### 1 Utilising a data capture tool to populate a cardiac rehabilitation registry: a feasibility study

### 2 Abstract

3 Background: Clinical registries are effective for monitoring clinical practice, yet manual data 4 collection can limit their implementation and sustainability. The objective of this study was to assess 5 the feasibility of using a data capture tool to collect cardiac rehabilitation (CR) minimum variables 6 from electronic hospital administration databases to populate a new CR registry in Australia. 7 Methods: Two CR facilities located in Melbourne, Australia participated, providing data on 42 8 variables including: patient socio-demographics, risk factors and co-morbidities, CR program 9 information (e.g. number of CR sessions), process indicators (e.g. wait time) and patient outcomes 10 (e.g. change in exercise capacity). A pre-programmed, automated data capture tool (GRHANITE™) was installed at the sites to extract data available in an electronic format from hospital sites. 11 12 Additionally, clinicians entered data on CR patients into a purpose-built web-based tool (REDCap). 13 Formative evaluation including staff feedback was collected. 14 Results: The GRHANITE<sup>™</sup> tool was successfully installed at the two CR sites and data from 176 15 patients (median age=67 years, 76% male) were securely extracted between September – December 16 2017. Data pulled electronically from hospital databases was limited to seven of the 42 requested 17 variables. This is due to CR sites only capturing basic patient information (e.g. socio-demographics, 18 CR appointment bookings) in hospital administrative databases. The remaining clinical information 19 required for the CR registry were collected in formats (e.g. paper-based, scanned or Excel 20 spreadsheet) deemed unusable for electronic data capture. Manually entered data into the web-tool 21 enabled data collection on all remaining variables. Compared to historical methods of data 22 collection, CR staff reported that the REDCap tool reduced data entry time. 23 **Conclusions:** The key benefits of a scalable, automated data capture tool like GRHANITE<sup>™</sup> cannot be 24 fully realised in settings with under-developed electronic health infrastructure. While this approach

- 25 remains promising for creating and maintaining a registry that monitors the quality of CR provided to
- 26 patients, further investment is required in the digital platforms underpinning this approach.

27 Key words: cardiac rehabilitation; registry; data scraping

28 Introduction

29 The ability to quantify healthcare quality relies on the implementation of appropriate systems 30 that can accurate capture how care is being delivered [1]. In a recent scientific statement, the 31 American Heart Association called for the systematic redesign of cardiovascular care to enable a 32 'learning healthcare system' which uses information technology and data infrastructures to enhance 33 optimal healthcare delivery [2]. In Australia, the Commission on Safety and Quality of Health Care 34 (the Commission) promotes the use of clinical registries to systematically monitor healthcare, 35 highlight variations in outcomes, and inform quality improvement efforts [3]. Ischaemic heart 36 disease ranks as the highest priority area identified by the Commission that would benefit from 37 registry development due to the high burden of disease, serious consequences associated with poor quality care and strong clinical support [4]. This follows the success of cardiac registries 38 39 internationally including the Global Registry of Acute Coronary Events (GRACE)[5] and effective 40 system-wide changes seen by countries such as Sweden which has established more than 100 health 41 registries including some that have been maintained for more than 25 years [6].

42 A key component of secondary prevention of heart disease is cardiac rehabilitation (CR). 43 Although CR is extremely effective in preventing cardiovascular recurrent events and complications 44 [7] and recommended in clinical guidelines [8, 9], there is variability in program delivery and quality 45 [10] some of which stems from a lack of uniform data collection and monitoring systems. The need 46 to develop quality indicators and implement systems that collect standardised CR outcome data is 47 recognised by several national associations internationally [11-13] including the Australian Cardiovascular Health and Rehabilitation Association's (ACRA; the Australian association of CR 48 49 professionals) [14]. Specifically, ACRA recommend that all CR services collect a minimum set of data

50 and report on key performance indicators to promote continuous quality improvement of services 51 and benchmarking[14]. Despite these calls, quality indicator data from CR sites are, for the most 52 part, not systematically collected or collated. One jurisdiction in Australia, Queensland, has recently 53 established the Queensland Cardiac Outcomes Registry (QCOR) which includes the collection of CR 54 quality indicator variables as part of the registry and will be the first state in Australia to 55 systematically collect CR data [15]. In the state of Victoria, the Victorian Cardiac Outcomes Registry 56 (VCOR) [16] collects data on cardiac patients across 35 hospitals on three modules (percutaneous 57 coronary intervention, heart failure and the early treatment of acute myocardial infarction). 58 However, CR data are not included within VCOR.

59 Globally, custodians of CR registries have noted challenges, common to any registry, such as 60 site investment or 'buy-in', privacy and security considerations, as well as limited resources for 61 contributing data [17]. Indeed, sites are often required to manually enter data, which is time-62 consuming for clinical staff and increases the risk of data errors [18]. Ideally, data collection should 63 be automated and linked to administrative databases or electronic medical records (EMRs). With 64 advances in technology, this is becoming more feasible. Automated data capture techniques using 65 specially-designed software can be used to extract routinely-collected data. Such software can also 66 incorporate automated safeguards built-in to the data entry systems to ensure privacy protection. 67 This has been previously demonstrated within primary care and other settings in Australia [19] using 68 the GRHANITE<sup>™</sup> (GeneRic Health Network Information for the Enterprise [20]: 69 https://www.grhanite.com/) tool.

The aim of this manuscript was to assess the feasibility of extracting routinely-collected
minimum data (as defined by the NSW division of ACRA [21]) from CR sites and hospital
administration databases using the GRHANITE<sup>™</sup> automated data capture tool in order to populate a
Victorian CR Registry (VCRR).

74 Methods

I

76	This feasibility study consisted of a 3-month (September-December 2017) data collection
77	period involving quantitative data capture from two pilot sites and formative evaluation of the
78	process including feedback from CR clinicians. The design of the registry was guided by technical
79	standards outlined by the Commission [3], as illustrated in a logic model (Figure 1).
80	*FIGURE 1*
81	Figure 1 Clinical Quality Registries Information Model [16]. Reproduced with permission from Logical Design
82	for Australian Clinical Quality Registries, developed by the Australian Commission on Safety and Quality in
83	Health Care (ACSQHC), for use exclusively in Australia. ACSQHC: Sydney. 2012.
84	Acronyms: CQR: clinical quality registry; MBS: Medicare Benefits Schedule; PBS: Pharmaceutical Benefits
85	Scheme
86	
87	Selection of the minimum variables for the VCRR
88	The registry comprised a minimum set of variables selected from the New South Wales
89	(NSW) ACRA association quality indicators and data dictionary which was based on expert
90	
50	consensus [21]. The 42 selected data elements consisted of: demographic information (e.g. sex, age),
91	consensus [21]. The 42 selected data elements consisted of: demographic information (e.g. sex, age), disease/condition (e.g. principal referral diagnosis) risk factors and co-morbidities (e.g. diabetes
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100 public and one private site to invite to participate in the study. These sites were purposively selected 101 to ensure sample representation of: funding sources (public and private), settings (acute hospital, 102 rehabilitation hospital), and location (metropolitan and suburban). Site 1 was a large publicly-funded 103 program, which runs a six-week CR program for approximately 40 outpatients per week. Site 2 was a 104 private facility primarily funded through health insurance funds and the Department of Veteran 105 Affairs, which runs a 12-week program for approximately 15 outpatients per week. Participating 106 sites were offered a stipend of AU\$6,000 (USD\$4700) to cover cost related to staff time for the set-107 up of automated data collection. Both CR sites agreed to participate.

108 Ethics approval

109 The study was approved by the Human Research Ethics Committee (HREC) at the University 110 of Melbourne (HREC number: 1748609) and included a waiver of consent for individual patient data 111 (which was de-identified). Site-specific research ethics approval was also obtained. Staff who 112 participated in qualitative interviews provided informed consent.

# 113 Automated collection procedure (GRHANITE<sup>TM</sup>)

The team at the University of Melbourne's Health and Biomedical Informatics Centre Research Information Technology Unit (led by DB) assisted in the development of the data extraction protocol and worked with the sites' Information Technology (IT) teams to create an interface regime. This required the development of a "mapping" document which linked the variables requested from the research team with the variables collected and available electronically at the sites. The overview of the study methods can be seen in Figure 2.

120 **\*FIGURE 2\*** 

121 Figure 2 Overview of the study methods

122

123 Manual web-based data collection (REDCap)

124 To capture variables that were not available electronically at the sites, a secure web-based 125 data collection form was designed using the REDCap (Research Electronic Data Capture: 126 https://www.project-redcap.org/) software. The web-based form included three sections (Section 1: 127 identifiable patient information; Section 2: pre-CR data; Section 3: post-CR data) and was trialled for 128 two weeks at both sites, with feedback from the CR sites informing refinement of the data entry 129 template. Once finalised, clinicians entered data for patients who were enrolled in the CR programs 130 during the data collection period. The REDCap data collection forms contained mandatory fields to 131 reduce missing data and in-built logic checks to increase the accuracy of data. Authorised staff were 132 provided with a secure log-in which enabled access to the REDCap template; data access restrictions 133 ensured clinicians could only view data from their site. Additional detail on REDCap is provided in 134 Supplementary File 2.

135 Data extraction and linkage

136 CR data were extracted from the sites via the University of Melbourne's GRHANITE™ research data acquisition system. The GRHANITE™ interface was installed at both sites and 137 138 scheduled to extract pre-determined variables on patients who participated in the CR program during the data collection period. GRHANITE<sup>™</sup> enabled data to be extracted in a de-identified 139 140 manner by incorporating advanced privacy-preserving hashing techniques to generate unique 141 'signatures'. These data were then securely transmitted to the VCRR database based on the 142 University of Melbourne's server, with data stored in Microsoft SQL. Further details regarding data 143 security and storage can be found in Supplementary File 1 and 2.

144 Data quality

The system highlighted any GRHANITE<sup>™</sup> data extraction failures or omissions and IT
representative at each site reviewed the data to ensure it was coherent before it was forwarded to
the central registry. The REDCap data collection forms contained mandatory fields to reduce missing
data (data must be entered before being able to move to the next section) and in-built logic checks
to increase the accuracy of data. Missing patient records were assessed by comparing the number

of patients booked CR appointments in the electronic administrative database (total numbers) withnumber of patients manually entered into REDCap.

152 Formative evaluation

153 Semi-structured interviews were conducted within one week of the completed data 154 collection period (December 2017) to ascertain any barriers or enablers to implementation of the CR 155 registry. Individual interviews were held with clinical staff members involved with clinical data 156 collection at the two pilot sites (N=3). The interviews were conducted by a member of the research 157 team (ET). They were audio-recorded and then transcribed verbatim except to preserve anonymity. 158 The interview guide consisted of three parts: (i) historical approaches to data collection, (ii) 159 barriers to measuring and collecting variables and (iii) recommendations for future registry 160 implementation. Feedback provided by the clinicians was synthesised under the same three 161 headings and identified barriers were coded in themes and sub-categories using content 162 analysis[22].

163 Results

### 164 Characteristics of patients included in VCRR

165 The combined electronic and manual data revealed that across the two sites, 176 patients had a 166 booked CR appointment, 115 patients (65.34%) completed the initial CR appointment and 48 167 patients (27.27%) completed the CR program (achieved patient goals and/or attended an agreed 168 number of exercise and education sessions) within the data extraction period. The study sample was 169 predominantly male (76%) with a mean age of 67 years and 83% spoke English as their preferred 170 language (Table 2). The participant's sociodemographic characteristics differed across the two sites, 171 with participants at Site 2 being 10 years older on average (74 years vs. 65 years) and having a lower 172 baseline exercise capacity (95m less on the six-minute walk test) (Table 2). 173 **\*TABLE 2\*** 

174 **Table 2**. Characteristics of patients included in VCRR

Variables available from the electronic hospital administrative databases were limited to
 seven (age, sex, postcode, Aboriginal and Torres Strait Islander status, preferred language, CR
 booking, referral date) for each of the patients. This is due to hospital administrative databases at
 the sites only collecting basic information on patient sociodemographic characteristics and CR
 appointment bookings. Data extracted from the manual entry component (REDCap) enabled
 collection of all 42 variables in the minimum data set, supplementing the electronic data.
 *CR Quality*

The minimum variables extracted were useful in informing assessment of CR site quality in many instances (Table 3). There were site-specific differences in process indicators of care, suggesting the minimum variables are sensitive. For example, participants in Site 1 experienced a longer wait time to receive CR (44 days vs. 19 days) and were less likely to be screened for depression (54% vs. 92%). None of the identified smokers (across either site) were reported to have been referred for smoking cessation. There was a large amount of missing and unknown data from the manual-entry source.

Discrepancies existed between the number of patients booked CR appointments in the hospital administrative database (n=176) and those who attended the initial assessment and were entered into REDCap (n=115). Reasons for non-attendance to the initial session were not routinely collected and therefore unable to be ascertained for all cases. Further, many values in the post-CR assessment were reported as unknown (e.g. CR medication status was unknown for 44% of patient who completed a post-CR assessment).

- 195 **\*TABLE 3\***
- 196 **Table 3.** CR process indicators
- 197

198 CR Staff Perceptions of Data Capture Processes

Feedback from the two sites revealed that the manual entry component was straight-forward,
easy to use, and quicker than traditional forms of data collection (i.e., clinician-selected variables

201 entered into an Excel spreadsheet; Table 4). The training provided was perceived as sufficient and 202 staff felt in-built features such as mandatory fields enabled them to feel more confident about the 203 data quality. Staff expressed desire to have the capacity to search more easily for entered patient 204 data (a feature that is available in REDCap but was not highlighted during the training session) and 205 additional information about the rationale/evidence for some of the selected minimum variables. All 206 interviewees wanted to continue using REDCap and preferred this approach over traditional 207 methods; as described by the CR co-ordinator at Site 2 "I just can see that REDCap is the bright new 208 future that we can start to get the cardiac rehab product out there with consistency between 209 programs... Because at the moment we can all say that we are doing cardiac rehab and we can all be 210 members of ACRA but I don't know what you're providing and you don't know what I am doing 211 unless you are there". 212 Five main barriers were identified regarding historic methods of measuring and entering 213 variables (see Supplementary file 3): i) workload and competing responsibilities (e.g. time 214 constraints), ii) environmental context and resources (e.g. information technology issues, and not 215 having access to a quiet and secure space to enter data); iii) patient factors (e.g. patient 216 needs/concerns conflicting with data collection requirements); iv) care delivery processes and co-217 ordination (e.g. referrals getting lost because sent via post/fax ) and v) outcome expectations (e.g. 218 reduced confidence in data because of measurement errors). \*TABLE 4 \* 219

- 220 Table 4. Feedback from sites on web-based data entry
- 221

### 222 Discussion

To our knowledge, this was the first study to assess the feasibility of utilising a data capture tool to automatically extract minimum CR registry variables within public and private facilities. While CR sites collected large amounts of clinical data, the majority of these data (i.e., 83% of the 42

226 variables) were not readily-available in an appropriate electronic format rendering automated data 227 extraction unfeasible. Until such time that the current infrastructure in public and private CR settings 228 in Australia develops, the key benefits of scalable, automated data capture tools like GRHANITE™ 229 will remain unrealised. While this approach remains promising for creating and maintaining a 230 registry that monitors the quality of CR provided to patients, further investment is required in the 231 digital platforms underpinning this approach including ensuring electronic platforms are i) accessible 232 to CR sites, ii) fit for purpose and, iii) capturing high quality data. In the interim, a web-based data 233 collection tool housed on the REDCap system can enable standardised data to be collated from 234 various CR sites with known limitations associated with manual data entry. These key findings are discussed further below. 235

236 Greater emphasis must be placed on ensuring CR staff have access to EMRs[9]. In general, allied 237 health and community-based settings have had low-levels of adoption of electronic health 238 infrastructure compared to acute settings and primary care [23]. To ensure more timely access, 239 national associations such as ACRA, the Cardiac Society of Australia and New Zealand (CSANZ) and 240 the National Heart Foundation (NHF) need to facilitate advocacy efforts at the local, state and 241 national-level for improved electronic infrastructure within the CR setting. For example, ACRA could 242 provide guidance to CR co-ordinators and managers to push the agenda within local settings; 243 enhanced CR representation on state-based cardiac clinical networks could drive the issue at a state-244 level; and the development of a national strategic plan and committee could be established with the 245 aim of improving monitoring of CR and enhancing national efforts.

Future digital health investments will be driven by specific business needs and the identification and demonstration of local and system-wide benefits[24]. Consequently, a clear business case for enhanced monitoring of CR is required which details the digital requirements necessary to fulfil the current gap. Additionally, the workplace will likely need to up-skill to ensure adequate digital capability. Well-developed and robust change management is a crucial factor in deploying new

systems and clinicians must be involved in the process and actively champion health technologyactivities [24].

Ideally, as EMR uptake increases, all CR minimum variables would be available electronically, and
a registry could be pre-filled. In other countries CR registries have begun to simultaneously link with
administrative electronic databases to enable auto-filling of data (e.g. the Danish registry and
Canadian registry) [17, 25]. In states where different EMR systems are being implemented, flexible
tools like GRHANITE<sup>™</sup> will be crucial in enabling interoperability of data across various systems
(including public and private) whilst adhering to privacy and security concerns.

259 Ultimately, the success of data capture through EMRs will depend on multiple factors, including 260 minimum variables being: i) clearly defined, ii) entered consistently across sites, iii) of sufficient 261 reliability/validity, and iv) extractable. The CR field can begin to prepare for this now by ensuring 262 quality indicators are clearly defined and comparable across states.

263 In the interim, CR data collection can be improved via the use of a standardised web-based 264 tool housed on platforms such as the REDCap system. REDCap had multiple advantages including: i) 265 ease of implementation without any need for the sites' IT departments, ii) usable at both public and 266 private CR sites, iii) secure and password-protected access, iv) straight-forward and quick data 267 entry, v) in-built functions (e.g. mandatory fields, character limits, drop down options, automated reports) to enhance data quality and completeness, vi) available for use at no costs for affiliated 268 269 research institutes. Further, REDCap was supported by those entering the data who expressed an 270 interest in continuing beyond the study period.

Use of the web-based tool, however, could be enhanced. For example, future studies should incorporate data quality checks early in the data collection period that include a comparison of enrolled and entered patient data to ensure such data match and reasons for missing data are ascertained. In Australia CR sites often refer patients to more convenient programs (e.g. closer to home); such information needs to be captured on all patients so that reasons for non-attendance

276 can be more accurately documented. Additionally, unknown data requires additional clarification.

277 For example, post-CR medication status had larger amounts of unknown responses than other

278 variables and is potentially not being checked at post-CR interviews. Automated alerts could be in-

built for this variable to clarify the reason for the unknown information.

# 280 Study limitations

We acknowledge that this study has limitations. Due to the small sample size and Victorian setting, results from this feasibility study may not be generalizable to other settings and saturation of themes in the staff interviews were not realised. Additionally, the 'snap-shot' method of data collection meant that many patients had not completed CR at the time of data extraction. Further, enhanced methods are required to ensure all who enrolled into the CR programs were captured even if they did not attend the initial assessment session to reduce reporting bias towards CR attenders.

# 288 Implications and future recommendations

The transition to digital health systems holds great potential for enhancing clinical care within the CR setting. However, many jurisdictions have been slow to adopt e-health infrastructure limiting the application of tools like GRHANITE<sup>™</sup>. Key organisations need to advocate for EMRs in CR programs so that automated data-capture technologies can increase the viability of CR registries in the future. Efforts must also focus on preparing the field for the digital transition and preparing a clear business case delineating the local- and system-wide benefits and the digital requirements so systems are built in a way that is fit for purpose.

In the interim, a web-based data entry tool shows promise as an approach that should be
explored further and could enable the monitoring of CR quality across the private and public sector.

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### 299 References

- 300 [1] Spertus JA, Eagle KA, Krumholz HM, Mitchell KR, Normand SL, American College of
- 301 Cardiology/American Heart Association Task Force on Performance M. American College of
- 302 Cardiology and American Heart Association methodology for the selection and creation of
- performance measures for quantifying the quality of cardiovascular care. J Am Coll Cardiol.
   2005;45:1147-56.
- 305 [2] Maddox TM, Albert NM, Borden WB, Curtis LH, Ferguson TB, Jr., Kao DP, et al. The Learning
- 306 Healthcare System and Cardiovascular Care: A Scientific Statement From the American Heart
- 307 Association. Circulation. 2017.
- 308 [3] Australian Commission on Safety and Quality in Health Care. Logical design: Australian Clinical
   309 Quality Registries. Sydney: ACSQHS; 2012.
- [4] Australian Commission on Safety and Quality in Health Care. Prioritised list of clinical domains forclinical quality registry development. Sydney ACSQHC; 2016.
- 312 [5] Fox KA, Eagle KA, Gore JM, Steg PG, Anderson FA, Grace, et al. The Global Registry of Acute
- 313 Coronary Events, 1999 to 2009--GRACE. Heart. 2010;96:1095-101.
- [6] Essen A, Lindblad S. Innovation as emergence in healthcare: unpacking change from within. SocSci Med. 2013;93:203-11.
- 316 [7] Anderson L, Thompson DR, Oldridge N, Zwisler AD, Rees K, Martin N, et al. Exercise-based cardiac
- rehabilitation for coronary heart disease. Cochrane Database Syst Rev. 2016:CD001800.
- 318 [8] Chew DP, Scott IA, Cullen L, French JK, Briffa TG, Tideman PA, et al. National Heart Foundation of
- Australia and Cardiac Society of Australia and New Zealand: Australian clinical guidelines for the
   management of acute coronary syndromes 2016. Med J Aust. 2016;205:128-33.
- [9] Stone JA, Arthur HM, Suskin N. Canadian Guidelines for Cardiac Rehabilitation and Cardiovascular
- 322 Disease Prevention: Translating Knowledge Into Action. 3rd ed. ed. Winnipeg, MB: Canadian
- 323 Association of Cardiac Rehabilitation; 2009.
- 324 [10] Somanader DS, Chessex C, Ginsburg L, Grace SL. Quality and Variability of Cardiovascular
- 325 Rehabilitation Delivery: Applying the Canadian quality indicators. J Cardiopulm Rehabil Prev.
- 326 2017;37:412-20.
- 327 [11] Scottish Intercollegiate Guidelines Network. Cardiac rehabilitation: a national clinical guideline. .
   328 Edinburgh: SIGN; 2017.
- 329 [12] Piepoli MF, Hoes AW, Agewall S, Albus C, Brotons C, Catapano AL, et al. 2016 European
- 330 Guidelines on cardiovascular disease prevention in clinical practice: The Sixth Joint Task Force of the
- 331 European Society of Cardiology and Other Societies on Cardiovascular Disease Prevention in Clinical
- 332 Practice (constituted by representatives of 10 societies and by invited experts)Developed with the
- 333 special contribution of the European Association for Cardiovascular Prevention & Rehabilitation
- 334 (EACPR). Eur Heart J. 2016;37:2315-81.
- 335 [13] British Association of Cardiovascular Prevention and Rehabilitation. Cardiovascular disease
- prevention and rehabilitation 2017. London: British Cardiovascular Society; 2017.
- 337 [14] Woodruffe S, Neubeck L, Clark RA, Gray K, Ferry C, Finan J, et al. Australian Cardiovascular
- 338 Health and Rehabilitation Association (ACRA) core components of cardiovascular disease secondary
- prevention and cardiac rehabilitation 2014. Heart Lung Circ. 2015;24:430-41.
- 340 [15] Queensland Health. Queensland Cardiac Outcome Registry
- 341 <u>https://clinicalexcellence.qld.gov.au/improvement-exchange/cardiac-outcomes-registry:</u>
- 342 Queensland Government 2018.
- 343 [16] Stub D, Lefkovits J, Brennan AL, Dinh D, Brien R, Duffy SJ, et al. The Establishment of the
- 344 Victorian Cardiac Outcomes Registry (VCOR): Monitoring and Optimising Outcomes for Cardiac
- Patients in Victoria. Heart Lung Circ. 2018;27:451-63.
- 346 [17] Poffley A, Thomas E, Grace SL, Neubeck L, Gallagher R, Keech W, et al. A Systematic Review of
- Cardiac Rehabilitation Registries: a Global Perspective. European Journal of Preventive Cardiology.
   2017;24:1596-609.
- 349 [18] Grace SL, Parsons TL, Heise K, Bacon SL. The Canadian Cardiac Rehabilitation Registry: Inaugural
- Report on the Status of Cardiac Rehabilitation in Canada. Rehabil Res Pract. 2015;2015:278979.

- 351 [19] Weaver ER, Bowring AL, Guy R, van Gemert C, Hocking JS, Boyle DI, et al. Reattendance and
- chlamydia retesting rates at 12 months among young people attending Australian general practice
   clinics 2007-10: a longitudinal study. Sex Health. 2014;11:366-9.
- 354 [20] University of Melbourne. GRHANITE<sup>™</sup> Health Informatics Unit. In: Boyle D, editor.
- 355 <u>https://www.grhanite.com/2018</u>.
- 356 [21] Zecchin R, Candelaria D, Ferry C, Ladak LA, McIvor D, Wilcox K, et al. Development of Quality
- Indicators for Cardiac Rehabilitation in Australia: A Modified Delphi Method and Pilot Test. Heart,
   Lung and Circulation. 2018.
- 359 [22] Graneheim UH, Lundman B. Qualitative content analysis in nursing research: concepts,
- 360 procedures and measures to achieve trustworthiness. Nurse Educ Today. 2004;24:105-12.
- 361 [23] National E-Health Transition Authority. Evolution of eHealth in Australia: achievements, lessons,
- and opportunities Sydney: NEHTA; 2016.
- 363 [24] Victoria State Government. Digitising health: How information and communications technology
- will enable person-centred health and wellbeing within Victoria. In: Services DoHaH, editor. Victoria2016.
- 366 [25] Zwisler AD, Rossau HK, Nakano A, Foghmar S, Eichhorst R, Prescott E, et al. The Danish Cardiac
- 367 Rehabilitation Database. Clin Epidemiol. 2016;8:451-6.

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6	from electronic hospital administration databases to populate a new CR registry in Victoria,	
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8	Methods: Two Victorian CR facilities located in Melbourne, Australia participated, providing data on	
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21	clinical information required for the CR registry were collected in formats (e.g. paper-based, scanned	
22	or Excel spreadsheet) deemed unusable for electronic data capture. Manually entered data into the	
23	web-tool enabled data collection on all remaining variables. Consequently, manual data entry into a	
24	purpose built online template housed on the REDCap platform was undertaken to complement data	

- 25 capture. Compared to historical methods of data collection, CR staff reported that the REDCap tool
   26 reduced data entry time.
- 27 Conclusions: The key benefits of a scalable, automated data capture tool like GRHANITE™ cannot be
- 28 fully realised in settings with under-developed electronic health infrastructure. While this approach
- remains promising for creating and maintaining a registry that monitors the quality of CR provided to
- 30 patients, further investment is required in the digital platforms underpinning this approach.
- 31 Key words: cardiac rehabilitation; registry; data scraping

32 Introduction

33 The ability to quantify healthcare quality relies on the implementation of appropriate systems 34 that can accurate capture how care is being delivered [1]. In a recent scientific statement, the American Heart Association called for the The need to systematically redesign of cardiovascular care 35 to be a enable a 'learning healthcare system' which uses information technology and data 36 37 infrastructures to enhance optimal healthcare delivery has recently been highlighted in a Scientific 38 Statement [2]. In Australia, the Commission on Safety and Quality of Health Care (the Commission) 39 promotes the use of clinical registries to systematically monitor healthcare, highlight variations in outcomes, and inform quality improvement efforts [3]. Ischaemic heart disease ranks as the highest 40 priority area identified by the Commission that would benefit from registry development due to the 41 high burden of disease, serious consequences associated with poor quality care and -strong clinical 42 43 support and the existence of a current national registry (Australian Cardiac Outcome Registry) that 44 could be expanded in the future to include non-surgical interventions[4]. This follows the success of cardiac registries internationally including the Global Registry of Acute Coronary Events (GRACE)[5] 45 46 and effective system-wide changes seen by countries such as Sweden which has established more than 100 health registries including some that have been maintained for more than 25 years [6]. 47 48 A key component of secondary prevention of heart disease is cardiac rehabilitation (CR). 49 Although CR is extremely effective in preventing cardiovascular recurrent events and complications

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50	[7] and recommended in clinical guidelines [8, 9], there is variability in program delivery and quality
51	[10] some of which stems from a lack of uniform data collection and monitoring systems. The need
52	to develop quality indicators and implement systems that collect standardised CR outcome data is
53	recognised by several national associations internationally [11-13] National Heart Foundation of
54	Australia recognises the need to "develop national key performance indicators for secondary
55	prevention services and implement systems to collect standardised outcome data" [11, 12] including
56	Moreover, evaluation and quality improvement has been identified as a core component in the
57	delivery of comprehensive CR programs by the Australian Cardiovascular Health and Rehabilitation
58	Association's (ACRA; the national Australian association of CR professionals) [14]. Specifically, ACRA
59	recommend that all CR services collect a minimum set of data and report on key performance
60	indicators to promote continuous quality improvement of services and benchmarking[14]. Despite
61	these calls, quality indicator data from CR sites are, for the most part, not systematically collected or
62	collated. One jurisdiction in Australia, Queensland, has recently established the The Queensland
63	Cardiac Outcomes Registry (QCOR) has recently expanded to which includes the collection of CR
64	quality indicator variables as part of the registry and will be the first state in Australia to
65	systematically collect CR data [15]. In the state of Victoria, the Victorian Cardiac Outcomes Registry
66	(VCOR)_[16] collects data on cardiac patients across 35 hospitals on three modules (percutaneous
67	coronary intervention, heart failure and the early treatment of acute myocardial infarction).
68	However, CR data are not included within VCOR.
69	Globally, c
70	as site investment or 'buy-in', privacy and security considerations, as well as limited resources for
71	contributing data_[17]. Indeed, sites are often required to manually enter data, which is time-
72	consuming for clinical staff and increases the risk of data errors [18]. Ideally, data collection should
73	be automated and linked to administrative databases or electronic medical records (EMRs). With
74	advances in technology, this is becoming more feasible. Automated data capture techniques using
75	specially-designed software can be used to extract routinely-collected data. Such software can also

76	incorporate automated safeguards built-in to the data entry systems to ensure privacy protection.	
77	This has been previously demonstrated within primary care and other settings in Australia [19] using	
78	the GRHANITE <sup>™</sup> (GeneRic Health Network Information for the Enterprise_[20]:	
79	https://www.grhanite.com/ <del>[15]</del> ) tool.	
80	Accordingly, The aim of this manuscript was to we assessed the feasibility of extracting	
81	routinely-collected minimum data (as defined by the NSW division of ACRA_[21]) from CR sites and	
82	hospital administration databases using the GRHANITE™ automated data capture tool <u>in order</u> to	
83	populate a Victorian CR Registry (VCRR).	
84	Methods	 Formatted: Line spacing: Double
85	Overarching design of VCRR	Formatted: No underline
86	- This feasibility study consisted of a 3-month (September-December 2017) data collection	Formatted: Left
00		
87	period involving quantitative data capture from two pilot sites and formative evaluation of the	
88	process including feedback from CR clinicians. The design of the registry was guided by technical	
89	standards outlined by the Commission [3], as illustrated in a logic model (Figure 1).	
90	*FIGURE 1*	
91		
92	Figure 1 <u>Clinical Quality Registries Information Model [16]</u> , Reproduced with permission from Logical Design	Field Code Changed
93	for Australian Clinical Quality Registries, developed by the Australian Commission on Safety and Quality in	Formatted: Font: Not Italic
		Formatted: Font: Not Italic
94	Health Care (ACSQHC), for use exclusively in Australia. ACSQHC: Sydney. 2012.	Formatted: Font: +Body
95	Australian Commission on Safety and Quality in Health Care's (2012) [16] Clinical Quality Registries Information	Formatted: Font: Not Italic
96	Model	Formatted: Left, Line spacing: Double
97	Acronyms: CQR: clinical quality registry; MBS: Medicare Benefits Schedule; PBS: Pharmaceutical Benefits	
98	Scheme	

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100	Selection of the minimum variables for the VCRR		Formatted: No underline	
101	The registry comprised a minimum set of variables selected from the New South Wales			
102	(NSW) ACRA association quality indicators and data dictionary which was based on expert			
103	consensus [21]. The 42 selected data elements consisted of: demographic information (e.g. sex, age),			
104	disease/condition (e.g. principal referral diagnosis) risk factors and co-morbidities (e.g. diabetes			
105	status, smoking status), intervention (e.g. number of CR sessions), process indicators (e.g. CR wait			
106	time) and individual patient outcomes (e.g. change in pre-post exercise capacity) (Table 1).			
107	*TABLE 1 *			
108	Table 1. Victorian Cardiac Rehabilitation Registry minimum variables			
109	Setting and recruitment		Formatted: No underline	
110	In the state of Vistoria in South Fast Australia, there are 126 CB programs, delivered across		Formatted: Left	
110	In the state of victoria in South East Australia, there are 156 CK programs, delivered across			
111	publicly and privately-funded hospitals and community health settings. TACRA-he national			
112	association of CR professionals (ACRA) has a State-level directory of all CR facilities which was used			
113	to identify one public and one private site to invite to participate in the study. These sites were			
114	purposively selected to ensure sample representation of: funding sources (public and private),			
115	settings (acute hospital, rehabilitation hospital), and location (metropolitan and suburban). Site 1			
116	was a large publicly-funded program, which runs a six-week CR program for approximately 40			
117	outpatients per week. Site 2 was a private facility primarily funded through health insurance funds			
118	and the Department of Veteran Affairs, which runs a 12-week program for approximately 15			
119	outpatients per week. Participating sites were offered a stipend of AU\$6,000 (USD\$4700) to cover			
120	cost related to staff time for the set-up of automated data collection. Both CR sites agreed to			
121	participate.			
122	Ethics approval	_	Formatted: No underline	
123	The study was approved by the Human Research Ethics Committee (HREC) at the University $\checkmark$		Formatted: Left	
124	of Melbourne (HREC number: 1748609) and included a waiver of consent for individual patient data			
	5			

125 (which was de-identified). Site-specific research ethics approval was also obtained. Staff who

126 participated in qualitative interviews provided informed consent.

	74		
127	Automated Pata-collection procedure (GRHANITE <sup>TM</sup> )	<	Formatted: No underline
128	The team at the University of Melbourne's Health and Biomedical Informatics Centre	$\mathbb{N}$	<b>Formatted:</b> Font: 11 pt, Not Bold, Italic, Superscript
129	Research Information Technology Unit (led by DB) assisted in the development of the data extraction	$\langle \rangle$	Formatted: No underline
130	protocol and worked with the sites' Information Technology (IT) teams to create an interface regime.		Formatted: Font: +Body, 11 pt, Not Bold
131	This required the development of a "mapping" document which linked the variables requested from		
132	the research team with the variables collected and available electronically at the sites. The overview		
133	of the study methods can be seen in Figure 2.		
134	<u>*FIGURE 2*</u>		
135	Figure 2 Overview of the study methods		
136	•		Formatted: Left
137	Manual <u>Amendment to the study protocol to add a manual data entry component-web-based data</u>		
138	collection (REDCap)		
139	In order to To capture variables that were not available electronically at the sites, a secure		
140	web-based data collection form was designed using the REDCap (Research Electronic Data Capture:		
141	https://www.project-redcap.org/) software. The amendment was approved by the University of		
142	Melbourne's HREC in July 2017. The web-based form included three sections (Section 1: identifiable		
143	patient information; Section 2: pre-CR data; Section 3: post-CR data) and was traialled for two weeks		
144	at both sites, with feedback from the CR sites informing refinement of the data entry template. Once		
145	finalised, clinicians entered data for patients who were enrolled in the CR programs during the data		
146	collection period. The REDCap data collection forms contained mandatory fields to reduce missing		
147	data and in-built logic checks to increase the accuracy of data. Authorised staff were provided with a		
148	secure log-in which enabled access to the REDCap template; d-Data access restrictions ensured		

149	clinicians could only view data from their site. Additional detail on REDCap is provided in		
150	Supplementary File 2.		
151	•		Formatted: Left, Indent: First line: 0.63 cm, Space After: 0 pt
152	Data extraction and linkage	$\leftarrow$	Formatted: No underline
153	CR data were extracted from the sites via the University of Melbourne's GRHANITE™		Formatted: Left
154	research data acquisition system. The GRHANITE <sup>™</sup> interface was installed at both sites and		
155	scheduled to extract pre-determined variables on patients who participated in the CR program		
156	during the data collection period. GRHANITE™ enabled data to be extracted in a de-identified		
157	manner by incorporating advanced privacy-preserving hashing techniques to generate unique		
158	'signatures'. These data were then securely transmitted to the VCRR database based on the		
159	University of Melbourne's server, with data stored in Microsoft SQL. Further details regarding data		
160	security and storage can be found in Supplementary File 1 and 2.		
161	Pata quality		Formatted: No underline
162	The system highlighted any GRHANITE <sup>™</sup> data extraction failures or omissions and IT		
163	representative at each site reviewed the data to ensure it was coherent before it was forwarded to		
164	the central registry. The REDCap data collection forms contained mandatory fields to reduce missing		
165	data (data must be entered before being able to move to the next section) and in-built logic checks		
166	to increase the accuracy of data. Missing patient records were assessed by comparing the number		
167	of patients booked CR appointments in the electronic administrative database (total numbers) with		
168	number of patients manually entered into REDCap.		
169	Formative evaluation		Formatted: No underline
170	Semi-structured interviews were conducted within one week of the completed data		
171	collection period (December 2017) to ascertain any barriers or enablers to implementation of the CR		
172	registry. Individual interviews were held with clinical staff members involved with clinical data		
173	collection at the two pilot sites (N=3). The interviews were conducted by a member of the research		
174	team (ET). They were audio-recorded and then transcribed verbatim except to preserve anonymity.		

175	The interview guide consisted of three parts: (i) historical approaches to data collection, (ii)		
176	barriers to measuring and collecting variables and (iii) recommendations for future registry		
177	implementation. Feedback provided by the clinicians was synthesised under the same three		
178	headings and identified barriers were coded in themes and sub-categories using content		
179	analysis[22].		
180	Results		Formatted: Line spacing: Double
181	Characteristics of patients included in VCRR		
182	The combined electronic and manual data revealed that across the two sites, 176 patients had a		
183	booked CR appointment, 115 patients (65.34%) completed the initial CR appointment and 48		
184	patients (27.27%) completed the CR program (achieved patient goals and/or attended an agreed		
185	number of exercise and education sessions) within the data extraction period. The study sample was		
186	predominantly male (76%) with a mean age of 67 years and 83% spoke English as their preferred		
187	language (Table 2). The participant's sociodemographic characteristics differed across the two sites,		
188	with participants at Site 2 being 10 years older on average (74 years vs. 65 years) and having a lower		
189	baseline exercise capacity (95m less on the six-minute walk test) (Table 2).		
190	<u>*TABLE 2*</u>		
191	Table 2. Characteristics of patients included in VCRR		
192	Variables available from the electronic hospital administrative databases were limited to $\$		Formatted: Left
193	seven (age, sex, postcode, Aboriginal and Torres Strait Islander status, preferred language, CR		
194	booking, referral date) for each of the patients. This is due to hospital administrative databases at		
195	the sites only collecting basic information on patient sociodemographic characteristics and CR		
196	appointment bookings. The remaining clinical information selected for the CR registry minimum data		
197	set were collected on paper based records and manually transferred by clinicians onto an Excel		
198	spreadsheet or scanned into patient records and deemed unusable for electronic data capture.		
199	Amendment to the study protocol to add a manual data entry component	_	Formatted: No underline

200	In order to capture variables that were not available electronically at the sites, a secure web-		
201	based data collection form was designed using the REDCap (Research Electronic Data Capture:		
202	https://www.project-redcap.org/) software. The amendment was approved by the University of		
203	Melbourne's HREC in July 2017. The web-based form included three sections (Section 1: identifiable		
204	patient information; Section 2: pre-CR data; Section 3: post-CR data) and was trailed for two weeks		
205	at both sites, with feedback from the CR sites informing refinement of the data entry template. Once		
206	finalised, clinicians entered data for patients who were enrolled in the CR programs during the data		
207	collection period. The REDCap data collection forms contained mandatory fields to reduce missing		
208	data and in-built logic checks to increase the accuracy of data. Authorised staff were provided with a		
209	secure log-in which enabled access to the REDCap template. Data access restrictions ensured		
210	clinicians could only view data from their site. Additional detail on REDCap is provided in		
211	Supplementary File 2.		
212	<b>Combining electronic data and REDCap data extracts via GRHANITE™</b>	_	Formatted: No underline
213	The GRHANITE™ data capture software was configured to extract data from both the electronic data◄		Formatted: Left, Indent: First line:
214	(from hospital administrative databases) and manually entered clinical data (from REDCap) into the		0 cm
215	study database hosted on the University of Melbourne's server and secured within the University's		
216	IT infrastructure. The unique 'signatures' generated by GRHANITE™ enabled anonymous record		
217	linkage between the electronic and manually entered data. Data extracted from the manual entry		
218	component (REDCap) enabled collection of all 42 variables in the minimum data set, supplementing		
219	the electronic data. The overview of the amended study methods can be seen in Figure 2.		
220	*FIGURE 2*		Formatted: Body Text, Left, Line
-			spacing: Double
221	Figure 2 Overview of amended study methods		
222	<u>۸</u>		Formatted: Font: 11 pt
223	Characteristics of patients included in VCRR		Formatted: Left
224	The combined electronic and manual data revealed that across the two sites, 176 patients had a		
225	booked CR appointment, 115 patients (65.34%) completed the initial CR appointment and 48		
	9		

226	patients (27-27%) completed the CR program (achieved patient goals and/or attended an agreed	
227	number of exercise and education sessions) within the data extraction period. The study sample was	
228	predominantly male (76%) with a mean age of 67 years and 83% spoke English as their preferred	
229	language (Table 2). The participant's sociodemographic characteristics differed across the two sites,	
230	with participants at Site 2 being 10 years older on average (74 years vs. 65 years) and having a lower	
231	baseline exercise capacity (95m less on the six-minute walk test) (Table 2).	
232	<u>*TABLE 2*</u>	
233	Table 2. Characteristics of patients included in VCRR	
234	•	Formatted: Normal, Left
235	CR Quality	Formatted: No underline
236	The minimum variables extracted were useful in informing assessment of CR site quality in	
237	many instances (Table 3). There were site-specific differences in process indicators of care,	
238	suggesting the minimum variables are sensitive. For example, participants in Site 1 experienced a	
239	longer wait time to receive CR (44 days vs. 19 days) and were less likely to be screened for	
240	depression (54% vs. 92%). None of the identified smokers (across either site) were reported to have	
241	been referred for smoking cessation.	
242	There was a large amount of missing and unknown data from the manual-entry source.	
243	Discrepancies existed between the number of patients booked CR appointments in the hospital	
244	administrative database (n=176) and those who attended the initial assessment and were entered	
245	into REDCap (n=115). Reasons for non-attendance to the initial session were not routinely collected	
246	and therefore unable to be ascertained for all cases. Further, many values in the post-CR	
247	assessment were reported as unknown (e.g. CR medication status was unknown for 44% of patient	
248	who completed a post-CR assessment).	
249		Formatted: Left, Indent: First line
250	*TABLE 3*	0.63 cm
751	Table 2 CP process indicators	Formatted: Lett
201	Table 5. Ch process multators	
	10	

253	CR Staff Perceptions of Data Capture Processes	_	Formatted: Font: 11 pt, No
254	Feedback from the two sites revealed that the manual entry component was straight-forward, 🛛 🔸		Formatted: Left
255	easy to use, and quicker than traditional forms of data collection (i.e., clinician-selected variables		
256	entered into an Excel spreadsheet; Table 4). The training provided was perceived as sufficient and		
257	staff felt in-built features such as mandatory fields enabled them to feel more confident about the		
258	data quality. Staff expressed desire to have the capacity to search more easily for entered patient		
259	data (a feature that is available in REDCap but was not highlighted during the training session) and		
260	additional information about the rationale/evidence for some of the selected minimum variables. All		
261	interviewees wanted to continue using REDCap and preferred this approach over traditional		
262	methods; a-s described by the CR co-ordinator at Site 2 "I just can see that REDCap is the bright new		
263	future that we can start to get the cardiac rehab product out there with consistency between		
264	programs Because at the moment we can all say that we are doing cardiac rehab and we can all be		
265	members of ACRA but I don't know what you're providing and you don't know what I am doing		
266	unless you are there".		
267	Five main barriers were identified regarding historic methods of measuring and entering		
268	variables (see Supplementary file 3): i) workload and competing responsibilities (e.g. time		
269	constraints), ii) environmental context and resources (e.g. information technology issues, and not		
270	having access to a quiet and secure space to enter data); iii) patient factors (e.g. patient		
271	needs/concerns conflicting with data collection requirements); iv) care delivery processes and co-		
272	ordination (e.g. referrals getting lost because sent via post/fax ) and v) outcome expectations (e.g.		
273	reduced confidence in data because of measurement errors).		
274	*TABLE 4 *		
275	Table 4. Feedback from sites on web-based data entry		Formatted: Line spacing: Double
276			
277	Discussion		
	11		

278 To our knowledge, tThis was the first study to assess the feasibility of utilising a data capture -Formatted: Left 279 tool to automatically extract minimum CR registry variables within public and private facilities in 280 Australia. While CR sites collected large amounts of clinical data, the majority of these data (i.e., 83% 281 of the 42 variables) were not readily-available in an appropriate electronic format rendering 282 automated data extraction unfeasible. Until such time that the current infrastructure in public and 283 private CR settings in Australia develops, the key benefits of scalable, automated data capture tools 284 like GRHANITE<sup>™</sup> will remain unrealised. While this approach remains promising for creating and 285 maintaining a registry that monitors the quality of CR provided to patients, further investment is 286 required in the digital platforms underpinning this approach including ensuring electronic platforms 287 are i) accessible to CR sites, ii) fit for purpose and, iii) capturing high quality data. In the interim, a 288 web-based data collection tool housed on the REDCap system can enable standardised data to be 289 collated from various CR sites with known limitations associated with manual data entry. These key 290 findings are discussed further below. 291 Enhancing access and use of EMRs Formatted: Font: Not Bold 292 Greater emphasis must be placed on ensuring CR staff have access to EMRs[9]. In general, allied 293 health and community-based settings have had low-levels of adoption of electronic health infrastructure compared to acute settings and primary care [23]. To ensure more timely access, 294 295 national associations such as ACRA, the Cardiac Society of Australia and New Zealand (CSANZ) and 296 the National Heart Foundation (NHF) need to facilitate advocacy efforts at the local, state and 297 national-level for improved electronic infrastructure within the CR setting. For example, ACRA could provide guidance to CR co-ordinators and managers to push the agenda within local settings; 298 299 enhanced CR representation on state-based cardiac clinical networks could drive the issue at a state-300 level; and the development of a national strategic plan and committee could be established with the

aim of improving monitoring of CR and enhancing national efforts.

302	Within Victoria (and likely other states)Future, digital health investments will be driven by			
303	specific business needs and the identification and demonstration of local and system-wide			
304	benefits[24]. Consequently, a clear business case for enhanced monitoring of CR is required which			
305	details the digital requirements necessary to fulfil the current gap. Additionally, the workplace will			
306	likely need to up-skill to ensure adequate digital capability. Well-developed and robust change			
307	management is a crucial factor in deploying new systems and clinicians must be involved in the			
308	process and actively champion health technology activities [24].			
309	Ensuring EMRs are fit for purpose			
310	Ideally, as EMR <u>uptake increases</u> s develop in Australia, all CR minimum variables would be			
311	available electronically, and a registry could be pre-filled. In other countries CR registries have begun			
312	to simultaneously link with administrative electronic databases to enable auto-filling of data (e.g. the			
313	Danish registry and Canadian registry) [17, 25]. In states where different EMR systems are being			
314	implemented, flexible tools like GRHANITE™ will be crucial in enabling interoperability of data across			
315	various systems (including public and private) whilst adhering to privacy and security concerns.			
316	Ultimately, the success of data capture through EMRs will depend on multiple factors, including			
317	minimum variables being: i) clearly defined, ii) entered consistently across sites, iii) of sufficient			
318	reliability/validity, and iv) extractable. The CR field can begin to prepare for this now by ensuring			
319	quality indicators are clearly defined and comparable across states.			
320	Monitoring CR in settings with under-matured electronic platforms			
321	Many states are a long way from having fully integrated electronic health systems. Between			
322	2004 2013 Victoria invested over \$300 million to reform the IT ecosystem with the HealthSMART			
323	initiative which was eventually abandoned due to a 'one size fit all approach' being			
324	unsuccessful[21]. Consequently, the responsibility of developing digital solutions was placed back on			
325	health services providers resulting in a wide range of clinical information systems implemented to			

I

# varying degrees across hospitals and health centres[22]. Many CR sites have no access to EMRs and as demonstrated in this feasibility study are relying on paper-based data collection methods.

328 In the interim, CR data collection can be improved via the use of a standardised web-based 329 tool housed on platforms such as the REDCap system. REDCap had multiple advantages including: i) 330 ease of implementation without any need for the sites' IT departments, ii) usable at both public and 331 private CR sites, iii) secure and password-protected access, iv) straight-forward and quick data 332 entry, v) in-built functions (e.g. mandatory fields, character limits, drop down options, automated 333 reports) to enhance data quality and completeness, vi) available for use at no costs for affiliated 334 research institutes. Further, REDCap was supported by those entering the data who expressed an interest in continuing beyond the study period. 335

336 Use of the web-based tool, however, could be enhanced. For example, future studies should 337 incorporate data quality checks early in the data collection period that include a comparison of 338 enrolled and entered patient data to ensure such data match and reasons for missing data are 339 ascertained. In Australia CR sites often refer patients to more convenient programs (e.g. closer to 340 home); such information needs to be captured on all patients so that reasons for non-attendance 341 can be more accurately documented. Additionally, unknown data requires additional clarification. 342 For example, post-CR medication status had larger amounts of unknown responses than other 343 variables and is potentially not being checked at post-CR interviews. Automated alerts could be in-344 built for this variable to clarify the reason for the unknown information.

#### 345 Study limitations

We acknowledge that this study has limitations. Due to the small sample size <u>and Victorian</u> setting, results from this feasibility study <u>may not be are not</u> generalizable <u>to other settings</u> and saturation of themes in the staff interviews were not realised. Additionally, the 'snap-shot' method of data collection meant that many patients had not completed CR at the time of data extraction. Further, enhanced methods are required to ensure all who enrolled into the CR programs were

351 captured even if they did not attend the initial assessment session to reduce reporting bias towards352 CR attenders.

### 353 Implications and future recommendations

- 354 The transition to digital health systems holds great potential for enhancing clinical care within
- 355 the CR setting. However, many jurisdictions have been slow to adopt e-health infrastructure limiting
- 356 the application of tools like GRHANITE<sup>™</sup>. Key organisations need to advocate for EMRs in CR
- 357 programs so that automated data-capture technologies can increase the viability of CR registries in
- 358 the future. Efforts must also focus on preparing the field for the digital transition and preparing a
- 359 clear business case delineating the local- and system-wide benefits and the digital requirements so
- 360 systems are built in a way that is fit for purpose.

- 361 In the interim, a web-based data entry tool shows promise as an approach that should be
- 362 explored further and could enable the monitoring of CR quality across the private and public sector.

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364	•	Formatted: Line spacing: Double
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368	References	
369	[1] Spertus JA, Eagle KA, Krumholz HM, Mitchell KR, Normand SL, American College of	
370	Cardiology/American Heart Association Task Force on Performance M. American College of	
371	Cardiology and American Heart Association methodology for the selection and creation of	
372	performance measures for quantifying the quality of cardiovascular care. J Am Coll Cardiol.	
373	2005;45:1147-56.	
374	[2] Maddox TM, Albert NM, Borden WB, Curtis LH, Ferguson TB, Jr., Kao DP, et al. The Learning	
375	Healthcare System and Cardiovascular Care: A Scientific Statement From the American Heart	
376	Association. Circulation. 2017.	
377	[3] Australian Commission on Safety and Quality in Health Care. Logical design: Australian Clinical	
378	Quality Registries. Sydney: ACSQHS; 2012.	
379	[4] Australian Commission on Safety and Quality in Health Care. Prioritised list of clinical domains for	
380	clinical quality registry development. Sydney ACSQHC; 2016.	

- 381 [5] Fox KA, Eagle KA, Gore JM, Steg PG, Anderson FA, Grace, et al. The Global Registry of Acute
- 382 Coronary Events, 1999 to 2009--GRACE. Heart. 2010;96:1095-101.

383 [6] Essen A, Lindblad S. Innovation as emergence in healthcare: unpacking change from within. Soc 384 Sci Med. 2013:93:203-11.

385 [7] Anderson L, Thompson DR, Oldridge N, Zwisler AD, Rees K, Martin N, et al. Exercise-based cardiac

386 rehabilitation for coronary heart disease. Cochrane Database Syst Rev. 2016:CD001800.

387 [8] Chew DP, Scott IA, Cullen L, French JK, Briffa TG, Tideman PA, et al. National Heart Foundation of

388 Australia and Cardiac Society of Australia and New Zealand: Australian clinical guidelines for the

389 management of acute coronary syndromes 2016. Med J Aust. 2016;205:128-33.

- 390 [9] Stone JA, Arthur HM, Suskin N. Canadian Guidelines for Cardiac Rehabilitation and Cardiovascular
- 391 Disease Prevention: Translating Knowledge Into Action. 3rd ed. ed. Winnipeg, MB: Canadian

392 Association of Cardiac Rehabilitation; 2009.

- 393 [10] Somanader DS, Chessex C, Ginsburg L, Grace SL. Quality and Variability of Cardiovascular
- 394 Rehabilitation Delivery: Applying the Canadian quality indicators. J Cardiopulm Rehabil Prev. 395 2017:37:412-20.

396 [11] Scottish Intercollegiate Guidelines Network. Cardiac rehabilitation: a national clinical guideline. . 397 Edinburgh: SIGN; 2017.

- 398 [12] Piepoli MF, Hoes AW, Agewall S, Albus C, Brotons C, Catapano AL, et al. 2016 European
- 399 Guidelines on cardiovascular disease prevention in clinical practice: The Sixth Joint Task Force of the
- 400 European Society of Cardiology and Other Societies on Cardiovascular Disease Prevention in Clinical
- 401 Practice (constituted by representatives of 10 societies and by invited experts)Developed with the
- 402 special contribution of the European Association for Cardiovascular Prevention & Rehabilitation 403 (EACPR). Eur Heart J. 2016;37:2315-81.
- 404 [13] British Association of Cardiovascular Prevention and Rehabilitation. Cardiovascular disease prevention and rehabilitation 2017. London: British Cardiovascular Society; 2017. 405
- 406 [14] Woodruffe S, Neubeck L, Clark RA, Gray K, Ferry C, Finan J, et al. Australian Cardiovascular
- 407 Health and Rehabilitation Association (ACRA) core components of cardiovascular disease secondary 408
- prevention and cardiac rehabilitation 2014. Heart Lung Circ. 2015;24:430-41.
- 409 [15] Queensland Health. Queensland Cardiac Outcome Registry
- 410 https://clinicalexcellence.gld.gov.au/improvement-exchange/cardiac-outcomes-registry:

411 Queensland Government 2018.

- 412 [16] Stub D, Lefkovits J, Brennan AL, Dinh D, Brien R, Duffy SJ, et al. The Establishment of the
- 413 Victorian Cardiac Outcomes Registry (VCOR): Monitoring and Optimising Outcomes for Cardiac
- 414 Patients in Victoria. Heart Lung Circ. 2018;27:451-63.
- 415 [17] Poffley A, Thomas E, Grace SL, Neubeck L, Gallagher R, Keech W, et al. A Systematic Review of
- 416 Cardiac Rehabilitation Registries: a Global Perspective. European Journal of Preventive Cardiology. 417 2017;24:1596-609.
- 418 [18] Grace SL, Parsons TL, Heise K, Bacon SL. The Canadian Cardiac Rehabilitation Registry: Inaugural
- 419 Report on the Status of Cardiac Rehabilitation in Canada. Rehabil Res Pract. 2015;2015:278979.
- 420 [19] Weaver ER, Bowring AL, Guy R, van Gemert C, Hocking JS, Boyle DI, et al. Reattendance and
- 421 chlamydia retesting rates at 12 months among young people attending Australian general practice 422 clinics 2007-10: a longitudinal study. Sex Health. 2014;11:366-9.

423 [20] University of Melbourne. GRHANITE<sup>™</sup> Health Informatics Unit. In: Boyle D, editor.

424 https://www.grhanite.com/2018.

- 425 [21] Zecchin R, Candelaria D, Ferry C, Ladak LA, McIvor D, Wilcox K, et al. Development of Quality
- 426 Indicators for Cardiac Rehabilitation in Australia: A Modified Delphi Method and Pilot Test. Heart, 427 Lung and Circulation. 2018.
- 428 [22] Graneheim UH, Lundman B. Qualitative content analysis in nursing research: concepts,
- 429 procedures and measures to achieve trustworthiness. Nurse Educ Today. 2004;24:105-12.
- 430 [23] National E-Health Transition Authority. Evolution of eHealth in Australia: achievements, lessons,
- 431 and opportunities Sydney: NEHTA; 2016.

- 432 [24] Victoria State Government. Digitising health: How information and communications technology
- 433 will enable person-centred health and wellbeing within Victoria. . In: Services DoHaH, editor. Victoria
- 434 2016.
- 435 [25] Zwisler AD, Rossau HK, Nakano A, Foghmar S, Eichhorst R, Prescott E, et al. The Danish Cardiac
- 436 Rehabilitation Database. Clin Epidemiol. 2016;8:451-6.

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# Table 1. VCRR minimum variables

CORE DATA		
Person identifying	1.	Name
information	2.	Medicare number
	3.	Patient Unit Record number
	4.	Date of birth
	5.	Sex
	6.	Postcode
	7.	Culturally and linguistically diverse (CALD)
	8.	Aboriginal and Torres Strait Islander status
Provider organization	9.	Service provider name
CQR SPECIFIC DATA		
Disease/condition	10	Principal CR referral diagnosis
Risk factors and co-	11	Interventions/complications (e.g. PCI, CABG)
morbidities (for risk	12	Diabetes diagnosis
adjustment)	13	Smoking status
	14-18	Prescribed medications (i. oral antiplatelet, ii. Beta-blockers, iii. ACE-
		I/ARB, iv. lipid-lowering, v. sublingual nitrate)
	19	Waist circumference
	20	Exercise capacity
Intervention	21	CR program model
	22	CR referral date
	23	CR commencement date
	24	Number of CR sessions attended
	25	CR completion status

	26	Reason for CR withdrawal (if applicable)
Process indicators of	27	CR wait time (CR commencement date – CR referral date)
evidence based care	28	Screened for depression
	29	Positive cases for depression referred for management
	30	Current/recent smokers referred or provided with smoking
		cessation advice
	31-35	Prescribed medications (i. oral antiplatelet, ii. Beta-blockers, iii. ACE-
		I/ARB, iv. lipid-lowering, v. sublingual nitrate)
	36	Provided a symptom-management plan
	37-40	Referred for ongoing care (i. General Practitioner, ii.
		specialist/Cardiologist, iii. CR follow-up, iv. Phase 3 CR or equivalent)
Individual patient	41	Pre-post change in exercise capacity
outcome measures	42	Pre-post change in waist circumference

Acronyms: ACE-1: angiotensin-converting enzyme; ARB: angiotensin receptor blockers; CR: cardiac

rehabilitation

	SITE 1	SITE 2	Total	Missing %
	Freq (%);	Freq (%);	Freq (%);	
	Mean [SD]	Mean [SD]	Mean [SD]	
	n=131	n=45	n=176	
Male	99 (75.57)	35 (77.78)	134 (76.14)	0
Age (years)	64.96 [11.82]	74.11 [9.21]	67.30 [11.88]	0
Aboriginal or Torres				
Strait Islander	1 (0.76)	0 (0)	1 (0.57)	0
English not preferred				
language	30 (22.90)	0 (0)	30 (17.04)	0
Referral indication				34.65*
STEMI	20 (15.26)	4 (8.89)	24 (13.64)	
NSTEMI	14 (10.68)	1 (2.22)	15 (8.52)	
CT surgery	37 (28.24)	9 (20.00)	46 (26.14)	
Interventions				34.65*
Non-elective PCI	19 (14.50)	4 (8.89)	23 (13.07)	
Elective PCI	30 (22.90)	6 (13.33)	36 (20.45)	
CT surgery	37 (28.24)	4 (8.89)	41 (23.29)	
Diabetic	25 (19.01)	7 (15.55)	32 (18.18)	34.65*
Smoker	8 (6.11)	1 (2.22)	9 (5.11)	34.65*
Exercise capacity <sup>+</sup>	480.50 [93.22]	383.91 [126.89]	456.61 [110.11]	47.16*

**Table 2**. Characteristics of patients included in the VCRR

Acronyms: CT: cardiothoracic; Freq: frequency; NSTEMI: non-ST elevated myocardial infarction; PCI:

percutaneous coronary intervention; SD: standard deviation; STEMI: ST-elevated myocardial infarction.

\*Manually entered data had missing variables; † six-minute walk test

Process indicator	SITE 1	SITE 2	Total	Unknown/
	Freq (%);	Freq (%);	Freq (%);	missing*
	Mean [SD]	Mean [SD]	Mean [SD]	Freq (%)
	n=89 <sup>†</sup>	$n=26^{\dagger}$	n=115 <sup>+</sup>	n=115 <sup>+</sup>
CR wait time (days)	44.26 [22.53]	19. 21 [19.46]	38.94 [24.13]	2 (1.74)
Screened for depression	48 (53.93)	24 (92.31)	72 (62.61)	43 (37.39)
Positive case for depression	1 (2.38 <sup>)‡</sup>	2 (22.22) <sup>‡</sup>	3 (5.88) <sup>‡</sup>	43 (84.31) <sup>‡</sup>
referred				
No. of smokers	8 (8.99)	1 (3.85)	9 (7.83)	2 (1.74)
Smokers referred for	0 (0) <sup>§</sup>	0 (0) <sup>§</sup>	0 (0) <sup>§</sup>	3 (33.33) <sup>§</sup>
cessation				
Post-CR medications				
Antiplatelet	21 (23.60)	20 (76.92)	41 (35.65)	74 (64.35)
Beta-blockers	18 (20.22)	12 (46.15)	30 (26.09)	75 (65.22)
ACE-I/ARB	14 (15.73)	10 (38.46)	24 (20.87)	75 (65.22)
Lipid-lowering	21 (23.60)	13 (50.00)	34 (29.57)	75 (65.22)
Sublingual nitrate	11 (12.36)	5 (19.23)	16 (13.91)	75 (65.22)
Provided a symptom -	48 (53.93)	22 (84.61)	70 (60.87)	45 (39.13)
management plan				
Referred for ongoing care	44 (49.44)	24 (92.31)	68 (59.13)	47 (40.87)

# Table 3. Process indicators of evidence based care

Acronyms: ACE-1: angiotensin-converting enzyme; ARB: angiotensin receptor blockers; CR: cardiac rehabilitation; Freq: frequency; SD: standard deviation.

\*These data were part of a prospective 3-month snap-shot, as such not all data were known at the time of data extraction highlighting issues using these data to compare sites; <sup>†</sup>Denominator = number of patient records entered into REDCap; <sup>‡</sup>Denominator = number of patients screened positive for depression; <sup>§</sup>Denominator = number of identified smokers

# Table 4. Feedback from sites on use of web-based data entry

# How sites were traditionally collecting clinical information about CR participants

- paper-based medical notes or hard copy worksheets
- data manually transferred into an Excel spreadsheet when time allowed
- collected variables were determined individually by the sites and relied on clinician knowledge of CR

'best practice' and influenced by management requirements

# Identified issues with traditional methods of data collection

- time consuming
- unnecessary data collected (i.e. not used in analysis or reporting)
- analysis of data in Excel was challenging
- unable to compare data across sites
- collected data was influenced by patient needs, time constraints and perceived importance of the

clinical information

### Experience using the REDCap web-based standardized templates

- straight-forward and easy
- data entry was quick
- training was sufficient
- appreciated quick responses if any questions arose
- reports more professional compared to Excel

### Future use of the REDCap web-based templates

- potential to improve the consistency between CR programs
- expressed desire to continue using REDCap
- staff wanted to be able to search more easily for previously entered patients
- additional evidence/rationale behind why certain variables were selected as the minimum data is

required

- would like available data to be automatically imported from hospital databases
- would like to enter data during the patient assessment (e.g. via an I-Pad)





Supplementary Material Click here to download Supplementary Material: Supplementary Material .docx