective difference its made is to drive some of the lesser operators further underground. I would say that is a big problem”*

(Dan - Practitioner, page 3, line 20)

*“I’m not sure we are going to get into the people tattooing at home or mobile....”*

(Fiona - Enforcer, page 12, line 23)

*“...the underground piercing people still exist. They operate from their home, they operate from bebo sites, they operate from back rooms of tattoo shops that aren’t regulated for delivering piercing...its all still there.”*

(Frances - Practitioner, page 11, line 1)

Through interpretation of these findings, the assertion that regulation would be “*effective in minimising risk to health ...by ensuring only those practitioners willing and able to practice safely remain in practice*” (Walters, 2001: 52) was judged as inherently flawed. In terms of the principles of good regulation, these findings have implications for the principle of targeting, where effective intervention requires a focus on greatest risk (BRTF, 2000). Indeed, these findings highlighted the under-inclusiveness as a danger to the achievement of both substantive and rule compliance (Baldwin, Hutter & Rothstein, no date). Coupled with evidence drawn from the practitioner network ‘Compliance decision-making ensures business preservation’ (See Figure 5.5), which showed the industry, in the absence of external prompt, as historically inactive, the existence of this ‘continuation to practice decision’ outside the regulatory implementation process was deemed to negatively affect the ability of regulation to address all creators of risk, actual or perceived. Therefore, these integrated findings were interpreted as sufficient evidence to confirm regulation’s inability to attain substantive and/or rule compliance (See Figure 6.5).

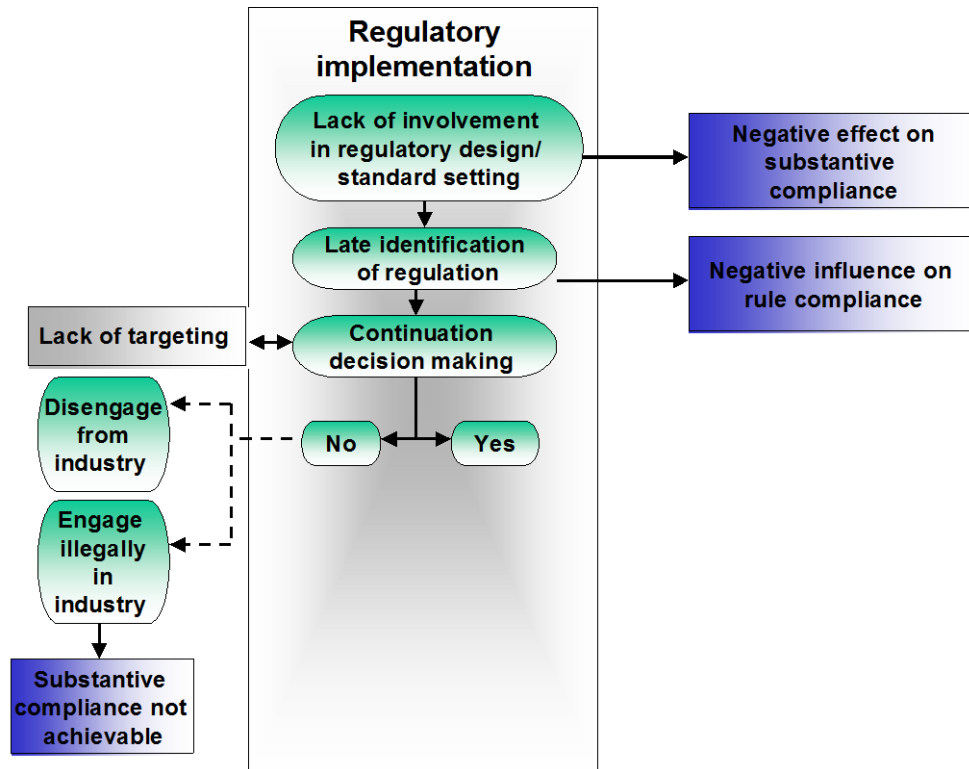


Figure 6.5: Understanding continuation decision-making

However, study findings also identified how unregulated/ illegal practice did not simply equate with poor/ unsafe practice. Practitioner interview data explained how the natural evolution of becoming a licensed practitioner frequently involved a phase of what now would be described as illegal/unregulated practice. Moreover, findings showed how regulation has negatively impacted on the anticipated progress towards regulated practice:

*“Those amateur tattooers usually either ...either they carry on doing it...or they go professional you know...more often they open their own shop. I think regulation is stopping those people from opening a shop...”* (Gavin - Practitioner, page 16, line 6)

*“...originally...we were tattooing from home...”*  
(Hugh - Practitioner, page 2, line7)

*“Started tattooing when I was 19 on my friends...pretty humble beginnings...no any different tae 99% of other artists.”*  
(Dan - Practitioner, page 1, line 9)

Reflecting the findings of Keene, Markum and Samadpour (2004), where risk persisted in regulated practices, this study's practitioner interview data and observational field note data demonstrated how regulated practice did not necessarily equate with good practice:

*"It is a wee bit of a double edged sword here. This is allowing really bad studios to operate and hide behind the license"*

(Ben - Practitioner, page 8, line 26)

*"I hear stories about one tattooer in town, with people saying they aren't made to fill in consent forms..."*

(Gavin – Practitioner, page 20, line 6)

*"When I arrived at the studio, there was a dog sitting in reception...they put it out. I didn't see it back in the studio during the remainder of my visit, but who knows how reflective this is of day-to-day practice. I asked... They said it stays outside, creeps in now and again and they put it straight back out..."*

(Extract from observational fieldnotes, 4<sup>th</sup> September 2009)

*"One of the environmental health officers says...'Aye, I've been in there and I've seen the dogs actually'..."*

(Ben – Practitioner, page 23, line 25)

Despite this, 82% (n=88) of respondents agreed/ strongly agreed there was a need for improvement in industry practices, and 80% (n=86) agreed/ strongly agreed regulation was the best way to achieve this (See Figures 6.6 and 6.7). This was further corroborated by the findings contained within the practitioner network 'There has been support for regulation' and the enforcer network 'Greater control through regulation'.

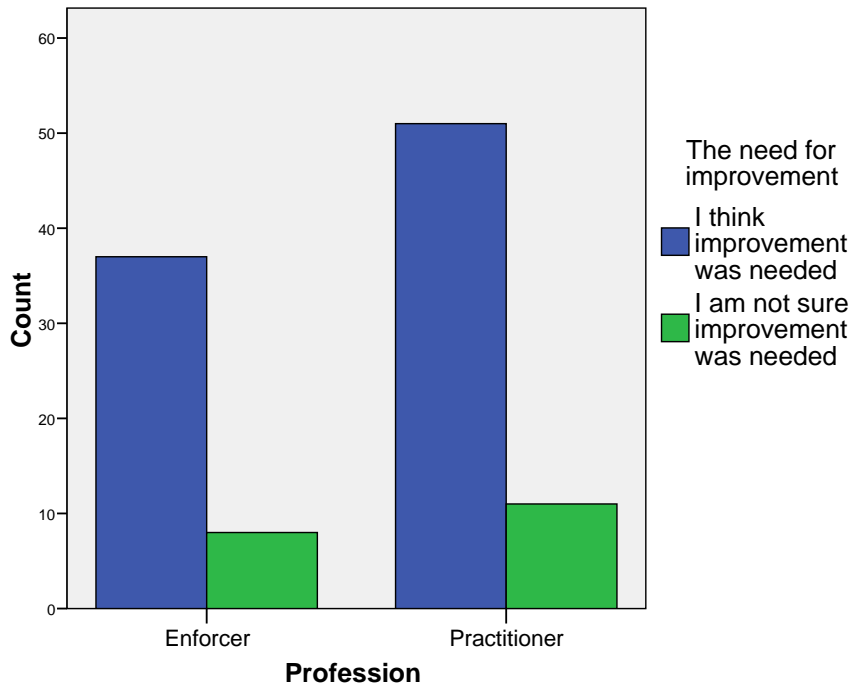


Figure 6.6: Respondents attitude to the statement ' There was a need for improvement to practice', by profession

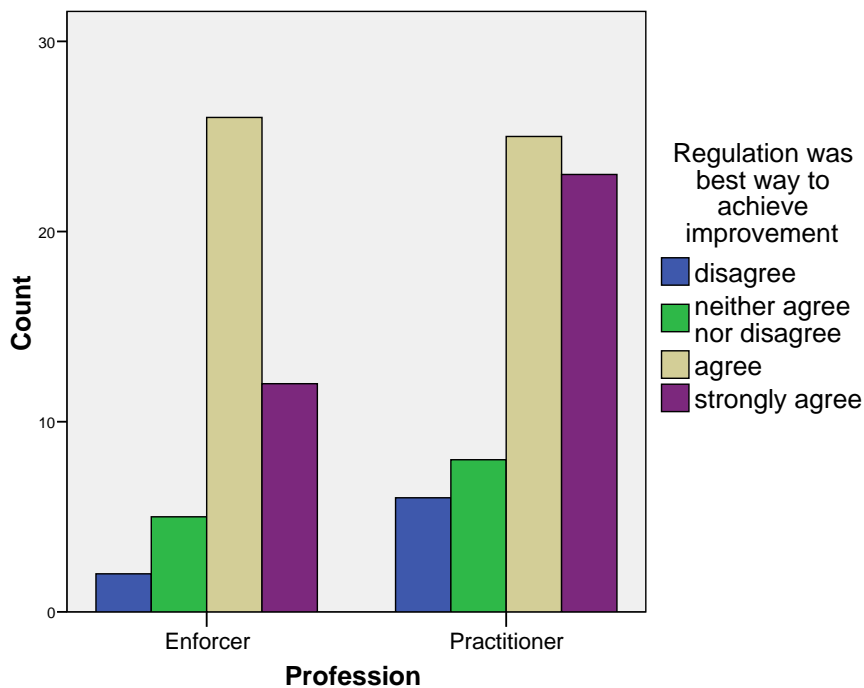


Figure 6.7: Respondents attitude to the statement 'Regulation was the best way to achieve improvement', by profession

Chi-square tests for independence indicated no evidence of an association between profession and attitude towards the need for improvement ( $\chi^2=0$ ,  $p=0.996$ ), or between profession and attitude towards regulation as the best way to achieve this ( $\chi^2=3.558$ ,  $p=0.313$ ).

Although 24% (n=25) of respondents disagreed regulation was the only way to improve practice, the citing of self-regulation and the implementation of a good practice guide as alternative approaches demonstrated respondents' awareness of alternative strategies designed to reduce risk. While such disagreement was at odds with the current international thinking on industry management (NPHP, 2002; Papameletiou, Zenie & Schwela, 2003; Armstrong, 2005), it was not considered synonymous with a lack of support for regulation.

Integrated, these findings highlight the complexity of determining who poses risk (actual or potential). In also recognising that support/ buy-in for regulation does not necessarily equate to compliance with regulation (IpsosMORI, 2007), the influence of a positive continuation decision on achieving compliance was considered undeterminable (See Figure 6.8).

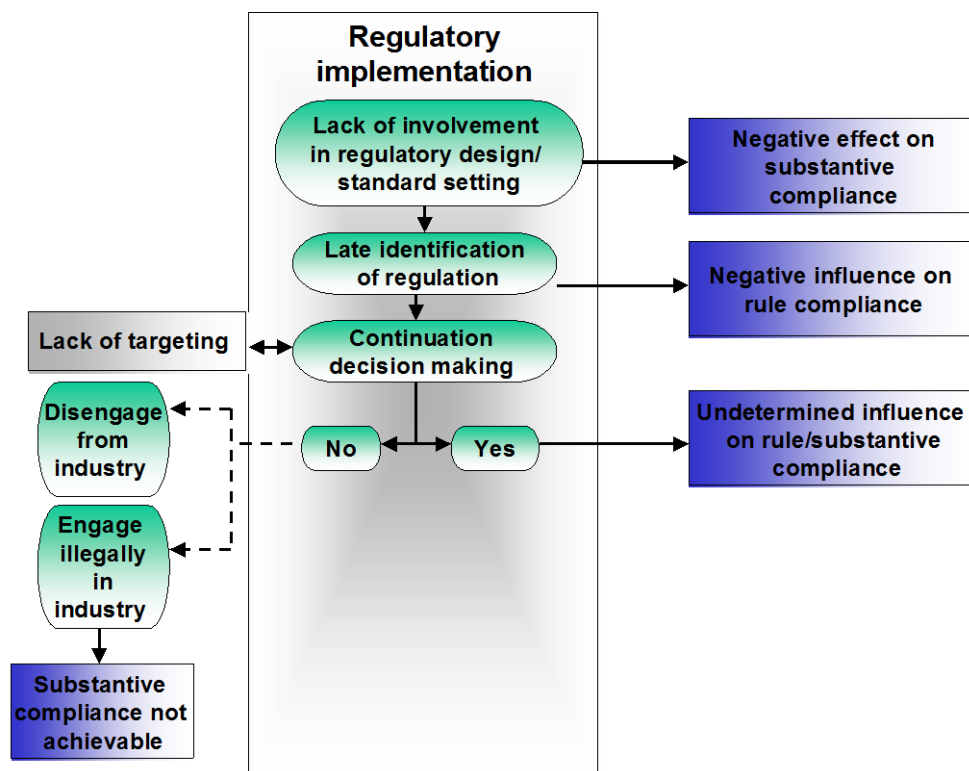


Figure 6.8: The relationship between continuation decision-making, support and compliance

#### 6.5.4 Interpretation of regulation and identification/implementation of changes

From the study data, those choosing to continue with regulatory implementation thereafter addressed the issues of regulation interpretation, identification of change and implementation of change collectively. Through review of the enforcer network 'Greater control through regulation' and the practitioner network 'Compliance decision-making ensures business preservation', the level of interpretation was found to be minimal. This was rationalised within the findings from interview data, where use of phrases such as "*black and white*", "*cut and dried*" "*even playing field*" and "*singing from the same hymn sheet*" by practitioners and enforcers highlighted their perception of regulation as prescriptive (Baldwin & Cave, 1999). Collective evidence associated this with clarity/ predictability (See Chapter 5, Figure 5.20. This was further corroborated by the 63% (n=67) of survey respondents, who agreed/ strongly agreed that regulation made clear its requirements (See Figure 6.9). These integrated findings could be construed to concur with the theoretical perspective of state-controlled regulation as rigidly "*imposing*" standards (Baldwin & Cave, 1999: 35), and resultantly with Lange's (1999) formal concept of compliance.

A Chi-square test for independence indicated no evidence of a significant association between the profession and attitude to the statement 'Regulation makes clear the requirements' ( $\chi^2=3.113$ ,  $p=0.539$ ).

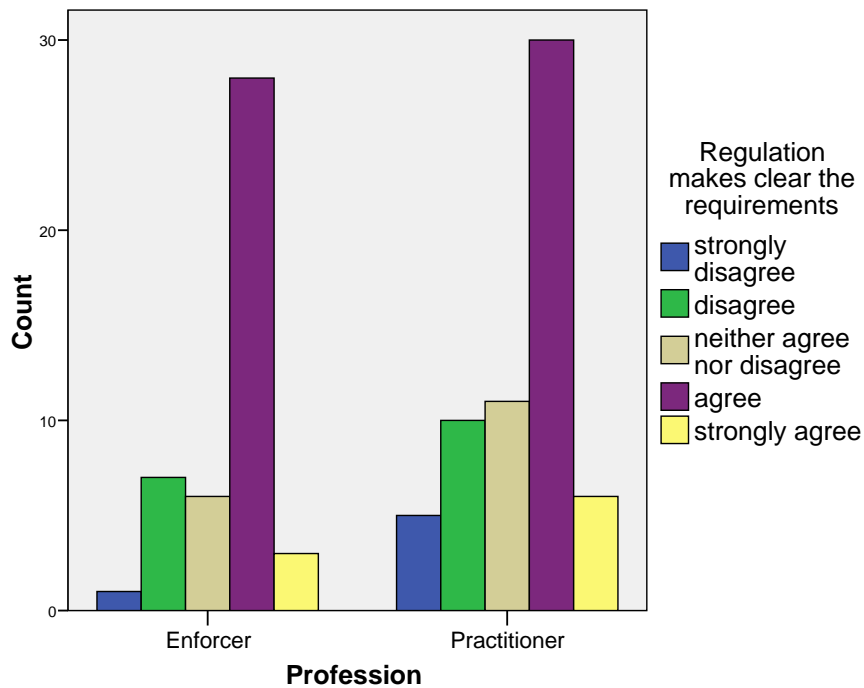


Figure 6.9: Respondents attitude to the statement 'Regulation makes clear the requirements'

However, further review of data on interpretation of the regulation; identification and implementation of changes established these were undertaken in a supportive manner between practitioners and enforcers. From enforcer interview data, this appeared a joint process towards meeting the regulatory requirements:

*“So we’ve tried to work with them...to see gradual improvement...”* (Graeme – Enforcer, page 9, line 31)

*“...we were able to put in the effort to work with them to ensure they were compliant....”* (Andy – Enforcer, page 13, line 10)

*“I always push that they come to me for advice...”* (David – Enforcer, page 13, line 15)

*“I think there was a desire to comply...the way we went about it was done...you know, an educational advisory way”* (Ian – Enforcer, page 19, line 2)

This co-operation appeared to contradict respondents’ previous description of regulation as prescriptive, instead seeming to more accurately depict regulatory negotiation (Baldwin, Hutter & Rothstein, no date). Indeed, this was further emphasised when integrated with data associated with responsiveness/ timeliness (See Chapter 5, 5.21).



Such findings were viewed as evidence of enforcers' use of the compliance paradigm, purported to secure compliance in a helpful and supportive way (Walshe, 2002; Fairman & Yapp, 2004).

In contrast however, and despite a Chi-square test for independence indicating no significant association between profession and attitude to the statement 'Support was given to aid compliance' ( $\chi^2=6.372$ ,  $p=0.173$ ), only 52% (n=32) of practitioners felt support was given to aid compliance compared to 67% (n=30) of enforcers. Such disparity highlighted the complex debate surrounding the nature of regulation (Hutter, 1997; Lange, 1999). Furthermore, the practitioner network 'Challenges to sustaining/ enhancing compliance' and the enforcer network 'Greater control through regulation' noted how practitioners and enforcers held convergent opinions on enforcers' competence to objectively and effectively assess industry/ infection control practices. These networks also identified differences of opinion in relation to the issue of consistent controls during regulatory implementation: Enforcers were confident in their ability to use regulation to exercise consistent controls across the industry, and reported no experience/ awareness of evidence of inconsistency. On the contrary, practitioners reported and gave examples of inconsistent application of the regulatory requirements.

Observational data helped to explain these divergent findings. From these data, enforcers were found to have operated consistently to secure compliance. Different interpretations of how to achieve the requirements of the regulation (as opposed to different interpretations of the regulatory requirements per se) were evident however, and this was judged to explain the perception of inconsistency held by practitioners:

*"I completed my planned observational visits last month, and all my data is now collected...have spent more than 200 hours within the industry setting, watching the practitioners interact with their equipment, their colleagues, their clients. Looking back through my notes and reflecting on what I observed, what has struck me is the consistent practice of practitioners amidst a variety of structural setting. Applying the regulation in such different environments must have been a challenge to achieving consistency. On reflection, like my experiences of infection control practice in healthcare settings, its about applying the principles..."*

*...Somehow, the prescriptive content of the Order makes application of principles problematic. For example, the need for a separate room to be provided for the waiting area....in many ways dictates the operation in a fixed premise, and makes application of this requirement difficult to mobile/ home premises. Surely the requirement should have been to ensure privacy...and left open to interpretation. Non-hand operated taps – this has resulted in a variety of types of equipment being installed, but sensor operated systems being removed....again the infection control principle seems to have gotten lost in the prescriptive nature of this type of legislation. ”*

(Extract from observational field notes, 10<sup>th</sup> June 2010)

*“...they appear to have been subject to a different level of change to meet the requirements of ‘floor to ceiling partition’ than that of (studio name). Different concept of what meets the requirements to constitute a floor to ceiling partition. A different interpretation...certainly with significant cost implications that (practitioner) has not had to bear..But arguably still a floor to ceiling partition.”*

(Extract from observational field notes, 16<sup>th</sup> May 2010)

Despite the differing perspectives on how to meet regulatory requirements, it was supposed that regulatory interpretation and identification/ implementation of changes had both positively and negatively influenced the achievement of rule compliance. Through integrated analysis and interpretation of these data with findings from observational fieldwork, failure to address key aspects of practice encompassed within the regulatory standards (as reported in the observer networks ‘Scope to enhance practice’ and ‘Observed challenges to sustaining/ enhancing compliance’) was evidenced. It was subsequently concluded that rule compliance had not been achieved as a result of regulatory interpretation and identification/ implementation of changes during regulatory implementation (See Figure 6.10):

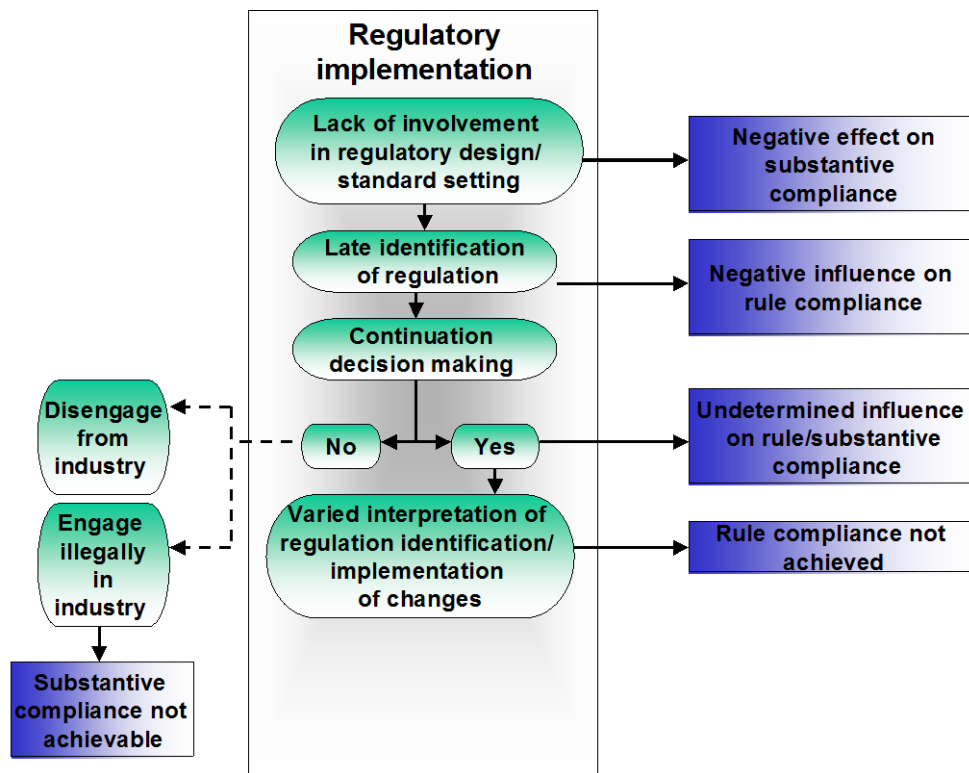


Figure 6.10: Regulatory interpretation and identification/ implementation of changes as part of regulatory implementation

From the sharing of activity between practitioners and enforcers during the interpretation of regulation and identification/ implementation of changes, evidence emerged which highlighted enforcer involvement in continuation decision-making, a decision that had earlier appeared to be made solely by the practitioner (See Figure 6.11):

*“...there was one. It wasn’t being looked at enough before regulation came in. They were using their autoclave in an incorrect fashion...not enough wash hand basins, poor ventilation...They’re not there now. We looked at what would be required to meet licensing – and between us decided the work was too great, probably best to shut up shop.”*

(Karl - Enforcer, page 20, line 26)

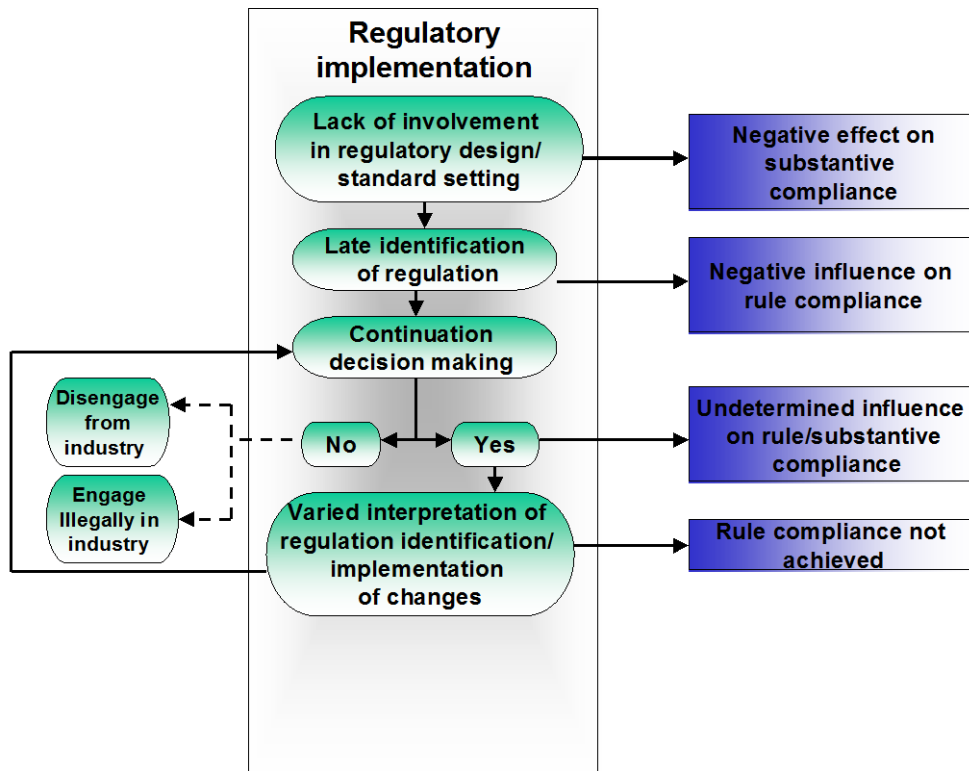


Figure 6.11: The potential influence of interpretation of regulation/ identification and implementation of changes on continuation decision-making

#### 6.5.5 Evaluation/ monitoring

Only 42% of respondents (n=45) agreed/ strongly agreed that the aim of minimising risk to health had been achieved through regulation. A further 35% (n=38) remained undecided (See Figure 6.12). Moreover, a Chi-square test for independence indicated a significant association between profession and attitude to the statement 'The aim of minimising risk to health through regulation has been achieved' ( $\chi^2=11.017$ ,  $p=0.004$ ). Practitioners were statistically more likely to have disagreed/ strongly disagreed.

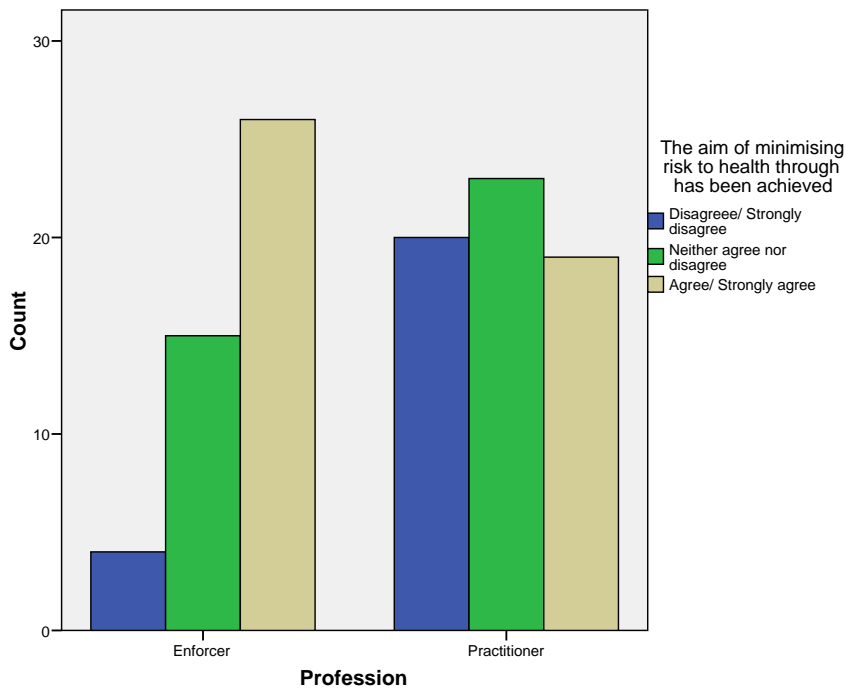


Figure 6.12: Respondents attitude to the statement ‘The aim of minimising risk to health through regulation has been achieved’, by profession

To better understand such dichotomy, these findings were interpreted alongside those from the practitioner network ‘Compliance decision-making ensures business preservation’ and the enforcer network ‘Sustaining/enhancing compliance remains a challenge’. From these data, practitioners and enforcers alike acknowledged the persistence of unregulated practice, but their attitudes to such practice differed by profession: On one hand, practitioners were frustrated and somewhat aggrieved by the lack of attention regulatory implementation had paid to this practice. Given the assertion by Walters (2001: 52) that regulation would be “*effective in minimising risk to health ...by ensuring only those practitioners willing and able to practice safely remain in practice*”, such attitude was judged conducive to the belief that regulation has not achieved its aim.

On the other, enforcers were more resigned to the fact that regulation could do little to address this issue. Instead, they determined the achievements of regulation through appraisal of the regulated practices only. To this end, and reflective of findings from this study (See Figure 6.5), the enforcers’ view was also deemed plausible.

Collectively, these interpretations offered explanation as to why practitioners held different views on the regulation's achievement of aim. Their expectations were different. Indeed, it could be argued that the collective goal of the regulation was different for each.

In evaluating change, although noted as minimal, respondents were confident in its sustainability, and lacked concern that changes would be short term (See Figures 6.13 and 6.14).

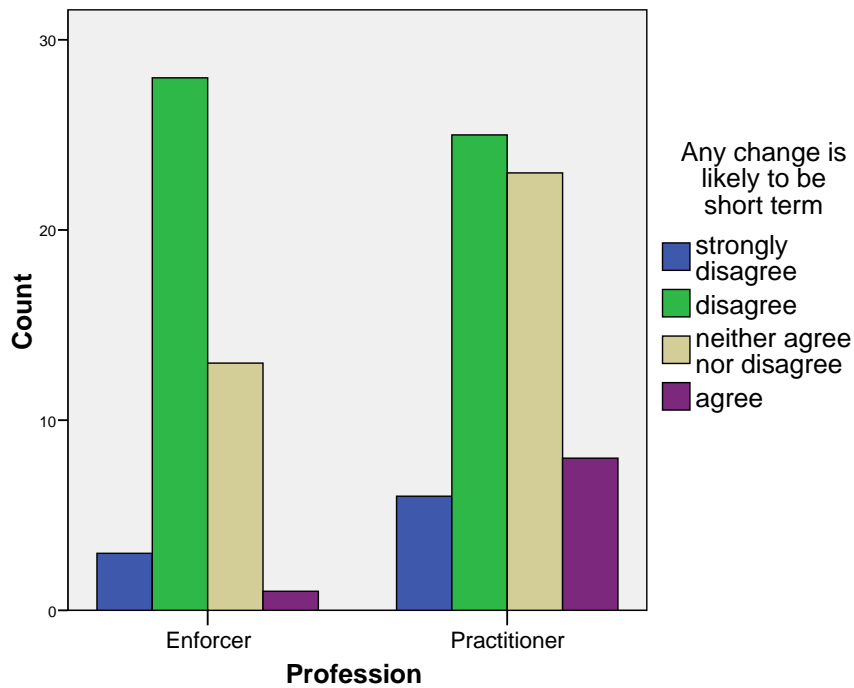


Figure 6.13: Respondents' attitude to the statement 'Any change is likely to be short term', by profession

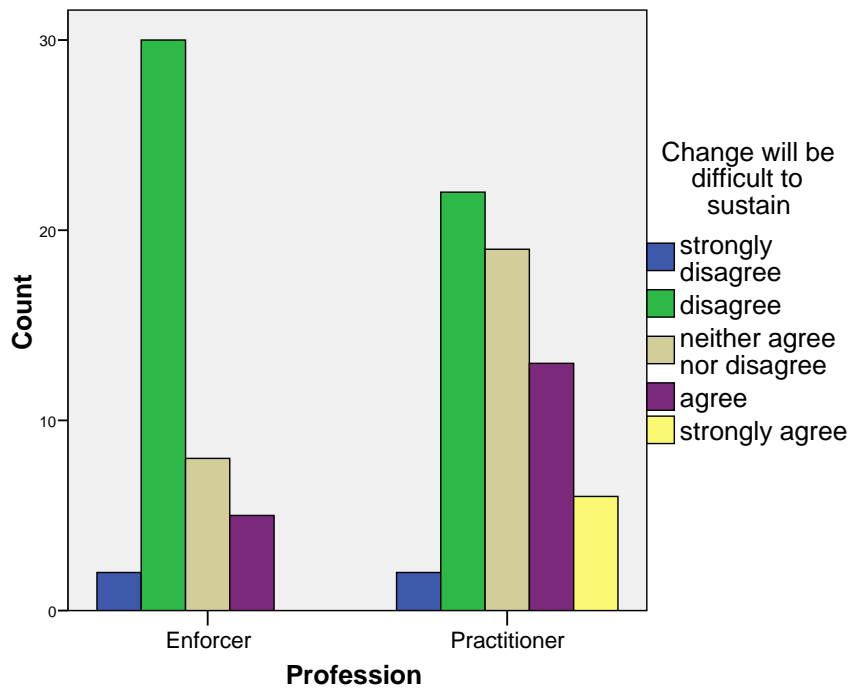


Figure 6.14: Respondents' attitude to the statement 'Change will be difficult to sustain', by profession

This could be reasoned through evidence of improved awareness of monitoring following the implementation of regulation: Prior to regulation, 65% (n=29) of enforcers and 52% (n=32) of practitioners reported awareness of monitoring through EHO visits and health and safety inspections. A Chi-square test for independence indicated no evidence of association between profession and awareness of monitoring prior to regulation ( $\chi^2=1.755$ ,  $p=0.416$ ). Since monitoring, 87% (n=39) of enforcers and 63% (n=39) of practitioners were aware of monitoring via EHO visits, programmed inspections, increased studio awareness and the licensing process itself. A Chi-square test for independence did however indicate a significant association between profession and awareness of monitoring since regulation, with practitioners statistically less likely to be aware of monitoring than enforcers ( $\chi^2=8.796$ ,  $p=0.012$ ). Furthermore, a Wilcoxon Signed Rank test revealed no statistical association in awareness of monitoring following the implementation of regulation ( $p=0.917$ ).

The lack of concern over sustainability, and improved awareness of monitoring were viewed as mechanisms to support achievement of rule compliance. However, the lack of enforcement highlighted in the enforcers network ‘Enforcer challenges to sustaining/ enhancing compliance’, coupled with the absence of industry-led approaches to monitoring justified a conclusion that current approaches to evaluation and monitoring were unlikely to promote achievement of rule compliance (See Figure 6.15). Such a conclusion reflected the findings of a study by IpsosMORI (2007), where the need for consistent and effective enforcement to assure effective risk regulation. Moreover, it concurred with findings of previous research, noting how small businesses are unlikely to carry out monitoring and evaluation unless persistently reminded by enforcers, and who believe they are compliant until told otherwise by enforcers (Fairman & Yapp, 2004). Furthermore, it was in accord with the findings of studies within Themes 5 and 6 (2.4.5 & 2.4.6).

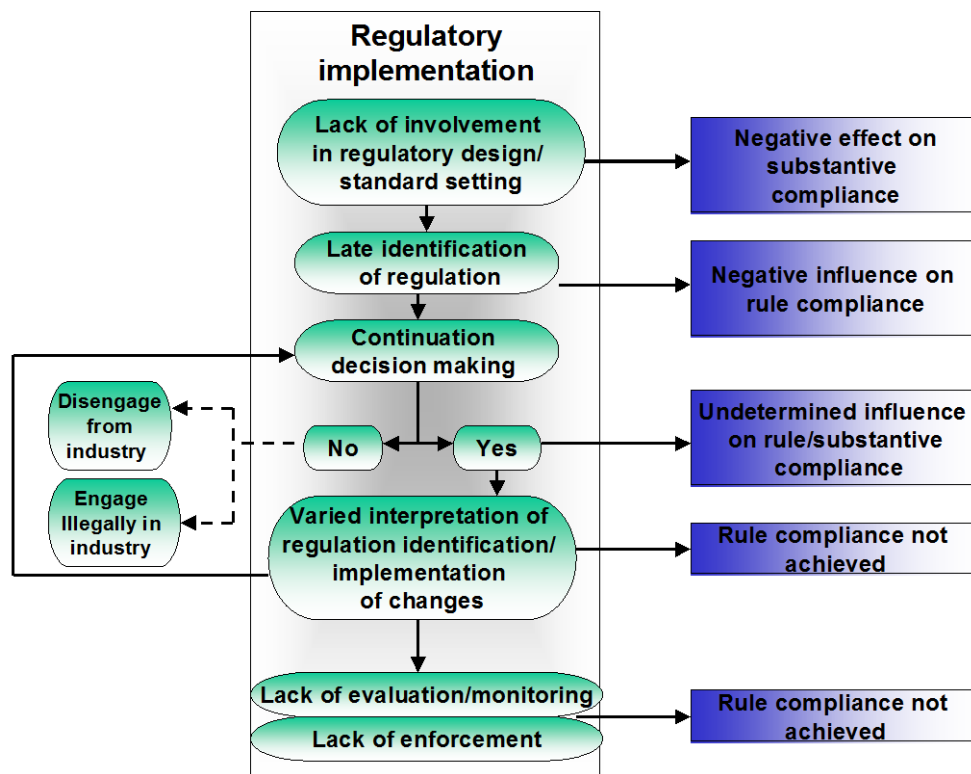


Figure 6.15: Regulatory evaluation/ monitoring as part of regulatory implementation



## **6.6 Determining the overall extent of compliance from users' experiences of regulatory implementation**

Integrative analysis of this study's mixed methods data across the stages of regulatory implementation has facilitated entwined exploration and explanation of regulatory implementation. This has achieved a greater understanding of the 'what' and 'why' of users' response to regulatory implementation than was attained through individual analyses in Chapter 5. Simultaneous interpretation of this analysis has expounded the meaning of the inter-connected data. From this, it is concluded that overall, neither substantive or rule compliance has been achieved as a result of implementing the Civic Government (Scotland) Act 1984 (Licensing of skin piercing and tattooing) Order 2006.

Such a conclusion does not however bring this work to a close. Interpretation of this study's integrative analysis has also yielded an account of why substantive and rule compliance were not achieved. Supplementing the already enhanced understanding, this further emphasises the capacity of mixed methods data to generate fuller understanding (Yin, 2006; Woolley, 2009).

### *6.6.1 Understanding activities and decision-making during regulatory implementation*

In the context of regulatory implementation and compliance, the findings from this study differed in many ways from those of previous associated research. Indeed, respondents' progress through the regulatory implementation process was shown to take an alternative path to that described by either Henson and Heasman (1998) or Fairman and Yapp (2004), the outcome being non-compliance with substantive and rule requirements of regulation. To better understand why substantive and rule compliance were not achieved, attention turned to the study findings relating to the activities/ decision-making undertaken by respondents during their progress through regulatory implementation. Differing from the findings of Fairman and Yapp (2004) (See Figure 3.2), integrative analysis of the study data identified shared activity/ decision-making across each of the step of regulatory implementation, where there had been enforcer and practitioner involvement (See Figure 6.16).

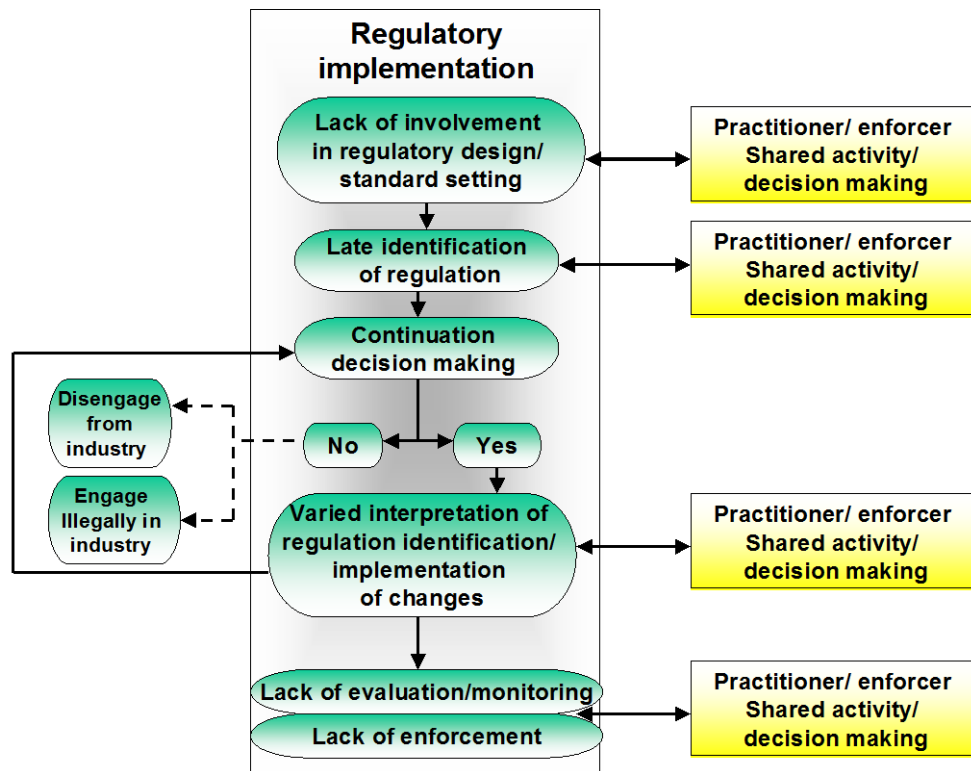


Figure 6.16: Activity/ decision making between practitioners and enforcers

This shared activity included, but very much extended beyond the compliance paradigm associated with enforcer activity, reflecting neither of the one-sided persuasive or insistent approaches associated with this paradigm (Hutter, 1997). Instead, a two-way approach to managing the activities associated with regulatory implementation emerged, identified in the data embedded within the enforcer and practitioner networks and epitomised by the training activity for enforcers by practitioners.

Within the context of current compliance theory, this shared training activity directed by the practitioner was, through individual analysis of the study's qualitative data, initially appraised as a challenge to the sustainability and enhancement of compliance. Furthermore, it could have been considered evidence of 'capture', a concept currently used within the field of regulatory compliance to illustrate the output from relationships that have become so close as to be pursuing the interests of the regulated (Hood, Rothstein & Baldwin, 2001; Baldwin & Cave, 1999).

It was however recognised that even with state-controlled regulation, the enforcer-practitioner relationship relies on a significant degree of co-operation. Indeed, Morgan and Yeung (2007) argue that the notion of capture misleadingly regards regulatory authority as void of public influence.

In this study, the extent of shared activity/decision-making was found to be associated with the specialist nature of the tattooing and cosmetic body piercing industry, where enforcers recognised their limited understanding and awareness of the industry and its practices at the point of regulatory implementation. This was shown in the quantitative findings reported in Chapter 5 (See Figure 5.13). The shift in enforcer knowledge, earlier cited as unexplainable, was now better understood through integrative analysis of qualitative interview data from enforcers and practitioners: Through these data, the lack of enforcer and practitioner confidence in enforcers' understanding of the industry during regulatory implementation became evident. Equally, so did the shared activity which served to up skill enforcers' knowledge and awareness of industry practices:

*"...if you asked them (EHOs) about hepatitis B and how is spread, they might have been struggling...there maybe was a wee bit of a knowledge gap."* (Carol, Enforcer, page 14, line 18)

*"They (EHOs) always come to us for help. If anybody's got any questions got anything, they always phone us and say..'right...I've been faced with this blah, blah, blah...what would happen if this happened?' and I'm telling him and that'd be it."* (Ed, Practitioner, page 7, line 7)

*"...they (practitioners) trained us...but you shouldn't expect the practitioners to train the enforcement officer...."* (Andy, Enforcer, page 14, line 7)

Based on the general description of compliance as 'doing what is asked', 'compliance' as a term did not accurately reflect the experiences of either practitioners or enforcers within this study. This explained why regulatory compliance - either substantive or rule compliance – was not achieved during the implementation of Civic Government (Scotland) Act 1984 (Licensing of skin piercing and tattooing) Order 2006 within Scotland's tattooing and cosmetic industry.

Indeed, from integrative analysis and interpretation of the findings from this study, it was reasoned that use of the term 'compliance' had in fact undermined the real achievements to emerge from regulatory implementation. To substantiate this deduction, reference was made to healthcare theory, specifically in relation to the healthcare construct of compliance.

#### 6.6.2 *The healthcare construct of compliance*

In 1970's UK healthcare, 'compliance' was described as the extent to which a person's behaviour was analogous with the advice given by healthcare professionals (Pollock, 2005). This emphasised the dominant philosophy underlying the therapeutic relationship at that time, where the professional was considered to know best. This was not however a new perspective. Indeed, Talcott Parsons had highlighted this viewpoint in seminal work on the 'sick role' during the 1950s (Crouch & Chapelhow, 2008).

Over the years, healthcare has debated the issue of compliance, particularly in relation to the evident dichotomy between healthcare professional advice and client/patient practice (Conrad, 1985; Donovan & Blake, 1992; Stevenson & Scrambler, 2005; Badger & Nolan, 2006). More recently, arguably through better understanding of factors affecting compliance and non-compliance, and specifically associated with a shift change in societal culture and expectation, this debate has been transformed. It has made a transition away from 'compliance' and towards a 'concordance' model (Chatterjee, 2006; Hobden, 2006).

#### 6.6.3 *From compliance to concordance*

Although reflected implicitly in the partnership practises of healthcare professionals over many years (Dowell, Williams & Snadden, 2007), the term 'concordance' and the evolution from 'compliance' to 'concordance' in healthcare has been attributed to the work of the Royal Pharmaceutical Society of Great Britain (Chatterjee, 2006). At that time, concordance was described as a means of maximising the effectiveness of medication usage through a new approach to healthcare consultation. Now it is applied to a wider range of healthcare situations.

Its essence however remains firmly rooted in the notion of 'agreement', with mutuality and respect key elements within shared decision-making (Hobden, 2006; Dowell, Williams & Snadden, 2007). From a healthcare perspective, concordance acknowledges the differences between health beliefs of professionals and patients/clients, proposing neither to be less rational or significant than the other in respect of health-associated decision-making (Dickinson, Wilkie & Harris, 1999). Upholding the philosophy of shared decision-making, concordance makes explicit the equality of partnerships (Snelgrove, 2006).

It is contested that while compliance refers to an end result, concordance describes a process – a process of discussion, negotiation and finally agreement (Clarke & Walsh, 2009). From this stance, concordance (agreement on what has to be achieved) can improve compliance (adherence with the said agreement). Unlike compliance therefore, concordance focuses not on the patient/client, but rather on the consultative experience (Snowden, 2008; Clarke & Walsh, 2009). To realise concordance, patient-centred relationships or therapeutic alliances are forged, resultantly shifting the balance of power/control (Hobden, 2006). This way, in the absence of external pressures, patients/clients are empowered with the knowledge, skills and understanding to make intentional decisions. Where agreement is not reached, 'agreement to differ' (discordance) is considered the positive outcome. Avoiding use of the judgemental term 'non-concordance', authors stress its disassociation with the term 'non-compliance' (Dowell, Williams & Snadden, 2007).

The application of the concordance model in healthcare has not however been straightforward. Segal's (2007: 81) concerns over its use as a "*more politically acceptable*" term for compliance have been borne out within healthcare literature. Found to advocate the replacement of the term 'compliance' with the term 'concordance', the literature frequently uses both terms to define the same concept – that concept being compliance.

Moreover, Segal (2007: 88) also raises concerns of over-generalisation, and the reality of its “*egalitarian rhetoric*”, citing evidence of disrespect and hostility to patients by physicians. Furthermore, the potential for concordance to generate poor health outcomes has been found to engender paternalism (Hobden, 2006). Additionally, having renounced all other models and positioned concordance as the ‘one new model’, healthcare research has found that at times, such therapeutic relationships fail to facilitate treatment planning or indeed recovery (Badger & Nolan, 2006). Countering such argument however has been the claim that the agreed outcome of a concordant consultation can be the assignment of decision-making authority to the professional (Pollock, 2005).

#### 6.6.4 *Concordance in regulatory implementation*

While explicit use of the term concordance is absent from the business of regulation, such discourse can be found implicitly within health, social and environmental policy. Interventions and strategies developed to empower the making of ‘better choices’ are now deemed ‘stewardship’ (Jochelson, 2005), and joint partnerships are now considered central to progressing population health. In fact, the action plan derived from the ‘Better Health, Better Care’ consultations (SGHD, 2007a; 2007b) offers a good example of the shift towards a mutually co-operative patient-centred approach to the delivery of healthcare in Scotland.

By exploring the definitions and rationale behind the transition from ‘compliance’ to ‘concordance’ in healthcare, it is reasoned that ‘concordance’ more appropriately describes users’ experiences of regulatory implementation within this study, where the extensive levels of shared activity/decision-making were associated with the specialist nature of industry activities. As such, rather than replacing the concept of compliance, and cognisant of the perceived prescriptive nature of state-controlled regulation, concordance is offered as a transitional concept to describe users’ immediate experiences of regulatory implementation within a specialist industry.

This intermediate step towards compliance reflects the level of discussion, negotiation and agreement required to achieve an understanding of the practices to be regulated and the context within which these are to be applied (Parker, 2000).

#### *6.6.5 Determining the extent of concordance from users' experiences of regulatory implementation*

Through integrative analysis and interpretation of the study findings in relation to the concept of concordance, consideration was then given to the extent of concordance achieved as a result of regulatory implementation within Scotland's tattooing and cosmetic skin piercing industry. Building upon the compliance definitions by Yeung (2004), concordance was sub-divided into goal concordance - agreement on the collective goal(s) of the regulation, and rule concordance – agreement on the regulatory standards to be met. The findings from this study were then integrated, analysed and interpreted in accordance with these definitions.

To determine the extent of goal concordance, the study findings were revisited and re-appraised: Enforcers and practitioners have been previously noted as agreeing on the 'black and white' nature of regulation, and shared the same lack of involvement in consultation and regulatory design. Moreover they both agreed on the need to reduce the risk to health from tattooing and cosmetic body piercing activities, recognising the inherent risk to health from industry practices while void of knowledge on actual risk. However, appraisal of this study's mixed methods findings showed a lack of agreement in respect of the efficiency of the regulation in achieving its aim, varying in their understanding of why the regulation was implemented, and reporting different perspectives and experiences on the consistency of implementation. Furthermore, they differed in their views on how unregulated practice should be managed. To this end, it was concluded that goal concordance (agreement on the collective goals of the regulation) has not been achieved through regulatory implementation.

In relation to rule concordance (agreement on the regulatory standards to be met), again the study findings were re-evaluated: Enforcers and practitioners were found to agree on the competence of practitioners to practice safely, identifying an acceptable standard of infection control practice and minimal changes as a result of regulatory implementation. In addition, they agreed on the lesser competence of enforcers and demonstrated a willingness to work together to address this deficit. Moreover, they agreed practitioners were unlikely to have made the changes associated with regulation of their own accord, recognising the historical inactivity, and seeing regulation as a catalyst for necessary change. Such confidence in industry practices was found to sit amidst omissions and deficits in standards: The issue of qualification had not been addressed, nor had the lack of aseptic technique (associated with the use of a sterile field and dressing application) and ink management. Collectively, these findings demonstrated how enforcers and practitioners had come to agree those standards to be met, highlighting that while rule compliance had not been achieved, rule concordance had been.

#### **6.7 The development of a concordance-compliance model**

Having established the extent of concordance with the Civic Government (Scotland) Act 1982 (Licensing of skin piercing and tattooing) Order 2006 within the tattooing and cosmetic body piercing industry in Scotland, a model has been proposed to reflect the relationship between regulatory implementation, concordance and compliance within a specialist industry (See Figure 6.17). The development of this model emphasises the wider implications for this study's integrative findings, analysis and interpretation in terms of regulatory compliance/concordance, and their contribution as new knowledge.



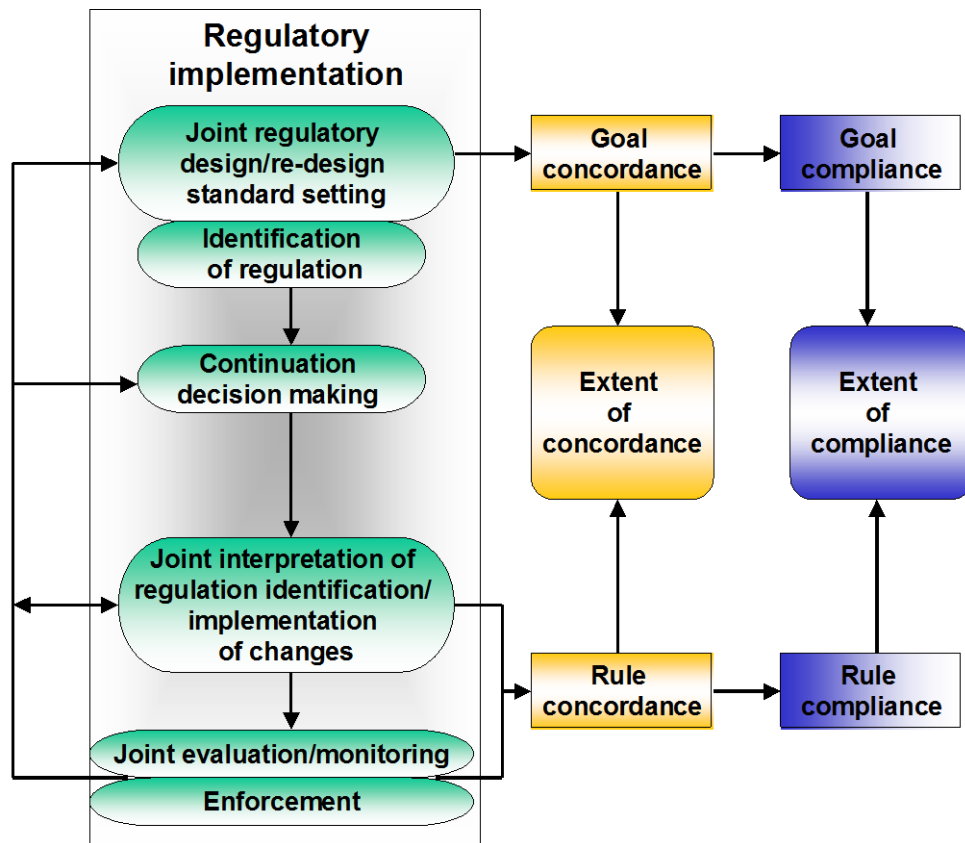


Figure 6.17: Specialist Industry Concordance-Compliance Model

The model depicts both concordance and compliance as outputs of the cyclical process that is regulatory implementation. Within this model it is evident that both concordance and compliance are potential end results, while their achievement is viewed as part of a process. This contributes new knowledge to the ongoing debate on the issue of compliance as a process or event. Equally it contributes new knowledge to the ongoing debate on the issue of concordance as a process or end result.

The model also contributes new knowledge on how to maximise compliance with the collective goals of regulation: The model clearly indicates user involvement (in this case, the users are practitioners and enforcers) in the design and re-design of regulation as critical to the achievement of goal compliance. Reflecting upon the principles of good regulation (BRTF, 2000), this in itself cannot be considered new knowledge. The model does however contribute to new knowledge by highlighting the need to achieve goal concordance if goal compliance is ultimately to be achieved.

As such, the model stresses the insufficiency of user involvement, which fails to engage all users in mutual and co-operative partnership at regulatory design/re-design stage. Such involvement promotes establishment and agreement on the need and aim of regulation. This new knowledge has significant implications for the use of regulation to minimise risk (be that risk to health or otherwise), where the achievement of compliance is considered a measure of regulatory effectiveness (WHO, 2008).

In addition, the model highlights how shared engagement in regulatory interpretation, identification and implementation of changes, and evaluation and monitoring/enforcement supports continuation decision-making, and facilitates the re-design of regulation. While reflecting previous awareness of the significance of enforcement to promote compliance (Oberdorfer et al., 2004; Worp et al., 2006), it offers new knowledge on the significant role of practitioners in ongoing monitoring and evaluation of practices, and the impact of this on the process of re-design, as well as on the achievement of both goal and rule concordance and compliance.

## **6.8 Chapter 6 summary**

This chapter has focused on the integrative analysis and interpretation of this study's data, making use of the study's conceptual framework to focus this activity: Critical appraisal of respondents' experiences of regulatory design; identification of regulation; continuation decision making; interpretation of regulation and identification/implementation of change; and regulatory evaluation/ monitoring, illustrated how each had influenced the achievement of compliance. Collectively, this appraisal was able to determine the extent of compliance with regulation, concluding that neither substantive or rule compliance had been achieved.

Further exploration of the data associated with enforcer and practitioner activity/decision-making during regulatory implementation determined 'compliance' as inappropriate in describing users' experiences of regulatory implementation. To better understand these experiences, attention was turned to healthcare theory of compliance.

Through critique of the concept of healthcare compliance, it was deduced that the concept of 'concordance' better explained users' experiences of regulatory implementation. From review of the study findings on this basis, it was concluded that while goal concordance was not achieved, rule concordance had been achieved. Complementing rather than conflicting with existing literature (Fairman & Yapp, 2004; Yapp & Fairman, 2005; 2006), these findings are offered as an alternative outcome to that of 'compliance' with regulatory implementation. From these conclusions, a specialist industry concordance-compliance model was presented. As well as serving to explain the process by which practitioners and enforcers implement new regulation/meet regulatory requirements within a specialist industry, its significant contribution to new knowledge was emphasised.

# Chapter 7

## Conclusions

## **7.1 Introduction and overview**

Regulation, an accepted population-based approach to securing population-wide reduction in risks to health (WHO, 2000), was the policy option selected by the Scottish Government to address concerns over risk to health from tattooing and cosmetic body piercing activities in Scotland. In 2006, the Civic Government (Scotland) Act 1982 (Licensing of skin piercing and tattooing) Order 2006 was implemented, with the aim of minimising risk to health through consistent controls.

Once implemented, regulation requires to be monitored for ongoing fitness for purpose and effectiveness (BRTF, 2000). While fitness for purpose can be determined by the extent of risk reduction, effectiveness can be established on the basis of targeting, coverage and compliance (WHO, 2008).

## **7.2 Background**

In Chapter 1 of this thesis, I outlined the history of tattooing and cosmetic body piercing and its management, setting in context the background from which the implementation of the Civic Government (Scotland) Act (Licensing of skin piercing and tattooing) Order 2006 emerged. I followed this by reviewing, in Chapter 2, literature associated with regulatory and infection control compliance. Organised thematically, across six related topics, I systematically reviewed the literature within each theme utilising the principles of rapid evidence assessment. From this review process, I ascertained gaps in existing knowledge and developed a pertinent purpose statement, encompassing my study intent, research questions and study objectives. My study intent was to determine the extent of regulatory compliance with the Civic Government (Scotland) Act 1982 (Licensing of skin piercing and tattooing) Order 2006 in Scotland's tattooing and cosmetic body piercing industry.

Making my study's theoretical underpinning explicit, I dedicated Chapter 3 of this thesis to the development of a conceptual framework, borne out of the theory relating to regulatory implementation and compliance. This I considered would be of key benefit to the process of integration across my research study, a key element of good mixed methods studies (Yin, 2006). Consequently, I returned to this framework later in my research development.

In Chapter 4, I gave account of my study design and methodology, noting pragmatism as the worldview underpinning my study and concurrent mixed methods as the chosen design to support its implementation. In identifying three approaches to data collection - semi-structured questionnaire, focused interview and non-participant observation - I proffered the claim that collectively these would offer a fuller understanding of regulatory compliance than each in isolation. I regarded this a key tenet of my chosen design, and a contributing factor in producing good quality mixed methods research (Woolley, 2009).

Chapter 5 made use of the opportunity afforded by concurrent mixed methods study design to report my study findings sequentially (Creswell & Plano-Clark, 2007). Presenting my qualitative and quantitative results successively, I began to establish a picture of how and why practitioners and enforcers had experienced implementation of the Civic Government (Scotland) Act 1982 (Licensing of skin piercing and tattooing) Order 2006, identifying some factors with the potential to influence the extent of compliance with this regulation. These factors included support; motivations; systems and processes; relationships; competence; expectation and experience, reflecting much of the previous literature on this topic (Baldwin, Hutter & Rothstein, no date). While able to draw the conclusion that compliance was influenced by these factors, analysis of the datasets consecutively did not offer robust conclusions on the extent of this influence. Although a justifiable conclusion, I did not consider this adequately addressed my study intent/research questions. Nor did I perceive it as sufficiently novel to be presented as new knowledge.

In Chapter 6, I undertook integrative analysis of my data, utilising my data collectively as 'mixed methods data'. This facilitated integrative interpretation, the outcome of which was an overall greater understanding of regulatory compliance. Thus, I was able to construct the more substantiated conclusion that rule concordance with regulatory standard requirements had been achieved through regulatory implementation of the Civic Government (Scotland) Act 1982 (Licensing of skin piercing and tattooing) Order 2006 within the tattooing and cosmetic body piercing industry in Scotland. To illustrate the relationship between regulatory implementation, concordance and compliance, I have devised a model for use within specialist industries such as the tattooing and cosmetic body piercing industry, where extensive levels of shared activity/decision-making during regulatory implementation were found necessary to promote understanding of those practices to be regulated and the context within which these were to be applied (Parker, 2000). The model was explained in the context of its contribution to new knowledge.

Having provided summation of the preceding chapters in this thesis, I will use the remainder of Chapter 7 – 'Conclusions' to bring this work to its completion. In doing so, I will account for those aspects of my study, which may be deemed study limitations and offer a reflexive account of the learning and experience gained in its undertaking. Thereafter I will outline what I consider are the implications for policy and practice from my study findings and conclusions; make recommendations; and describe my dissemination strategy. Finally, I will tender my concluding comments.

### **7.3 Study limitations**

Hemingway and Brereton (2009: 7) state "*all research has flaws*". In this respect, they argue researchers must be prepared to acknowledge such flaws - or study limitations - and judge objectively the impact of these on their study's findings, conclusions and/or recommendations. In determining the limitations of this study, its quality has been critically appraised using the same approach adopted in Chapter 2 – 'Literature review' (Moule et al., 2003). The intention is to present the identified study limitations impartially.

### 7.3.1 *Limitations in reviewing the literature*

The decision to undertake a rapid evidence assessment instead of a full systematic review may be considered a limitation of this study, where setting criteria to include only articles published in English from 2000 onwards had the potential to omit relevant literature. It is however recognised as a robust and replicable approach to review of literature, affording systematic and rigorous synthesis (Hemingway & Brereton, 2009). Moreover, its ability to offer a comprehensive review of literature in a more concise time frame justified its use in this study.

### 7.3.2 *Limitations in methodology*

The decision to adopt a concurrent mixed methods design, including focused interviews and non-participant observation may have limited the study findings, by offering less/no scope to probe for additional information during the data collection phase of the study. In addition, the concurrent design, where all data were gathered prior to analysis removed the opportunity to engage in an iterative approach to data analysis and interpretation during this period. As an inherent limitation associated with concurrent design, it may be deemed to have compromised the depth of qualitative data gained from interviews/observation. In terms of impact on the overall study findings/conclusions, the range of data collected for this study, coupled with the iterative process during the study's mixed methods data analysis and interpretation has minimised any effect. In addition, the limitations must be set against the advantages of this study design, such as its ability to collect multiple independent data sources, to collect these in parallel, and to collect them without subjective influence from each other (Creswell, 2009).

The small sample size in practitioner interviews/observation and the questionnaire response rate may be considered limitations of this study. The study's sampling and data collection approaches were rationalised within the methodology chapter of this thesis (Chapter 4, 4.10.3 & 4.10.5). Furthermore, the questionnaire response rate was previously appraised (Chapter 5, 5.4.2). Collectively, this provides adequate justification to dismiss such a claim.



Similar to the comment above, the decision to collect mixed methods data through a range of approaches, and subsequently subject this to integrative analysis and interpretation has further served to negate the effects of both these issues.

While there was no available alternative, the use of a newly devised/previously unvalidated questionnaire may be considered a study limitation (Parahoo, 2006). However, the efforts to promote validity and reliability of this tool, as detailed in Chapter 4 (4.10.5) are deemed to have addressed this potential concern. Also, while the use of self-reported information may be considered a study limitation (Van de Mortel, 2008), the multiple approaches to data collection, and inclusion of an observational element to data collection (Chapter 4, 4.10.5) counteract the doubt raised over self-reported data in this study.

#### **7.4 Reflexive account**

While considered complex and difficult to define, the essence of personal and epistemological reflexivity is to explore how the beliefs, values, views and attitudes influence and inform research (Lipp, 2007). This concept is eloquently and simplistically expressed through the recent work of an artist, exhibiting at Chatelershaut Country House, Lanarkshire, who wrote across an exhibition wall:

*“Every writer seeks his/her own voice. It will be shaped by many other voices: the voices of other writers, the people he grew up with, the sounds and voices he hears around him in the world.”*  
(David Almond, 2009, no page)

##### *7.4.1 Personal reflexivity*

In reflecting upon the work to complete this study, I feel in tune with Almond's (2009) artwork. In trying to find my own way through the research process, I have sought, as a novice researcher, guidance and advice from a range of others. I have acknowledged the contribution of these family members, friends and colleagues in the writing of this thesis.

While recognising my own and their contribution to the construction of meaning, I feel I have now found my own voice – and presented this in the words and numbers that form the construct of this thesis. In turn, by demonstrating the need for a range of media to tell a complete story, I feel I have gone full circle, and returned to where I began (Chapter 4, 4.3). The notion of ‘turning back’ on myself (Lipp, 2007) has been played out in the undertaking of this research. Having continually reflected upon my own attitudes, actions and assumptions – and indeed those of others (Parahoo, 2006), I am now acutely aware of the concept of ‘interpretation’, how I have sculpted my research and how my research has sculpted me. I have not found it easy to step back and reflect upon my own characteristics – indeed, it has taken for me to complete this research to recognise the existence of some of these characteristics.

I recognised early in this research journey that my desire was to research something practical in a practical way, leading me to consider the philosophy of pragmatism to underpin my study (Maxcy, 2003). From a ‘what works’ approach, it has helped me to progress this work, focusing on the research questions, and avoiding the need to choose between positivist/postpositivist and constructivist approaches. When progress was slow, when questionnaires did not return completed, when work got in the way of study and study got in the way of family, reading around, I was able to take a pragmatic stance, standing back and reflecting on where I had come from, and the eventual (potential) outcome. This has helped me persist with the process. Taking such a pragmatic approach has shaped the type of research I have chosen to partake in - a mixed methods study. I strongly believe that to see the world completely requires art and science, text and number. Pragmatism afforded me the opportunity to entwine my interest in both art and science. Reviewing the outcome of my decision, I feel vindicated in my choice of study design, and consider the understanding gleaned from my findings and interpretation far exceed that obtainable from a single data approach.

I was also quick to become aware of my own prejudices to the practice of tattooing and cosmetic body piercing, choosing initially to develop this study on the basis of an evidenced risk to health from these activities. Ashamedly, it took for me to attend a public health conference, where I was challenged to defend this assumption, to realise its existence. This taught me a lot about the value of reflexivity and helped me avoid such bias in the ongoing development, implementation and appraisal of my study. It taught me about the need to stay in the moment - to be, for example, a researcher when I am a researcher. In the multi-tasking world I live within, this has been a challenge. Being a registered healthcare professional operating under a professional code (NMC, 2008), this has been more challenging. Positively, it has been beneficial for my own personal debate, helping me learn how to find a middle ground - a pragmatic solution.

The experience at the public health conference (June 2007) also made me acutely aware of the concerns I had in undertaking my planned research, and the dilemma I faced in possibly offending a respondent through the identification and publication of poor knowledge, attitudes, or behaviour. As a nurse however, I was again conscious of my professional code of conduct (NMC, 2008), and my experience as a communicator, educator and advice giver – and used these characteristics to ensure tact and diplomacy in the conduct of this study. In addition, the research ethics process supported me through this. I did however remain concerned about the impact negative research findings could have on my career as an academic and clinician. To this end, I engaged actively in dissemination of my work in progress, making myself known to those involved in the design and implementation of the regulation associated with this work. I thereafter relied on my knowledge of the research process and methodology to avoid bias from lack of objectivity. Indeed this pendulum movement between objective and subjective stances helped me undertake the practical elements of this study.

The study has changed me – I am now more of a pragmatist (or at least more aware of my pragmatic tendencies) than previously. Taking a more balanced approach to all things in life, this I feel has made me a better person – in all aspects of my personal and professional life.

Engagement in personal reflexivity (and the use of a reflexive journal during this period of researching) has helped me to gain clarity surrounding my personal characteristics, to be self-aware, and to recognise how this awareness impinges on my research, now and in the future.

#### 7.4.2 *Epistemological reflexivity*

Epistemological reflexivity requires engagement with research process and methodology associated questions. Argued by some as compulsory in qualitative research, there is now recognition of its need within quantitative research too (Lipp 2007). This facilitates the seeing of objective views subjectively, and the examination of those more subject aspects of research design such as the choice of topic, question or method. From this perspective, the need for and appropriateness of reflexivity in mixed methods is justified. I have reflected on what I have learned and experienced from undertaking this research. I formed views and opinions on:

*My approach to scholarly writing:* As a mixed methods study I debated the issue of writing in the first or third person. By drawing on available literature, I feel that my decision to use both approaches in the writing of this work, showing sensitivity to both academic traditions, has been justified. Initially I had difficulty reading my 'combined first-third person' work. I read the work of Sandelowski (2003) and Webb (1992) to help me understand and address this. I reviewed the guidance by Webb (2002) on readability, and thereafter, rationalised where I would use each approach. This, I feel, has improved the ease with which my thesis can be read.

*The influence of my approach to reviewing the literature, and subsequent research intent, questions and objectives on what I have found:* Developing a themed approach to structure, and rapid evidence assessment approach to review was the right decision for this work for it supported robust appraisal of available literature, and identified gaps in the literature. Having arisen from these gaps, I feel my research intent, questions and objectives were appropriately aligned, affording me opportunity to make a significant contribution to new knowledge.

The approach to literature review also focused me on a more specific aspect of the topic reviewed, and helped in the structuring of subsequent thesis chapters.

*Whether I could have designed this study differently, and the impact this would have had on the results:* I consider the use of mixed methods (underpinned by pragmatism) to have been appropriate, and agree with the literature that this contributed to a fuller understanding of my study topic (Yin, 2006; Woolley, 2009). It would have been difficult to gain as full an understanding from a single source of data, particularly given the reported limitations of self-reported information (van de Mortel, 2008) – this I feel has been demonstrated by the differing outputs from Chapters 5 and 6 of this work. Reflecting upon the writing of Muncey (2006) and my own research journey, the decision to undertake mixed methods research, collecting both qualitative and quantitative data no longer seems like a ‘bridge too far’. Indeed, the range of data collected was found to maximise achievement of my study intent. My decision to design the study as concurrent mixed methods, with focused interviews and non-participant observation, did impact on the depth of qualitative data and scope to think iteratively, these being noted as limitations of this study. The breadth of data collected countered this, and as such, I do not feel these limitations impacted significantly on the results achieved.

*The weighting associated with qualitative and quantitative data collection, and its influence on the study outcomes:* While well-designed concurrent mixed methods studies are considered equally weighted in terms of the collection of qualitative and quantitative data collection (Creswell & Plano-Clark, 2007), the nature of each source of dataset in this study made it difficult for me to determine ‘equal’. Furthermore, the advice and guidance available on what defines ‘equal’ and how this is to be achieved is limited. In designing this study, I was conscious of the multiple strands of qualitative being collected (through interviews and observation), in contrast to the single quantitative data source. Moreover, I was aware that large numbers of participants engaged with the quantitative data were not replicated in the qualitative datasets.

To 'square this round peg', I endeavoured to depict equal weighting of qualitative and quantitative aspects of this work, and how their cumulative effect was greater than their component parts through my writing. I have evidenced the success of this approach through the creation of a word cloud from the text of my thesis (See Figure 7.1).



Figure 7.1: Thesis word cloud – a diagrammatic depiction of ‘weighting’ within this research study

Diagrammatically giving prominence to those words used more frequently, this word cloud has represented 'qualitative' and 'quantitative' similarly sized – that is 'equal' in weighting. 'Mixed' and 'methods' appear larger, indicating their more frequent use within my text, and arguably serving as evidence of mixed methods as greater than the sum of 'qualitative' and 'quantitative'. Furthermore, the focus of the study is highlighted through the significant size of the word 'compliance'. Despite the significant contribution of the word 'concordance' to this work, its size within the word cloud reflects the timing of its appearance within the text.

*My effect as the researcher during data collection:* Through reflexivity I was aware of the effect I might have on the participants and the potential this could have in influencing my findings. Memos on interview data, field notes, and the use of a personal journal promoted my reflexivity, and offered me an audit trail of notes, which I could re-visit and identify any assumptions I might have made. In addition, the regular supervision sessions with my supervisory team provided a wealth of opportunity to reflect upon the development and implementation of this work, to explore and explain my thought processes and to learn from the experiences of others. Such academic discussion and debate helped me to avoid the potential bias I could have introduced to this study. In addition, through reflexivity, my ability to carry out the interviews without interjecting improved with practice, and the focused nature of these helped me to ask only the planned questions. As a non-participant observer, I remained aware of the effect I might have on those being observed, and took what action I could to address this. To this end, I spent extensive/multiple periods of time in industry settings to minimise any effect, positioning myself inconspicuously and wearing casual clothing to help me blend into the environment.

*How I managed the issue of quality:* Using a newly designed questionnaire, I engaged in measures to ensure validity and reliability. Equally, credibility and trustworthiness were addressed for the interview data through member validation (Chapter 4). Moreover, the integrative analysis and interpretation (Chapter 6) within this study promoted it to what must be considered as a high quality study.



*The need for an underpinning theory to support the development of my work:* I feel the decision to develop a conceptual framework was appropriate for this study. As well as avoiding the concerns of an atheoretical study, it supported integration of other aspects of the research process, and increased the legitimacy of my study as mixed methods. Of greater importance was the influence of this underpinning theory on my ability to promote this study as one, which offers a significant contribution to new knowledge.

*How I used my data to make interpretations and draw conclusions:* I feel it was the right decision to undertake individual analysis of the study data and follow this with integrative and analysis and interpretation. While it presented a danger of repetition, it enabled me to clearly see the different level of understanding from each approach, and to explicitly evidence the development of more robust conclusions during use of the data collectively as mixed methods data. As such, this approach facilitated the answering of my mixed methods research questions, and highlighted the value of mixed methods research as greater than the sum of its individual parts.

## **7.5 Implications for policy and practice**

With its roots steeped in pragmatism, the need for this research emerged from a 'real world' concern (Gray, 2004), seeking to find answers to/understanding of a very practical issue – that being compliance with regulation in Scotland's tattooing and cosmetic body industry. Resultantly, its findings have very tangible implications not only for those working operationally within these disciplines, but also those functioning strategically within the fields of environmental, health, and social sectors.

Specifically, within the field of tattooing and cosmetic body piercing, the potential impact of this work in managing inherent risk to health from tattooing and cosmetic body piercing activity, the perceived risk to health from unregulated/illegal tattooing and cosmetic body piercing activity as well as actual and potential risk to health from wider risk-related behaviour is far-reaching.

Indeed, the proposed compliance-concordance model offers the industry a mechanism to formally inform and enhance current understanding of industry practices. Without this voice, the potential remains for perceived risks from industry practices to persist, for poor quality research with implications for professional credibility to go unchallenged, and for the industry's rightful place as skilled practitioners to remain an aspiration. The implications for practice are reflected in the personnel targeted by the dissemination strategy below.

Perhaps more significantly are the broader reaching policy and practice implications of this work's findings, analyses, interpretations and conclusions. These offer scope to influence how practitioners and policy makers across many disciplines view regulation. Indeed, they offer an alternative way to look at the use of regulation, the design of regulation, the implementation of regulation and the monitoring/evaluation of regulation. The findings offer the potential to transform regulatory implementation in its widest sense. While traditionally aiming to promote and maximise regulatory compliance, the findings of this study introduce concordance as a desirable and acceptable aim/outcome of state-controlled regulation. While at this stage of development the Specialist Industry Compliance-Concordance Model considers concordance as an alternative output, it is not inconceivable to suggest that, through time and with further research, concordance may become the preferred option. Reflecting upon the shift from compliance to concordance within healthcare, this is not proffered as an easy option. However, the emergent governmental trends in health and social care towards patient/client-centred care (SGHD, 2007b), coupled with the current national and international approaches to quality improvement and patient safety (WHO, 2011; SGHD, 2010a, SGHD, 2010b) acknowledge the role of service users as vital to service improvement, viewing no single person as the expert, instead harnessing service users' expertise.

Rather than aiming for compliance, and persistently achieving sub-optimal outcomes (Crouch & Chapelhow, 2008), the findings of this research present an opportunity to make regulation work more effectively. Adopting concordance as the primary output of regulation would however require a shift in the philosophy underpinning regulatory implementation, taking the concept of prescription to that of participation. This extends beyond existing debates on whether regulation is prescriptive or negotiated (Lange, 1999; Baldwin, Hutter & Rothstein, no date), necessitating a shift in the balance of power away from the regulator towards greater partnership working. The findings of this study demonstrate how this partnership working, with shared decision-making is already operating in practice. It may not be too great a chasm to cross. This also requires a shift in the fundamental assumption of regulator as expert. Again, the findings of this work suggest the regulator-regulatee relationship becoming much more of an alliance currently exists in practice, although the balance of power had not necessarily shifted.

Finally, the findings have implications for the principles of good regulation, which are currently very much situated within a power-based relationship. Reflecting upon these principles – proportionality, accountability, consistency, transparency and targeting (BRTF, 2000), a concordant approach through shared decision-making must be considered fundamental to their achievement.

## 7.6 Recommendations

It is recognised that researchers, enthused by the attachment and familiarity of their study findings, can easily go beyond the evidence from their study data to draw exaggerated conclusions and make inappropriate recommendations. Hemingway and Brereton (2009: 7) advise recommendations should be “*based firmly on the quality of the evidence presented*”. To this end, the following recommendations are offered:

### 7.6.1 Recommendations for future research

1. Undertake research to establish how the specialist industry concordance-compliance model translates into other regulated industries, determining the effectiveness of current approaches to regulation, and establishing the extent of concordance with existing regulation.
2. Undertake research to determine the impact of concordant approaches to regulatory implementation, to establish their impact on the management of risk and achievement of collective regulatory goals.
3. Undertake research to establish the extent of actual risk to health from licensed tattooing and cosmetic body piercing in Scotland, to inform and enhance current and future tattooing and cosmetic body piercing industry management. In particular, this research should consider unregulated/illegal tattooing and cosmetic body piercing in Scotland, its potential impact on regulated activity, and its relationship with risk to health.

### 7.6.2 Recommendations for policy and practice

1. The Scottish Government should review the current philosophy of regulatory implementation, to consider concordance and compliance as potential outputs.
2. The Scottish Government should formalise concordance as an output of regulation within specialist industries, thereafter monitoring its impact on the management of risk and achievement of collective regulatory goals.
3. The Scottish Government should undertake a detailed review of the regulation associated with the tattooing and cosmetic body piercing industry, to ensure its fitness of purpose, in line with the principles of ‘good regulation’.
4. Scotland’s Local Authorities, in conjunction with the tattooing and cosmetic body piercing industry should establish local/national systems of practitioner-enforcer communication, through which effective evaluation, monitoring and enforcement (and re-design, where applicable) of regulation associated with the industry can be achieved.

## **7.7 Dissemination**

Research dissemination offers the chance to learn (Gerrish & Lacey, 2006). Despite this, researchers often fail to disseminate the knowledge generated through their research into practice. Personal, contextual and organisational factors all contribute to what is recognised as a historic and ongoing problem (Parahoo, 2006). To address this issue, strategies have been devised to increase the use of research in practice, some of which will be utilised to ensure the sharing of this study's findings with relevant personnel. Given the efforts to undertake ongoing dissemination of the work of this study during its development and implementation (See Appendix 7), a network of contacts and venues has been established. This forms the base for ongoing/future dissemination.

University, Local Authority and Health Board meetings/seminars will be exploited to present the study findings as well as to explore future avenues for research and funding opportunities. Building upon the four articles already published from this work, efforts will be made to secure future publication in relevant academic and professional journals. In addition, further abstracts will be submitted to up-and-coming national and international conferences with the anticipation of presenting the findings of this work as an oral or poster presentation to a wider audience. In addition to previous conference attendance (See Appendix 7), an abstract has been accepted for the 7<sup>th</sup> Mixed Methods Conference, University of Leeds in July 2011.

Conscious that the internet offers a web/online resource and the scope for extensive exposure, consideration will be given to its use in promoting further dissemination. Discussion with colleagues and fellow researchers will be undertaken to explore making part or this entire thesis freely available to internet users, this being the selected option taken by fellow researchers in recent years (Macduff, 2009).

## **7.8 Concluding comments**

The research documented within this thesis was undertaken, in partial fulfilment of the requirements of Edinburgh Napier University, for the award of Doctor of Philosophy. It has determined that rule concordance with the required standards within the Civic Government (Scotland) Act 1982 (Licensing of skin piercing and tattooing) Order 2006 has been achieved.

In reaching this conclusion, a concordance-compliance model, applicable to specialist industries, has been developed. This diagrammatically illustrates the relationship between regulatory implementation, concordance and compliance. Offering a fuller understanding of regulatory compliance than previously existed, the findings, analyses and conclusions presented within this work represent a significant contribution to new knowledge within the field of regulatory compliance/concordance.

# References

Abiona, T.C., Balogun, J.A., Adefuve, A.S. & Sloan, P.E., 2010. Body art practices among inmates: Implications for transmission of bloodborne infections. *American Journal of Infection Control*, **38** (2) pp121-129.

Adami, M.F. & Kiger, A., 2005. The use of triangulation for completeness of purposes. *Nurse Researcher*, **12** (4) pp19-29.

Anaf, S. & Sheppard, L.A., 2007. Mixing research methods in health professional degrees: Thoughts for undergraduate students and supervisors. *The Qualitative Report*, **12** (2) pp184-192.

Anderson, R.R., 2006. Commentary: Tattoos and body piercing. *Journal of the American Academy of Dermatology*, **55** (3) p422.

Argyrous, G., 2005. *Statistics for research*. 2<sup>nd</sup> edition. London: Sage Publications.

Armitage, G. & Hodgson, I.J., 2004. Using ethnography or qualitative methods to investigate medication errors: a critique of a published study. *Journal of Research in Nursing*, **9** (5) pp2-9.

Armstrong, M.L., 2005. Tattooing body piercing and permanent cosmetics: a historical and current view of state regulations, with continuing concerns. *Journal of Environmental Health*, **67** (8) pp38-43.

Armstrong, M.L. & Kelly, L., 2001. Tattooing body piercing and branding are on the rise: perspectives for school nurses. *The Journal of School Nursing*, **17** (1) pp12-13

Atkinson, R. & Flint, J., 2001. Accessing hidden and hard to reach populations: snowball research strategies. *Social Research Update*, Issue 33. Accessed from <http://sru.soc.surrey.ac.uk/SRU33.html> on 12th January 2007.

Attride-Stirling, J., 2001. Thematic networks: an analytic tool for qualitative research. *Qualitative Research*, **1** (3) pp385-405.

Aveyard, H., 2007. *Doing a literature review in health and social care: A practical guide*. Berkshire: Open University Press.

Badger, F. & Nolan, P., 2006. Concordance with antidepressant medication in primary care. *Nursing Standard*, **20** (52) pp35-40.

Baiche, B., Walliman, N. & Ogden, R., 2006. Compliance with building regulations in England and Wales. *Structural Survey*, **24** (4) pp279-299.

Baldwin, R., Hutter, B. & Rothstein, H., no date. *Risk regulation, management and compliance: A report to the BRI Inquiry*. London: The London School of Economics and Political Science.

Baldwin, R. & Cave, M., 1999. *Understanding regulation: Theory, strategy and practice*. Oxford: Oxford University Press.



Barclay, S., Todd, C., Finlay, I., Grande, G. & Wyatt, P., 2002. Not another questionnaire! Maximising the response rate, predicting non-response and assessing non-response bias in postal questionnaire studies of GPs. *Family Practice*, **19** (1) pp105-111.

Barnett, J.R., 2009. Double protection: reaching accord on the ethical conduct of child observational research. *Environmental Health Perspectives*, **117** (8) ppA354-A357.

Barnett, J., Ejidokun, T., Greaves, L., Haris, M., Vosper, D. & Duncan, S., 2003. Body piercing and tattooing – body adornment at a price? *British Journal of Infection Control*, **4** (3) pp12-16.

Begley, C., 1996. Using triangulation in nursing research. *Journal of Advanced Nursing*, **24** (1) pp122-128.

Benjamins, L.J., Risser, W.L., Cromwell, P.F., Feldman, J., Bortot, A.T. & Eissa, M.A., Nguyen, A.B., 2006. Body art among minority high school athletes: Prevalence, interest and satisfaction: Parental knowledge and consent. *Journal of Adolescent Health*, **39** (6) pp933-935.

Benson, A. & Dickson, W.A., 2006. ABC of wound healing – burns. *British Medical Journal*, **332** (7542) pp649-652.

Better Regulation Commission, 2006. *Risk, responsibility and regulation – whose risk is it anyway?* October. London: Better Regulation Commission.

Better Regulation Task Force, 1999. *Self-regulation interim report*. October. London: Better Regulation Commission.

Better Regulation Task Force, 2000. *Principles of good regulation* (leaflet). London: Better Regulation Commission.

Better Regulation Task Force, 2004. *Avoiding Regulatory Creep*. October. London: Better Regulation Commission.

Better Regulation Task Force, 2005. *Better Regulation Task Force Annual Report for 2004/5*. London: Better Regulation Commission.

Bolton, M., 2004. *The impact of regulation on voluntary organisations*. London: National Council for Voluntary Organisations.

Bond, S. & Lacey, A., 2006. Sources of funding and support for research. **In:** Gerrish, K. & Lacey, A., (ed) 2006. *The research process in nursing*. Oxford: Blackwell Publishing. Chapter 4 pp43-52.

Bone, A., Ncube, F., Nichols, T. & Noah, N.D., 2008. Body piercing in England: a survey of piercing at sites other than earlobe. *British Medical Journal*, **336** (7658) pp1-7.

Braithwaite, R., Robillard, A., Woodring, T., Stephens, T. & Arriola, K.J., 2001. Tattooing and body piercing among adolescent detainees: Relationship to alcohol and other drug use. *Journal of Substance Abuse*, **13** (1) pp5-16.

- Brannen, J. & Halcomb, E.J., 2009. Data collection in mixed methods research. In: Andrew, S. & Halcomb, E.J., (ed) 2009. *Mixed methods research for nursing and the social health sciences*. Oxford: Blackwell Publishing. Chapter 5 pp67-83.
- Braverman, P.K., 2006. Body art, tattooing and scarification. *Adolescent Medicine Clinics*, **17** (3) pp505-519.
- Breitmayer, B., Ayres, L. & Knafl, K.A., 1993. Triangulation in qualitative research: Evaluation of completeness and confirmation purposes. *Journal of Nursing Scholarship*, **25** (3) pp237-243.
- Brewer, J. & Hunter, A., 1989. *Foundations of multi-method research: Synthesising styles*. Thousand Oaks, California: Sage Publications.
- Brooker, C. & Waugh, A., 2007. *Foundations of nursing practice: fundamentals of holistic care*. Edinburgh: Mosby.
- Brown, L., 2010. *Observational Field Research*. Accessed from <http://www.socialresearchmethods.net/tutorial/Brown.htm>. On 3rd April 2010.
- Bryman, A., 2007. Barriers to integrating quantitative and qualitative research. *Journal of Mixed Methods Research*, **1** (1) pp8-22.
- Callejo, R.M., Nacinovich, F., Prieto, M.A., Lambert, S., Vizzotti, C., Villar, H., Szejfman, M., Navia, D. & Stambouljian, D., 2010. *Moraxella lacunata* Infective Endocarditis after Tattooing as Confirmed by 16S rRNA Gene Sequencing from Heart Valve Tissue. *Clinical Microbiology Newsletter*, **32** (1) pp6-7.
- Casey D. & Murphy, K., 2009. Issues in using methodological triangulation in research. *Nurse Researcher*, **16** (4) pp40-55.
- Castel, A.D., Reed, G., Davenport, M.G., Harrison, L.H. & Blythe, D., 2007. College and university compliance with a required meningococcal vaccination law. *American Journal of College Health*, **56** (2) pp119-127.
- Celegon, L., Mastrangelo, G., Mazzoleni, F., Majori, S., Baldoon, T. & Xodo, C., 2010. Body art in 4277 Italian secondary school adolescents: Associations with personal and family characteristics. *Clinical Research and Methods*, **42** (4) pp273-279.
- Center for Disease Control (CDC), 2006. CDCs position on tattooing and HCV infection. Accessed from <http://www.cdc.gov/ncidod/diseases/hepatitis/c/tattoo.htm> on 3rd December 2007.
- Chalmers, C., 2009a. Charting the existence and approaches to management of the tattooing and body piercing industry – a historical overview. *Journal of Infection Prevention*, **10** (3) pp102-105.

Chalmers, C., 2009b. Appraising the need for tighter control over the practices of the tattooing and body piercing industry. *Journal of Infection Prevention*, **10** (4) pp134-137.

Chalmers, C., 2009c. Debating the appropriateness and effectiveness of regulation as a mechanism to manage and control the risk to health from tattooing and body piercing activities. *Journal of Infection Prevention*, **10** (5) pp180-183.

Chan M.F., Ho, C.A. & Day, M.C., 2007. Investigating the knowledge attitudes and practice patterns of operating room staff towards standard and transmission based precautions: results of a cluster analysis. *Journal of Clinical Nursing*, **17** (8) pp1051-1062.

Chartered Institute of Environmental Health, 2007. Tattoo parlours face licence shock. *Environmental Health News*. 23<sup>rd</sup> February 2007. Accessed from <http://www.cieh.org/ehn/ehn3.aspx?id=3376> on 19<sup>th</sup> August 2007.

Chatterjee, J.S., 2006. From compliance to concordance in diabetes. *Journal of Medical Ethics*, **32** (9) pp507-510.

Chiang, W., Wang, H., Chen, S., Chen, L., Yao, Y., Wu, G., Ko, C., Yang, C., Tsai, M., Hsai, C., Su, C., Chen, S. & Ma, H., 2008. Lack of compliance with basic infection control measures during cardiopulmonary resuscitation – are we ready for another epidemic? *Resuscitation*, **77** (3) pp356-362.

Cho, J. & Trent, A., 2006. Validity in qualitative research revisited. *Qualitative Research*, **6** (3) pp319-340.

Christie, B., 2009. Fear of minimum alcohol pricing spreading to other countries led to opposition in Scotland. *British Medical Journal*, **339** (5339) p1333.

Clarke, V. & Walsh, A., 2009. *Fundamentals of Mental Health Nursing*. Oxford: Oxford University Press.

Cole, R.J. & Sommers, P., 1981. Business and government regulation: a theory of compliance decisions. *Journal of Contemporary Business*, **10** pp143-153.

Conner, M. & Norman, P., 2005. Predicting health behaviour: A social cognition approach. **In:** Conner, M., Norman, P., (ed) 2005. *Predicting health behaviour*. 2<sup>nd</sup> Edition. Maidenhead: Open University Press. Chapter 1 pp1-27.

Conner, M. & Sparks, P., 2005. Theory of planned behaviour and health behaviour. **In:** Conner, M., Norman, P., (ed) 2005. *Predicting health behaviour*. 2<sup>nd</sup> Edition. Maidenhead: Open University Press. Chapter 5 pp170-222.

Conrad, P., 1985. The meaning of medications: another look at compliance. *Social Science and Medicine*, **20** (1) pp29-37.

Costa, J., Mossialos, E., 2006. Which policies effectively enable smoking cessation? Evidence from the European Union. *International Journal of Social Economics*, **33** (1) pp77-100.

Coyle, J. & Williams, B., 2000. An exploration of the epistemological intricacies of using qualitative data to develop a quantitative measure of users views of healthcare. *Journal of Advanced Nursing*, **31** (5) pp1235-1243.

Creswell, J.W., 2009. *Research design: Qualitative , quantitative and mixed methods approaches*. 3<sup>rd</sup> edition. London: Sage publications.

Creswell, J.W. & Tashakkori, A., 2007. Exploring the nature of research questions in mixed methods research (Editorial). *Journal of Mixed Methods Research*, **1** (3) pp207-211.

Creswell, J. W. & Plano Clark, V.L., 2007. *Designing and conducting mixed methods research*. London: Sage Publications.

Creswell, J.W., Plano Clark, V.L., Gutmann, M.L. & Hanson, W.E., 2003. Advanced mixed methods research designs. In: Tashakkori, A. & Teddlie, C., (ed) 2003. *Handbook of mixed methods in social and behavioural research*. London: Sage publications. Chapter 8 pp209-240.

Crotty, M., 1998. *The foundations of social research: Meaning and perspectives in the research process*. London: Sage Publications.

Crouch, S. & Chapelhow, C., 2008. *Medicines Management: A Nursing Perspective*. Harlow: Pearson Education.

Cummings, K. M., Becker, M. H. & Maile, M. C., 1980. Bringing the models together: An empirical approach to combining variables used to explain health actions. *Journal of Behavioral Medicine*, **3** (2) pp123–145.

Davies, H.T.O. & Crombie, I.K., 2009. What are confidence intervals and p-values? *What is...? Series*. April. 2<sup>nd</sup> edition. London: Hayward Medical Communications pp1-8.

Dawood, M., 2008. Sampling rare populations. *Nurse Researcher*, **15** (4) pp35-41.

Denton, D., 2001. *Body art, cosmetic therapies and other special treatments: the Barbour index*. London: Chadwick House Group Ltd.

Department of Health (DH), 2004. *Local Government Act 2003: Regulation of cosmetic piercing and skin colouring businesses*. London: The Stationery Office.

Dickinson, D., Wilkie, P., Harris, M., 1999. Taking medicines: concordance is not compliance. *British Medical Journal*, **319** (7212) p787.

Di Folco, P., 2004. *Skin art*. Paris: Fitway Publishing.

- Donaldson, L.J., Donaldson, R.J., 2003. *Essential Public Health*. 2<sup>nd</sup> Edition. Plymouth: Petroc Press.
- Donovan, J.L. & Blake, D.R., 1992. Patient non-compliance: deviance or reasoned decision-making? *Social Science and Medicine*, 34 (5) pp507-513.
- Dowell, J., Williams, B. & Snadden, D., 2007. *Patient centred prescribing: seeking concordance in practice*. Oxford: Radcliffe Publishing.
- Drage, L., Philips, K. & Ecker, P., 2009. An outbreak of Mycobacterium chelonae infections in association with tattoos. *Journal of American Academy of Dermatology*, 60(suppl).
- Dubose, J. & Pratt, J.W., 2004. Victim of fashion: Endocarditis after oral piercing. *Current Surgery*, 61 (5) pp474-477.
- Edelman, L.B., Petterson, S., Chambliss, E. & Erlanger, H.S., 1991. Legal ambiguity and the politics of compliance: Affirmative action officers' dilemma. *Law & Policy*, 13 (1) pp73-97.
- Elliott M. Antman, E.M., Lau, J., Kupelnick, B., Mosteller, F. & Chalmers, T.C., 1992. A Comparison of Results of Meta-analyses of Randomized Control Trials and Recommendations of Clinical Experts: Treatments for Myocardial Infarction. *Journal of the American Medical Association*, 268 (2) pp240-248.
- Endacott, R. & Botti, M., Clinical research 3: Sample selection. *Accident and Emergency Nursing*, 15 (4) pp234-238.
- EPPI-Centre, 2007. *EPPI-Centre methods for conducting systematic reviews*. March. London: EPPI-Centre, Social Science Research Unit, Institute of Education, University of London.
- Evans, D. & Pearson, A., 2001. Systematic reviews: gatekeepers of nursing knowledge. *Journal of Clinical Nursing*, 10 (5) pp593-599.
- Fairman, R. & Yapp, C., 2004. Compliance with food safety legislation in small and micro-businesses: enforcement as an external motivator. *Journal of Environmental Health Research*, 3 (2) pp40-48.
- Faugier, J. & Sargeant, M., 1997. Sampling hard to reach populations. *Journal of Advanced Nursing*, 26 (4) pp790-797.
- Ferguson, H., 1999. Body piercing. *British Medical Journal*, 319 (7225) pp1627-1629
- Field, A., 2003. *Questionnaire design: Designing a questionnaire*. Accessed from [http://www.statisticshell.com/designing\\_questionnaires.pdf](http://www.statisticshell.com/designing_questionnaires.pdf) on 14th June 2007.
- Forbes, G.B., 2001. College students with tattoos and piercings; motives, family experiences, personality factors and perceptions by others. *Psychological Reports*, 89 (3) pp774-786.

- Forster, J.L., Lazovich, D., Hickle, A., Sorensen, G. & Demierre, M.F., 2006. Compliance with restrictions on sale of indoor tanning sessions to youth in Minnesota and Massachusetts. *Journal of American Academy for Dermatology*, **55** (6) pp962-967.
- Freyenberger, B., 1998. *Tattooing and body piercing: decision making for teens*. Accessed from <http://www.vh.org/Patients/IHB/Derm/Tattoo/index.html> on 5th December 2006.
- Fuller, C.W. & Vassie, L.H., 2004. *Health and safety management: Principles and best practice*. Harlow: Prentice Hall.
- Gammon, J., Morgan-Samuel, H. & Gould, D., 2008. A review of the evidence for sub-optimal compliance of healthcare practitioners to standard/universal infection control precautions. *Journal of Clinical Nursing*, **17** (2) pp157-167.
- Gerrish, K. & Lacey, A., 2006. Communicating and disseminating research. **In:** Gerrish, K. & Lacey, A., (ed) 2006. *The research process in nursing*. Oxford: Blackwell Publishing. Chapter 30 pp477-490.
- Ghorpade, A., 2002. Inoculation (tattoo) leprosy: a report of 31 cases. *Journal of the European Academy of Dermatology and Venereology*, **16** (5) pp494-499.
- Golafshani, N., 2003. Understanding reliability and validity in qualitative research. *The Qualitative Report*, **8** (4) pp597-607.
- Gold, M., Schorzman, C.M., Murray, P.J., Downs, J. & Tolentino, G., 2005. Body piercing practices and attitudes among urban adolescents. *Journal of Adolescent Health*, **36** (4) pp352e15-21.
- Golden-Biddle K. & Locke, K., 1993. Appealing work: An investigation of how ethnographic texts convince. *Organisation Science*, **4** (4) pp595-616.
- Goodwin, A.H., Wells, J.K., Foss, R.D. & Williams, A.F., 2006. Encouraging compliance with graduated driver licensing restrictions. *Journal of Safety Research*, **37** (4) pp343-351.
- Goudey, R. & Thompson, S., 1997a. Knowledge of and attitudes to infection control of tattooists at registered premises in Victoria 1994. *Australian and New Zealand Journal of Public Health*, **2** (1) pp17-22.
- Goudey, R. & Thompson, S., 1997b. Evaluation of infection control in registered tattooing premises in Victoria 1994. *Australian and New Zealand Journal of Public Health*, **21** (1) pp22-28.
- Greene, J.C., 2007. *Mixed methods in social inquiry*. San Francisco: Wiley and Sons Ltd.

- Greene, J.C. & Caracelli, V.J., 2003. Making paradigmatic sense of mixed methods practice. In: Tashakkori, A. & Teddlie, C., (ed) 2003. *Handbook of mixed methods in social and behavioural research*. London: Sage publications. Chapter 3 pp91-110.
- Gray, D.E., 2004. *Doing research in the real world*. London: Sage Publications.
- Grigg, N.P. & Williams, J., 2000. Issues relating to the enforcement and de-regulation of Part V of the weights and measures Act 1985: An exploratory study involving Trading Standards Officers in Scotland. *British Food Journal*, **102** (8) pp562-584.
- Gunningham, N. & Kagan, R.A., 2005. Regulation and business behavior. *Law and Policy*, **27** (2) pp213-218.
- Gurau, C., Ranchhod, A. & Gauzente, C., 2003. To legislate or not to legislate: a comparative exploratory study of privacy/personalisation factors affecting French, UK and US websites. *Journal of Consumer Marketing*, **20** (7) pp652-664.
- Halcomb, E.J. & Andrew, S., 2005. Triangulation as a method for contemporary nursing research. *Nurse Researcher*, **13** (2) pp71-82.
- Hanif, J., Frosh, A., Marnane, C., Ghufloor, K., Rivron, R. & Sandu, G., 2005. Lesson of the week: High ear piercing and the rising incidence of perichondritis of the pinna. *British Medical Journal*, **322** (7291) pp906-907.
- Harden, A., 2010. Mixed methods systematic reviews: Integrating quantitative and qualitative findings. *FOCUS Technical Brief* Number 25. National Center for the Dissemination of Disability Research.
- Harden, A. & Thomas, J., 2005. Methodological issues in combining diverse study types in systematic reviews. *International Journal of Social Research Methodology*, **8** (3) pp257-271.
- Harris, S.A. & Nicolai, L.A., 2010. Occupational exposure in emergency medical service providers and knowledge of and compliance with universal precautions. *American Journal of Infection Control*, **38** (2) pp86-94.
- Hartman, J.M., Forsen, J.W., Marks, S., Wallace, M.S. & Neely, J.G., 2002. Tutorials in clinical research Part IV: Recognising and controlling bias. *Laryngoscope*, **112** (1) pp23-31.
- Hawkins, K., 1984. *Enforcement and environment*. Oxford: Oxford University Press.
- Health Protection Scotland (HPS), 2006. Licensing of skin piercing and tattooing in Scotland. *HPS Weekly Report*, **40** (3). Accessed from <http://www.hps.scot.nhs.uk/ewr/article.aspx> on 27th June, 2007.
- Heckathorn, D., 1997. Respondent-driven sampling: a new approach to the study of hidden populations. *Social Problems*, **44** (2) pp174-199.

- Hellard, M., Aitken, C., Macintosh, A., Ridge, A. & Bowden, S., 2003. An investigation of hepatitis C and commercial body piercing in Victoria. *American Journal of Infection Control*, **31** (4) pp215-225.
- Hellard, M.E., Aitken, C.K. & Hocking, J.S., 2007. Tattooing in prisons – not such a pretty picture. *American Journal of Infection Control*, **35** (7) pp477-480.
- Hemingway, P. & Brereton, N., 2009. What is a systematic review? *What is...? Series*. April. 2nd.ed. London: Hayward Medical Communications pp1-8.
- Henson, S. & Heasman, M., 1998. Food safety regulation and the firm: understanding the compliance process. *Food Policy*, **23** (1) pp9-23.
- Hobden, A., 2006. Concordance: a widely used term, but what does it mean? *British Journal of Community Nursing*, **11** (6) 257-260.
- Hood, C., Rothstein, H. & Baldwin, R., 2001. *The government of risk: understanding risk regulation regimes*. Oxford: Oxford University Press.
- Howe, K.R., 1988. Against the quantitative-qualitative incompatibility thesis. *Educational Researcher*, **17** (8) pp10-16.
- Hudspith, J. & Rayatt, S., 2004. ABC of burns: first aid and treatment of minor burns. *British Medical Journal*, **328** (7454) pp1487-1489.
- Hutter, B., 1997. *Compliance: Regulation and environment*. Oxford: Clarendon Press.
- Hutter, B. & Amodu, T., 2008. *Risk regulation and compliance: Food safety in the UK*. London: The London School of Economics and Political Science.
- Inter-departmental Liaison Group on Risk Assessment (ILGRA), 2002. The precautionary principle: Policy and application. London: ILGRA
- Ioannidis, J.P.A., 2005. Why most published research findings are false. *Public Library of Science Medicine*, **2** (8) e124.
- Ipsos MORI, 2007. *Businesses' perceptions of regulation*. March. London: Ipsos MORI Social Research Institute.
- Iribhogbe, P.E. & Osime, C.O., 2008. Compliance with seat belt use in Benin City, Nigeria. *Prehospital Disaster Medicine*, **23** (1) pp16-19.
- Ivankova, N.V. & Creswell, J.W., Stick, S., 2006. Using mixed methods sequential explanatory design: from theory to practice. *Field Methods*, **18** (1) pp3-20.
- Jick, T.D., 1979. Mixing qualitative and quantitative methods: Triangulation in action. *Administrative Science Quarterly*, **24** (4) pp602-611.



- Jochelson, K., 2005. *Nanny or steward? The role of government in public health*. October. London: King's Fund.
- Johnson, M., Long, T. & White, A., 2001. Arguments for British pluralism in qualitative health research. *Journal of Advanced Nursing*, **33** (2) pp 243-249.
- Johnson, B. & Turner, L.A., 2003. Data collection strategies in mixed methods research. **In**; Tashakkori, A. & Teddlie, C., (ed) 2003. *Handbook of mixed methods in social and behavioural research*. London: Sage publications. Chapter 11 pp297-320.
- Jootun, D., McGhee, G. & Marland, G.R., 2009. Reflexivity: promoting rigour in qualitative research. *Nursing Standard*, **23** (23) 42-46.
- Keene, W.E., Markum, A.C. & Samadpour, M., 2004. Outbreak of *Pseudomonas aeruginosa* infections caused by commercial piercing of upper cartilage. *Journal of American Medical Association*, **291** (8) pp981-985.
- Kelley, K., Clark, B., Brown, V. & Sitzia, J., 2003. Good practice in the conduct and reporting of survey research. *International Journal for Quality in Health Care*, **15** (3) pp261-266.
- Kember, D. & Leung, Y.P., 2008. Establishing the validity and reliability of course evaluation questionnaires. *Assessment and Evaluation in Higher Education*, **33** (4) pp341-353.
- Kermode, M., Jolley, D., Landkham, B., Thomas, M.S. & Holmes, W., 2005. Compliance with universal/standard precautions among health care workers in rural north India. *American Journal of Infection Control*, **33** (1) pp27-33.
- Kish, L., 1991. Taxonomy of elusive populations. *Journal of Official Statistics*, **7** (3) pp339-347.
- Khundkar, R. & Wilson, P.A., 2009. Basal cell carcinoma at the site of a nasal piercing. *Journal of Plastic Reconstructive and Aesthetic Surgery*, **64** (4) pp557-558.
- Koch, G., 2008. *Basic Allied Health Statistics and Analysis*. London: Cengage Learning.
- Kretzer, E.K. & Larson, E.L., 1998. Behavioural interventions to improve infection control practices. *American Journal of Infection Control*, **26** (3) pp245-253.
- Kuhn, T.S., 1970. *The structure of scientific revolutions*. Chicago: University of Chicago Press.
- Kuwahara, M., 2005. *Tattoo: an anthropology*. New York: Berg Publishers.
- Lacey, A., 2006. The research process. **In**: Gerrish, K. & Lacey, A., (ed) 2006. *The research process in nursing*. Oxford: Blackwell Publishing. Chapter 2 pp19-30.

- Lange, B., 1999. Compliance Construction in the Context of Environmental Regulation. *Social & Legal Studies*, **8** (4) pp549-567
- Lathlean, J., 2006. Qualitative analysis. In: Gerrish, K., Lacey, A., (ed) *The research process in nursing*. Oxford: Blackwell Publishing. Chapter 27 pp417-434.
- Laudan, L., 1971. Towards reassessment of Comte's 'methode positive'. *Philosophy of Science*, **38** (1) pp35-53.
- Laumann, A.E. & Derick, A.J., 2006). Tattoos and body piercing in the United States: A national data set. *Journal of the American Academy of Dermatology*, **55** (3) pp413-421.
- Lee, R.M., 1993. *Doing research on sensitive topics*. London: Sage.
- Leichter, H., 1986. Lives, liberty and seat belts in Britain: lessons for the United States. *International Journal of Health Services*, **16** (2) pp213-226.
- Lick, S.D., Edozie, S.N., Woodside, K.J. & Conti, V.R., 2005. Streptococcus viridans endocarditis from tongue piercing. *Journal of Emergency Medicine*, **29** (1) pp57-59.
- Lipp, 2007. Developing the reflexive dimension of reflection: a framework for debate. *International Journal of Multiple Research Approaches*, 1 (1) pp18-26.
- Lopez-Jornet, P., Carnacho-Alonso, F. & Pons-Fuster, J.M., 2005. A complication of lingual piercing: A case report. *Oral Surgery Oral Medicine Oral Radiology Endodontology*, **99** (2) ppE18-19.
- Lopez-Jornet, P. & Camacho-Alonso, F., 2006. Oral and dental complications of intra-oral piercing. *Journal of Adolescent Health*, **39** (5) pp767-9.
- Lowes, L. & Prowse, M.A., 2001. Standing outside the interview process? The illusion of objectivity in phenomenological data generation. *International Journal of Nursing Studies*, **38** (4) 471-480.
- McGaghie, W.C., Bordage, G. & Shea, J.A., 2001. Problem statement, conceptual framework and research question. *Academic Medicine*, **76** (9) pp923-924.
- McKenna, H., Hasson, F. & Keeney, S., 2006. Surveys. In: Gerrish, K., Lacey, A., (ed) 2006. *The research process in nursing*. Oxford: Blackwell Publishing. Chapter 17 pp260-273.
- McLane, C., Chenelly, S., Sylwestrak, M.L. & Kirchhoff, K.T., 1983. A nursing practice problem: failure to observe aseptic technique. *American Journal of Infection Control*, **11** (5) pp178-182.
- MacLeod, T.M. & Adeniran, S., 2004. An unusual complication of penile piercinh: A report and literature review. *The British Association of Plastic Surgeons*, **57** (5) pp462-464.

- McRae, C., 2003. *Body and skin piercing amongst students in Glasgow: Practices, attitudes and negative sequelae*. MSc dissertation, unpublished.
- Makkai, T. & McAllister, I., 2001. Prevalence of tattooing and body piercing in the Australian community. *Communicable Diseases Intelligence*, **25** (2) pp67-72.
- Macduff, C., 2009. An evaluation of the process and initial impact of disseminating a nursing thesis. *Journal of Advanced Nursing*, **65** (5) pp1010-1018.
- Mander, R., 1992. Seeking approval for research access: the gatekeeper's role in facilitating a study of the care of the relinquishing mother. *Journal of Advanced Nursing*, **17** (12) pp1460-1464.
- Marcus, A.A., 1984. *The adversary economy: Business responses to changing government requirements*. Westport: Quorum Books.
- Mason, P., 2004. *Need to know body piercing and tattooing*. Oxford: Harcourt Education Ltd.
- Maudsley, G., 2011. Mixing it but not mixed up: Mixed methods research in medical education (a critical narrative review). *Medical Teaching*, **33** (2) 92-104.
- May, P.J., 2004. Compliance motivations: Affirmative and negative bases. *Law and Society Review*, **38** (1) pp41-68.
- May, P.J., 2005. Regulation and compliance motivations: Examining different approaches. *Public Administration Review*, **65** (1) pp31-44
- Mays, N. & Pope, C., 2000. Assessing quality in qualitative research. *British Medical Journal*, **320** (7226) pp50-52.
- Mayers, L.B.I, Judelson, D.A., Moriarty, B.W., & Rundell, K.W., 2002. Prevalence of body art (body piercing and tattooing) in university undergraduates and incidence of medical complications. *Mayo Clinic Proceedings*, **77** (1) pp29-34.
- Mayers, L.B. & Chiffriller, S.H., 2008. Body Art (Body Piercing and Tattooing) among Undergraduate University Students: "Then and Now", *Journal of Adolescent Health*, **42** (2) pp201-203.
- Maxcy, S.J., Pragmatic threads in mixed methods research in the social sciences: The search for multiple modes of inquiry and the end of the philosophy of formalism. In: Tashakkori, A. & Teddlie, C., (ed) 2003. *Handbook of mixed methods in social and behavioural research*. London: Sage publications. Chapter 2 pp51-90.
- Maxwell, J.A. & Loomis, W.E., 2003. Mixed methods design: An alternative approach. In: Tashakkori, A., Teddlie, C., (ed) 2003. *Handbook of mixed methods in social and behavioural research*. London: Sage publications. Chapter 9 pp241-272.

- Mertens, D.M., 2007. Transformative paradigm: Mixed methods and social justice. *Journal of Mixed Methods Research*, **1** (3) 212-225.
- Meurman, J.H. & Uttamo, J., 2008. Oral micro-organisms in the etiology of cancer. *Acta Odontologica Scandanavica*, **66** (6) pp321-326 (abstract only).
- Miles, M.B., Huberman, A.M., 1994. *Qualitative data analysis: an expanded sourcebook*. 2<sup>nd</sup> edition. London: Sage Publications.
- Morgan, D.L., 2007. Paradigms lost and pragmatism regained: Methodological implications of combining qualitative and quantitative methods. *Journal of mixed methods research*, **1** (1) pp48-76.
- Morgan, D., 1998. Practical strategies for combining qualitative and quantitative methods: Applications to health research. *Qualitative Health Research*, **8** (3) pp362-376.
- Morgan, B. & Yeung, K., 2007. *An introduction to law and regulation: text and materials*. Cambridge: Cambridge University Press.
- Morse, J.M., 1991. Approaches to qualitative-quantitative methodological triangulation. *Nursing Research*, **40** (2) pp120-123.
- Morse, J.M., 2003. Principles of mixed methods and multimethod research design. In: Tashakkori, A., Teddlie, C., (ed) 2003. *Handbook of mixed methods in social and behavioural research*. London: Sage publications. Chapter 7, pp189-208.
- Moule, P., Pontin, D., Gilchrist, M. & Ingram, R., 2003. Critical appraisal framework. Accessed from <http://hsc.uwe.ac.uk/dataanalysis/critFrame.asp> on 21st January 2007.
- Mulhall, A., 2003. In the field: notes on observation in qualitative research. *Journal of Advanced Nursing*, **41** (3) pp306-313.
- Muncey, T., 2006. Mixing art and science: a bridge over troubled water or a bridge too far? *Journal of Research in Nursing*, **11** (3) pp223-233.
- Muncey, T., 2009. Does mixed methods constitute a change in paradigm? In: Andrew, S. & Halcomb, E.J., (ed) 2009. *Mixed methods research for nursing and the social health sciences*. Oxford: Blackwell Publishing. Chapter 2 pp13-30.
- Murphy-Black, T., 2006. Using questionnaires. In; Gerrish, K., Lacey, A., (ed) 2006. *The research process in nursing*. Oxford: Blackwell Publishing. Chapter 24 pp367-382.
- National Public Health Partnership, 2002. *Regulation of infection control in the body art industry in Australia and New Zealand*. January. Melbourne: National Public Health Partnership
- Naidoo, J. & Wills, J., 2005. *Public health and health promotion*. 2<sup>nd</sup> Edition. London: Balliere Tindall.

- Neuman, W.L., 2000. *Social research methods: Qualitative and quantitative approaches*. Boston: Allyn and Bacon.
- Newell, R. & Burnard, P., 2006. *Research for evidence based practice*. Oxford: Blackwell Publishing.
- Newman, I. & Benz, C.R., 1998. *Qualitative-quantitative research methodology: Exploring the interactive continuum*. Carbondale: University of Illinois Press.
- Ng, M.F., Clarkson, J.H. & Hogg, F.J., 2010. Basal cell carcinoma arising from nasal piercing: cause or coincidence. *Journal of Plastic Reconstructive and Aesthetic Surgery*, **63** (2) pp153-154.
- Nichols, D.P., 1999. My coefficient alpha is negative! *SPSS Keywords*, 68. Accessed from <http://www.ats.ucla.edu/stat/spss.library/negalpha.htm> on 15th February 2008.
- Nimpitakpong, P. & Kanokthed, T., 2010. Compliance of drugstores with a national smoke free law. A pilot survey. *Public Health*, **124** (3) pp123-182.
- Noah, N., 2006. Tattooing and piercing – the need for guidelines in EU (Editorial). *Eurosurveillance Quarterly Releases*, **11** (1-3) p4.
- Noar, S.M. & Zimmerman, R.S., 2005. Health behavior theory and cumulative knowledge regarding health behaviors: are we moving in the right direction? *Health Education Research*, **20** (3) pp275-290.
- Norman, P. & Conner, M., 2005. Predicting and changing health behaviour: Future directions. In: Conner, M. & Norman, P., (ed) 2005. *Predicting health behaviour*. 2<sup>nd</sup> Edition. Maidenhead: Open University Press. Chapter 8 pp324-371.
- Nurius, P.S. & Yeaton, W.H., 1987. Research synthesis reviews: an illustrated critique of hidden judgements, choices and compromises. *Clinical Psychology Review*, **7** (6) pp695-714.
- Nursing and Midwifery Council (NMC), 2008. *The code: standards of conduct, performance and ethics for nurses and midwives*. London: NMC.
- O'Caithain, A., Murphy, E. & Nicholl, J., 2007. The quality of mixed methods studies in health services research. *Journal of Health Services Research and Policy*, **13** (2) pp92-98.
- O'Leary, Z., 2004. *The essential guide to doing research*. London: Sage Publications.
- Oberdorfer, A., Wiggers, J.H., Bowman, J. & Lecathelinias, C., 2003a. Infection control practices among tattooists and body piercers in Sydney Australia. *American Journal of Infection Control*, **31** (8) pp447-456.

- Oberdorfer, A., Wiggers, J.H., Bowman, J. & Cockburn, J., 2003b. Infection control operators' knowledge and attitudes towards infection control. *American Journal of Health Behaviour*, **27** (2) pp125-134.
- Oberdorfer, A., Wiggers, J.H., Bowman, J., Burrows, S., Cockburn, J. & Considine, R.J., 2004. Monitoring and educational feedback to improve the compliance of tattooists and body piercers with infection control standards: a RCT. *American Journal of Infection Control*, **32** (3) pp147-154.
- Oldfield, S.J., 2001. A critical review of the use of time sampling in observational research. *Journal of Research in Nursing*, **6** (2) pp597-608.
- Onwuegbuzie, A.J. & Teddlie, C., 2003. A framework for analysing data in mixed methods research. In; Tashakkori, A. & Teddlie, C., (ed) 2003. *Handbook of mixed methods in social and behavioural research*. London: Sage publications. Chapter 13 pp351-384.
- Pallant, J., 2007. *SPSS survival manual*. 3<sup>rd</sup> edition. Berkshire: Open University Press.
- Papameletiou, D., Zenie, A. & Schwela, D., 2003. *Risks and health effects from tattoos, body piercing and related practices*. Ispra. European Commission Joint Research Council.
- Parahoo, K., 2006. *Nursing research: Principles, process and issues*. 2<sup>nd</sup> edition. Basingstoke: Palgrave MacMillan.
- Parker, C., 2000. *Reducing the risk of policy failure: Challenges for regulatory compliance*. Paris: Organisation for Economic Co-operation and Development (OECD).
- Parker, S., 2010. *Sampling versus census: A comparative analysis*. Accessed from <http://tnsemployeeinsight.com> on 4<sup>th</sup> June 2010.
- Patton, M.Q., 2002. *Qualitative research and evaluation methods*. California: Sage Publications.
- Pautz, M.C., 2009a. Perceptions of the regulated community in environmental policy: the view from below. *Review of Policy Research*, **26** (5) pp533-550.
- Pautz, M.C., 2009b. Trust between regulators and the regulated: a case study of environmental inspectors and facility personnel in Virginia. *Politics and Policy*, **37** (5) pp1047-1072.
- Perez-Barrio, S., Gonzalez-Hermosa, M.R., Raton-Nieto, J.A. & Diaz-Perez, J.L., 2009. Molluscum contagiosum over a tattoo. *Actas Dermo-Sifiliograficas (English Edition)*, **100** (2) pp152-154.
- Petrie, A. & Sabin, C., 2000. *Medical statistics at a glance*. Oxford: Blackwell Science.

- Phillips, D.C. & Burbles, N.C., (2000). *Postpositivism and educational research*. New York: Rowman and Littlefield.
- Pittet, D., 2001. Improving adherence to hand hygiene practice: A multidisciplinary approach. *CDC Emerging Infectious Diseases*, **7** (2) pp234-240.
- Pluye, P., Gagnon, M., Griffiths, F. & Johnson-Lafleur, J., 2009. A scoring system for appraising mixed methods research, and concomitantly appraising qualitative, quantitative and mixed methods primary studies in Mixed Studies Reviews. *International Journal of Nursing Studies*, **46** (4) pp529-546.
- Pollock, K., 2005. *Concordance in medical consultations: a critical review*. Oxford: Radcliffe Publishing.
- Popay, J., 2006. *Moving beyond effectiveness in evidence synthesis: Methodological issues in the synthesis of diverse sources of evidence*. London: National Institute for Health and Clinical Excellence.
- Pope, C., Mays, N. & Popay, J., 2007. *Synthesising qualitative and quantitative health evidence: A guide to methods*. Berkshire: Open University Press.
- Pope, C. & Ziebland, S., Mays, N., 2000. Qualitative research in health care: analysing qualitative data. *British Medical Journal*, **320** (7227) pp114-116.
- Porter, D., 1999. *Health, civilisation and the state: A history of public health from ancient to modern times*. London: Routledge.
- Public Health Resource Unit, 2006. *Critical appraisal skills programme – making sense of evidence*. London: Public Health Resource Unit.
- Qudeimat, M.A., Farrah, R.Y. & Owais, A.I., 2006. Infection control knowledge and practices among dentists and dental nurses at a Jordanian University Teaching Center. *American Journal of Infection Control*, **34** (4) pp218-222.
- Quedley, M., Ng, B., Sapre, N., Blakiston, M., Crawford, A., Devadas, R., McLaren, H, Anand, S., Tipu, M., Dayal, V., Chandrasiri, S., Thamson, G. & Edwards, R., 2008. In sight in mind: retailer compliance with legislation on limiting retail tobacco displays. *Nicotine Tobacco Research*, **10** (8) pp1347-1354.
- Raymond, M.J., Halcon, L.L. & Pirie, T.V., 2003. Regulation of tattooing in Minneapolis and St Paul, Minnesota: Tattooists attitudes and relationships between regulation and practice. *Public Health Reports*: May-June. **116** pp249-256.
- Regina, C. & Molassiotis, A., 2002. Nurses' knowledge of and compliance with universal precautions in Hong Kong. *International Journal of Nursing Studies*, **39** (2) pp157-163.

- Robertson, G., 2004. Body art forum. *Environmental Health Scotland*, **16** (1) p29
- Rose, G., 2002. *The strategy of preventive medicine*. Oxford: Oxford University Press.
- Rossmann, G.B. & Wilson, B.L., 1985. Numbers and words: Combining quantitative and qualitative methods in a large scale evaluation study. *Evaluation Review*, **9** (5) pp627-643.
- Rossow, I., Karlsson, T. & Raitasalo, K., 2008. Old enough for a beer? Compliance with minimum legal age for alcohol purchases in monopoly and other off-premise outlets in Finland and Norway. *Addiction*, **103** (9) pp1468-1473.
- Ruane, J.M., 2005. *Essentials of research methods. A guide to social science research*. Oxford: Blackwell Publishing.
- Sale, J.E.M. & Brazil, K., 2004. A strategy to identify critical appraisal criteria for primary mixed-methods studies. *Quality and Quantity*, **38** (4) pp351-365.
- Sandelowski, M., 1998. The call to experts in qualitative research. *Research in Nursing and Health*, **21** (5) pp467-471.
- Sandelowski, M., 2003. Tables or tableaux? The challenge of writing and reading mixed methods studies. In: Tashakkori, A., Teddlie, C., (ed) 2003. *Handbook of mixed methods in social and behavioural research*. London: Sage Publications. Chapter 12 pp321-350
- Sandelowski, M., Voils, C.I. & Barroso, J., 2006. Defining and designing mixed research synthesis studies. *Research in the Schools*, **13** (1) pp29-40.
- Schorzman, C.M., Gold, M.A., Downs, J.S. & Murray, P.J., 2007. Body art: Attitudes and practices regarding body piercing among urban undergraduates. *Journal of American Osteopathic Association*, **107** (10) pp432-438.
- Scottish Centre for Infection and Environmental Health (SCIEH), 1998. Infection associated with tattooing. *SCIEH Weekly Report*, **32** (31), 4<sup>th</sup> August.
- Scottish Centre for Infection and Environmental Health (SCIEH), 2003a. Body piercing and tattoo parlour incident in Tayside. *SCIEH Weekly Report*, **37** (27), 8<sup>th</sup> July.
- Scottish Centre for Infection and Environmental Health (SCIEH), 2003b. Report on tattoo studio, Helensburgh. *SCIEH Weekly Report*, **37** (35), 2<sup>nd</sup> September.
- Scottish Executive Health Department, 2001. Regulation of skin piercing: a consultation paper. Edinburgh: Stationery Office.



Scottish Executive Health Department, 2003. *Managing incidents presenting actual or potential risks to the public health: Guidance on the Roles and Responsibilities of Incident Control Teams*. Edinburgh: Stationery Office.

Scottish Executive Health Department, 2005. *The Smoking, Health and Social Care (Scotland) Act 2005, Draft (Prohibition of Smoking in Certain Premises) Regulations 2005 and Regulatory Impact Assessment. Report of Consultation Responses*. Edinburgh: Stationery Office.

Scottish Executive Health Department, 2006a. *Civic Government (Scotland) Act 1982 (Licensing of skin piercing and tattooing) Order 2006*. Edinburgh: Stationery Office.

Scottish Executive Health Department, 2006b. *Prohibition of Smoking in Certain Premises (Scotland) Regulations 2006*. Edinburgh: Stationery Office.

Scottish Government Health Directorate, 2007a. *Better health , better care: A discussion paper*. Edinburgh: Stationery Office.

Scottish Government Health Directorate, 2007b. *Better health , better care: Action plan*. Edinburgh: Stationery Office.

Scottish Government Health Directorate, 2009. *The Public Health etc (Scotland) Act 2008 (Sunbed) Regulations 2009*. Edinburgh: Stationery Office.

Scottish Government Health Directorate, 2010a. *Self directed support: A national strategy for Scotland*. Edinburgh: Stationery Office.

Scottish Government Health Directorate, 2010a. *The healthcare quality strategy for NHSScotland*. Edinburgh: Stationery Office.

Scottish Government Health Directorate, 2010b. *Health in Scotland 2009. Time for change: Annual report of the Chief Medical Officer*. Edinburgh: Stationery Office.

Scottish Licensing of Skin Piercing and Tattooing Working Group, 2007. *Civic Government (Scotland) Act 1982 (Licensing of skin piercing and tattooing) Order 2006: Guidance to Scottish Local Authorities on implementation (draft)*. January. Glasgow: Health Protection Scotland.

Segal, J.Z., 2007. Compliance to concordance: a critical view. *Journal of Medical Humanities*, 28 (1) pp81-96.

Shadish, W., Cook, T. & Campbell, D., 2002. *Experimental and quasi-experimental designs for causal inference*. Boston: Houghton Mifflin Company.

Shuttleworth, M., 2009. *Research bias*. Accessed from <http://www.experiment-resources.com/research-bias.html> on 28 January 2007.

- Shwom, R., Bidwell, D., Dan, A., Dietz, T., 2010. Understanding US public support for domestic climate change policies. *Global Environmental Change*, **20** (3) pp472-482.
- Silverman, D., 1985. *Qualitative methodology and sociology*. Aldershot: Gower.
- Silverman, A.L., Sekhon, J.S., Saginaw, S.J., Wiedbrauk, D., Balasubramaniam, M. & Gordon, S.C., 2000. Tattoo application is not associated with an increased risk for chronic viral hepatitis. *American Journal of Gastroenterology*, **95** (5) pp1312-1315.
- Snowden, A., 2008. Medication management in older adults: a critique of concordance. *British Journal of Nursing*, **17** (2) pp114-119.
- Stead, L.R., Williams, J.V., Williams, A.C. & Robinson, C.M., 2005. An investigation into the practice of tongue piercing in the South West of England. *British Dental Journal*, **200** (2) pp103-107.
- Steckler, A., McLeroy, K.R., Goodman, R.M., Bird, S.T. & McCormick, L., 1992. Toward integrating qualitative and quantitative methods: an introduction. *Health Education Quarterly*, **19** (1) pp1-8.
- Stevenson, F. & Scrambler, G., 2005. The relationship between medicine and the public: the challenge of concordance. *Health*, **9** (5) pp5-21.
- Stirn, A., Hinz, A. & Brahler, E., 2006. Prevalence of tattooing and body piercing in Germany and perception of health mental disorders and sensation seeking among tattooed and body pierced individuals. *Journal of Psychomatic Research*, **60** (5) pp531-534.
- Steedman, S. & Younossi, Z.M., 2000. Hepatitis C: An Update on the Silent Epidemic. *Journal of Clinical Gastroenterology*, **30** (2) pp125-143.
- Steinbrook, R. & Drazen, J.M., 2001. AIDS — Will the Next 20 Years Be Different? *New England Journal of Medicine*, 7<sup>th</sup> June, **344** pp781-1782.
- Sudman, S. & Kalton, G., 1986. New developments in the sampling of special populations. *Annual Review of Sociology*, **12** pp401-429
- Talisse, R.B. & Aikin, S.F., 2008. *Pragmatism: A guide for the perplexed*. New York: Continuum International Publishing Group.
- Tashakkori, A., Teddlie, C., 1998. *Mixed methodology: Combining qualitative and quantitative approaches*. California: Sage Publications.
- Teddlie, C., Tashakkori, A., 2003. Major issues and controversies in the use of mixed methods in the social and behavioural sciences. In: Tashakkori, A. & Teddlie, C., (ed) 2003. *Handbook of mixed methods in social and behavioural research*. London: Sage publications. Chapter 1 pp3-50
- Teddlie, C. & Tashakkori, A., 2009. *Foundations of mixed methods research*. London: Sage Publications.

Teddle, C. & Yu, F., 2007. Mixed methods sampling: a typology with examples. *Journal of Mixed Methods Research*, **1** (1) pp77-100.

Thurmond, V.A., 2001. The point of triangulation. *Journal of Nursing Scholarship*, **33** (3) pp253-258.

Townsend, P. & Davidson, N., (ed) 1982. *Inequalities in health: The Black report*. Harmondsworth: Penguin Books.

Tweeten, S. & Rickman, L., 1998. Infectious complications of body piercing. *Clinical and Infectious Disease*, **26** (3) pp735-740.

Underwood, I., Thomas, J., Williams, T. & Thieba, A., 2007. *Systematic rapid evidence assessment. The effectiveness of interventions for people with common mental health problems on employment outcomes*. London: EPPI-Centre, Social Science Research Unit, Institute of Education, University of London.

Van de Mortel, T.F., 2008. Faking it: social desirability response bias in self-report research. *Australian Journal of Advanced Nursing*, **25** (4) pp40-48.

Van der sar, R., Brouwers, E.P., van de Goor, I.A. & Garretsen, H.F., 2010. The opinion of adolescents and adults on Dutch restrictive educational alcohol policy measures. *Health Policy*, **99** (1) pp10-16.

van Ingen, J., Blaak, H., de Beer, J., de Roda Husman, A.M. & van Soolingen, D., 2010. Rapidly growing nontuberculous mycobacteria cultured from home tap and shower water. *Applied and Environmental Microbiology*, **76** (17) pp6017-6019.

Van Wijk, M.P., Kummer, J.A. & Kon, M., 2008. Ear piercing techniques and their effect on cartilage: A historic study. *Journal of Plastic Reconstructive and Aesthetic Surgery*, **61** (supp) pp104-109.

Venta, I., Lakoma, A., Haahtela, S., Peltola, J., Ylipaavalniemi, P. & Turtola, L., 2005. Oral piercings among first year university students. *Oral Surgery, Oral Medicine, Oral Pathology, Oral Radiology and Endodontology*, **99** (5) pp546-549.

Walsh, R.A., Paul, C.A., Tzelepis, F., Stojanovski, E. & Tang, A., 2008. Is government action out-of-step with public opinion on tobacco control? Results of a New South Wales population survey. *Australian and New Zealand Journal of Public Health*, **32** (5) pp482-488.

Walshe, K., 2002. The rise of regulation in the NHS. *British Medical Journal*, **324** (7343) pp967-970.

Walters, R., 2001. *Regulation of skin and body piercing: Analysis of written submission to consultation*. May. Edinburgh: Scottish Executive Central Research Unit.

Wanless, D., 2004. *Securing good health for the whole population: Final report*. London: The Stationery Office.

- Watters, J.K. & Biernacki, P., 1989. Targeted sampling: options for the study of hidden populations. *Social Problems*, **36** (4) pp416-430.
- Webb, C., 1992. The use of the first person in academic writing: objectivity, language and gatekeeping. *Journal of Advanced Nursing*, **17** (6) pp747-752.
- Whitmand, M.V. & Harbison, P.A., 2010. Examining general hospitals' smoke free policies. *Health Education*, **110** (2) pp98-108.
- Willaims, A., How to...Write and analyse a questionnaire. *Journal of Orthodontics*, **30** (3) pp245-252.
- Wilson, N., Weerasekera, D., Blakely, T., Edwards, R., Thomson, G. & Gifford, H., 2010. What is behind smoker support for new smokefree areas? National survey data. *BMC Public Health*, **10** (498) pp1-11.
- Woolley, C.M., 2009. Meeting the mixed methods challenge of integration in a sociological study of structure and agency. *Journal of Mixed Methods Research*, **3** (1) pp7-25.
- World Health Organisation, 2002. *The World Health Organisation Report 2002: Reducing risks, promoting healthy life*. Geneva: World Health Organisation.
- World Health Organisation (WHO), 2008. Behaviour change strategies and health: the role of health systems. *Regional Committee for Europe 58<sup>th</sup> session, 15-18<sup>th</sup> September, pp1-26, Tibilisi, Georgia: Paper EUR/RC58/conf.doc/5*.
- World Health Organisation, 2011. *WHO Patient Safety Newsletter*, 6, January.
- Worp, J., Boonstra, A., Coutinho, R.A. & van der Hoek, J.A.R., 2006. Tattooing permanent makeup and piercing in Amsterdam: guidelines, legislation and monitoring. *Eurosurveillance*, **11** (1-3) pp34-36.
- Wroblewski, C., 2004. *Skin shows: the tattoo bible*. London: Collins & Brown.
- Yapp, C. & Fairman, R., 2005. Assessing food compliance with food safety legislation in small businesses. *British Food Journal*, **107** (3) pp150-161.
- Yapp, C. & Fairman, R., 2006. Factors affecting food safety compliance within small and medium sized enterprises: implications for regulatory and enforcement strategies. *Food Control*, **17** (1) pp42-51.
- Yeung, K., 2004. *Securing compliance: A principled approach*. Oxford: Hart Publishing.
- Yin, R.K., 2006. Mixed methods research: Are the methods genuinely integrated or merely parallel? *Research in the Schools*, **13** (1) pp41-47.
- Zheung, P., Fu, H. & Li, G., 2009. Smoke-free restaurants in Shanghai: should it be mandatory and is it acceptable? *Health Policy*, **89** (2) pp216-224.

# Appendices

# Appendix 1

## Order

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SCOTTISH STATUTORY INSTRUMENTS

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**2006 No. 43**

**LICENCES AND LICENSING  
PUBLIC HEALTH**

**The Civic Government (Scotland) Act 1982  
(Licensing of Skin Piercing and Tattooing) Order 2006**

Made - - - - - 1st February 2006

*Coming into force in accordance with article 1*

The Scottish Ministers, in exercise of the powers conferred by section 44(1)(b) and (2) of the Civic Government (Scotland) Act 1982<sup>(a)</sup> and of all other powers enabling them in that behalf, hereby make the following Order, a draft of which has, in accordance with section 44(3) of that Act, been laid before and approved by a resolution of the Scottish Parliament:

**Citation, commencement and interpretation**

1.—(1) This Order may be cited as the Civic Government (Scotland) Act 1982 (Licensing of Skin Piercing and Tattooing) Order 2006 and shall come into force on the day after the day on which it is made.

(2) In this Order—

“the 1982 Act” means the Civic Government (Scotland) Act 1982;

“acupuncture” means the insertion of needles into living tissue for remedial or therapeutic purposes;

“cosmetic body piercing” means the perforation of the skin and underlying tissue in order to create a tunnel in the skin through which jewellery may be inserted;

“electrolysis” means the removal of body hair by electrocution of the hair roots with an electrified needle;

“hospital” means any health service hospital within the meaning of section 108(1) of the National Health Service (Scotland) Act 1978<sup>(b)</sup>;

“independent clinic” has the same meaning as in section 77(1) of the Regulation of Care (Scotland) Act 2001<sup>(c)</sup>;

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<sup>(a)</sup> 1982 c. 45; the functions of the Secretary of State were transferred to the Scottish Ministers by virtue of section 53 of the Scotland Act 1998 (c. 46).

“skin piercing” includes any of the following—

- (a) acupuncture;
- (b) cosmetic body piercing; or
- (c) electrolysis; and

“tattooing” means the insertion into the skin of any colouring material designed to leave a semi-permanent or permanent mark including micro pigmentation.

#### **Licensing of activity**

2.—(1) The activity specified in paragraph (2) is hereby designated as an activity for which a licence under Part I of the 1982 Act shall be required, but no such licence shall be required—

- (a) in respect of the carrying on of that activity before 1st April 2006; or
- (b) for the carrying on of that activity by a registered medical practitioner within—
  - (i) a hospital; or
  - (ii) an independent clinic.

(2) The activity referred to in paragraph (1) is the carrying on of a business which provides skin piercing or tattooing.

#### **Application of Part I of the 1982 Act**

3. Part I of the 1982 Act shall have effect, subject to the modifications specified in the Schedule, for the purposes of the licensing of the activity designated by article 2.

#### **Transitional provision**

4.—(1) A person who on or after 1st April 2006 carries on the activity designated by article 2 without a licence under Part I of the 1982 Act shall not be guilty of an offence under section 7(1) of that Act<sup>(d)</sup> if—

- (a) that person made application to the licensing authority before that date for the grant of a licence under Part I of that Act in respect of the activity being carried on by the person; and
  - (b) that application has not yet been finally determined.
- (2) For the purposes of paragraph (1)(b), an application is finally determined—
- (a) when it is withdrawn by the applicant;
  - (b) when it is refused by the licensing authority and the period of 28 days specified in paragraph 18(4) of Schedule 1 to the 1982 Act expires without an appeal against the refusal being made to the sheriff;
  - (c) in a case where an appeal is made against a refusal by the licensing authority, when that appeal is disposed of.
- (3) For the purposes of paragraph (2)(c), an appeal is disposed of—
- (a) when it is abandoned by the appellant;
  - (b) when a decision on it is made by the sheriff or a higher court and any period for making a subsequent appeal to a higher court expires without such a subsequent appeal being made.

(d) Section 7(1) was amended by the Entertainments (Increased Penalties) Act 1990 (c. 20), section 2(1); the reference in section 7(1) to a fine not exceeding £500 became a reference to a fine not exceeding level 4 on the standard scale by virtue of section 289G of the Criminal Procedure (Scotland) Act 1975 (c. 21), which section by consolidation became section 225 of the Criminal Procedure (Scotland) Act 1995 (c. 46).



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*Status: This is the original version (as it was originally made). Scottish  
Statutory Instruments are not carried in their revised form on this site.*

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St Andrew's House, Edinburgh  
1st February 2006

*LEWIS MACDONALD*  
Authorised to sign by the Scottish Ministers

## APPLICATION OF PART I OF THE 1982 ACT

1. Part I of the 1982 Act shall have effect subject to the modifications in paragraphs 2 to 7 of this Schedule.

2. In section 3 (discharge of functions of licensing authorities)–

- (a) in subsection (1), for “6 months” substitute “12 months”; and
- (b) in subsections (2) and (4), for “6 month” substitute in each place “12 month”.

3. In section 6 (powers of entry to and search of unlicensed premises)–

- (a) in subsections (1) and (2), after “constable” in each place insert “(or any authorised officer of the licensing authority)”; and
- (b) in subsection (3)–
  - (i) after “uniform” insert “(and where the person executing the warrant is an authorised officer of a licensing authority, that officer)”; and
  - (ii) after “constable” where it second occurs insert “(or such authorised officer of the licensing authority)”; and
- (c) in subsection (4)(e)–
  - (i) after “constable” where it first occurs insert “(or authorised officer of the licensing authority)”; and
  - (ii) after “constable” where it second occurs insert “(or such authorised officer)”.

4. In paragraph 4 of Schedule 1–

(a) before sub paragraph (1) insert–

“(A1) Where the application for the grant or renewal of a licence which is made for the carrying on of a business which provides skin piercing or tattooing specifies the address of the premises from which the activity is to be carried on as required by paragraph 1(2)(d) above, the licensing authority shall not make a final decision upon the application unless an authorised officer of the licensing authority has visited and inspected the premises.”

(b) in sub paragraph (1) at the beginning insert “Without prejudice to the requirement at sub paragraph (A1) above,”.

5. In paragraph 5 of Schedule 1–

(a) in sub-paragraph (1)(a) at the beginning insert “subject to sub-paragraphs (2C) and (2D) below,”;

(b) after sub-paragraph (2) insert–

“(2A) Where the licensing authority is considering an application for the grant or renewal of a licence–

(a) for the carrying on of a business which provides skin piercing or tattooing; and

(b) where the activity is to be carried out wholly or mainly in premises,

the licensing authority shall not grant the licence unless it is satisfied that the conditions in sub-paragraph (2B) below are met.

(2B) The conditions referred to in sub-paragraph (2A) above are that–

(a) separate rooms are provided for–

- (i) the waiting area; and
- (ii) the carrying out of skin piercing or tattooing;
- (b) the waiting area has displayed a notice advising–
  - (i) that skin piercing and tattooing will not be carried out on any person under the influence of alcohol or drugs;
  - (ii) that skin piercing will not be carried out on any child under the age of 16 unless accompanied by a person who has parental rights and responsibilities in respect of that child and who has also given their consent in writing to the skin piercing; and
  - (iii) that tattooing will not be carried out on any person under the age of 18;
- (c) the room to be used for the purposes of carrying out the skin piercing or tattooing has the following facilities–
  - (i) a sink with hot and cold running water and which uses non-hand operated taps;
  - (ii) a paper towel holder containing paper towels;
  - (iii) a soap dispenser containing soap;
  - (iv) a washable bench or chair with disposable paper sheet;
  - (v) a dispenser containing alcohol solution;
  - (vi) a waste bucket with a pedal operated lid;
  - (vii) a sharps container for storage of needles after use; and
  - (viii) a first aid kit;
- (d) the following equipment is stored and properly maintained for use on the premises–
  - (i) ultrasonic cleaners;
  - (ii) instrument baths; and
  - (iii) autoclaves and autoclaves pouches; and
- (e) the premises are well ventilated and illuminated for the purposes of skin piercing and tattooing.

(2C) Without prejudice to the generality of sub-paragraph (2) above or the requirements of sub-paragraphs (2A) and (2B) above, where a licensing authority grants or renews a licence for the carrying on of a business which provides skin piercing or tattooing and the activity is to be carried out wholly or mainly in premises, the following conditions shall be imposed–

- (a) the accommodation and facilities within the premises are to be maintained in good repair and in a good state of cleanliness;
- (b) only sterile single use disposable needles may be used for skin piercing or tattooing;
- (c) for the purposes of tattooing, only sterile pigment or ink pre-packed in single use vials may be used;
- (d) the activity of tattooing or skin piercing must be carried out by an operator wearing disposable vinyl or latex gloves, which must be changed for each client;
- (e) a supply of the following must be maintained–
  - (i) disposal vinyl or latex gloves;

- (ii) disposable razors; and
- (iii) disposable single use needles;
- (f) any equipment which is not disposable shall be thoroughly cleaned with fresh disinfectant after each use;
- (g) skin piercing shall not be carried out on a child under the age of 16 unless accompanied by a person who has parental rights and responsibilities in respect of that child and who has also given their consent in writing to the skin piercing;
- (h) any equipment which is disposable must be disposed of immediately after use in an appropriate waste receptacle;
- (i) for ear piercing, a sterile cartridge for ear piercing must be used;
- (j) for tongue piercing, a sterilised clamp must be used; and
- (k) information, in an easy to understand format, must be provided to prospective clients to explain–
  - (i) the process of the skin piercing or tattooing;
  - (ii) the risks of the procedure; and
  - (iii) the after care requirements of the procedure.

(2D) Without prejudice to the generality of sub-paragraph (2) above or the requirements of paragraphs (2A) and (2B) above, where a licensing authority grants or renews a licence for the carrying on of a business which provides skin piercing or tattooing and the activity is not to be carried out wholly or mainly in premises, the following conditions shall be imposed–

- (a) disposable vinyl or latex gloves must be worn and changed for each client;
  - (b) the skin piercing or tattooing may only be carried out through use of disposable razors or single use needles;
  - (c) any seating used for the skin piercing or tattooing must be washable and covered with a disposable paper sheet which shall be renewed after each use;
  - (d) any equipment which is not disposable shall be thoroughly cleaned with fresh disinfectant after each use;
  - (e) any equipment which is disposable must be disposed of immediately after use in an appropriate waste receptacle;
  - (f) for tongue piercing, a sterilised clamp must be used;
  - (g) for ear piercing, a sterile cartridge for ear piercing must be used;
  - (h) skin piercing shall not be carried out on a child under the age of 16 unless accompanied by a person who has parental rights and responsibilities in respect of that child and who has also given their consent in writing to the skin piercing; and
  - (i) information, in an easy to understand format, must be provided to prospective clients to explain–
    - (i) the process of the skin piercing or tattooing;
    - (ii) the risks of the procedure; and
    - (iii) the after care requirements of the procedure.”
- (c) at the beginning of sub-paragraph (3) insert “Subject to sub-paragraph (3A) below,”;
- (d) after sub-paragraph (3) insert–

“(3A) For the purposes of sub-paragraph (3)(a)(ii) above, where the licence applied for is for the carrying on of a business which provides skin piercing or tattooing, the licensing authority, when determining whether the applicant is a fit and proper person to be the holder of the licence, shall have regard to the knowledge, skill, training and experience which the applicant (or, where the applicant is not a natural person, those individuals who will be carrying on the activity or activities) can demonstrate in relation to the activity or activities which are to be carried on.”

(e) after sub-paragraph (7) insert—

“(7A) Where a licensing authority makes out a licence under sub-paragraph (7) above for the carrying on of a business which provides skin piercing or tattooing, the licence shall specify—

- (a) the name and address of the person to whom the licence is granted;
- (b) the address of the premises (if any) in which the activity is to be carried out; and
- (c) where the premises are used for the carrying on of any trade or business, the name of that business.”

6. In paragraph 8(3) of Schedule 1 after “Act” insert “or in the case where a licence has been granted for the carrying on of a business which provides skin piercing or tattooing”.

7. After paragraph 19 of Schedule 1 insert—

“20. In this Schedule, “parental responsibilities” in relation to a child has the meaning given by section 1(3) of the Children (Scotland) Act 1995(f) and “parental rights” in relation to a child has the meaning given by section 2(4) of that Act.

21. In this Schedule—

“autoclave” means a pressure vessel in which the lid is sealed by the internal pressure in the vessel and which is used to steam sterilise equipment used for skin piercing or tattooing;

“sharps container” means a container used for holding medical waste and devices which can cause physical injury;

“skin piercing” and “tattooing” have the same meanings as in the Civic Government (Scotland) Act 1982 (Licensing of Skin Piercing and Tattooing) Order 2006; and

“ultrasonic cleaner” means a cleaning device which uses sound waves propagated through an aqueous medium at frequencies higher than the audible range.”

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#### EXPLANATORY NOTE

*(This note is not part of the Order)*

This Order designates the activity of the carrying on of a business which provides skin piercing or tattooing as an activity for which a licence under the Civic Government (Scotland) Act 1982 (“the 1982 Act”) shall be required in terms of section 44(1)(b) of that Act (article 2). Skin piercing and

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(f) 1995 c. 36.

tattooing are defined in article 1(2). An exemption from the licensing regime is provided where a registered medical practitioner carries out the activity in certain circumstances (article 2).

The licensing provisions at Part I of the 1982 Act (including Schedule 1) will apply to such licences with the following modifications as set out in the Schedule to the Order—

- (a) allowing local authorities 12 months (rather than 6) to determine licence applications (paragraph 2 of the Schedule);
- (b) granting a power of search of unlicensed premises to officers of the licensing authority (paragraph 3 of the Schedule);
- (c) requiring the licensing authority to inspect the premises prior to making a final decision on the application (paragraph 4 of the Schedule);
- (d) allowing a licence to be granted where the activity is to be carried out wholly or mainly in premises but also where the activity is not restricted to premises. Paragraph 5 of the Schedule sets certain pre-conditions which must be met before the licensing authority grant the application where the activity is to be carried out wholly or mainly in premises. Paragraph 5 further provides that certain mandatory conditions will attach to the grant or renewal of a licence, stipulating the conditions which will be imposed in each case where the activity is to be carried out wholly or mainly in premises (new paragraph 5(2C) of Schedule 1 to the 1982 Act) or otherwise for all other licences for the activity (new paragraph 5(2D)). One of the conditions attaching to the grant of any licence is that skin piercing should not be carried out on a person under the age of 16 years unless the consent of a person with parental rights and responsibilities is obtained;
- (e) disapplying paragraph 8(3) of Schedule 1 to the 1982 Act which provides that, on the death of a licence holder, the licence shall be deemed to have been granted to his executor and will remain in force for 3 months from the death of the licence holder (paragraph 6 of the Schedule); and
- (f) providing additional definitions in Schedule 1 to the 1982 Act (paragraph 7 of the Schedule).

The Order requires the designated activity to be licensed as from 1st April 2006 but transitional provision is made where an application is made before that date for the grant of an appropriate licence (article 4). In such a case, the activity may be carried on (without a licence) until the licensing authority has made a decision on the licence and, where a decision to refuse an application is then appealed to the sheriff, until that appeal has been disposed of.

# Appendix 2

## Outcome of literature searches

Appendix 2: Outcome of literature searches

Theme	Title	Search engines	Search terms	Returns	Exclusions	Inclusions
1a	Evidence to support need for tighter controls	Ebscohost interface Emerald Journals (Emerald) database ScienceDirect (Elsevier) database	Tattoo* Pierc* Prevalence	590	569+7+3	11
1b	Evidence of infection	Ebscohost interface Emerald Journals (Emerald) database ScienceDirect (Elsevier) database	Tattoo* Pierc* Infection	770	730+21	19
2	Professional and public opinion of the influence of regulation in health behaviour	Ebscohost interface Emerald Journals (Emerald) database ScienceDirect (Elsevier) database	Attitude* (Public)opinion (Government)regulation (Public) health(behaviour)(policy)	671	380+283	8
3	Evidence of compliance with regulation	Ebscohost interface Emerald Journals (Emerald) database ScienceDirect (Elsevier) database	Compliance (Govenrment)regulation (Environment)health(behaviour)	757	745+3	9
4	Evidence of compliance with infection control practice within healthcare	Ebscohost interface Emerald Journals (Emerald) database ScienceDirect (Elsevier) database	Compliance Health(care) (Standard)infection(control)precaution*	1180	1151+22	7



Appendix 2: Outcome of literature searches, continued

Theme	Title	Search engines	Search terms	Returns	Exclusions	Inclusions
5	Evidence of compliance with infection control practice within the tattooing and cosmetic body piercing industry	Ebscohost interface Emerald Journals (Emerald) database ScienceDirect (Elsevier) database	Tattoo* Pierc* Compliance (Standard)infection(control)precaution*	109	104	5+1
6	Effectiveness of regulation and other interventions aimed at promoting compliance within the tattooing and cosmetic body piercing industry	Ebscohost interface Emerald Journals (Emerald) database ScienceDirect (Elsevier) database	Tattoo* Pierc* Compliance (Standard)infection(control)precaution* Intervention (Health)behaviour	109	104	5+1

# Appendix 3

## Critical appraisal framework

### Appendix 3: Critical appraisal framework (Moule et al., 2003)

#### The Introduction

- Is there a clear statement about the topic being investigated?
- Is there a clear rationale for the research?
- Is there a clear statement about the limitations of the research?

#### The Literature Review

- Do the researchers use contemporary material about the topic being investigated?
- Do the researchers link their work to a wider body of knowledge through the references cited?
- Do the researchers link the topic to the questions about theory?
- Is there a clear link between the literature and the formulation of the research question(s)?
- Is the research question clearly stated?

#### The Methods Section

- Is the research design clearly described?
- Are the research methods appropriate for the topic being investigated?
- Are any advantages or disadvantages of the design acknowledged by the researchers?
- Is there a clear statement about who participated in the research?
- Is there a clear statement about how the participants were selected?
- Is the selection of participants appropriate to the design?
- Is there a clear statement about the number of people taking part in the research?

#### Data Collection and Analysis

- Is there a clear description about how the data was collected?
- Was the data collected by appropriate people?
- Is the approach to data analysis appropriate to the type of data collected?

#### *Quantitative*

- Is there any explanation of sample size used?
- Is the level of significance of the tests (alpha) used indicated, or implied to be the customary 5%?
- If Pearson correlation coefficients are being calculated, is there any evidence of a check for a linear relationship?
- If t-tests or analysis of variance (ANOVA) are to be performed, is there any evidence of check(s) to demonstrate that the data follows a normal distribution, or of assumptions made?
- Are reasons/assumptions re the level of measurement of the data given? (This affects the appropriateness of the descriptive statistics given and the tests used.)
- Is there a clear statement describing how valid and reliable the measures are?

### Appendix 3: Critical appraisal framework, continued

Are the type of statistical tests used appropriate for the sorts of data collected?

Is the use of any statistical analysis package, such as SPSS discussed?

Is there evidence of a statistician's input to the analysis?

#### *Qualitative*

Is there a clear reflexive statement about the researcher's role in the analysis?

Is the approach taken to data analysis clear?

Is the use of any electronic analysis package discussed?

Is there a clear statement about how the researcher validated interpretations?

#### Ethics

Is there a clear statement about ethical committee approval?

Is there a clear description about gaining consent, maintaining anonymity and or confidentiality?

#### The Results/ Findings

Are the results related back to the literature review?

Are the weaknesses in research design acknowledged?

#### *Quantitative*

Is the presentation of results clear and unambiguous?

Are all the results presented?

Do the tables and charts used give a clear picture of the sample data and results?

Are the charts used appropriate?

Are the tables easy to use?

If percentages are recorded, are actual numbers also clearly shown?

Are results of tests interpreted rightly?

#### *Qualitative*

Does the research present evidence of the data collected?

Does the data presented as part of a theme support the analysis suggested?

Is there a clear audit trail?

#### The Conclusions

Are the implications for further research acknowledged?

Are areas for further research identified?

Are further recommendations made for practice that come from the results/discussion?

# Appendix 4

## Ethics letter 1

School of Nursing, Midwifery  
& Social Care  
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Edinburgh EH9 2TB  
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Ms C Chalmers  
11 STRATHVIEW ROAD  
BELLSHILL  
LANARKSHIRE  
ML4 2UA

28 March 2007

Dear Claire

**APPLICATION FOR ETHICAL APPROVAL FOR A RESEARCH PROJECT**

I am pleased to confirm that Ethical Approval for phase one of your study has now been granted.

If you have any questions please do not hesitate to contact me, or Dr Maureen Macmillan ([m.Macmillan@napier.ac.uk](mailto:m.Macmillan@napier.ac.uk)) tel. 0131 455 5663.

Yours sincerely



Lesley Laidlaw  
Assistant Faculty Manager  
Faculty of Health & Life Sciences  
Email: [L.Laidlaw@napier.ac.uk](mailto:L.Laidlaw@napier.ac.uk)  
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**NAPIER UNIVERSITY**  
EDINBURGH

# Appendix 5

## Ethics letter 2

Napier University  
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Edinburgh EH9 2TB  
Scotland

t +44 (0)131 455 5689  
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w [www.napier.ac.uk/flhs](http://www.napier.ac.uk/flhs)

Ms C Chalmers  
11 Strathview Road  
Bellshill  
Lanarkshire  
ML4 2UA

31 May 2007

Dear Claire

**APPLICATION FOR ETHICAL APPROVAL FOR A RESEARCH PROJECT-  
Regulation of the tattooing and cosmetic body piercing industry in  
Scotland: its impact on practice and public health.**

I am pleased to confirm that Ethical Approval has now been granted.

If you have any questions please do not hesitate to contact me, or Dr  
Maureen Macmillan ([m.Macmillan@napier.ac.uk](mailto:m.Macmillan@napier.ac.uk) tel. 0131 455 5663).

Yours sincerely



Lesley Laidlaw  
Assistant Faculty Manager  
Faculty of Health, Life & Social Sciences  
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# Appendix 6

## Ethics letter 3

**Claire Chalmers**

---

**From:** "Allen, Stella" <S.Allen@napier.ac.uk>  
**To:** "Claire Chalmers" <claire.chalmers@blueyonder.co.uk>  
**Sent:** 05 December 2008 18:03  
**Subject:** The Faculty Research Ethics and Governance Committees findings

Dear Claire,

The Faculty Research Ethics and Governance Committees findings for your project:

'The impact of regulation on the infection control practices of the tattooing and cosmetic body piercing industry in Scotland: a mixed Methods study

Ethical Approval Granted

However some additional comments were made.

I think the study is well designed and appears to add to the body of knowledge. I think it is a good exploratory study, my only methodological reservation regards the reliability and objectivity of the data collection. A practitioner is likely to defend poor practice by saying that 'you only observed one session' I'm normally much more rigorous etc. Is there anyway around this? The proposal is ethically sound, issues have been considered and addressed. I'd like to see some mention of how anonymity will be maintained and how practice feedback will be delivered.

Stella Allen  
Faculty Research Ethics and Governance Committees  
Napier University  
10 Colinton Road  
Edinburgh EH10 5DT  
Tel: 0131 771 4100  
Fax: 0131 771 4101  
Email: stella.allen@napier.ac.uk

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06/12/2008

# Appendix 7

## Gantt chart

Appendix 7: Gantt chart

Activity	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
<b>2006</b>												
Registration												
Literature review												
Proposal development												
<b>2007</b>												
PDP – PhD training session – Edinburgh Napier												
Skin piercing training session - REHIS												
PG conference presentation – Edinburgh Napier												
Literature review												
Proposal development												
Ethical approval (quantitative data collection - survey)												
Pilot work/ questionnaire												
Ethical approval (qualitative data collection – interviews)												
PH Annual conference - presentation												
PDP - Literature review/ appraisal training - Napier												
REHIS H&S session – presentation												
RCN research conference - presentation												
<b>2008</b>												
Literature review												
Transfer review												
PG conference – presentation												
Ethical approval (quantitative / qualitative data collection - observation)												
Funding approval												
PDP – HealthQWest seminar												
PDP – UWS research forum seminar												

Activity	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
<b>2008 cont'</b>												
PDP – UWS seminar on intellectual property												
PDP – SPSS training												
Data collection – EHO interviews												
Data collection – EHO survey												
Freedom of information request – LA, Scotland												
PDP – HealthQWest event – qualitative data interpretation												
<b>2009</b>												
Literature review												
Data collection – EHO interviews												
Data collection – EHO survey												
Progress review												
JIP article submission and publication (x3 articles)												
PDP – SPSS training update												
REHIS - presentation												
PDP – RAE event												
PG conference - presentation												
Data collection – Practitioner survey												
Data collection – Practitioner survey – 2 <sup>nd</sup> distribution												
Mixed Methods conference - presentation												
Data collection – Practitioner interviews												
PH conference - presentation												
Data collection – Practitioner observation												
<b>2010</b>												
Thesis development												
Literature review												
Data collection - observation												
Progress review												

Activity	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
<b>2010 cont'</b>												
PG conference – presentation				■								
Data analysis – individual/ specific aspects – for REHIS conference purposes				■	■							
REHIS Annual conference – presentation					■							
EH Scotland article submission and publication					■	■						
BBV Prevention Network- presentation									■			
Data analysis							■	■	■	■	■	■
Data integration									■	■	■	■
Data interpretation									■	■	■	■
<b>2011</b>												
Lanarkshire Research Advisory Group presentation - questionnaire design	■											
Thesis development	■	■										
Literature review	■	■										
Data integration	■	■										
Data interpretation	■	■										
Mixed Methods Conference – abstract acceptance		■										
Draft submission	■	■										
Review of draft submission		■	■									
Final submission			■									
Viva				■								

### Coding

■	Indicator of timing of activity
Activity colour coding	
	Research implementation
■	Formal progression/ approvals
■	Research associated professional development
■	Research dissemination

Appendix 8  
Survey covering letter and  
information sheet

Ref: Claire Chalmers

Date:

Users of:

Civic Government (Scotland) Act 1982

(Licensing of Skin Piercing and Tattooing) Order 2006

Scotland

Dear Sir/ Madam

**GIVE YOUR VIEWS ON THE REGULATION OF THE TATTOOING AND  
COSMETIC BODY PIERCING INDUSTRY**

It has been almost three years since the introduction of mandatory licensing for the skin piercing and tattooing industry in Scotland. How has this impacted on you, your practice, or the practices of your employees? Has licensing been implemented consistently? Was regulation needed to manage/ minimise risk to health from skin piercing and tattooing activities? To help answer these questions, I am undertaking a study and **I would like to invite you to participate.**

If you would like to consider participating, please read the attached information. Then, if you decide to participate, complete and return the questionnaire in the stamped addressed envelope provided.

You will shortly be contacted again, and given the option to participate further by taking part in:

- An interview
- An observation of practice

By completing this questionnaire, you will be under no obligation to participate further.

The findings from this work will be shared with industry users, Environmental Health Services, Health Protection Scotland and the Scottish Government, to inform the future debate around this regulation. This is a valuable opportunity for you to contribute to that debate by giving your views on the implementation and impact of this regulation for you as a user of the regulation.

I look forward to hearing from you, and thank you, in anticipation, for your help and support with this work.

CLAIRE CHALMERS  
PhD Student (Napier University)  
Senior Lecturer (UWS)  
Tel 01698 283100, Ext 8658



Regulation of the tattooing and cosmetic body piercing industry in Scotland  
Survey information sheet

Background/ introduction

My name is Claire Chalmers and I am a postgraduate student from the School of Nursing Midwifery and Social care at Napier University in Edinburgh. I am undertaking my PhD, and the working title of my research study is "Regulation of the tattooing and cosmetic body piercing industry in Scotland".

Background to study

Regulation of the skin piercing and tattooing industry in Scotland was implemented in April 2006, through the Order, with a one-year transition period was incorporated for existing acupuncture; cosmetic body piercing; electrolysis; and tattooing businesses to ensure they met the requirements of the Order.

Intent of the study

This study will consider users' response to the regulation within the tattooing and cosmetic body piercing industry in Scotland, with the intent of determining the extent of regulatory compliance.

Why undertake the study?

There is currently very little research within this area. The findings of this study will therefore be valuable both to those involved in implementing and enforcing the regulation, by providing a better understanding of regulatory compliance within the tattooing and cosmetic body piercing industry in Scotland. It is also anticipated that this work will contribute to the wider debate surrounding regulation as a mechanism to manage/ reduce the risk to health both within the tattooing and cosmetic body piercing industry as well as within healthcare and environmental settings.

I am inviting staff from Local Authority Environmental Health Services and the Tattooing and Cosmetic Body Piercing Industry in Scotland to participate in the study. The only criterion for entry to the study is that you have/ have had involvement with either the implementation or enforcement of the Order.

How does this affect you?

You are invited to take part in this part of the study by completing the attached questionnaire, and returning it to me (Claire Chalmers) in the stamped addressed envelope provided. As the researcher, I am not aware of any risks associated with participation, and the procedure should take no more than 15-20 minutes to complete. Return of the questionnaire will imply your consent to participate.

You will shortly be contacted again, and invited to take part further in the study by participating in an interview and/ or observation of practice. By completing this questionnaire, you will be under no obligation to participate further.

What will happen to the results from this study?

As well as being presented as part of my PhD submission, the results of this work may be published in a journal or presented at conference. All data from questionnaires is anonymous, and it will not be possible for you to be identified in the reporting of the data gathered. Any data collected will be kept in a secure place to which only I will have access. These will be kept until the end of the examination process.

What do you do now?

If you have read and understood this information, and would like to participate in this part of the study, please read and complete the questionnaire, and return it by **(date TBC)**, using the stamped addressed envelope provided, to:

Claire Chalmers  
PhD Student/ Senior Lecturer  
University of the West of Scotland  
Hamilton Campus  
Almada Street  
Hamilton  
Lanarkshire, ML3 0JB

# Appendix 9

## Survey questionnaire

Regulation of tattooing and cosmetic body piercing in Scotland:  
Questionnaire

Section 1: Some questions about you and your work

1. What gender are you? (Select by **ticking one** of the following choices)

Male	<input type="checkbox"/>
Female	<input type="checkbox"/>

2. What age band are you in? (Select by **ticking one** of the following choices)

18-30 years	<input type="checkbox"/>
31-40 years	<input type="checkbox"/>
41-50 years	<input type="checkbox"/>
51-60 years	<input type="checkbox"/>
61+ years	<input type="checkbox"/>

3. What is your profession? (Select by **ticking as many of the following choices as apply to you**)

Trained Tattoo Artist	<input type="checkbox"/>
Apprentice Tattoo Artist	<input type="checkbox"/>
Trained Cosmetic Body Piercer	<input type="checkbox"/>
Apprentice Cosmetic Body Piercer	<input type="checkbox"/>
Studio Manager/ Owner	<input type="checkbox"/>
Environmental Health Officer	<input type="checkbox"/>
License holder	<input type="checkbox"/>

4. What Local Authority area do you work within? (Select by **ticking one** of following choices)

Aberdeen	East Ayrshire	Highland	Renfrewshire
Aberdeenshire	East Dunbartonshire	Inverclyde	Scottish Borders
Angus	East Lothian	Midlothian	Shetland
Argyll & Bute	East Renfrewshire	Moray	South Ayrshire
Clackmannanshire	Edinburgh City	North Ayrshire	South Lanarkshire
Comhairle Nan Eilean Siar	Falkirk	North Lanarkshire	Stirling
Dumfries & Galloway	Fife	Orkney	West Dunbartonshire
Dundee City	Glasgow City	Perth & Kinross	West Lothian

5. How many years of experience do you have of working in (or with) the tattooing and cosmetic body piercing industry? (Select by **ticking one** of the following choices)

Less than 5 years	<input type="checkbox"/>
Between 5-10 years	<input type="checkbox"/>
More than 10 years	<input type="checkbox"/>

6. Did you take part in the consultation on regulation of skin piercing by responding to the consultation paper entitled "Regulation of skin piercing: a consultation paper" or subsequent design of the regulation? (Select by **ticking one** of the following choices)

CONSULTATION		DESIGN OF REGULATION	
Yes	<input type="checkbox"/>	Yes	<input type="checkbox"/>
No	<input type="checkbox"/>	No	<input type="checkbox"/>
Cannot remember	<input type="checkbox"/>	Cannot remember	<input type="checkbox"/>

Section 2: Your views of practices within the tattooing and cosmetic body piercing industry generally

7. How do you feel about practice within the tattooing and cosmetic body piercing industry in Scotland? (Select by **ticking one of the available options for each statement**)

Statement	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
Improvements to practice were required within the tattooing and cosmetic body piercing industry in Scotland					
Some practitioners within the tattooing and cosmetic body piercing industry in Scotland operate poor practice despite regulation					

8. **Prior to regulation**, was anything being done to monitor tattooing/ cosmetic body piercing practice? (Select by **ticking one** of the following choices)

Yes	
No	
Don't know	

If yes, please give some detail in the space provided below

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9. **Since regulation**, is anything being done to monitor tattooing and cosmetic body piercing practice? (Select by **ticking one** of the following choices)

Yes	
No	
Don't know	

If yes, please give some detail in the space provided below

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10. How do you feel about the following? (Select by **ticking one of the available options for each statement**)

Statement	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
Regulation of the tattooing and cosmetic body piercing industry in Scotland has resulted in me making changes to my practice					
I did not need to change my practice as a result of regulation of the tattooing and cosmetic body piercing industry in Scotland					

Section 3: Your views of infection control practices within the tattooing and cosmetic body piercing industry

11. **Prior to regulation**, how would you rate your awareness of the following?  
(Select by **ticking one of the available options for each statement**)

Statement	Unsafe	Poor	OK	Good	Excellent	Don't know	NA
The infection control practice of the tattooing and cosmetic body piercing industry <b><u>across Scotland</u></b>							
The infection control practice of tattooing and cosmetic body piercing Industry <b><u>in your Local Authority area</u></b>							
The infection control practice of tattooing and cosmetic body piercing industry <b><u>in your studio</u></b>							
<b><u>Your own</u></b> infection control practice within the tattooing and cosmetic body piercing industry							

\*N/A = not applicable

12. **Since regulation**, how would you rate your awareness of the following? (Select by **ticking one of the available options for each statement**)

Statement	Unsafe	Poor	OK	Good	Excellent	Don't know	NA
The infection control practice of the tattooing and cosmetic body piercing industry <b><u>across Scotland</u></b>							
The infection control practice of tattooing and cosmetic body piercing Industry <b><u>in your Local Authority area</u></b>							
The infection control practice of tattooing and cosmetic body piercing industry <b><u>in your studio</u></b>							
<b><u>Your own</u></b> infection control practice within the tattooing and cosmetic body piercing industry							

13. How do you see the link between regulation and infection control practice within the tattooing and cosmetic body piercing industry in Scotland? (Select by **ticking one of the available options for each statement**)

Statement	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
Regulation was introduced in Scotland because of poor infection control practice					

Section 4: Your views of regulation within the tattooing and cosmetic body piercing industry

14. How do you feel about regulation of the tattooing and cosmetic body piercing industry in Scotland? (Select by **ticking one of the available options for each statement**)

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
Regulation was the only way to improve the practices of the industry across Scotland					
The aim of minimising risk to health from tattooing and cosmetic body piercing has been achieved through regulation in Scotland					
Regulation was the best way to achieve improvements to practices within the industry in Scotland					
Regulation has done little to improve practice across the industry in Scotland					
Regulation was required in Scotland to minimise the risk to health from tattooing and cosmetic body piercing activities					
Regulation has been applied consistently across Scotland's tattooing and cosmetic body piercing industry					
The regulation made the requirements for infection control practice clear to those working within the tattooing and cosmetic body piercing industry in Scotland					
Time was given to the tattooing and cosmetic body piercing industry in Scotland to comply with the requirements of the regulation					
Support was given to the tattooing and cosmetic body piercing industry in Scotland to aid compliance with the requirements of the regulation					

15. Other than regulation, is/ was there any alternative option to improve/ enhance practice within the tattooing and cosmetic body piercing industry in Scotland? (Select by **ticking one** of the following choices)

Yes	
No	
Don't know	

If yes, please give some detail in the space provided below

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**Section 5: Your views on regulatory compliance within the tattooing and cosmetic body piercing industry**

15. How do you feel about compliance with regulation within the tattooing and cosmetic body piercing industry in Scotland? (Select by **ticking one of the available options for each statement**)

Statement	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
Any changes to practice as a result of regulation are likely to be short term changes					
Changes to infection control practice within the tattooing and cosmetic body piercing industry as a result of regulation will be difficult to sustain					

17. Can you identify any factors that have supported/ helped with compliance with regulation within the tattooing and cosmetic body piercing industry in Scotland? Please give some detail in the space provided below

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18. Can you identify any factors that have inhibited/prevented compliance with regulation within the tattooing and cosmetic body piercing industry in Scotland? Please give some detail in the space provided below

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19. Can you identify anything that would help sustain compliance with regulation within the tattooing and cosmetic body piercing industry in Scotland? Please give some detail in the space provided below

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**If you are currently working within the industry, continue with the remaining sections of the questionnaire (Sections 6 and 7)**

**If you are an Environmental Health Officer, go straight to Section 7**



Section 6: Your views on your own infection control practice

20. **Prior to regulation**, how would you rate yourself on the following infection control practices? (Select by **ticking one of the available options for each statement**)

Statement	Unsafe	Poor	OK	Good	Excellent
Hand hygiene					
Personal protective equipment use (gloves aprons and masks)					
Sharps management					
Waste management					
Environmental decontamination					
Equipment decontamination					
Food hygiene					

21. **Since regulation**, how would you rate yourself on the following infection control practices? (Select by **ticking one of the available options for each statement**)

Statement	Unsafe	Poor	OK	Good	Excellent
Hand hygiene					
Personal protective equipment use (gloves aprons and masks)					
Sharps management					
Waste management					
Environmental decontamination					
Equipment decontamination					
Food hygiene					

22. Identify which (if any) aspects of your infection control practice you have changed as a result of regulation (Select by **ticking as many options as applicable**)

Hand hygiene	
Personal protective equipment use (gloves aprons and masks)	
Sharps management	
Waste management	
Environmental decontamination	
Equipment decontamination	
Food hygiene	
Other (please specify) .....	
Other (please specify).....	
I have not changed any of my infection control practice	

23. How do you feel about the changes to your practice as a result of regulation? (Select by **ticking one of the available options for each statement**)

Statement	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	NA
Changing my practice as a result of regulation has made me a safer practitioner within the tattooing and cosmetic body piercing industry in Scotland						



# Appendix 10

## Interview protocol

Regulation of the tattooing and cosmetic body piercing industry in  
Scotland  
Qualitative focused interview protocol

Introduction/ Background

The Order, was implemented in April 2006, with a one year transition period for existing businesses to ensure they met the requirements

The aim of the Order was to introduce consistent controls which would manage/ reduce the risk to health associated with these activities – The Order covered acupuncture; cosmetic body piercing; electrolysis and tattooing

The overall intent of my research project is to better understand regulatory compliance - By understanding users' response to regulation within the tattooing and cosmetic body piercing industry in Scotland, and determining the extent of regulatory compliance. This part of the study involves speaking directly (through interviews like this one) with environmental health officers and practitioners from within the tattooing and cosmetic body piercing industry, about their experiences of regulation and the regulatory process.

It is important for me to say:

- there are no rights/ wrongs...
- you can stop at any time
- interrupt/ ask for explanations if required at any time
- any identifiable reference to you (your studio) (your LA) will be removed from the tape and the transcript of the tape

Can I confirm that you:

- have read the information sheet and understand the purpose of the study?
- have agreed in writing (by signing the consent form) to take part in this interview?
- have given your written consent to this interview being taped?

### Warm up question

1. Tell me a bit about yourself, and your work with the tattooing and body piercing industry?

### Main questions

#### National situation...

1. Tell me about your awareness of practice/ infection control practices within Scotland's tattooing and cosmetic body piercing prior to regulation?

#### PROMPT

- a. Do you know of anything that was being done to monitor infection control practice nationally prior to regulation?
  - b. What was your general feeling about practice/ infection control practice of the tattooing and cosmetic body piercing industry across Scotland prior to regulation? Why?
  - c. Is there anything specifically that, in your view, prompted the decision to move toward/ implement this regulation?
2. What was your involvement in the national consultation leading up to the implementation of this regulation?

#### Experience of regulatory process

1. How do you feel about regulation? Why?
2. What did the licensing process involve for you?
  - a. (Practitioner) – how did you achieve compliance?
  - b. (Enforcer) - how did you determine compliance?
3. Can you explain to me, in your view, what is it about regulation that makes a difference to practice/ infection control practice?
4. What changes have resulted from regulation?

The main aim of the regulation was to introduce consistent controls that would minimise risk to health from tattooing and cosmetic body piercing activities

3. How do you feel about the concept of consistent control?
4. What do you think about risk to health from tattooing and CBP? Can you explain if/ how it has been minimised through regulation?
5. What other changes are required to achieve/ better achieve the aim of regulation?

### To finish with

6. Almost 2.5/ 3 years since implementation, how then would you sum up the current infection control practice within the industry generally?
7. Is there anything else you would like to add?

### Close of interview

What happens next...

Interview will be transcribed – returned to interviewee for verification

Data used anonymously to address the research aims/ objectives/ questions

Thanks.....(Practitioners) - invitation to participate in observation ....

Appendix 11  
Interview covering letter, information  
sheet and consent form

Ref: Claire Chalmers

Date:

Users of:

Civic Government (Scotland) Act 1982

(Licensing of Skin Piercing and Tattooing) Order 2006

Scotland

Dear Sir/ Madam

**GIVE YOUR VIEWS ON THE REGULATION OF THE TATTOOING AND COSMETIC BODY PIERCING INDUSTRY**

It has been almost three years since the introduction of mandatory licensing for the skin piercing and tattooing industry in Scotland. How has this impacted on you, your practice, or the practices of your employees? Has licensing been implemented consistently? Was regulation needed to manage/ minimise risk to health from skin piercing and tattooing activities? To help answer these questions, I am undertaking a study to help understand users' response to the regulation.

Having already invited you to participate in this study by completing a questionnaire, I am now writing to invite you to participate further by taking part in an interview.

If you would like to consider participating, please read the attached information. Then, if you decide to participate, complete and return the enclosed consent form in the stamped addressed envelope provided. Once I receive this, I shall contact you to arrange an interview at a date and time that suits you.

By completing this consent form, you will be under no obligation to participate further. All information will be discussed again, prior to any participation.

The findings from this work will be shared with industry users, Environmental Health Services, Health Protection Scotland and the Scottish Government, to inform the future debate around this regulation. This is a valuable opportunity for you to contribute to that debate by giving your views on the implementation and impact of this regulation for you as a user of the regulation.

I look forward to hearing from you, and thank you, in anticipation, for your help and support with this work.

CLAIRE CHALMERS  
PhD Student (Napier University)  
Senior Lecturer (UWS)  
Tel 01698 283100, Ext 8658

Regulation of the tattooing and cosmetic body piercing industry in Scotland  
Information Sheet for Potential Participants - Interviews

Introduction

My name is Claire Chalmers and I am a postgraduate student from the School of Nursing Midwifery and Social Care at Napier University in Edinburgh. I am undertaking my PhD, and the working title of my research study is "Regulation of the tattooing and cosmetic body piercing industry in Scotland".

Background to study

In April 2006, the Order ("the Order") was implemented, to regulate the skin piercing and tattooing industry in Scotland. The Order covers acupuncture; cosmetic body piercing; electrolysis and tattooing.

Intent of the study

This study will consider users' response to the regulation within the tattooing and cosmetic body piercing industry in Scotland, with the intent of determining the extent of regulatory compliance.

Why undertake the study?

There is currently very little research within this area. The findings of this study will therefore be valuable both to those involved in implementing and enforcing the regulation, by providing a better understanding of regulatory compliance within the tattooing and cosmetic body piercing industry in Scotland. It is also anticipated that this work will contribute to the wider debate surrounding regulation as a mechanism to manage/ reduce the risk to health both within the tattooing and cosmetic body piercing industry as well as within healthcare and environmental settings.

I am inviting staff from Local Authority Environmental Health Services and the Tattooing and Cosmetic Body Piercing Industry in Scotland to participate in the study. The only criterion for entry to the study is that you have/ have had involvement with either the implementation or enforcement of the Order.

How does this affect you?

If you agree to participate in this part of the study, you will be asked to take part in a taped interview. As the researcher, I am not aware of any risks associated with participation, and the whole procedure should take no longer than one hour. You will be free to withdraw from the study at any time, and will not require to give any reason for such a decision. No expenses will be incurred, as I will travel to you to undertake this work.

What will happen to the results from this study?

As well as being presented for submission as part of my PhD, the results of this work may be published in a journal or presented at a conference. All data will however be anonymised, with your name being replaced with a participant number/ pseudonym. While you may be identifiable from tape recordings of your voice, it will not be possible for you to be identified in any reporting of the data gathered. Any data collected will be kept in a secure place to which only I will have access. These will be kept until the end of the examination process, after which they will be destroyed.



What do you do now?

All of the above information will be discussed again, prior to any participation.

If you have read and understood this information sheet, and you would like to consider participating in this part of the study, please now read and complete the consent form, thereafter returning it to me in the stamped addressed envelope provided. Once I receive this, I shall contact you to arrange an interview at a date and time that suits you.

If you would like to speak to an independent person, who knows about this project but is not involved in it, please contact:

Dr Jayne Donaldson

Senior Lecturer

School of Nursing Midwifery and Social Care

Napier University

Tel: 0131 455 3697

E-mail: [j.donaldson@napier.ac.uk](mailto:j.donaldson@napier.ac.uk)

Regulation of the tattooing and cosmetic body piercing industry in Scotland  
Interview Consent Form

Please tick the following boxes as appropriate:

I have read and understood the information sheet, and have had an opportunity to ask questions about my participation.

I understand that I am under no obligation to take part in this study, and that I have the right to withdraw any stage without giving any reason.

I agree to participate in this study.

I agree to the interview being recorded.

Name of participant: \_\_\_\_\_  
Signature of participant: \_\_\_\_\_  
Date \_\_\_\_\_

Your contact details for arranging an interview:  
Please provide below the most acceptable means of contacting you (ie mobile, telephone, e-mail, home address)

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**Please post the completed consent form using the stamped addressed envelope**

.....  
.

Contact details of the researcher

Name of researcher: Claire Chalmers  
PhD Student, Napier University  
Senior Lecturer, University of the West of Scotland

Address: University of the West of Scotland  
Hamilton Campus  
Almada Street  
Hamilton  
Lanarkshire  
ML3 0JB

Email / Telephone: [claire.chalmers@uws.ac.uk](mailto:claire.chalmers@uws.ac.uk) / 01698 283100 Ext 8658

Agreed date for interview: \_\_\_\_\_  
Signature of researcher: \_\_\_\_\_  
Date: \_\_\_\_\_

Appendix 12  
Observation covering letter,  
information sheet and consent  
form

Ref: Claire Chalmers

Date:

Users of:

Civic Government (Scotland) Act 1982

(Licensing of Skin Piercing and Tattooing) Order 2006

Scotland

Dear Sir/ Madam

**GIVE YOUR VIEWS ON THE REGULATION OF THE TATTOOING AND COSMETIC BODY PIERCING INDUSTRY**

It has been almost three years since the introduction of mandatory licensing for the skin piercing and tattooing industry in Scotland. How has this impacted on you, your practice, or the practices of your employees? Has licensing been implemented consistently? Was regulation needed to manage/ minimise risk to health from skin piercing and tattooing activities? To help answer these questions, I am undertaking a study to help understand users' response to the regulation.

Having already invited you to participate in this study by completing a questionnaire, I am now writing to invite you to participate further by taking part in observation of practice.

If you would like to consider participating, please read the attached information. Then, if you decide to participate, complete and return the enclosed consent form in the stamped addressed envelope provided. Once I receive this, I shall contact you to arrange a date and time that suits you to undertake the observation.

By completing this consent form, you will be under no obligation to participate further. All information will be discussed again, prior to any participation.

The findings from this work will be shared with industry users, Environmental Health Services, Health Protection Scotland and the Scottish Government, to inform the future debate around this regulation. This is a valuable opportunity for you to contribute to that debate by giving your views on the implementation and impact of this regulation for you as a user of the regulation.

I look forward to hearing from you, and thank you, in anticipation, for your help and support with this work.

CLAIRE CHALMERS  
PhD Student (Napier University)  
Senior Lecturer (UWS)  
Tel 01698 283100, Ext 8658

Regulation of the tattooing and cosmetic body piercing industry in Scotland  
Information Sheet for Potential Participants - Observation

Introduction

My name is Claire Chalmers and I am a postgraduate student from the School of Nursing Midwifery and Social Care at Napier University in Edinburgh. I am undertaking my PhD, and the working title of my research study is "Regulation of the tattooing and cosmetic body piercing industry in Scotland".

Background to study

In April 2006, the Order ("the Order") was implemented, to regulate the skin piercing and tattooing industry in Scotland. The Order covers acupuncture; cosmetic body piercing; electrolysis and tattooing.

Intent of the study

This study will consider users' response to the regulation within the tattooing and cosmetic body piercing industry in Scotland, with the intent of determining the extent of regulatory compliance.

Why undertake the study?

There is currently very little research within this area. The findings of this study will therefore be valuable both to those involved in implementing and enforcing the regulation, by providing a better understanding of regulatory compliance within the tattooing and cosmetic body piercing industry in Scotland. It is also anticipated that this work will contribute to the wider debate surrounding regulation as a mechanism to manage/ reduce the risk to health both within the tattooing and cosmetic body piercing industry as well as within healthcare and environmental settings.

I am inviting practitioners from the tattooing and cosmetic body piercing industry in Scotland to participate in the study. The only criterion for entry to the study is that you have/ have had involvement with the implementation of the Order.

How does this affect you?

If you agree to participate in this part of the study, you will be asked to allow me as the researcher to observe your practice/ infection control practice. This may involve observing you undertake an infection control procedure (such as hand washing), or may involve observing your practice as you carry out a procedure on a client.

I am not aware of any risks associated with participation. The whole process would be done as part of your normal routine (over the course of at least one day), and would not interfere with your day-to-day work activity. You will be free to withdraw from the study at any time, and will not require to give any reason for such a decision. No expenses will be incurred, as I will travel to you to undertake this work.

How does this affect your clients?

I may wish to observe your practice/ infection control practice as you carry out a procedure on a client. If this is the case, then consent for this to happen will be required from the client. Information and consent forms would be

provided to you to give to the client prior to any such observation. Again, I am not aware of any risks to the client associated with such participation, and the client will also be free to withdraw their consent at any time. No reason is required to be given for such a decision.

If any client decides not to consent to such involvement, then your practice as you carry out a procedure on this client would not be observed. Such a decision would not exclude you from involvement in other parts of the study where observation did not involve a client-related procedure.

No expenses will be incurred for the client.

What will happen to the results from this study?

As well as being presented for submission as part of my PhD, the results of this work may be published in a journal or presented at a conference. All data will however be anonymised, with your name being replaced with a participant number/ pseudonym, and it will not be possible for you or your clients to be identified in any reporting of the data gathered. Any data collected will be kept in a secure place to which only I will have access. These will be kept until the end of the examination process, after which, they will be destroyed.

What do you do now?

All of the above information will be discussed again, prior to any participation.

If you would like to speak to an independent person, who knows about this project but is not involved in it, please contact:

Dr Jayne Donaldson  
Senior Lecturer  
School of Nursing Midwifery and Social Care  
Napier University  
Tel: 0131 455 3697  
E-mail: [j.donaldson@napier.ac.uk](mailto:j.donaldson@napier.ac.uk)

If you have read and understood this information sheet, and you would like to participate in this part of the study, please now read and complete the consent form, and return it to me in the stamped addressed envelope provided.

Once I am in receipt of your consent form, I shall contact you to arrange a suitable date and time to undertake the observation. In addition, if any client-related procedures are to be observed, information and consent forms will be sent to you to issue to any clients that will be seen during the agreed period of observation. The client should be asked to bring this consent form with them on the day they attend for their tattoo/ piercing, and only procedures involving clients who have agreed to participate will be included in the observation.

Regulation of the tattooing and cosmetic body piercing industry in Scotland  
Observation Consent Form

Please tick the following boxes as appropriate:

I have read and understood the information sheet, and have had an opportunity to ask questions about my participation.

I understand that I am under no obligation to take part in this study, and that I have the right to withdraw any stage without giving any reason.

I agree to participate in this study.

I have provided the relevant clients with information about the study

Name of participant: \_\_\_\_\_

Signature of participant: \_\_\_\_\_

Date \_\_\_\_\_

Your contact details for arranging a date/ time for the observation to take place:  
Please provide below the most acceptable means of contacting you (ie mobile, home/ work telephone, home/ work e-mail, home/ work address)

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**Please post the completed consent form using the stamped addressed envelope**

.....  
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Contact details of the researcher

Name of researcher: Claire Chalmers  
PhD Student, Napier University  
Senior Lecturer, University of the West of Scotland

Address: University of the West of Scotland  
Hamilton Campus  
Almada Street  
Hamilton  
Lanarkshire  
ML3 0JB

Email / Telephone: [claire.chalmers@uws.ac.uk](mailto:claire.chalmers@uws.ac.uk) 01698 283100 Ext 8658

Agreed date/ time for observation: \_\_\_\_\_

Signature of researcher: \_\_\_\_\_

Date: \_\_\_\_\_

Appendix 13  
Observation information sheet and  
consent form for clients



Regulation of the tattooing and cosmetic body piercing industry in  
Scotland  
Information Sheet for Clients  
(indirect involvement in observation)

Introduction

My name is Claire Chalmers and I am a postgraduate student from the School of Nursing Midwifery and Social Care at Napier University in Edinburgh. I am undertaking a PhD, looking at the regulation of the tattooing and cosmetic body piercing industry in Scotland.

The findings of this study will be valuable both to those involved in implementing and enforcing recently introduced regulation, by providing an understanding of users' response to regulation and determining the extent of regulatory compliance within the tattooing and cosmetic body piercing industry in Scotland.

How does this affect you?

You are due to have a tattoo/ piercing on the same day I am attending the studio to observe practice/ infection control practice. While this observation does not involve you directly, it may involve observing the tattooist/ piercer during your time in the studio, and while you are having your tattoo/ piercing done.

As the researcher, I am not aware of any risks associated with involvement, however, it is important that you are given the opportunity to choose whether you wish to be involved in this indirect way. The tattooist/ piercer carrying out your tattoo/ piercing will only be observed by the researcher on your agreement.

Any decision you make will not affect you having your tattoo/ piercing done.

Should you decide to be involved, then change your mind, you will be free to withdraw that agreement at any time, and will not require to give any reason for such a decision.

You will incur no expenses if you decide to be involved.

What will happen to the results from this study?

As well as being presented for submission as part of my PhD, the results of this work may be published in a journal or presented at a conference. All data is anonymised, and it will not be possible for you to be identified in any reporting of the data gathered. Any data collected will be kept in a secure place to which only I will have access. These will be kept until the end of the examination process, after which, they will be destroyed.

What do you do now?

All of the above information will be discussed again, prior to any participation.

If you have read and understood this information sheet, and agree to be involved in the way that is described, please complete the consent form and bring it with you to the studio on the day you are having your tattoo/ piercing done.

If you would like to speak to an independent person, who knows about this project but is not involved in it, please contact:

Dr Jayne Donaldson  
Senior Lecturer  
School of Nursing Midwifery and Social Care  
Napier University  
Tel: 0131 455 3697  
E-mail: [j.donaldson@napier.ac.uk](mailto:j.donaldson@napier.ac.uk)

Regulation of the tattooing and cosmetic body piercing industry in Scotland  
Consent Form (Client)

Please tick the following boxes as appropriate:

I have read and understood the information sheet, and have had an opportunity to ask questions about my participation.

I understand that I am under no obligation to take part in this study, and that I have the right to withdraw any stage without giving any reason.

I understand that my involvement in this study is in an indirect way only.

I agree to participate (indirectly) in this study

Name of participant: \_\_\_\_\_  
Signature of participant: \_\_\_\_\_  
Date \_\_\_\_\_

**Please bring this consent form with you when you attend for your tattoo/ piercing**

.....  
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Contact details of the researcher  
Name of researcher: Claire Chalmers  
PhD Student, Napier University  
Senior Lecturer, University of the West of Scotland

Address: University of the West of Scotland  
Hamilton Campus  
Almada Street  
Hamilton  
Lanarkshire  
ML3 0JB

Email / Telephone: [claire.chalmers@uws.ac.uk](mailto:claire.chalmers@uws.ac.uk) / 01698 283100 Ext 8658

Date of collection of consent form from client: \_\_\_\_\_  
Signature of researcher: \_\_\_\_\_  
Date: \_\_\_\_\_

# Appendix 14

## Steps in thematic network analysis

<b>ANALYSIS STAGE A: REDUCTION OR BREAKDOWN OF TEXT</b>
Step 1: Code material (a) Devise a coding framework (b) Dissect text into text segments using the coding framework
Step 2: Identify themes (a) Abstract themes from coded text segments (b) Refine themes
Step 3: Construct thematic network (a) Arrange themes (b) Select basic themes (c) Re-arrange into organising themes (d) Deduce global themes (e) Illustrate as thematic network(s) (f) Verify and refine the network
<b>ANALYSIS STAGE B: EXPLORATION OF TEXT</b>
Step 4: Describe and explore thematic networks (a) Describe the network (b) Explore the network
Step 5: Summarise thematic network
<b>ANALYSIS STAGE C: INTEGRATION OF EXPLORATION</b>
Step 6: Interpret patterns

# Appendix 15

## 12-item 'attitude to regulation' scale

Appendix 15: 12-item 'attitude to regulation' scale

	N	Minimum	Maximum	Mean
Regulation was best way to achieve improvement	107	2	5	4.06
Regulation was required to minimise risk to health	107	1	5	4.11
Regulation has resulted in improvement	107	1	5	3.59
Regulation was the only way to improve practices	107	1	5	3.36
Aim of minimising risk has been achieved through regulation	107	1	5	3.17
Regulation has been applied consistently	107	1	5	2.85
Regulation has done little to improve practices	107	1	5	2.67
Any change is likely to be short term	107	1	4	2.42
Change will be difficult to sustain	107	1	5	2.72
Regulation makes clear the requirements	107	1	5	3.44
Time was given to comply	107	1	5	3.78
Support was given to aid compliance	107	1	5	3.36