Improving cardiac rehabilitation in Victoria

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Abstract

Background: Hospital admission rates due to cardiovascular disease are rising. Consequently, evidence-based, secondary prevention programs that enable people to self-manage their condition(s) within the community are becoming critical. For people with heart disease, cardiac rehabilitation (CR) is recommended within clinical guidelines to enable risk factor reduction and prevent new cardiac events. However, utilisation rates of CR programs remain low and the quality of program delivery is variable. In Victoria, Australia, there is no mechanism to systematically monitor attendance of CR programs, the quality of the service provided or associated patient outcomes. Registries are effective instruments for capturing data that reflect daily clinical practice, providing insights into patient characteristics and patterns of care to help address variability in service referral, uptake and quality. The purpose of this thesis was to use a learning healthcare system model to determine how the monitoring of CR could be improved in Victoria.

Methods: This thesis consists of several complementary projects. First, to quantify the benefits of attending CR, a cohort of Victorian patients with acute coronary syndrome (ACS) was analysed to determine the impact of CR on all-cause hospital readmission rates up to 24-months post-ACS event. Second, a systematic review of the international literature on CR registries was undertaken to identify how other countries evaluate CR, and the associated challenges. Subsequently, the feasibility of collecting CR minimum variables via an automated data capture tool and manual-entry, web-based tool was assessed. Finally, a national think tank with researchers, policy-makers and clinicians representing every Australian state and territory was held to develop recommendations for improving the measurement of CR quality and effectiveness across Australia.

Results: In a Victorian ACS population (n=416, 79% male, mean age 58.4 years) CR attendance was associated with lower frequency of hospital admissions (OR: 0.53; 95%CI: 0.31, 0.91; p-value: 0.019).
0.022) and length of stay (Coef. -1.21 days; 95\%CI: -2.46, 0.26; p-value: 0.055) in fully adjusted models. Within the systematic review, it was identified that the use of registries for characterising CR and providing a standard for quality improvement is in its early stages but shows promise for national and global benchmarking. Data are commonly entered manually into web-based tools; a process that potentially limits sustainability. However, the feasibility study determined that an automated data capture tool is currently unfeasible in Victoria due to under-developed electronic health infrastructure. Last, the national think tank determined that to improve the monitoring of CR at a national level, enhanced governance structures, leadership and collaboration across jurisdictions are required.

**Conclusion:** This thesis substantiates that attending CR is associated with lower frequency of hospital admissions in an ACS population. However, the ability to quantify healthcare quality relies on the implementation of appropriate systems that can accurately capture how care is being delivered. Clinical registries provide a vehicle for measuring the delivery of care. Nevertheless, challenges associated with the establishment and cost of registries often impact implementation and sustainability. Innovative solutions are required to reduce the burden of data entry on time-poor clinicians and these solutions need to be supported by enhanced infrastructure, governance and national collaborative efforts. This thesis has contributed towards the important discussion on how CR can be improved in Victoria and more broadly across Australia, as evidenced by the collective development of national CR quality indicators that is currently underway.
Declaration

This is to certify that

i) the thesis comprises only my original work towards the Doctor of Philosophy except where indicated in the Preface,

ii) due acknowledgement has been made in the text to all other material used,

iii) the thesis is fewer than 100,000 words in length, exclusive of tables, maps, bibliographies and appendices.

Emma Thomas
Preface

In 2016, I participated in a think tank at the National Heart Foundation of Australia (NHFA) to discuss how cardiac rehabilitation (CR) could be improved in Victoria. I presented reflections from 416 acute coronary syndrome patients who were enrolled in a Victorian cohort study. The study participants had been asked ‘how could you have been helped or better supported since having your heart event nearly two years ago?’ The participants’ responses suggested that the provision of CR across Victoria was highly variable; while some were never referred to CR, others were still accessing the CR gym nearly two years after their cardiac event. This think tank was formative to the conception of the projects included in this thesis and the reason for the title ‘Improving cardiac rehabilitation in Victoria’.

This thesis comprises data from a prospective cohort study (Anxiety Depression & heart rate Variability in cardiac patients: Evaluating the impact of Negative emotions on functioning after Twenty-four months (ADVENT)) and a feasibility study (Victorian Cardiac Rehabilitation Registry feasibility study (VCRR)). My contributions to these studies are briefly outlined below (see Appendix A for additional detail).

For the cohort study (Chapter Two), I was responsible for the 24-month follow-up data collection including managing the collection of computer-assisted telephone interviews of 416 participants. I oversaw the data collection (including training and management of two research assistants) and personally conducted >120 participant interviews (each taking approximately 1.5 hours). I was responsible for ensuring appropriate data collection, storage and cleaning of these data. I conducted the statistical analysis with support of the second author (Dr Mojtaba Lotfaliany) and wrote the initial draft of the manuscript and subsequent revisions. Readmission data was collected by Dr WP Thanuja Rangani and Dr DS Anoja Dheerasinghe. This work was conducted
under the supervision of Associate Professor Adrienne O’Neil and Professor Brian Oldenburg (the lead investigator of the ADVENT study).

For the feasibility study (VCRR) I contributed towards the study protocol, completed the University of Melbourne and site-specific ethics applications, met with all collaborators and participating sites, oversaw the implementation of the project and data collection, and ensured quality checks were completed and all aspects of the project were conducted in accordance with ethical requirements. I cleaned and analysed the data independently and wrote the initial draft and subsequent revisions of the VCRR feasibility study paper (Chapter Four). Professor Douglas Boyle’s team (including Sandra Henley-Smith) led the installation and data extraction using the GRHANITETM tool. Sandra Henley-Smith also provided expertise regarding the REDCap software including guidance on how best to develop the VCRR data collection template. This work was conducted under the supervision of Associate Professor Adrienne O’Neil.

Regarding the systematic review (Chapter Three), Ms Poffley was involved in the development of search terms and running the literature search under the guidance of myself and Associate Professor Adrienne O’Neil (as part of a 12-week public health internship at the University of Melbourne in 2016). As co-first authors, both myself and Ms Poffley independently reviewed all abstracts and full texts and extracted relevant data. I wrote the first draft of the manuscript and subsequent drafts incorporating all feedback from co-authors and completed the submission process of the manuscript. This work was completed under the supervision of Associate Professor Adrienne O’Neil.

Chapters Five and Six developed from discussions I had with clinicians from the VCRR participating sites regarding the rationale behind the inclusion of some of the requested quality indicators. Simultaneously, I had discussed with researchers (namely Professor Robyn Gallagher and Associate Professor Carolyn Astley) regarding the discrepancies in monitoring of CR across different states in Australia and the need for national quality indicators. To combat this issue, the
South Australian Academic and Health Science Translation Centre (SA Translation Centre) offered to host a national think tank on improving CR measurement on 26 September 2018 with the aim of discussing state-based activities and future national directions. At the Australian Cardiovascular Health and Rehabilitation Association (ACRA) Annual Scientific Meeting in July 2018, Associate Professor Carolyn Astley (SA Translation Centre), Professor Robyn Gallagher (ACRA National President), Rachelle Foreman (NHFA Queensland), Julie-Anne Mitchell (NHFA New South Wales), Professor Robyn Clark (Flinders University, South Australia) and I met to plan for this national meeting and set the agenda. I was invited to represent Victoria at the national meeting, co-organise the agenda and present on national and international activities related to measuring the effectiveness of CR. In preparation for the national think tank, I conducted a literature review on which quality indicators were being collected internationally (Chapter Five) and tabled these findings at the think tank. Further, the recommendations and discussions from the think tank provided the foundation of a ‘call to action’ for Australia (Chapter Six).

In October 2018, I travelled to Toronto, Canada to attend and present at the Canadian Cardiovascular Congress, complete an observership at the Toronto Rehabilitation Institute's Cardiovascular Prevention Program and spend time with Professor Sherry Grace's research team. During this time, I had the opportunity to learn in detail about the Canadian Cardiac Rehabilitation Registry and met with researchers, clinicians and the software developer to understand how the software ‘Cardiologica’ was being used as a patient management software tool that could also provide aggregated data to the national registry. When I returned to Australia, I presented this information to the research team. We have since incorporated the Cardiologica software into research grant applications.

Associate Professor Adrienne O’Neil, Professor Sherry L Grace, Professor Dominique A Cadilhac, Professor Brian Oldenburg, Professor C. Barr Taylor, Professor David L Hare, Professor Robyn Gallagher, Professor Lis Neubeck, Associate Professor Nicholas Cox, Professor Douglas Boyle, Professor Josef Niebauer, Dr Jo-Anne Manski-Nankervis, Associate Professor Carolyn Astley, Julie-
Anne Mitchell, Rachelle Foreman, Dr Stephen Bunker and Alexander Clark provided critical review of the various manuscripts included in this thesis. Citations acknowledging contributions are included at the beginning of each relevant chapter, and co-author forms have been submitted with this thesis.

In addition to this thesis, I also worked with the NHFA to develop an evidence-based and standardised program content outline for Phase II CR sites (Appendix B, study 3). Since completing the thesis, I have continued to work at the NHFA as a Senior Coordinator for Heart Health, namely working on enhancing secondary prevention programs.

N.B. This thesis has been professionally proofread by Dr Kate Rears. She offered no guidance beyond copyediting and proofreading as covered in Parts D and E of the *Australian Standards for Editing Practice*. 
Acknowledgements

This body of work would not have been possible without the support, mentorship and expertise of many wonderful people. Firstly, I wish to thank my primary supervisor, Dr Adrienne O’Neil, who gave me the opportunity to be involved in this research, and provided constant guidance and support navigating the project, academic life and all the other hurdles that arose. I deeply appreciate your mentorship and thank you for your dedication in seeing me through this journey.

Thank you to my co-supervisors. Firstly, to Professor Sherry Grace, the most amazing international collaborator I could ever have, your international expertise deeply enhanced my thinking and understanding of cardiac rehabilitation and I’ve never known of anyone to provide such detailed, informative and speedy feedback. Thank you to Professor Dominique Cadilhac, who has an incredible ability to see the broader picture, think strategically and has a deep understanding of the Australian registry and health system context. Your work within stroke has shown me what is possible, and your feedback has been incredibly helpful. To Dr Rebecca Armstrong, thank you for your input and expertise regarding the implementation of this work and more importantly for your warm mentorship and encouragement. Thank you for being with me from the very beginning of this PhD journey when the project and topic was quite different!

I would like to thank all the participants who were involved in the ADVENT study and the cardiac rehabilitation staff who participated in or supported the feasibility study. Without them, this project would not have been possible.

I wish to thank some very special colleagues and mentors in cardiac rehabilitation. Dr Susie Cartledge for providing constant enthusiasm for the work, inspiration and support. Professor Robyn Gallagher, Professor Lis Neubeck, Dr Stephen Bunker, Dr Carolyn Astley, Professor Ralph Maddison and Emma Boston – thank you for providing valuable insights, feedback, support and mentorship.
Financial support for the VCRR feasibility study came from a University of Melbourne seed funding grant (#1655329). ADVENT was funded by a National Health and Medical Research Council (NHMRC) project grant (#1021294). NHMRC also provided my salary via a Postgraduate Scholarship (#1113920). I thank the organisations for their support.

I was blessed to complete this PhD alongside a group of internationally diverse, fun and intelligent students who have become life-long friends. Thanks to Shaira Baptista, Patricia Rarau, Teralynn Ludwick, Tess Hall, Juan Pablo Villanueva Cabezas, Shane Hamilton, Lucas Calais Ferreira, Emily O’Kearney, Ben Lyons and many others for their friendship, emotional support and help navigating the PhD process. Special thanks to Mojtaba Lotfaliany who on top of friendship also provided wonderful statistical expertise where required.

Special thanks to my family (including my extended Farrar family) and dear friends who are like family. To my parents, brothers and sisters who always support and cheer me on. To my beautiful nephews and nieces (three of which arrived during this PhD) who provide the best escape from writing. To my best friend Simone Howells who happened to be completing a PhD at the same time and always provided great emotional support, a listening ear and a wonderful writing-retreat buddy.

Lastly, and most importantly, I wish to thank my partner, Mitch Farrar, who was truly with me throughout this entire PhD – beginning to end, in all the ups and downs. Over the years I have learnt to listen to your calm words of wisdom. Thank you for always inspiring me to live a life of integrity, for putting up with my idiosyncrasies and constant stream of new ideas, for cooking most of the meals and making the mundane parts of life fun.
Publications

Publications included in the thesis


Publications included in the appendices


Additional publications completed during the PhD candidature


7. Ryan B, Hudson K, Worrall L, Thomas E, Simmon-Mackie N, Clark K, Lethlean J. The Aphasia Action, Success, and Knowledge program: Results from a Phase 1 trial of a speech-

Presentations

International presentations

- Canadian Cardiovascular Congress, Toronto, Canada, 2018
  **Workshop presentation:** Cardiac rehabilitation quality.

- University Health Network, Toronto Rehabilitation Institute, Toronto, Canada, 2018
  **Invited presentation:** Early beginnings: enhancing the monitoring and evaluation of cardiac rehabilitation in Australia.

- European Society of Cardiology Congress, Barcelona, Spain, 2017
  **Poster presentation:** A global perspective of cardiac rehabilitation registries: a systematic review.

- International Congress of Behavioural Medicine, Melbourne, 2016
  **Presentation:** Reconstructing time use to understand human behaviour: combining accelerometry, wearable cameras, diaries and interviews.

National presentations

- Australian Cardiovascular Health and Rehabilitation Association ASM, Sydney, 2019
  **Accepted presentation:** What content is essential to deliver within a cardiac rehabilitation program? Results of a modified-Delphi approach

- National Think Tank on Improving the Effectiveness of Cardiac Rehabilitation in Australia, South Australian Heath and Medical Research Institute, Adelaide, 2018
  **Invited presentation:** A national and global scan of quality indicators for cardiac rehabilitation.
  **Invited presentation:** Cardiac rehabilitation initiatives and progress in Victoria.

- Australian Cardiovascular Health and Rehabilitation Association (Victorian Branch) Education Day, Melbourne, 2018
  **Invited presentation:** Technology in cardiac rehabilitation.
• Stroke Neuroscience Seminar, The Florey Institute of Neuroscience and Mental Health, Melbourne, 2017
  *Invited presentation*: Developing a cardiac rehabilitation registry.

• Australian Cardiovascular Health and Rehabilitation Association ASM, Brisbane, 2018
  *Poster presentation*: Developing a Victorian cardiac rehabilitation registry: a mixed-methods study.

• Cardiac Society of Australia and New Zealand ASM, Brisbane, 2018
  *Poster presentation*: Using an automated data capture tool to develop a cardiac rehabilitation registry.

• Australian Cardiovascular Health and Rehabilitation Association ASM, Perth, 2017
  *Research prize session presentation*: Is cardiac rehabilitation protective against long-term morbidity following acute coronary syndrome?


• Australian Institute of Health Innovation, Sydney, 2017
  *Invited presentation*: Data scraping techniques and clinical quality registries.

• World Congress of Public Health, Melbourne, 2017
  *Symposium*: Adapting and scaling-up diabetes prevention programs in low- and middle-income countries: an example from India.

• National Heart Foundation of Australia, Melbourne, 2016
  *Invited presentation*: Perspectives of people post heart events: analysis of the ADVENT study.

• Melbourne School of Population and Global Health PhD Conference, 2016
  *Presentation (Judge’s choice award)*: Scaling-up the Kerala Diabetes Prevention Program.
Awards

- **Travel grant** - Population Health Investing in Research Students’ Training (PHIRST) grant to attend the Canadian Cardiovascular Congress in Toronto, Canada. Awarded by the University of Melbourne, Australia, 2018 (AUD715)

- **Travel grant** - Population Health Investing in Research Students’ Training (PHIRST) grant to attend the ACRA and CSANZ conferences in Brisbane, Australia. Awarded by the University of Melbourne, Australia, 2018 (AUD585)

- **Travel grant** - Australian Cardiovascular Rehabilitation Association (Victorian branch) to attend the association’s annual conference in Perth, Australia, 2017 (AUD250)

- **Judges Choice Award – Best Presentation** - Melbourne School of Population and Global Health Conference, University of Melbourne, 2016 (AUD50)

- **Postgraduate scholarship** - National Health and Medical Research Council (NHMRC) APP1113920, 2016-2019 (AUD107, 000)
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Abbreviations

AACVPR: American Association of Cardiovascular and Pulmonary Rehabilitation

ACE: angiotensin-converting-enzyme inhibitors

ACRA: Australian Cardiovascular Health and Rehabilitation Association

ACSQHC: Australian Commission on Safety and Quality in Health Care

ACS: acute coronary syndrome

ADVENT study: Anxiety Depression & heart rate Variability in cardiac patients: Evaluating the impact of Negative emotions on functioning after Twenty-four months

AHA: American Heart Association

ARB: angiotensin II receptor blockers

BMI: body mass index

CABG: coronary artery bypass graphing

CHD: coronary heart disease

CI: confidence interval

CR: cardiac rehabilitation

CSANZ: Cardiac Society of Australia and New Zealand

CVD: cardiovascular disease

DASH: Dietary Approach to Stop Hypertension

DHHS: Department of Health and Human Services

EMR: electronic medical record

EuroCaReD: European Cardiac Rehabilitation Registry and Database

GRHANITE™: GeneRic Health Network Information for the Enterprise
HaBIC: Health and Biomedical Informatics Centre

HbA1c: Glycosylated Hemoglobin Test

HDL: high-density lipoprotein cholesterol

HR: hazard ratio

LDL: low-density lipoprotein

METeOR: Metadata Online Registry

MI: myocardial infarction

NACR: National Audit of Cardiac Rehabilitation

NHFA: National Heart Foundation of Australia

NSTEMI: non-ST-segment elevation myocardial infarction

OR: odds ratio

PCI: percutaneous coronary interventions

PROMS: patient reported outcome measures

PREMS: patient reported experience measures

QCOR: Queensland Cardiac Outcome Registry

RCT: randomised control trial

RAMIT: Rehabilitation After Myocardial Infarction Trial

REDCap: Research Electronic Data Capture

RR: risk ratio

STEMI: ST-segment elevation myocardial infarction

VCRR: Victorian Cardiac Rehabilitation Registry

WHO: World Health Organization
Structure of thesis

This thesis consists of seven chapters (Table 1) including four published or submitted manuscripts (Chapters 2, 3, 4, 6) and three traditional thesis chapters (Chapter 1, 5, 7).

The thesis is organised according to the six phases of the rapid-learning healthcare system model (Figure 1), which is recommended by the American Heart Association (AHA) in a Scientific Statement. The statement highlighted the need to systematically redesign cardiovascular care to be a ‘learning healthcare system’ by using information technology and data infrastructures to enhance optimal healthcare. The model is loosely based on the commonly used plan-do-study-act cycle and consists of six elements: 1) an internal and external scan, 2) intervention design, 3) implementation, 4) evaluation, 5) iterative adjustment, and 6) dissemination. The thesis is guided by these six phases, enabling a process of identifying, implementing and evaluating potential solutions for improving cardiac rehabilitation (CR).

Chapter One provides a review of the recent scientific literature on CR. After summarising the research gaps, the research aim and objectives are described. Chapter Two quantifies the benefits of attending CR for a cohort of Victorian patients following hospitalisation for ACS. Issues regarding variability of CR delivery are discussed. Chapter Three systematically reviews the international literature on CR registries to identify how other countries evaluate CR programs at the national level and describes the barriers and enablers of implementation. In Chapter Four, these lessons from the global community are applied to the Victorian context to determine how best to establish a CR registry in Victoria. In Chapter Five, considerations for developing Australian-wide quality indicators for CR are discussed. Chapter Six provides recommendations for improving the measurement of CR quality and effectiveness across Australia. Finally, Chapter Seven provides an overview and discussion of key findings, limitations and implications for future research.
Figure 1 The six phases of the rapid-learning healthcare system model

Source: Greene et al.¹
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PHASE 1: Internal and external scan

Identify problems and potentially relevant solutions
CHAPTER 1: INTRODUCTION
1 Chapter overview

This chapter provides an overview of the impact of heart disease on the Australian healthcare system. In addition, secondary prevention interventions (e.g., lipid management, blood pressure control, smoking cessation) for people with established heart disease are discussed. Cardiac rehabilitation (CR), as an important secondary prevention program, is introduced and critically discussed within the international, national and Victorian context. The applicability of historic CR evidence is also discussed considering recent improvements in cardiac care (e.g., revascularisation procedures and improved medications). Further, challenges to CR services, including under-utilisation and variability in the program delivery, are outlined. A lack of monitoring of the quality and outcomes of Victorian CR programs is highlighted. The use of registries as a means of monitoring and benchmarking CR programs is introduced. Last, the evidence gaps are summarised leading to a description of the research aim and objectives.
1.1 Cardiovascular disease: definitions and burden of disease

1.1.1 Cardiovascular disease
Cardiovascular disease (CVD) is a group of disorders of the heart and blood vessels and is the leading cause of mortality and disability-adjusted life years worldwide. The total number of global deaths due to CVD has reached 17.1 million per year. The Global Burden of Disease study estimates that in 2013, 30% of all deaths were due to CVD, of which coronary heart disease (CHD, or ‘heart disease’) and stroke were the largest contributors. The number of deaths due to CVD is projected to increase to 23.6 million people per year by 2030 and is likely to remain the single leading cause of death globally.

1.1.2 Heart disease
CHD develops as a result of atherosclerosis, which is a low-grade inflammatory state of the inner layer of the arteries. When atherosclerosis occurs in the coronary arteries it gradually leads to narrowing of the lumen. The atherosclerosis progression may be interrupted by either plaque disruption or plaque haemorrhage. The damage causes a complex interaction of risk factors including the cells of the artery wall and the blood and the molecular messages they exchange which can result in the occlusion of the coronary artery. The life-threatening presentation of heart disease is a spectrum of clinical conditions known as acute coronary syndrome (ACS), which results from a block of blood supply to the heart (myocardial ischemic states). ACS encompasses unstable angina, and myocardial infarctions (non-ST-segment elevation myocardial infarction (NSTEMI) and ST-segment elevation myocardial infarction (STEMI)).

The total number of global deaths due to heart disease has reached 7.4 million per year. Each year in Australia, almost 70,000 people experience an ACS event and approximately 20,000 people die, making heart disease the single leading cause of death. Promisingly,
over the past three decades, heart disease mortality rates have declined significantly in the main population of many high-income countries\textsuperscript{12, 13} including Australia\textsuperscript{11}, the United Kingdom\textsuperscript{14}, the United States\textsuperscript{15} and much of Europe.\textsuperscript{16} These lowered mortality rates are largely due to a concerted public health effort in risk factor reduction (e.g., smoking), advancements in risk-lowering medications, and improvements in treatment. Although these improvements in medical treatments are encouraging, major disparities continue, and the magnitude of change has varied dramatically between and within high-income countries.\textsuperscript{16} Among many low- and middle-income countries, age-adjusted mortality rates from CVD continues to rise\textsuperscript{17} and now account for more than 80% of global CVD deaths.\textsuperscript{13}

In Australia, death rates from heart disease vary among geographical regions and socio-economic status.\textsuperscript{11} The probability of a person experiencing a heart event is most closely related to their absolute CVD risk, which looks at multiple factors (e.g. smoking status, blood pressure, diabetes status, age and sex) that influence risk, rather than isolated individual risk factors.\textsuperscript{18} The mortality rate of Aboriginal and Torres Strait Islander people due to heart disease is two and a half times higher than the rest of the population.\textsuperscript{11} Further, an ageing population, the fact that Australians are having heart attacks earlier in life, and increasing survival following acute coronary events has resulted in large numbers of people living with heart disease as a chronic condition. The growing CHD population are at high risk of having a (subsequent) cardiovascular event and are in need of support to manage their condition.\textsuperscript{19}

1.1.3 Cost to the healthcare system and economy

In Australia, the number of annual hospitalisations where CVD was the primary diagnosis has increased by 7\% from 459,000 to 490,000 over the past decade.\textsuperscript{20} The resulting cost to the healthcare system is large; 60\% of Australia’s annual CVD expenditure is associated with hospitalisations\textsuperscript{21} and the costs of repeat events exceeds AUD\$8 billion (or >45\% of the total health-related costs).\textsuperscript{22} Consistent with increasing hospitalisation rates are increasing rates
of medical procedures to treat CHD. In the United Kingdom, the number of percutaneous coronary interventions (PCI) doubled between the years 2002 and 2012.\textsuperscript{14} Despite reductions in incidence and mortality rates associated with heart disease over the past few decades, the direct financial costs associated with the disease are expected to rise in Australia. As previously described, some contributing factors to this rise in cost include an ageing population, increasing life expectancy and increasing survival rates. The in-direct cost attributed to ACS events in 2017-18 to individuals and families is estimated at $4.8 billion due to productivity losses, out-of-pocket costs and informal care costs.\textsuperscript{23} As such, heart disease will continue to impose substantial costs on the healthcare system in addition to indirect financial costs and loss of health and wellbeing.\textsuperscript{22}

1.1.4 \textit{Risk of recurrent events}

While the burden of heart disease is well documented, there is less emphasis on the chronic nature of the disease and the risk of repeat events. Survivors of ACS have a chance of illness and death that is 1.5 to 15 times higher than that of the general population\textsuperscript{15} (depending on their sex and clinical outcomes). ACS patients have a worse 12-month prognosis than those with breast or prostate cancer.\textsuperscript{15} In the United States, a third of ACS patients are readmitted to hospital with unplanned events within 30 days, with over 60\% within one year.\textsuperscript{24} In Australia, one third of ACS events are repeat events, and the majority of survivors underestimate their chances of a repeat event.\textsuperscript{22} Women in particular are at greater risk of death from a repeat event (20.7\% versus 13.7\% for men).\textsuperscript{22} Due to the higher mortality risk associated with repeat events compared to initial events, the health-related costs are substantially higher.\textsuperscript{22}
1.2 Secondary prevention of cardiovascular disease

1.2.1 Preventing readmissions

The majority of ACS patients fail to meet or maintain optimal secondary prevention targets after discharge. As advocated by the Australian ACS guidelines, treatment of patients after an ACS event should include the management of key risk factors (obesity, hypercholesterolemia, hypertension, cigarette smoking, diabetes and depression); the appropriate prescription and adherence to cardio-protective drugs; and lifestyle modification (improved diet, increased physical activity and smoking cessation). These secondary prevention interventions are described in further detail below.

1.2.2 Smoking cessation

Smoking cessation is an effective and cost-effective measure for reversing damage to the endothelium and arteries, and preventing fatal CVD outcomes. Smoking cessation counselling delivered during hospitalisations with additional follow-up up to one-month has been shown to increase the smoking cessation rate by 37% at 6 to 12 months post hospital discharge. Pharmacological assistance (nicotine substitutes, bupropion, varenicline) has also been shown to support smoking cessation in CVD patients.

1.2.3 Increasing physical activity

Historically, cardiac patients were instructed to rest for a period of six weeks after an acute coronary event. It was not until the 1950s that early ambulation began to be recognised as safe and as a way to prevent complications of bed rest. Exercise training, a structured intervention to maintain or improve physical fitness, is now recommended as part of secondary prevention programs post-ACS. Exercise training has been shown to result in improved exercise tolerance and to reduce all-cause mortality. Direct benefits occur through improved endothelial function, myocardial oxygen demand, autonomic tone and
coagulation factors.\textsuperscript{19} Indirect or mediating effects have also been proposed whereby physical activity exerts beneficial effects on known risk factors for CVD such as blood pressure, lipids, lipoproteins and type 2 diabetes, thereby reducing overall CVD risk.\textsuperscript{34} The World Health Organization (WHO) recommend that adults (including those with CVD with no contraindications) should undertake a minimum of 2.5 hours per week of moderate aerobic activity, or 600 metabolic equivalent minutes.

1.2.4 \textit{Improving diet and nutrition}

The importance of nutrition in modifying the risk of a repeat CVD event has been repeatedly emphasised. As food is typically consumed in combination rather than individually, there is a growing emphasis on dietary patterns rather than individual food groups or components. Recent evidence suggests that to reduce the risk of a further CVD event, a dietary pattern should be encouraged that includes an intake of vegetables, fruits, whole grains, low-fat dairy products, poultry, fish, legumes and nuts; and limits intake of sweets, sugar-sweetened beverages and red meats.\textsuperscript{34} Diets such as the Dietary Approach to Stop Hypertension (DASH)\textsuperscript{35} and the Mediterranean diet\textsuperscript{36} have been shown to reduce cardiovascular risk factors in populations with established CVD.

1.2.5 \textit{Weight control}

Obesity is an independent risk factor for CVD. The literature suggests that intentional weight loss (achieved through behavioural weight loss and exercise) has beneficial effects on risk markers such as hypertension, diabetes control, measures of inflammation, metabolic syndrome and blood lipid levels.\textsuperscript{37, 38} Consequently, weight loss and its maintenance are encouraged for secondary prevention of CVD. It is recommended in clinical practice guidelines (e.g., the American Heart Association (AHA) guidelines) that CHD patients who are overweight or obese should lose an initial 10\% of body weight with the longer-term goal of achieving a body mass index (BMI) below 25.\textsuperscript{37} Studies have also
suggested that intentional weight loss positively affects long-term prognosis in patients with CHD, regardless of initial BMI. However, it is now increasingly recognised that the distribution of fat around the abdomen (intra-abdominal or visceral adipose tissue) is a more potent predictor of adverse health outcomes. Consequently, reducing waist circumference (if above normal limits) is an important target for improving the overall health of CVD patients.

1.2.6 Lipid management

Diet, exercise and weight loss can improve a patient's lipid profile. Pharmacological interventions, namely statins, are widely recommended to reduce low-density lipoprotein (LDL) cholesterol. A meta-analysis conducted by the Cholesterol Treatment Trialist's Collaboration including data from 170,000 individuals across 21 trials showed that lowering of LDL cholesterol by 1 mmol/L with a standard statin regime reduced the incidence of major vascular events by around one-fifth.

1.2.7 Blood pressure monitoring

Management of high blood pressure (>140/90 mmHg) is multifactorial and requires patient and healthcare provider awareness, appropriate lifestyle modification, access to care, evidence-based treatment, medication adherence and adequate follow-up. The National Health and Nutrition Evaluation Survey undertaken in the United States demonstrated that while a large percentage of participants with hypertension were aware of the disease (81.5%), only 52.5% had their hypertension under control. Anti-hypertensive therapy can include angiotensin-converting-enzyme (ACE) inhibitors, angiotensin II receptor blockers (ARB), beta-blockers and calcium antagonists or combination therapies and have been shown to significantly reduce cardiovascular risk and are recommended to patients with high blood pressure. Lifestyle modifications are an important aspect of reducing hypertension levels and include: reducing weight (if above a normal BMI/waist.
circumference); adopting a DASH diet (diet rich in fruit, vegetables and low-fat dairy products with reduced saturated and total fat); reducing salt intake; engaging in regular physical activity and moderating alcohol consumption.\textsuperscript{45}

\subsection*{1.2.8 Diabetes management}

Diabetes is a common comorbidity in people with CVD and shares many underlying risk factors such as smoking, hypertension, hypercholesterolemia and obesity. Approximately 26\% of patients referred to secondary prevention services will have diabetes.\textsuperscript{33} A study of nearly two million participants with a median follow-up of 5.5 years demonstrated that the association between diabetes and CVD differs among 12 CVD outcomes with the most common initial manifestations of CVD in type 2 diabetes patients being heart failure and peripheral arterial disease.\textsuperscript{49} Achieving glycaemic control (HbA1c concentration of <7\%) has been shown to reduce cardiovascular morbidity and mortality in patients with established CVD.\textsuperscript{33}

\subsection*{1.2.9 Psychosocial management}

Major depression is prevalent in over 10\% of the ACS population, approximately double the prevalence rates found in the general population.\textsuperscript{50, 51} Less severe depression occurs in 20\% to 30\% of the population; with similar rates for anxiety.\textsuperscript{51} It has not been determined, however, that treatment of depression post-myocardial infarction reduces mortality and reinfarction. The seminal ENRICHD trial, for example, decreased depression and improved social support, however, it did not affect the primary end point of death and nonfatal infarction.\textsuperscript{52} However, negative emotional states, such as anxiety and depression, are associated with poor outcomes after a cardiac event.\textsuperscript{53} Therefore, it is important to assess depression in cardiac patients with the goal of targeting those most in need of treatment and support services. This recommendation is supported in multiple clinical guidelines internationally (e.g., British\textsuperscript{54}, Scottish\textsuperscript{55} and the Australian Core Components\textsuperscript{56}).
1.2.10 *Secondary prevention services*

To promote optimal secondary prevention targets for patients after a heart event, multi-component secondary prevention programs have been established across Australia. The most common and well-known of these is cardiac rehabilitation (CR).

1.3 Cardiac rehabilitation

1.3.1 *What is cardiac rehabilitation?*

CR has been defined as the “coordinated sum of interventions required to ensure the best physical, psychological and social conditions so that patients with chronic or post-acute CVD may, by their own efforts, preserve or resume optimal functioning in society and, through improved health behaviours, slow or reverse progression of disease”.\(^57\)(pp.2) It is a complex (i.e., multi-component) intervention comprised of exercise sessions and lifestyle change education that focuses on regaining or maintaining physical capacity, wellbeing, medication compliance, and social and vocational participation. There are three main phases of CR as defined by Piepoli et al.\(^58\)(p666):

- **Phase I**: early intervention during the stay in acute hospital, including early mobilisation and prevention of complications secondary to immobilisation.
- **Phase II**: promotes and delivers preventive rehabilitation services to patients following an index CVD event with the aim of clinical stabilisation, risk stratification and promotion of long-term intervention. It may be performed in in-patient and/or out-patient settings.
- **Phase III**: long-term, out-patient CR, which seeks to provide sustained delivery of preventive and rehabilitative services in the out-patient setting and/or in the community.
In Australia, CR programs are provided by public and private health facilities in a range of hospital and community-based settings. Typically, group CR comprises of low or moderate intensity physical activity, behaviour modification strategies and education around psychosocial health, nutrition, physical activity, smoking cessation, medication adherence and return to work. In general, programs occur for 6 to 12 weeks in duration.59, 60

Figure 2 Location of CR programs in Victoria

Developed by Dr Suzanne Mavoa and Emma Thomas.

1 Public health services in Australia receive funding from the Australian Government and state and territory governments. Private facilities are mainly funded by private health insurance and out-of-pocket payments by patients. The Federal Government’s universal public health insurance scheme (Medicare) enables all Australian citizens and permanent residents’ universal access to free healthcare treatment in public hospitals and subsidies for pharmaceuticals and medical services.
Within Victoria, there are 136 CR programs (Figure 2). The Victorian health system is large and complex. It consists of primary, secondary and tertiary care, including over 300 hospitals and health services such as large public and private hospitals, regional health services and small specialist rehabilitation hospitals. The overall management of the public health system is managed by the Department of Health and Human Services (DHHS). Although every public hospital in Australia is part of a Local Hospital Network, some states and territories have consolidated their networks more than others, enhancing integration of services and infrastructure. For example, South Australia has just six Local Hospital Networks. Queensland has consolidated their hospitals into 15 networks that are largely inter-connected via the Queensland Health intranet. In contrast, Victoria has more than 80 Local Hospital Networks with limited connectivity between services.

1.3.2 International clinical guidelines and recommendations for cardiac rehabilitation

CR is recommended (as a Class 1 recommendation) in multiple clinical guidelines internationally. For example, the Australian, European, American, British, Scottish, and Canadian guidelines recommend that as part of integrated cardiac care, all patients hospitalised with a primary diagnosis of acute myocardial infarction (MI) or chronic unstable angina or who have undergone a revascularisation procedure (e.g., coronary artery bypass graphing (CABG), PCI) be referred to CR.

1.3.3 Australian core components and recommendations for cardiac rehabilitation

In 1999, Best Practice Guidelines for Cardiac Rehabilitation and Secondary Prevention were commissioned by the (then) Department of Human Services Victoria and developed by the Heart Research Centre. In 2004, the National Heart Foundation of Australia (NHFA) and the Australian Cardiovascular Health and Rehabilitation Association (ACRA) developed a recommended framework for CR for services delivering Phase I – III CR.
A decade later, ACRA developed a set of national standards consisting of five core components for CVD secondary prevention and CR. The core components for quality delivery and outcomes of services include: 1) equity and access to services; 2) assessment and short-term monitoring; 3) recovery and longer term maintenance; 4) lifestyle/behavioural modification and medication adherence; and 5) evaluation and quality improvement. In regards to core component 5 (evaluation and quality improvement), it is stated that all CR services must collect a minimum set of data and report on key performance indicators to promote continuous quality improvement of services and benchmarking. Following this, the New South Wales division of ACRA and the NHFA along with the Agency for Clinical Innovation developed a minimum set of CR quality indicators with an accompanying data dictionary for CR sites.

1.3.4 Effectiveness of cardiac rehabilitation

The most recent Cochrane review of 63 randomised controlled trials (RCTs) including 14,486 people with CHD reported that participation in exercise-based CR reduced the risk of cardiovascular mortality compared to controls (27 trials; risk ratio (RR): 0.74; 95%CI: 0.64, 0.86) but did not affect all-cause mortality. Further there was evidence that CR reduced the risk of hospital admissions with short-term follow-up (<12 months) (15 trials; RR: 0.82; 95%CI: 0.70, 0.96) and improved health-related quality of life.

However, the lack of benefit in some CR trials (e.g., Rehabilitation After Myocardial Infarction Trial (RAMIT), the largest pragmatic RCT to date) have resulted in renewed discussions regarding the effectiveness of CR. While it is recognised that the RAMIT trial had multiple limitations (including early closure related to recruitment), it has been argued that reviews of trials should be limited to recent studies given medical management of CHD has significantly changed in recent decades with advances in interventions (e.g., PCI) and pharmacotherapy. To clarify these issues, Powell et al. reviewed the effect of
‘contemporary’ exercise-based CR excluding any studies published prior to the year 2000. The review concluded that exercise-based CR had no effect on all-cause mortality or cardiovascular-mortality when compared to the non-exercise controls.\textsuperscript{68} This review led to commentaries from the International Council of Cardiovascular Prevention and Rehabilitation\textsuperscript{69}, as well as the British\textsuperscript{70}, Canadian\textsuperscript{71} and Australian\textsuperscript{72} associations for cardiovascular prevention and rehabilitation. These commentaries highlighted important considerations such as: the importance of dose and patient adherence\textsuperscript{71}, the potential of ‘active’ interventions such as cardio-protective medications impacting on the non-exercise group\textsuperscript{72}, and the difficulties of evaluating complex interventions.\textsuperscript{71, 72} Further, authors argued that a change in mortality alone does not exclusively determine the effectiveness of an intervention; outcomes such as reduced hospital admissions and clinically relevant improvements in quality of life are of importance.\textsuperscript{69, 70}

Rauch et al.\textsuperscript{73} also reviewed the effect of modern CR in patient with ACS, CABG or mixed populations with CHD who had an index event between 1995 and 2015. The review of 219,702 patients from 25 studies (including the RAMIT study\textsuperscript{67}) included RCTs and controlled cohort studies and concluded that modern CR reduced mortality in ACS (hazard ratio (HR) 0.37; 95%CI: 0.20, 0.69) and CABG patients (HR: 0.62; 95%CI: 0.54,0.70). However, the authors highlighted large heterogeneity in study designs and the need to define internationally accepted standards for CR delivery and evaluation.\textsuperscript{73}

Van Halewijn et al. (2017)\textsuperscript{74} also undertook a meta-analysis of contemporary (2010 – 2015) CR RCTs in the ACS population including 18 studies with 7691 randomised patients. The meta-analysis revealed that all-cause mortality was not reduced (RR 1.00; 95%CI: 0.88, 1.14); however, cardiovascular mortality was reduced by 58\% (95%CI: 0.21, 0.88), MI was reduced by 30\% (95%CI: 0.54, 0.91) and cerebrovascular events (which had not previously been reported in other studies) by 60\% (95%CI: 0.22, 0.74). Of interest, the subgroup
analysis revealed that comprehensive programs that addressed six or more risk factors (e.g., smoking, poor diet, overweight, physical inactivity, hypertension, dyslipidaemia, diabetes, low adherence cardioprotective medications) reduced all-cause mortality, but those managing fewer than six did not. This study highlights the importance of providing a truly comprehensive program to achieve best patient outcomes.

Kabboul et al. extrapolated on these findings and performed a network meta-analysis to evaluate the comparative effectiveness of CR core components (exercise training, risk factor modification, nutrition counselling, psychosocial management and patient education) on morbidity and mortality outcomes. Psychosocial management, exercise training and patient education were all found to reduce mortality. Combining all core components was most effective for reducing revascularisation, reiterating the benefits of a comprehensive CR program highlighted by Van Halewijn et al.

Addressing the methodological challenges identified in the above mentioned reviews, Sumner, Harrison and Doherty reviewed recent (2000 – 2017) observational studies. The review included a more homogenous CR population of acute MI patients and concluded that in non-RCT studies (which have a greater risk of bias), CR reduced the risk of all-cause and cardiac specific mortality and improved health-related quality of life. However, no significant benefits were found on re-hospitalisation following AMI.

While outcomes have varied across studies, it is consistently reported that there is heterogeneity in study designs and the delivery of CR programs. This heterogeneity makes it challenging to determine the effectiveness of CR and highlights the need for defining internationally accepted standards of CR delivery and evaluations.
1.3.5 **Under-utilisation of cardiac rehabilitation**

Despite the robust evidence supporting participation of CR, attendance rates are notoriously low; less than 50% of eligible patients attend worldwide. Recent data from England showed that just 50% of referred patients enroll in CR. In Australia and New Zealand only 25% of ACS patients successfully met or maintained optimal secondary prevention targets after discharge. Patients at the highest risk (i.e., those who have adverse risk profiles and poor knowledge of ACS risk factors), are the least likely to attend. Additionally, women are 55% less likely to attend compared to men. The elderly (>70 years of age) are less likely to attend than younger patients. A recent study investigating the economic and social impact of increasing CR determined that increasing uptake of CR in Victoria by 30% and 65% would have a net financial saving of $46.7 and $86.7 million, respectively.

1.3.6 **Barriers and enablers of cardiac rehabilitation attendance**

Predictors of CR non-attendance include: distance from CR centres, speaking a language other than English, low socioeconomic status, ethnicity, female gender, and older age. Neubeck and colleagues systematically reviewed the qualitative literature to provide a more in-depth understanding of the processes underlying non-attendance. The review revealed a range of barriers at the system and service-level (e.g., lack of recommendation from physician); along with physical (e.g., lack of transport, work commitments) and personal barriers (e.g., a personal belief that CR will not benefit). These barriers, along with their corresponding enablers, are depicted in Figure 3. Additional reasons for the underutilisation of CR reported in the literature include: underestimation of therapeutic benefits by potential referrers, poor referral processes and hospital-to-outpatient transition, and additional patient level factors such as depression, social isolation and lack of insurance coverage. Barriers specific to the Australian context include: diverse cultural and linguistic needs, transportation and logistics associated with an ageing population, and
a vast geographical area that complicates CR provision. Within Victoria, an emphasis on traditional models of CR delivery (e.g., face-to-face) and complex and unstable funding arrangements have been identified as additional barriers to CR uptake.

Figure 3 Enablers and barriers to CR
Source: Neubeck et al.

1.3.7 *Variability in the delivery of cardiac rehabilitation*

Variation in the delivery of CR programs (i.e., content, dose, staffing structures) across Australia is common and makes comparisons of services challenging. The content delivered in Australian CR programs is not standardised. Programs have typically expanded organically from model sites and been modified over time. The majority of programs are centre-based and offer group exercise and education. Telephone support is also offered in approximately 60% of programs, and a limited number of CR programs will also offer programs via other means (e.g., internet or video conferencing). Variation in programs is common internationally. The National Audit of Cardiac Rehabilitation (NACR) in the United
Kingdom established that only 30% of CR sites are delivering programs that achieve agreed standards of care.\textsuperscript{84}

Evidence shows the CR has the greatest treatment effect when the time lapse between the event and rehabilitation is shortest and the program duration is the longest.\textsuperscript{85} Australian CR programs provide a mean number of nine CR sessions\textsuperscript{82}, which compared to programs internationally, is very low. For example, programs in Canada run for 3 to 6 months on average\textsuperscript{86}, the United States programs provide up to 36 sessions\textsuperscript{87}, and European programs vary between 2 and 16 weeks.\textsuperscript{87} The program setting also impacts upon duration. For example, some programs in Europe (e.g. Norway, Germany) occur in residential (or in-patient) settings. Potentially, longer duration is more feasible when provided within community or at home. The only published meta-analysis to assess the effect of CR dose on mortality and morbidity suggests that a minimum of 12 sessions is required to reduce mortality and 36 sessions are required to reduce percutaneous coronary intervention.\textsuperscript{88}

Staffing also varies across CR programs in Australia. Most programs will involve a cardiac nurse, physiotherapist and engage with a dietician and pharmacist. However, depending on the program, an exercise physiologist, occupational therapist, social worker, psychologist, diabetes educator and cardiologist may also be involved in the delivery of the program.\textsuperscript{82} Currently in Australia, there are no set standards on staffing requirements or qualifications to deliver a CR program.

Recognising the paucity of data on the delivery and outcomes of CR, the NHFA called for action to establish uniform quality performance measures, data collection and routine reporting.\textsuperscript{89} The development of evidence-based quality indicators is one way to measure the delivery of care against guideline recommendations. A commonly accepted method of collating quality indicator data at the state or national level to enable benchmarking of
programs is clinical quality registries. However, currently in Victoria (and many other states and territories), there are no current quality indicators or data collection methods to enable routine reporting of CR processes or outcomes.

1.3.8 Information and communication technology environment in Victoria.

Large amounts of patient-related data are collected across the healthcare system by multiple stakeholders. However, the collected data are often maintained in separate databases and are not readily available or collated beyond the individual agency.\textsuperscript{90} The largest attempt to reform the Victorian information and communication technology (ICT) ecosystem was the HealthSMART initiative. The initiative commenced in 2004, received over $330 million in government funding, and aimed to implement a standardised clinical solution across Victoria’s dispersed public health system. However, the ‘one-size-fits-all’ approach was ultimately unsuccessful and by 2013 the HealthSMART initiative was officially ended. Consequently, the decision about ICT support systems was placed back on the individual health units such as hospitals. To understand why the HealthSMART initiative was unsuccessful and to provide guidance on future ICT developments a ministerial review of the Victorian health sector was undertaken. The review\textsuperscript{91} recommended that Victoria: 1) shifts from centrally controlled decisions about ICT to greater devolution of decision making to health service providers; 2) focuses on achieving critical business requirements and improving patient safety instead of trying to achieve fully integrated health records and 3) specifies interoperability standards and requirements rather than specifying specific technology products. To avoid a proliferation of new and uncoordinated systems it was recommended that a ministerial advisory body be set up to inform development of the state-wide ICT priorities and develop a Victorian ICT plan.

Consequently, a wide range of electronic clinical information systems are being used to varying degrees across Victoria. Some hospitals still rely on paper-based records and many
use scanned medical records.\textsuperscript{92} The details of the healthcare information captured, stored and used is variable and site dependent. Further, the quality of medical information varies across many categories. This causes inefficiencies in the recall of patient information, can potentially lead to adverse events (e.g., adverse drug events) and has far-reaching implications for both current and future healthcare management strategies.\textsuperscript{92}

1.3.9 Infrastructure plan for Victoria’s cardiac care

The Design, service and infrastructure plan for Victoria’s cardiac system (the Cardiac Plan)\textsuperscript{90} was developed in 2016 to provide continuing reform to the cardiac system to enhance efficiencies and quality of care. The Cardiac Plan has three key priorities: 1) better patient access, experience and outcomes; 2) a coordinated cardiac system of care; and 3) effective and innovative cardiac services. The Cardiac Plan highlights the importance of continual service improvement driven by monitoring of performance and outcomes and recognises that services need to adopt new technologies to improve patient care and outcomes. The Plan explicitly supports the development of clinical registries like the Victorian Cardiac Outcome Registry to provide a method by which healthcare providers can benchmark their performance against national and international service providers.

1.4 Clinical quality registries

The Australian Commission on Safety and Quality in Health Care (ACSQHC)\textsuperscript{93} defines clinical quality registries as ”clinical databases that systematically collect longitudinal health-related information on the quality of care provided to individuals”.\textsuperscript{93(2)} Registries are effective instruments for collecting and reporting information on both the appropriateness of care (process) in keeping with clinical practice guidelines and the effectiveness of care (outcomes) for individuals with CVD.\textsuperscript{94} Well-designed and well-executed registries hold great potential to capture data that reflect 'real-world' clinical practice to provide insights into patient characteristics and evaluate patterns of care and disparities.\textsuperscript{94} While registries
on their own have benefit, they are more beneficial when embedded within a quality improvement cycle (Figure 4). In such a system, registries provide data that support quality improvement initiatives, can determine whether evidence-based guideline recommendations are being adhered to and can support clinical trials and the generation of new evidence.

![Figure 4 The role of registries in the cycle of quality](image)

Source: Bhatt et al.

Although numerous ACS and other CVD registries exist globally (e.g., Global Registry of Acute Coronary Events), and some specifically monitor against guideline recommendations and have in-built quality improvement programs (e.g., Australian Cooperative National Registry of Acute Coronary care, Guideline Adherence and Clinical Events; CONCORDANCE, the Get With The Guidelines program), very few countries have established national CR registries. A systematic review of CR registries is provided in Chapter Three.
1.5 Summary and evidence gaps

Heart disease is the single leading cause of death internationally and costs the Australian healthcare system billions of dollars each year. Much of the financial cost is due to repeat events that could be reduced by improved preventive care. However, it is estimated that only one quarter of ACS patients receive ‘optimal care’ including lifestyle advice, referral to CR, and prescription of secondary prevention medications.

Meta-analyses suggest that participation in CR reduces mortality and morbidity, and improves exercise capacity, psychological wellbeing, quality of life, and adherence to pharmaco-therapy. International clinical practice guidelines, underpinned by the highest level of evidence, recommend that CR should be provided to patients with heart disease as part of integrated cardiac care. However, many eligible patients do not receive CR; less than 50% attend worldwide.

In Victoria, there is no routine measurement of who does (and does not) attend CR and their respective outcomes. Further, there is no mechanism to systematically monitor the quality of CR delivery and therefore, no way to routinely audit and benchmark the performance of the CR programs. The ability to quantify healthcare quality relies on the implementation of appropriate systems that can accurately capture how care is being delivered. Clinical registries provide a vehicle for measuring the ‘real-world’ delivery of care and have been shown to improve care quality and to have substantial return on investment. However, challenges associated with the establishment and cost of registries often impact implementation and sustainability. Therefore, innovative solutions are required to reduce the burden of data entry on time-poor clinicians.
1.6 Research aim and objectives

Based on the above evidence gaps, the overall aim of this thesis was to investigate feasible methods by which to improve the monitoring of CR quality and delivery across Victoria. This aim was achieved via the following four study objectives:

1. To determine whether attendance of a CR program is associated with reduced hospital readmissions post-discharge in Victoria;
2. To identify and describe how CR programs are monitored and evaluated internationally;
3. To investigate the feasibility of implementing a CR registry in Victoria;
4. To provide recommendations for improving the monitoring of CR delivery and quality.
CHAPTER 2: ASSOCIATION BETWEEN CARDIAC REHABILITATION AND 24-MONTH ALL-CAUSE HOSPITAL ADMISSION: A PROSPECTIVE COHORT STUDY
Chapter 2 – Research article

2 Chapter overview

The previous chapter highlighted the growing rate of hospital readmissions for patients with heart disease. Also highlighted, was uncertainty in the literature regarding the impact of CR on reducing readmission rates in the modern era of cardiology. This chapter uses data from a recent Victorian prospective cohort study (ADVENT study) to assess the association of CR on all-cause readmission rates up to 24-months post-ACS event including association of CR on the frequency of readmission events and length of stay.

2.1 Abstract

**Background:** Ageing populations and increasing survival following ACS has resulted in large numbers of people living with CVD and at high risk of hospitalisations. Rising hospital admissions have a significant financial cost to the healthcare system. The aim of this article is to determine whether CR is protective against long-term hospital readmission (frequency and length) following ACS.

**Methods:** Data from 416 Australian patients with ACS enrolled in the ADVENT prospective cohort study between January 2013 and June 2014 was analysed secondarily. Participants self-reported CR attendance over the 12-months post-discharge. All-cause readmission data were extracted from hospital records 24-months post-index event. The association between CR and all-cause readmission, frequency of readmissions, and length of stay was assessed using three methods 1) regression analysis 2) propensity score matching and 3) inverse probability treatment weighting.

**Results:** Overall, 416 patients consented (53% of eligible patients), of which 414 (99.5%) survived the first 30 days post-discharge and were included in the analysis. Medical records were located for 409 participants after 24 months (98% follow-up rate). In total, 267 (65%) reported attending CR; there were 392 readmissions by 239 patients. CR attendance was not associated with all-cause hospital readmission; however, it was associated with significantly lower frequency of hospital admissions (OR: 0.53; 95%CI: 0.31, 0.91; p-value: 0.022) and length of stay (Coef. -1.21 days; 95%CI: -2.46, 0.26; marginally significant p-value: 0.055) in fully adjusted models.

**Conclusion:** This study substantiates the long-term benefits of CR on readmissions, including length of stay, which would result in significantly lower costs to the healthcare system.
2.2 Introduction

Ageing populations and increasing survival following ACS has resulted in large numbers of people living with CVD. While acute revascularisation therapies are highly effective in restoring blood flow in specific vessels, CVD is a chronic condition which cannot be cured, as all vessels remain diseased. Thus, there are many individuals at high risk of readmission for further coronary artery stenosis. For instance, data from the Global Registry of Acute Coronary Events shows that 20% of ACS patients in Australia and New Zealand are readmitted within six months. In the United States, 30-day readmission rates post-MI are now publicly reported and a determinant of reimbursement by the Centres of Medicare and Medicaid Services; recent reports show a third of ACS patients are readmitted to hospital within 30 days, with over 60% readmitted within 1 year.

CR is comprised of structured exercise and lifestyle change education that focuses on risk reduction as well as optimizing physical capacity, wellbeing, and social and vocational participation. International guidelines recommend that patients with ACS should be referred to CR. Meta-analyses show that CR participation reduces cardiovascular deaths and improves health-related quality of life. The effect of CR on hospital readmissions more broadly remains equivocal. Some studies have reported reductions in hospital readmission owing to CR of between 17% and 79%, while others have reported no significant benefits. A recent Cochrane review of the evidence reported an overall reduction in risk of hospital readmission (from 31% to 26%) in the short-term period following CR (6-months to 12-months). Of the few studies (n=6) that had longer follow-up periods (>12 months), no significant protective associations were observed.

Hospital admissions are distressing and disruptive on both the lives of patients and their families. Approximately one in three patients report mild to moderate depressive symptoms post an ACS event and loss of work is common; within the European Union 90
million working days are lost annually due to coronary heart disease.\textsuperscript{107} The majority of healthcare costs post-MI are driven by hospitalisations\textsuperscript{108}, with longer stays being more expensive. Therefore, reducing both readmission \textit{frequency and length} have the additional importance of significantly reducing CVD healthcare expenditure (and offsetting the cost of delivering CR), as well as productivity losses and familial distress. There are few studies that have considered the impact of CR on frequency of readmission and length of stay. A study by Zwisler \textit{et al.}\textsuperscript{109} revealed that participants randomised to a comprehensive CR program had a \textit{15\%} (95\%CI: 0.1; 0.27) lower average length of stay at 12-months compared to controls.\textsuperscript{109} Reduction in duration of admission within 12 months was also reported by Canyon and Meshgin.\textsuperscript{103} Therefore, the aim of this study was to test the association between CR participation and all-cause hospital readmission (including frequency and length of stay) up to 24 months post-ACS discharge.

\textbf{2.3 Methods}

The methods of the ADVENT cohort study have previously been published.\textsuperscript{110} In brief, the ADVENT study was a prospective cohort study which aimed to examine: the role of somatic subtypes of depression and anxiety as predictors of health-related quality of life, long term vocational functioning and healthcare utilisation in ACS patients.\textsuperscript{110}

\textbf{2.3.1 Setting}

Australian CR programs are guided by a framework developed by the NHFA and ACRA\textsuperscript{89} and the ACRA core components document.\textsuperscript{56} Prior to hospital discharge, ACS patients are generally referred to a CR program located closest to their home (currently, there are 135 CR programs in Victoria). While patients with unstable angina are not always accepted into CR programs in other countries, Australian ACS guidelines\textsuperscript{27} recommend that all patients hospitalized with ACS be referred to CR; as such, these patients were also included in our analyses. While all ACS patients in Australia should have access to CR, it is not always
formally offered to every patient or if they are, many still decide not to attend for a variety of reasons. CR programs are conducted in either hospital outpatient or community-based settings, are generally multidisciplinary in nature and typically run for 6 to 12 weeks in duration. Programs generally involve group-based exercise training guided by a trained clinician (e.g., physiotherapist or exercise physiologist) and an education component including information on diet, physical activity, information on medications and psychological support. Additionally, many programs also provide vocational support to assist return to work and support for family/caregivers. Following CR, most ongoing care and management is provided by a patient’s general practitioner.

2.3.2 Participants

From January 2013 to June 2014, all patients who were admitted to Monash Heart (a large public and private metropolitan hospital in Melbourne, Australia) and diagnosed with ACS were invited to take part in the ADVENT study. Eligibility criteria included being over 21 years of age and having sufficient English-language proficiency to complete questionnaires. Patients were excluded if they: 1) were unable to provide informed consent; 2) cognitively impaired, 3) pregnant, 4) reported substance abuse, 5) had a terminal illness and/or other illness that impaired participation; or 6) were participating in other trials.

2.3.3 Procedure

Eligible patients were approached by study recruiters and those interested were provided with information on the study. Participants provided informed consent, including that their information could be linked to hospital records. Data were collected through:

Patient medical charts by study nurses (assessing participant sociodemographic characteristics, cardiac diagnosis, blood measurements and hospital discharge medication prescriptions) recorded during the index ACS admission.
Computer-assisted telephone interviews (CATI) performed by research assistants at 1-month (T0) and at 12-months (T1) post-discharge. The CATI assessments consisted of questions related to healthcare utilisation including CR use and a validated depression screener (which is an important predictor of both CR uptake and readmissions). Participants were asked: "Have you attended cardiac rehabilitation?" (yes/no). If yes, they were subsequently asked "Where did the program take place?", "How was the program delivered (e.g., face-to-face, via telephone)?" and "What date did cardiac rehabilitation commence?".

Clinical assessments at T0 were performed at the study centre including anthropometric measurements (height, weight).

Hospital medical records were audited at 24-months (T2) to obtain more detailed information on the index admission (including past medical history) as well as readmissions.

2.3.4 Measures

Primary outcome: Hospital readmissions. Participant medical records were reviewed through to 24-months post-index admission for all-cause hospital admissions by two medically trained Research Fellows. Hospital admissions were defined as a formal admission to hospital, including emergency visits. Hospital records were collected from Monash Health archives which has a combined catchment area of 1.2 million people (including transfers from 7 hospitals in surrounding regional areas)\textsuperscript{111,112}, making it one of Australia’s largest cardiology services. Services are provided to both public patients (no out-of-pocket expense) and patients with private health insurance. For every readmission, data were extracted on the admission hospital site, ward, or emergency department, discharge diagnosis, and length of stay (days).
Independent Variable: Cardiac rehabilitation attendance. Patients who reported that a) they had attended CR and b) could provide a start date that they commenced attending a CR program where considered CR attenders. Non-attenders were those who reported not attending CR. Those lost to follow-up or who had missing, or incomplete CR data were not included in the analyses.

Covariates: The following sociodemographic, clinical variables and risk factors were included as covariates.

Socio-demographics: Sex (male/female) and age (years) of participants was collected from hospital records during the index admission. Additional sociodemographic details (education level, living situation and employment status) were obtained during the CATI interviews (T0, T1).

Clinical variables: Cardiac diagnosis (ST-elevation myocardial infarction [STEMI]; non-ST-elevation myocardial infarction [NSTEMI]; or unstable angina) was obtained from hospital medical records by Study Nurses at T0. Revascularisation procedures (CABG or percutaneous coronary intervention: PCI) that occurred during the index admission were collected from hospital medical records by medically-trained research fellows at T2.

Risk Factors. During the index hospital admission tobacco smoking (current/former/never), medication prescriptions, and blood measurements including fasting blood glucose, lipids (cholesterol, triglycerides, high-density lipoprotein cholesterol [HDL], low density lipoprotein cholesterol [LDL]), high sensitivity C reactive protein (CRP), Left Ventricular Ejection Fraction (LVEF) and glycosylated haemoglobin (HbA1C) were obtained. Body mass index (BMI) was derived from anthropometric data collected during clinical assessments at T0. Finally, the Cardiac Depression Scale (CDS) is a depression screening tool developed specifically for cardiac patients and was collected during the CATI at T0 and T1. It is reliable
(Cronbach’s α=0.90)\textsuperscript{113} and has excellent properties for detecting major depressive disorder with a score of ≥95 having a 97% sensitivity and 85% specificity when indexed to the Mini-International Neuropsychiatric Interview\textsuperscript{114}.

### 2.3.5 Statistical analysis

Retention rate was computed. Descriptive statistics were used to compare baseline sociodemographic and clinical differences between those who attended CR versus non-attenders, as well as those with and without hospital readmission at 24-months post-ACS. Mean (standard deviations: SD) values were used for continuous variables, and frequencies (%) for categorical variables. Differences were tested using the Student’s t-test (continuous variables, log-transformed if required) and Pearson’s $\chi^2$ (categorical variables), with $p<.05$ considered significant.

The association of CR with outcomes was guided by the methods proposed by Dunlay et al.\textsuperscript{104}. First, all participants who died within the first 30 days were removed from the analysis, as they were unlikely to have accessed CR. Univariable Pearson’s $\chi^2$ analyses were used to assess: 1) hospital readmission (binary); 2) the number of hospital readmissions (0, 1, 2, 3, 4, 5, 6); as well as Student’s t-test for 3) mean days of hospitalisation, in those who participated versus did not participate in CR.

Three multivariable adjusted regression models were used to analyse the association between CR and the number (ordinal logistic) and length of stay (linear logistic) of CR readmissions in the 24-months following the index event. Model 1 was adjusted for age, sex and any other sociodemographic, risk factors or clinical differences if significant (P-value <0.05) baseline differences were identified between CR attenders/non-attenders or between participants with/without a hospital readmission by 24-months. Model 2 accounted for the difference in propensity to attend or not attend CR by adjusting for the
propensity score. Model 3 used the inverse probability of treatment weighting, which uses weights based on the propensity score to create an artificial sample in which the distribution of measured baseline covariates is independent to treatment assignment. All three models are presented with and without emergency department visits as these are not always accepted as hospital admissions.

Participants with missing values for the outcome (n=8, 2%) and covariates (n=85, 21%) were excluded from the main models (complete-case analyses). Sensitivity analyses were employed to impute missing values for the covariates in the data and was applied to the same three models. The multiple imputation (15 imputation) was done by chained equations using: binary logistic regressions to impute missing values for smoking status, CDS depression, prescribed Beta blockers and CR attendance; linear regressions to impute missing values for LVEF and; ordinal logistic regressions to impute missing values for education group. Sex and age were used as auxiliary variables.

Magnitudes of association were presented as Odds Ratios (OR) or Coefficients (Coef.) for the mean difference as applicable, with corresponding 95% Confidence Intervals (CIs). All analyses were conducted using Stata Version 14.

2.4 Results

Between January 2013 and June 2014, 416 patients were enrolled into the study (Figure 5). Two participants (0.5%) died within the first 30 days and were removed from the analysis. Of the remaining participants (414), we located medical records for 409 participants after 24 months from the index admission (98% follow-up rate). Out of 409 participants, only 8 (2%) had missing data for the main outcomes (i.e., number of hospital readmissions and readmission length of stay) and a further 85 (21%) had missing values for covariates and
thus were excluded in the main analyses. Sociodemographic and clinical characteristics are shown in Table 2.

2.4.1 **Cardiac rehabilitation participation**

CR participation was ascertained in 267 (73%) participants. Of these, all (100%) reported attending supervised, face-to-face CR programs (rather than computer or telephone-based). Participants attended 23 different programs, situated in hospitals (both public and private) and community health centres. Participants reported attending 6-weeks of CR on average (median: 6; 25th–75th percentile: 5–7; mean 6.13; SD 1.9) which is considered a complete dose in many CR programs in Australia. On average the wait time between discharge diagnosis and the self-reported start date of CR was 41 days (median: 37 days).
Total no. screened = 1673

Total no. enrolled = 416

EXCLUDED (Total = 1257)
1. INELIGIBLE
   • Non-ACS 254
   • Non-English speaking 246
   • Terminal illness 140
   • Cognitive impairments 66
   • Alcohol/substance abuse 42
   • Other research trial 27
   • Other 117
   Total: 892
2. ELIGIBLE BUT NOT ENROLLED
   • Declined 365

T0: 1-month post-discharge (Total = 48)
1. FORMALLY WITHDRAWN
   • Not interested 11
   • No time 4
   • Medical reason 2
   • Deceased 2
   • Participating in other trial 1
   Total: 20
2. UNABLE TO CONTACT 21
3. CLINICAL MEASURES EXTRACTED ONLY 7

T1: 12 months post-discharge (Total = 108)
1. PREVIOUSLY WITHDRAWN 20
2. FORMALLY WITHDRAWN
   • Not interested 17
   • Distance 4
   • No time 3
   • Deceased 3
   • Medical reason 1
   Total: 28
3. UNABLE TO CONTACT 56
4. CLINICAL MEASURES EXTRACTED ONLY 4

T2: 24 months post-discharge (Total = 5)
1. UNABLE TO OBTAIN MEDICAL CHART 5
2. DIED WITHIN THE FIRST 30 DAYS & REMOVED FROM ANALYSIS 2

Figure 5 Strengthening the Reporting of Observational studies in Epidemiology (STROBE) flow diagram
Acronyms: ACS: acute coronary syndrome; CR: cardiac rehabilitation; T0: Time point 0 – one month post-discharge from index event; T1: time point 12 months post-discharge from index event; T2: time point 24 months post-discharge from index event
*Percentage based on total number of patients enrolled (n=416)
Table 2 Baseline characteristics of those who attended CR and did not attend CR (N=366)

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Did not attend CR (n=99)</th>
<th>Attended CR (n=267)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sociodemographic</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>77 (77.78)</td>
<td>212 (79.40)</td>
<td>0.735&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>Age (years)</td>
<td>60.1 [11.33]</td>
<td>58.34 [9.94]</td>
<td>0.149&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td>Born in Australia</td>
<td>54 (56.25)</td>
<td>143 (54.58)</td>
<td>0.778&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>Education level</td>
<td></td>
<td></td>
<td>0.852&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>Primary/Secondary</td>
<td>48 (49.48)</td>
<td>129 (49.42)</td>
<td></td>
</tr>
<tr>
<td>Higher</td>
<td>49 (50.52)</td>
<td>132 (50.57)</td>
<td></td>
</tr>
<tr>
<td>Living situation</td>
<td></td>
<td></td>
<td>0.161&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>Couple</td>
<td>67 (69.07)</td>
<td>187 (71.37)</td>
<td></td>
</tr>
<tr>
<td>Single / Other</td>
<td>30 (30.92)</td>
<td>75 (28.63)</td>
<td></td>
</tr>
<tr>
<td>Employment status</td>
<td></td>
<td></td>
<td>0.571&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>Employed</td>
<td>53 (55.21)</td>
<td>160 (61.07)</td>
<td></td>
</tr>
<tr>
<td>Unemployed</td>
<td>16 (16.67)</td>
<td>41 (15.65)</td>
<td></td>
</tr>
<tr>
<td>Other (retired/student)</td>
<td>27 (28.13)</td>
<td>61 (23.28)</td>
<td></td>
</tr>
<tr>
<td>Clinical</td>
<td></td>
<td></td>
<td>&lt;0.001&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>Diagnosis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>STEMI</td>
<td>25 (25.25)</td>
<td>109 (40.82)</td>
<td>0.006&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>NSTEMI/Unstable Angina</td>
<td>29 (29.29)</td>
<td>94 (35.21)</td>
<td>0.287&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>CDS Major Depression</td>
<td>45 (45.45)</td>
<td>61 (22.85)</td>
<td>&lt;0.001&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>Revascularisation procedures</td>
<td>56 (56.57)</td>
<td>171 (64.04)</td>
<td>0.127&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>PCI</td>
<td>5 (5.05)</td>
<td>42 (15.71)</td>
<td>0.006&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>CABG</td>
<td>53 (55.21)</td>
<td>160 (61.07)</td>
<td></td>
</tr>
<tr>
<td>Medications prescribed</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ACE Inhibitors</td>
<td>72 (74.23)</td>
<td>198 (75.00)</td>
<td>0.881&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>Aspirin/antiplatelet</td>
<td>96 (98.97)</td>
<td>262 (99.24)</td>
<td>0.800&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>Beta Blockers</td>
<td>76 (78.35)</td>
<td>235 (89.02)</td>
<td>0.009&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>Statins/lipid-lowering</td>
<td>95 (97.94)</td>
<td>260 (98.48)</td>
<td>0.719&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>Risk factors</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Past medical history</td>
<td></td>
<td></td>
<td>&lt;0.001&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>ACS</td>
<td>44 (44.44)</td>
<td>63 (23.95)</td>
<td></td>
</tr>
<tr>
<td>Diabetes</td>
<td>35 (35.35)</td>
<td>66 (25.10)</td>
<td>0.052&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>Hypertension</td>
<td>60 (60.61)</td>
<td>145 (55.13)</td>
<td>0.349&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>Stroke</td>
<td>9 (9.09)</td>
<td>10 (3.80)</td>
<td>0.044&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>Overweight/obese (BMI&gt;25)</td>
<td>80 (85.11)</td>
<td>203 (79.92)</td>
<td>0.270&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>HbA1c (%)</td>
<td>6.35 [1.65]</td>
<td>6.42 [1.49]</td>
<td>0.714&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td>CDS Major Depression</td>
<td>23 (23.71)</td>
<td>46 (17.56)</td>
<td>0.189&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>Current/former smoker</td>
<td>60 (60.61)</td>
<td>151 (57.41)</td>
<td>0.583&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>Blood measures</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total cholesterol (mg/dL)</td>
<td>169.11 [45.17]</td>
<td>179.54 [50.19]</td>
<td>0.025&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td>Triglycerides (mg/dL)</td>
<td>132.74 [97.35-212.39]</td>
<td>132.74 [88.50-194.69]</td>
<td>0.992&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
</tbody>
</table>
Baseline characteristics of those who did and did not attend CR are shown in Table 2. There were no significant differences in sociodemographic characteristics between attenders and non-attenders. Regarding clinical characteristics, CR attenders were significantly more likely to have an index STEMI and significantly less likely to have an index diagnosis of unstable angina than non-attenders. Those who had undergone a CABG, had higher levels of total cholesterol, higher levels of LDL cholesterol, lower LVEF and did not have a past medical history of ACS, stroke or diabetes were also more likely to attend CR. CR attenders were also more likely to be prescribed beta-blockers than non-attenders.

2.4.2 Hospital admission

All-cause hospital readmission data were collected on 409 (98%) participants (Table 3). Five (1%) medical records could not be located (likely due to participants moving interstate). Overall, there were a total (including emergency department visits) of 392 readmissions from 239 (58%) participants. Of those who had a readmission, the mean number of readmissions per participant was $1.7 \pm 0.95$ (median = 1, 25th to 75th percentile: 1-2) and the mean length of stay was $3.96 \text{ days} \pm 4.63$ (median=2, 25th to 75th percentile: 1-4). The most common discharge diagnoses of those who were readmitted were: chest...
pain/angina (n=41, 17%), elective PCI (n=32, 14%), unstable angina (n=26, 11%) and CABG (n=13, 5%). Hospital readmission was more common in those who had major depression, a past medical history of ACS, diabetes and hypertension and less likely in those who were current or former smokers. No other differences were observed.

Table 3  Comparisons of participants with and without hospital readmission (all cause) up to 24 months (N=409)

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>No hospital admission (n=170)</th>
<th>Hospital readmission (n=239)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean [SD] / Freq (%) /</td>
<td>Mean [SD] / Freq (%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Median (Q1-Q3)</td>
<td>Median (Q1-Q3)</td>
<td></td>
</tr>
<tr>
<td>Sociodemographic</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>139 (81.76)</td>
<td>182 (76.15)</td>
<td>0.173&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>Age (years)</td>
<td>57.96 [9.88]</td>
<td>58.67 [11.20]</td>
<td>0.508&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
<tr>
<td>Born in Australia</td>
<td>91 (58.71)</td>
<td>109 (53.17)</td>
<td>0.295&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>Education level</td>
<td></td>
<td></td>
<td>0.621&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>Primary/Secondary</td>
<td>74 (47.44)</td>
<td>104 (50.98)</td>
<td></td>
</tr>
<tr>
<td>Higher</td>
<td>82 (52.56)</td>
<td>100 (49.02)</td>
<td></td>
</tr>
<tr>
<td>Living situation</td>
<td></td>
<td></td>
<td>0.841&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>Couple</td>
<td>108 (69.23)</td>
<td>147 (71.71)</td>
<td></td>
</tr>
<tr>
<td>Single /Other</td>
<td>48 (30.77)</td>
<td>58 (28.29)</td>
<td></td>
</tr>
<tr>
<td>Employment status</td>
<td></td>
<td></td>
<td>0.789&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>Employed</td>
<td>96 (61.94)</td>
<td>120 (58.54)</td>
<td></td>
</tr>
<tr>
<td>Unemployed</td>
<td>24 (15.48)</td>
<td>33 (16.10)</td>
<td></td>
</tr>
<tr>
<td>Other (retired/student)</td>
<td>35 (22.58)</td>
<td>52 (25.37)</td>
<td></td>
</tr>
<tr>
<td>Clinical</td>
<td></td>
<td></td>
<td>0.085&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>Diagnosis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>STEMI</td>
<td>68 (40.00)</td>
<td>81 (33.89)</td>
<td>0.206&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>NSTEMI</td>
<td>61 (35.88)</td>
<td>73 (30.54)</td>
<td>0.257&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>Unstable Angina</td>
<td>39 (22.94)</td>
<td>83 (34.73)</td>
<td>0.010&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>Revascularisation</td>
<td></td>
<td></td>
<td>0.107&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>procedures</td>
<td>115 (67.65)</td>
<td>138 (57.74)</td>
<td></td>
</tr>
<tr>
<td>PCI</td>
<td>20 (11.76)</td>
<td>32 (13.39)</td>
<td>0.627&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>CABG</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medications prescribed</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ACE Inhibitors</td>
<td>117 (73.58)</td>
<td>161 (76.30)</td>
<td>0.549&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>Aspirin/antiplatelet</td>
<td>158 (99.37)</td>
<td>208 (98.58)</td>
<td>0.533&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>Beta Blockers</td>
<td>139 (87.42)</td>
<td>180 (85.31)</td>
<td>0.559&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>Statins/lipid-lowering</td>
<td>157 (98.74)</td>
<td>207 (98.10)</td>
<td>0.231&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>Risk factors</td>
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<tr>
<td>Past medical history</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ACS</td>
<td>43 (34.40)</td>
<td>82 (65.60)</td>
<td>0.051&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>Diabetes</td>
<td>39 (33.33)</td>
<td>78 (66.67)</td>
<td>0.033&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
</tbody>
</table>
2.4.3 Association between CR and all-cause readmission to hospital

The univariable analysis results demonstrated that CR attenders did not have significantly lower all-cause hospital readmission (Table 4). However, CR participants did have reduced frequency of readmissions and spent one day less on average in hospital. Adjusted analyses (Table 5) corroborated that CR participants were readmitted to hospital on a significantly fewer number of occasions (40% lower odds) than those who did not attend CR and had marginally reduced length of stay (1.21 days lower) (Table 6). A dose-response association between the number of CR sessions attended and frequency and length of stay was also observed although was not statistical significance. For each additional CR session attended, CR participants had a 6% lower odds of readmission (OR: 0.94; 95%CI: 0.89, 1.00; p-value:

Data presented as n (%); mean [SD]; or median if not normally distributed (25th-75th percentile).

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Value 1</th>
<th>Value 2</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypertension Stroke</td>
<td>78 (33.91)</td>
<td>152 (66.09)</td>
<td>&lt;0.001*</td>
</tr>
<tr>
<td>Overweight/obese (BMI&gt;25)</td>
<td>124 (81.05)</td>
<td>169 (82.44)</td>
<td>0.735a</td>
</tr>
<tr>
<td>HbA1c (%)</td>
<td>6.38 [1.43]</td>
<td>6.52 [1.87]</td>
<td>0.448b</td>
</tr>
<tr>
<td>CDS Major Depression</td>
<td>23 (14.74)</td>
<td>47 (23.04)</td>
<td>0.049a</td>
</tr>
<tr>
<td>Current/former smoker</td>
<td>114 (67.06)</td>
<td>136 (56.90)</td>
<td>0.038b</td>
</tr>
</tbody>
</table>

Blood measures

<table>
<thead>
<tr>
<th>Measure</th>
<th>Value 1</th>
<th>Value 2</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total cholesterol (mg/dL)</td>
<td>178.27 [50.66]</td>
<td>175.95 [50.27]</td>
<td>0.571b</td>
</tr>
<tr>
<td>Triglycerides (mg/dL)</td>
<td>141.72 (97.43-186.01)</td>
<td>137.29 (88.57-212.58)</td>
<td>0.184b</td>
</tr>
<tr>
<td>HDL cholesterol (mg/dL)</td>
<td>40.22 [11.64]</td>
<td>37.90 [10.83]</td>
<td>0.083b</td>
</tr>
<tr>
<td>LDL cholesterol (mg/dL)</td>
<td>109.44 [44.08]</td>
<td>104.02 [43.31]</td>
<td>0.155b</td>
</tr>
<tr>
<td>C Reactive Protein (mg/L)</td>
<td>4.95 (2.0-20.0)</td>
<td>5 (1.9-15.0)</td>
<td>0.196b</td>
</tr>
<tr>
<td>LVEF (%)</td>
<td>55.38 [7.01]</td>
<td>54.26 [9.27]</td>
<td>0.205b</td>
</tr>
</tbody>
</table>

Acronyms: ACE: angiotensin-converting-enzyme; ACS: acute coronary syndrome; BMI: body mass index (kg/m²); CABG: coronary artery bypass graph; CDS: Cardiac Depression Scale; CR: cardiac rehabilitation; HbA1c: glycosylated haemoglobin; HDL: high-density lipoprotein; LDL: low-density lipoprotein; LVEF: Left Ventricular Ejection Fraction; PCI: percutaneous coronary intervention; NSTEMI: non-ST-elevation myocardial infarction; SD: standard deviation; STEMI: ST-elevation myocardial infarction
and their mean length of stay was reduced by 0.1 days (coeff. -0.10; 95% CI: -0.22, 0.032; p-value: 0.140).

Table 4 Univariable analysis of association of CR attendance with hospital readmission (up to 24 months) (N=361)

<table>
<thead>
<tr>
<th></th>
<th>No CR</th>
<th>CR</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>All-cause readmission</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(&lt;24 months)</td>
<td>Mean [SD] / Freq (%)</td>
<td>Mean [SD] / Freq (%)</td>
<td></td>
</tr>
<tr>
<td>No. of readmissions</td>
<td>1.15 [1.20]</td>
<td>0.82 [0.98]</td>
<td>0.006b</td>
</tr>
<tr>
<td>Length of stay (days)</td>
<td>2.93 [4.98]</td>
<td>1.884 [3.60]</td>
<td>0.027b</td>
</tr>
</tbody>
</table>

*Pearson’s χ²; bStudent’s t-test

Acronyms: CR: cardiac rehabilitation; Freq, frequency; SD: standard deviation

Table 5 Association between attending CR and number of hospital readmissions [1, 2, 3, 4, 5, 6] (N=320)

<table>
<thead>
<tr>
<th>Readmissions</th>
<th>Unadjusted</th>
<th>Model 1*</th>
<th>Model 2†</th>
<th>Model 3‡</th>
</tr>
</thead>
<tbody>
<tr>
<td>All-cause</td>
<td>0.57 (0.37, 0.88), p: 0.011</td>
<td>0.61 (0.36, 1.01), p: 0.054</td>
<td>0.66 (0.39, 1.09), p: 0.10</td>
<td>0.53 (0.31, 0.91), p: 0.022</td>
</tr>
<tr>
<td>All-cause (excluding ED admissions)</td>
<td>0.61 (0.39, 0.95), p: 0.030</td>
<td>0.66 (0.39, 1.13), p: 0.137</td>
<td>0.65 (0.38, 1.09), p: 0.101</td>
<td>0.61 (0.35, 1.04), p: 0.071</td>
</tr>
</tbody>
</table>

*Model 1: Ordered logistic regression adjusting for covariates
†Model 2: adjusted for propensity to participate in CR
‡Model 3: used inverse probability treatment weighting

Covariates: age, sex, acute coronary syndrome diagnosis, revascularisation procedure, smoking status, Cardiac Depression Screener score, prescribed Beta blocker, Left Ventricular Ejection Fraction, past medical history of ACS, past medical history of diabetes, past medical history of hypertension, past medical history of stroke

Acronyms: CI: confidence interval; CR: cardiac rehabilitation; ED: emergency department
Table 6 Association between attending CR and length of stay (N=320)

<table>
<thead>
<tr>
<th>Readmissions</th>
<th>Unadjusted</th>
<th>Model 1*</th>
<th>Model 2 †</th>
<th>Model 3‡</th>
</tr>
</thead>
<tbody>
<tr>
<td>All-cause</td>
<td>-1.04 (-1.97, -0.10)</td>
<td>-1.18 (-2.30, -0.79)</td>
<td>-1.35 (-2.47, -0.22)</td>
<td>-1.21 (-2.46, 0.26)</td>
</tr>
<tr>
<td></td>
<td>p: 0.030</td>
<td>p: 0.036</td>
<td>p: 0.019</td>
<td>p: 0.055</td>
</tr>
<tr>
<td>All-cause (excluding ED admissions)</td>
<td>-1.04 (-1.96, -0.12)</td>
<td>-1.21 (-2.32, -0.12)</td>
<td>-1.36 (-2.48, -0.24)</td>
<td>-1.19 (-2.45, 0.52)</td>
</tr>
<tr>
<td></td>
<td>p: 0.027</td>
<td>p: 0.030</td>
<td>P: 0.017</td>
<td>P: 0.060</td>
</tr>
</tbody>
</table>

*Model 1: Linear regression adjusting for covariates
†Model 2: adjusted for propensity to participate in CR
‡Model 3: used inverse probability treatment weighting
*Covariates: age, sex, acute coronary syndrome diagnosis, revascularisation procedure, smoking status, Cardiac Depression Screener score, prescribed Beta blocker, Left Ventricular Ejection Fraction, past medical history of ACS, past medical history of diabetes, past medical history of hypertension, past medical history of stroke

Acronyms: CI: confidence interval; Coef: coefficient; CR: cardiac rehabilitation; ED: emergency department

The results from the sensitivity analyses for missing data are reported in the Appendix C. Generally, both the original and sensitivity analyses showed similar trends and associations.

2.5 Discussion

Post-ACS, well over half of patients were readmitted to hospital over the subsequent 24 months, for a median of 1 time, typically staying 1 to 4 days each admission. CR attendance was associated with significant reductions in the frequency and length of these hospital admissions, but not the likelihood of being readmitted.

These results corroborate studies by Canyon and Meshgin as well as Zwisler et al. which demonstrated benefits of CR in regard to length of stay (reduction of 15% for all admissions) but no significant benefits in overall hospital admissions due to heart disease. Potentially, these results are due to low power considering CR participation was associated
with reduced risk of all-cause readmission in Dunlay et al.’s population-based surveillance study \((N=2991)\) and Anderson’s et al.’s Cochrane review \((N=14,486)\). In the modern era of cardiology, mortality rates have fallen and the association of CR on all-cause mortality rates does not appear to be as pronounced as it was in earlier studies such as Beauchamp et al.’s 14 year follow-up study of a 2004 Victorian cohort. Further, longer periods of exercise-based CR may be required to provide evidence of an effect on the overall likelihood of being readmitted. Taylor et al. demonstrated reduced all-cause mortality (HR: 0.67; 95%CI: 0.47, 0.97) over 14 years of follow-up in those who participated in supervised exercise training for greater than 36 months. Australia provides very short CR programs of just 6 to 12 weeks with often only 1 session provided per week (6 – 12 sessions in total). Comparatively, Canada and the United States provide approximately 36 sessions and Austria provides up to 12 months of supervised exercise training (2 x per week).

Difference were observed between ACS patients who did and did not attend CR; patients with STEMI and those with more invasive procedures (CABG) were more likely to attend CR. Potentially this reflects a referral bias to CR with physicians more likely to refer STEMI patients. This is supported by outcomes from the Victorian Cardiac Outcomes Registry which reports that referral rates to CR are varied according to clinical presentation and are highest for STEMI (85.5%) and lower for NSTEMI/ACS (78.9%) and non-ACS presentations (70.5%). ACS diagnosis, revascularisation procedures and other factors of disease severity (e.g., LVEF) are adjusted for in the models. Importantly, patients with a past medical history of CVD (ACS/stroke) and diabetes were less likely to attend CR. Having diabetes has previously been identified in the literature as a predictor of non-attendance to CR. However, in the largest cohort study \((n=>234,000)\) where predictors of CR initiation were reported, a prior cardiac event or procedure was predictive of CR attendance. Potentially, some of the participants in this current study with a previous history of ACS may have completed CR after a prior admission. Covariables relating to past medical history are an
important source of potential confounding and have been adjusted for in our statistical models.

Beta blockers prescription was greater among CR attenders and was therefore adjusted for in the models; no differences were noted among the prescription of other cardio-protective drugs. Adherence to prescribed medications, however, was not assessed. Potentially, attendance to CR may be an indirect proxy of those who are more likely to be adherent to cardioprotective medications.

Comparison between participants who did and did not have a hospital readmission showed that participants with major depression were at higher risk of being re-admitted. These results highlight the additional vulnerability of this population group, and potentially the need for greater follow-up and care post-ACS. Oddly, current and former smokers had lower rates of readmission compared to never-smokers. Age differences between the cohorts likely explain these results to some extent, with never-smokers being on average 59.87 years and current smokers being 53.87 years on average. As expected, participants with a previous history of CVD and CVD risk factors (e.g., diabetes, hypertension) were more likely to be readmitted.

Given the majority of healthcare costs post-ACS are driven by hospitalisations, reductions in both short- and longer-term readmissions have potential to significantly reduce CVD healthcare expenditure and offset the cost of delivering CR. In Australia, a repeat ACS admission is estimated to cost between AU$18,921 to AU$26,680 (US$14,500 to US$20,452) per separation. Comparatively, the cost of CR delivery in high income countries ranges from US$294 in the United Kingdom to US$12,409 in Italy. Beyond associated healthcare costs, reduced time in hospital is likely to be an important incentive
for patients to attend CR and for their families to encourage such participation. From a societal perspective there would be less disability and loss of productivity.

Caution is warranted in interpreting these results. The first limitation relates to generalisability. There was selection bias, in that 27% (n=99) of the eligible cohort did not attend CR. Also related to generalisability, is the age of participants in the cohort. Although the mean age of those who attended CR (58.3 years) is similar to the average age of participants in the most recent Cochrane review\(^\text{19}\) (56 years) it is much younger than that reported in national audits of CR programs (e.g. the National Audit of CR\(^\text{19}\) reports a mean age of 67 years). Additionally, CR attenders in this study had fewer comorbidities than those who did not attend CR (Table 2). Potentially, younger patients were more likely to enrol into the ADVENT study, and healthier patients were more likely to attend CR which may have had an impact on the readmission rates. To account for this, we adjusted for baseline difference between CR attenders and non-attenders (Model 1) and propensity to attend CR (Model 2, 3).

Second, there were measurement issues. CR attendance was self-reported, which has known limitations and referral to CR was not confirmed in patients' medical records. Unfortunately, Australia does not have consistent methods of monitoring CR (e.g., a CR registry), making cross-checking of CR attendance across multiple sites difficult. However, self-report of CR attendance has previously been found to have very high concordance with objective chart reports.\(^\text{120}\)

Third, it is known that variations exist between CR programs, however, the current data and sample size did not enable comparisons between CR sites. Fourth, readmissions were followed-up for the major cardiac hospitals (Monash Health; N=8) in the area including both public and private hospitals with expertise in cardiac care (catchment area of 1.2 million
people). It is possible patients were readmitted to other hospitals outside of the catchment area and as such not included in the readmission data.

Fourth, we were unable to differentiate between cardiac and non-cardiac causes of hospital admissions. Determining the cause of admission requires experienced medical staff to independently review cases and forward any uncertainties to an expert to adjudicate. Due to resource constraints, we were unable to undertake this process. Similarly, in-depth analysis on the reason for length of stay beyond discharge diagnosis (e.g., geographic access to services, co-morbidities, living alone, discharge delays due to transport issues or destination hold-ups) and the specific dates of readmissions were not recorded. Therefore, readmissions could have potentially occurred prior to or at the beginning of CR.

Finally, given the nature of the study design, conclusions regarding causality cannot be drawn. Future research should include additional multi-site randomized controlled trials examining the effects of CR on timing, frequency and length of readmissions.

In conclusion, this cohort study highlights the importance of CR in reducing frequency and length of all-cause admissions by one full day in the 24 months following ACS. These finding are particularly important in the context of rising healthcare costs associated with CVD and provide additional incentives for cardiac services to increase referrals to CR programs.
PHASE 2: Design

Design care and evaluation based on evidence generated here and elsewhere
CHAPTER 3: SYSTEMATIC REVIEW OF CARDIAC REHABILITATION REGISTRIES
3 Chapter overview

The previous chapter substantiates the long-term benefits of CR on the number and length of hospital readmissions. However, CR did not appear to have an impact on the odds of being readmitted. The impact of CR may be enhanced through the delivery of high-quality and comprehensive care.

This chapter focuses on clinical quality registries as a way of monitoring the quality of CR programs. Registries are frequently used instruments for audit and evaluation through systematic collection and reporting of information on the appropriateness of care (process) according to guidelines and the effectiveness of care (outcomes) for individuals with CVD. Well-designed and well-executed registries hold great potential to capture data that reflect ‘real-world’ clinical practice to provide insights into patient characteristics and evaluate patterns of care and disparities. However, the type and components of national CR registries have not been reported. This chapter systematically reviews the literature to identify and describe national and international CR registries and summarise their key features and barriers and enablers to implementation.


An editorial of this systematic review was also published in the same issue (Appendix B).
3.1 Abstract

Introduction: Despite CR being recommended in clinical practice guidelines internationally, these services are under-utilised, programs are not standardised and quality improvement methods and outcomes are rarely published. National registries are an important strategy to characterise service delivery, quality and outcomes, yet the number, type and components of national CR registries have not been reported. Accordingly, we aimed to identify and describe national and international CR registries and summarise their key features.

Methods: The literature reporting on the quality of CR at a national and international-level was systematically reviewed. A search of four databases was conducted in July 2016, with two reviewers independently screening title/abstracts and full-texts for inclusion. Data were extracted from included studies, independently checked by a second reviewer and synthesised qualitatively.

Results: Eleven articles were included in the review comprising seven national registries and one international registry (of 12 European countries) for a total sample of 265,608 patients. Data were most commonly provided to the registry via a web-based application, and included individual-level data (i.e., sociodemographic characteristics, medical history, and clinical measurements). When reported, service-level data most commonly included wait times, program enrolment and completion. The overarching governance, funding modes (e.g., industry (n=2), government (n=1)), and incentives for registry participation (e.g., benchmarking, financial reimbursement, or mandatory requirement) varied widely.

Conclusion: The use of national and international registries for characterising CR and providing a benchmark for quality improvement is in its early stages but shows promise for national and global benchmarking.
3.2 Introduction

CVD is the leading cause of mortality globally, accounting for 30% of all deaths in 2013.\textsuperscript{5} In high-income countries, survival rates following ACS (i.e., heart attacks and unstable angina) have improved significantly over recent decades largely due to advancements in pharmacotherapy and interventional procedures such as angioplasty, stents and bypass grafting.\textsuperscript{121} As a result, large numbers of people are living with heart disease as a chronic condition and require support to achieve changes in lifestyle and regain or maintain physical capacity, wellbeing, social and vocational participation.\textsuperscript{122, 123}

When delivered effectively, CR is pivotal for helping patients achieve secondary prevention targets and prevent readmission. Meta-analyses demonstrate that participation in CR reduces total deaths, cardiovascular deaths and hospital readmission by approximately 25% and increases adherence to pharmacotherapy, and improves quality of life.\textsuperscript{124} Clinical practice guidelines have been developed in several countries recommending the provision of CR to patients with CHD as part of integrated cardiac care.\textsuperscript{62, 125} However, many patients do not receive appropriate CR\textsuperscript{126, 127}. Recent data from England show that just 50% of referred patients enrol in CR\textsuperscript{78} and in Australia and New Zealand only 25% of ACS patients successfully met or maintained optimal secondary prevention targets after discharge.\textsuperscript{26} In the United States, a third of ACS patients are readmitted to hospital within 30 days, with over 60% readmitted within 1 year.\textsuperscript{24} Among those that do attend CR, the quality of the programs and consequential benefits vary substantially.\textsuperscript{84, 128, 129}

Audit and evaluation are promoted as core components of CR as reflected in clinical guidelines.\textsuperscript{60, 62, 63, 125} These processes of systematic monitoring of CR delivery and outcomes is recommended to improve participation.\textsuperscript{58, 63} Clinical registries are effective instruments for audit and evaluation through standardised, systematic collection and reporting of information on both the appropriateness of care (process) according to clinical practice
guidelines and the effectiveness of care (outcomes) for individuals with CVD. Well-designed and well-executed registries hold great potential to capture data that reflect “real-world” clinical practice in order to provide insights into patient characteristics and evaluate patterns of care and disparities. The AHA recently released a Scientific Statement highlighting the need to systematically redesign cardiovascular care to be a ‘learning healthcare system’, which utilises information technology and data infrastructures to enhance optimal healthcare delivery. The AHA has a longstanding commitment to promoting the innovation and effective use of clinical registries. While numerous ACS and other CVD registries have existed globally such as the Global Registry of Acute Coronary Events and the Myocardial Ischaemia National Audit Project, very few countries have established national CR registries. This is an important deficit because the provision of timely, relevant and reliable information through CR registries can assist in driving improvements in CR quality and increase CR utilisation.

Accordingly, the purpose of the current review was to identify CR registries internationally and characterize the nature of the data collected and their operation/organisation. The focus of the review includes characterising: 1) how these data were provided to the registry (i.e., manual, electronic upload); 2) who was responsible for collecting and inputting these data; 3) governance models; 4) issues related to privacy; 5) the incentives for CR programs to participate and contribute data; 6) funding sources to support the registry; and 7) barriers and enablers of implementation.

3.3 Methods

3.3.1 Search strategy

This review was conducted in accordance with Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines (Appendix D). In July of 2016, the
following databases were searched: CINAHL (EBSCOHost)[1982-present], Ovid MEDLINE(R) [OvidSP][1974-present], Pubmed (https://www.ncbi.nlm.nih.gov/pubmed/). In addition, Google Scholar (https://scholar.google.com.au/) was searched for unpublished studies and grey literature. The following key words were searched: “cardiac”, “acute coronary syndrome”, "myocardial infarction”, “percutaneous coronary intervention”, “coronary artery disease”, “rehabilitation”, “audit”, "registry", and "data". The full search terms and strategies are provided in the Supplementary materials (Appendix D). Reference lists of key articles were further searched to identify any other relevant publications. Additionally, we contacted authors of the included studies and asked if they were aware of any further registries.

3.3.2 Eligibility criteria

Specification of inclusion and exclusion criteria was guided by the scientific literature, in particular Cadilhac et al.’s review of stroke registries.133 Studies were included if they: 1) presented data from a register, databank, or database containing a minimum dataset and for which data had been collected prospectively; 2) captured data on CR as defined by the WHO as “the sum of activities required to influence favourably the underlying cause of the disease, as well as to provide the best possible physical, mental and social conditions, so that patients may, by their own efforts, preserve or resume when lost as normal a place as possible in the community”57; 3) comprised patients eligible for CR according to the National Institute of Health and Care Excellence (NICE)134-136 and European Guidelines58 which include those following: ACS – including MI (both ST elevation and Non-ST elevation), and unstable angina; revascularisation procedures (coronary artery bypass graft surgery and percutaneous coronary intervention); and coronary artery disease; and 4) monitored the quality of CR at a national or international-level where ‘national’ was defined as “accepted country-wide system for data collection; was titled as ‘national’; or carried the name of a country”133 and ‘international’ was defined as “the collection of uniform data across multiple
Registries were excluded if they were developed for population disease surveillance or epidemiological disease monitoring without collection of clinical care indicators or were not published in English, no limits on study design were imposed.

### 3.3.3 Study selection

The online systematic review management tool ‘Covidence’ ([www.covidence.org](http://www.covidence.org)) was utilised throughout the review to manage the screening process and conflicts. Two reviewers (AP and ET) independently screened all titles and abstracts identified from the search for inclusion. The full text of potentially relevant papers were retrieved. The same two reviewers also independently assessed the full texts for inclusion or exclusion. Any conflicts were discussed between the reviewers and if necessary, the senior author (AO) provided guidance in order to reach consensus.

### 3.3.4 Data extraction and management

After agreement on the final included studies was reached, one author independently extracted data using a standard data extraction form which was then cross-checked by the second reviewer. The data extraction form included: 1) registry name, 2) active dates of the registry, 3) included patients, 4) data source, 5) number of patient records, 6) methods of data collection across sites, 7) data collection time points, 8) patient-level data collected, 9) service-level data collected, 10) who was responsible for collecting and inputting data, 11) governance models, 12) issues related to privacy, 13) the incentives for CR programs to participate and contribute data, 14) funding sources to support the registry, and 15) barriers and enablers of implementation.

The corresponding authors of included registries were contacted via email when information on all data points could not be located. If the authors did not respond, two follow-up reminders were sent. If no response, or incomplete responses were received, ‘not reported’ was entered into the data extraction table.
3.3.5 *Synthesis of the literature*

Results from included papers were summarised in tabular format and qualitatively synthesised. Overall findings were then considered in terms of policy implications and directions for future research.

3.4 Results

3.4.1 *Summary of results*

The search strategy generated 6489 articles, including five papers known to the authors (Figure 6). After duplicates (969) were removed, title and abstract screening was undertaken on 5520 unique papers. One hundred and fifty-five full texts were retrieved and assessed; there was agreement between reviewers on inclusion or exclusion for 144/155 (93%) of the papers, and the remaining 11/155 (7%) papers were passed on to a third reviewer for arbitration. Ultimately, 11 studies met the inclusion criteria.

The included 11 papers described CR registries in seven countries: Austria, Canada, Denmark, Germany, Mexico, the United States, and the United Kingdom (excluding Scotland). The EuroCaReD registry was the only international registry, and comprised of CR sites from 12 European countries (including three sites that were previously included as national registries; Denmark, Germany and Austria). In total, these registries included 265,608 participants (excluding Mexico which did not report a total number of participants). The German registry, which combined two large-scale national registries, had the largest number of patient records (n=117938, 45.8% of all registries) and the earliest recorded data with collection commencing in 2000. The remaining registries commenced from 2001 (Austria) to 2015 (Denmark). The registries currently active are Austria, Canada, Denmark, the United Kingdom and the United States.
3.4.2 Methods of data collection

Six registries (75%) established web-based data entry systems in which data could be manually entered from participating sites by a member of the clinical team or a nominated data steward. Two reported alternatives included: 1) the German registry which utilised a standardised case report form (unclear if electronic or paper) which was completed by
Figure 6 The location of included studies with national and international-level CR registries.

Inset: Location of European CR registries. Red pin: identified national-level registries; purple pin: countries involved in the international-level EuroCaReD database; green pin: country has both a national-level CR registry and is involved in the EuroCaReD. Developed using ArcMap 10.5
physicians and sent to a data collection unit, and 2) the staffing details of the United Kingdom registry which were collected via the NACR annual paper surveys. The burden on the participating sites resulting from the data entry were not reported in any included source, and Denmark was the only registry that reported simultaneous linkage to central patient registries to enable data to be auto-filled and reduce time required for data entry.

3.4.3 **Patient- and service-level data collected**

The number of indicators captured across the registries varied widely, with the United States and Canada having more than 180 indicators. As shown in Table 8, at the individual patient level, 100% of the registries collected data on: demographics (e.g., age, sex), medical history (e.g., admitting diagnosis), clinical measures (e.g., lipids, glucose, and blood pressure) and anthropometrics (e.g., body mass index). Most registries (n=6, 75%) also included at least one psycho-social measure (e.g., depression screener) and cardiovascular-related medications. As shown in the second column of Table 8, service-level data were poorly reported. Included indicators were CR referral (n=3, 37.5%), CR enrolment (n=3, 37.5%), CR wait times (n=1, 12.5%), CR completion (n=4, 50%) and staffing requirements (n=2, 25%). The rationale behind the choice of indicators was not always clear, although the authors of the United Kingdom registry stated that the clinical outcome measures were selected based on their importance for risk factor management, and the indicators in the Canadian registry were developed to measure national quality indicators; Canada had a task force that created the data dictionary. Five (62.5%) registries collected data at CR enrolment and CR completion and one registry (United States) enabled sites to submit data at any time depending on the chosen data collection mechanism. Denmark was the only registry that reported follow-up data collection (six months) after program exit.
Table 7 Description of included studies

<table>
<thead>
<tr>
<th>Registry Name</th>
<th>Active dates</th>
<th>Included patients</th>
<th>Data sources</th>
<th>Patient records (n)</th>
<th>Method of data collection across sites</th>
<th>Data collection time points</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Austria</strong></td>
<td>2001-current</td>
<td>Patients who completed phase II (60 hrs over 4-6 weeks) or phase III (up to 90 hrs over 6-12 months) CR after cardiac events, cardiac interventions and operations on vessels, valves, and devices; heart failure, patients at high-risk to develop CAD</td>
<td>All (n=8) Austrian out-patient CR centres accredited by the AGAKAR entered data into a database of all consecutive patients who completed phase II (4–6 weeks) and/or III (6–12 months) rehabilitation since 2001</td>
<td>&gt;10900 phase II and/or phase III</td>
<td>Data entered manually into web-based electronic case report form</td>
<td>Enrolment into phase II, end of phase II, enrolment into phase III, end of phase III</td>
</tr>
<tr>
<td><strong>Canada</strong></td>
<td>2005-current</td>
<td>Patients enrolled in CR. Canadian guidelines state the following indications for CR: MI, chronic stable angina, heart failure, and recent revascularisation, heart transplantation, and device implantation</td>
<td>17/170 CR centres from across Canada (7.8%)</td>
<td>7154</td>
<td>Direct entry of consecutive data to the CCRR via a web-based interface done manually, or through electronic upload if the site pays a nominal amount to set this up</td>
<td>CR enrolment, CR completion</td>
</tr>
<tr>
<td><strong>Denmark</strong></td>
<td>2015-current</td>
<td>All patients who received CR following hospitalisation from CHD</td>
<td>All patients receiving CR following hospitalisation from CHD*</td>
<td>Approx. 14,000pts annually</td>
<td>Online database with simultaneous linkage to other central patient registers.</td>
<td>Patient level data includes: CR referral, CR enrolment, CR completion, Post-CR follow-up (6mths) Program level data collected every 3 years.</td>
</tr>
<tr>
<td><strong>Europe</strong></td>
<td>Oct – Nov</td>
<td>Patients attending CR, primarily with CAD</td>
<td>69 CR centres in 12 European countries</td>
<td>2,095</td>
<td>Collected electronically using a</td>
<td>CR enrolment, CR completion</td>
</tr>
<tr>
<td>Registry and Database (EuroCaReD)</td>
<td>2010; Oct 2011 – Feb 2012</td>
<td>(Austria, Belgium, Croatia, Denmark, Germany, Greece, Hungary, Portugal, Romania, Russia, Spain, Switzerland)</td>
<td>web-based data entry system (<a href="http://www.eurocared.org">http://www.eurocared.org</a>)</td>
<td></td>
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</tr>
<tr>
<td><strong>Mexico</strong>&lt;sup&gt;144&lt;/sup&gt; National Registry of Cardiac Rehabilitation Programs in Mexico II (RENAFREC II)</td>
<td>Not reported</td>
<td>Not reported</td>
<td>24 CR centres</td>
<td>Not reported</td>
<td>Not reported</td>
<td>Not reported</td>
</tr>
<tr>
<td><strong>United Kingdom</strong>&lt;sup&gt;146&lt;/sup&gt; The National Audit of Cardiac Rehabilitation (NACR) <a href="http://www.cardiacrehabilitation.org.uk/">www.cardiacrehabilitation.org.uk/</a></td>
<td>2005 - current</td>
<td>Patients who received CR following hospitalisation from MI, percutaneous coronary intervention, and coronary artery bypass surgery</td>
<td>178 hospital and community-based CR centres</td>
<td>48,476</td>
<td>Electronic data collection as part of the NACR. Staffing details collected from NACR paper surveys</td>
<td>CR enrolment, CR completion</td>
</tr>
<tr>
<td><strong>United States of America</strong>&lt;sup&gt;148&lt;/sup&gt; American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR) Outpatient Cardiac Rehab Registry <a href="http://www.aacvpr.org/Registry/Cardiac-Rehab-Registry">www.aacvpr.org/Registry/Cardiac-Rehab-Registry</a></td>
<td>2012 - current</td>
<td>Patients referred and enrolled in CR programs</td>
<td>Over 400 participating sites</td>
<td>More than 65,000 records</td>
<td>Data are entered manually into a web-based application</td>
<td>Participating programs are able to submit data at any time. Options for data submission correspond directly with the program's chosen data collection mechanism</td>
</tr>
</tbody>
</table>
Acronyms: CR, cardiac rehabilitation; CAD, coronary artery disease; AGAKAR, Arbeitsgruppe für ambulante kardiologische Rehabilitation (Working group on out-patient cardiac rehabilitation); CCRR, Canadian Cardiac Rehabilitation Registry; DCRD, Danish Cardiac Rehabilitation Database; STEMI, ST-segment elevation myocardial infarction NSTEMI, non-ST-segment elevation myocardial infarction; TROL, Transparency Registry to Objectify Guideline-Oriented Risk Factor Management; ROG, The Registry of Guideline-Based Therapy; NACR, National Audit of Cardiac Rehabilitation.

3.4.4 Governance models

The majority of registries (n= 5; 62.5%) were established by national CR associations and governed by working groups developed from within the associations. For example, the Austrian registry was founded and funded by the independent Austrian Working Group on Outpatient Cardiac Rehabilitation (AGAKAR), the Canadian registry was established by the Canadian Association of Cardiovascular Prevention and Rehabilitation (CACPR). The CACPR created a registry sub-committee to manage data transfer, facilitate training of incoming CR programs, provide support and an avenue for feedback for CR sites, and oversee the use of registry data for dissemination and research, the sub-committee reports to the CACPR board of directors and adheres to the committee's terms of reference and policies (e.g., research policy). At the individual site-level, registries that have web-based data entry systems (n=6, 75%) either enable the clinical team to directly enter data (e.g., Denmark) or nominated a data steward (e.g., Canada, USA) who were responsible for uploading or directly entering data and monitoring data integrity.

3.4.5 Issues related to privacy

With respect to patient privacy, the Austrian\textsuperscript{85} and the German\textsuperscript{142, 143} registries sought informed written consent from individual participants. The Canadian\textsuperscript{138-140}, United Kingdom\textsuperscript{146} and European\textsuperscript{147} registries obtained permission (e.g., from ethics committees) to collect de-identified data without consent. The United States\textsuperscript{145} registry also utilised a
waiver of consent for the registry, however, all patients provided informed consent to participate in CR. The Danish registry reported collecting and maintaining data according to Danish Data Protection Laws and Regulations without the need to obtain consent.

3.4.6 **Incentives**

In Denmark, entry of CR data is a mandatory requirement for all hospitals delivering Phase II CR (initial 8-12 weeks of outpatient rehabilitation). The United Kingdom, the United States and Austria incentivised data entry through making it an eligibility criteria for program certification and reimbursement. Canada and the United States enabled participating sites to generate individualised reports on outcome and quality indicators for benchmarking and auditing. Participation in the European registry was entirely voluntary.

3.4.7 **Funding sources**

Sources of registry funding varied greatly. The Danish registry is funded solely by the Danish Government. In Austria, costs are covered by individual sites and a fixed amount per patient entered is charged for maintenance of the registry. Similarly, in the United States, individual sites pay an annual subscription fee and additional support for the ongoing running and maintenance of the registry is provided by multiple industry sponsors. Industry support was also reported for the Canadian and the German registries and major research funding bodies supported the European and United Kingdom registries. The time-length of funding was not reported.
<table>
<thead>
<tr>
<th>Registry</th>
<th>Patient-level data captured</th>
<th>Service-level data captured</th>
<th>Data custodians</th>
<th>Governance</th>
<th>Privacy</th>
<th>Incentives</th>
<th>Funding</th>
</tr>
</thead>
</table>
| Austria 85 AGAKAR Registry (Working group on out-patient cardiac rehabilitation) | • Medical diagnosis/surgical procedure  
• Clinical: systolic and diastolic BP, glucose, HDL, LDL, triglycerides  
• Anthropometrics: BMI, waist circumference  
• Physical: resistance training measures, physical work capacity  
• Psychosocial measures: MacNew questionnaire (global, physical, social and emotional components), HADS-A, HADS-D | Not reported. | Data are maintained by a professional and independent external provider. | All out-patient CR is carried out mainly by centres accredited by the AGAKAR. | The ethical committee of the State of Salzburg approved the protocol. Patients gave written informed consent. The researchers complied with all privacy laws. Data are entered anonymously and is de-identified | To be eligible for reimbursement all centres accredited by AGAKAR are obliged to enter data of all patients into a web-based database. | Each CR site covers the cost themselves; a fixed amount per patient entered is charged for maintainence of the registry. |
| Canada 138-140, 149 Canadian Cardiac Rehabilitation Registry (CCRR) | Approx. 200 data elements are collected on each patient.  
• Demographics: age, sex, ethnicity, marital status, language preference, education, work, family support, residence, travel time to rehab  
• Medical history: referral event; interim events (any cardiac events that occurred during the CR period); comorbidities | Referral, type, and provider; enrolment; wait times; Completion, and premature termination; sessions completed; components received; referral to services to reduce risk factors e.g., | Each participating CR site nominates a data steward, whose responsibilities include the uploading or direct entry of data to the CCRR | The CCRR Committee, a Subcommittee of the Canadian Association of Cardiovascular Prevention and Rehabilitation’s Board of Directors provides leadership and direction, while overseeing Subcommittee work in the areas of Data | A privacy impact assessment was completed and changes made in order to respond to identified privacy threats. Only anonymized data goes to the CCRR. | Benchmarking – each program receives a quarterly report on outcome and quality indicators; can see program reports online in real-time | Funded through unrestricted grants from Pfizer Canada Inc. and Servier Canada Inc. (industry) |
<table>
<thead>
<tr>
<th><strong>cfrm</strong></th>
<th><strong>Medication:</strong> all cardiovascular-related medications at intake and discharge, dosages and contraindications, including herbals</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Clinical:</strong> BP, lipid control, blood glucose control, sleep apnea; CV severity (e.g., angina class, left ventricular ejection fraction); exercise capacity; <strong>Anthropometric:</strong> waist circumference, weight, height <strong>Behavioural:</strong> smoking status, diet, exercise 150 mins, resistance training <strong>Psychosocial measures:</strong> depression, QoL, <strong>Vocational measures:</strong> return to work and date</td>
<td></td>
</tr>
<tr>
<td>smoking cessation, psychology; discharge summary</td>
<td></td>
</tr>
<tr>
<td><strong>Transfer Compatibility Verification, Program Liaison, and Research</strong></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Denmark 141</strong></th>
<th><strong>The Danish Cardiac Rehabilitation Database (DCRD) <a href="http://www.danheart.dk">www.danheart.dk</a></strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Demographics:</strong> age, sex, education, marital status, cohabitation status, driving licence <strong>Medical history/co-morbidities:</strong> COPD, DM, smoking status, alcohol intake, other <strong>Cardiovascular-related medications:</strong> e.g., statins, Beta Blockers <strong>Clinical:</strong> CHD characteristics, LVEF, cardiac rhythm, <strong>Anthropometrics:</strong> BMI</td>
<td></td>
</tr>
<tr>
<td>Program level data are collected every three years including: referral procedures, program content, organisation, safety and documentation.</td>
<td></td>
</tr>
<tr>
<td>Patient-level data are entered by the clinical team directly into the online system at the time of entry into CR. Simultaneous data linkages to national administrative patient</td>
<td></td>
</tr>
<tr>
<td>Initiated by a national working group on preventative cardiology and rehabilitation, under the Danish Society of Cardiology. The database is headed by a Steering Committee with an</td>
<td></td>
</tr>
<tr>
<td>Data are collected and maintained according to Danish Data Protection Laws and Regulations, without the need to obtain patient consent.</td>
<td></td>
</tr>
<tr>
<td>It is a mandatory requirement for all hospitals delivering Phase II CR to register all patients onto the registry.</td>
<td></td>
</tr>
<tr>
<td>Funded by the Danish government.</td>
<td></td>
</tr>
<tr>
<td>Europe 147 European Cardiac Rehabilitation Registry and Database (EuroCaReD)</td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>• <strong>Psychosocial measures:</strong> depression screening, sick leave</td>
<td>• <strong>Initiating clinical event</strong></td>
</tr>
<tr>
<td>registers have been established.</td>
<td>CR program completion, CR dropout rates, program content and program length</td>
</tr>
<tr>
<td>• <strong>Demographics:</strong> sex, age, education</td>
<td>• <strong>Medical history/risk factors:</strong></td>
</tr>
<tr>
<td>• <strong>Medical history/risk factors:</strong></td>
<td></td>
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</tbody>
</table>

**Germany**

<p>| | | | | |</p>
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<tbody>
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<td></td>
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</tbody>
</table>
### Mexico
- **Demographics:** sex, age
- **Diagnostic:** e.g., heart failure, ischemic heart disease etc.
- **Clinical:** systolic and diastolic BP, cholesterol, triglycerides, fasting blood glucose
- **Medications:** prescribed cardiovascular-related medications e.g., Beta blockers, statins, ACE inhibitors
- **Anthropometrics:** BMI
- **Physical:** exercise capacity

| Registries (ROG & TROL). Participating physicians documented CR patient's information on standardized case report forms. | Representatives of the scientific society (DGPR) and additional members with expertise in registries supervised both registries. | Physician Chamber approved the registry, and all patients provided informed consent. Patient data protection was closely observed. | Benchmarking | An unrestricte
d grant from MSD Sharp & Dohme, Germany |
|---|---|---|---|---|

### United Kingdom
- **Clinical:** systolic and diastolic BP, total cholesterol
- **Anthropometrics:** BMI
- **Behavioural:** smoking status, self-reported physical activity
- **Physical:** exercise capacity through the ISWT

<table>
<thead>
<tr>
<th>CR enrolment (the total number of patients who had started CR), CR completion,</th>
<th>Data governance and approval is obtained through NHS Digital and also monitored through the Department of</th>
<th>Approval is provided by the NHS to collected anonymised patient data. These data are hosted by the HSCIC. The</th>
<th>There are no financial incentives for entering data. Centres do use the data to audit their own</th>
<th>The Research was performed by the NACR team, which is</th>
</tr>
</thead>
</table>

---

**United Kingdom**

**The National**

- **Clinical:** systolic and diastolic BP, total cholesterol
- **Anthropometrics:** BMI
- **Behavioural:** smoking status, self-reported physical activity
- **Physical:** exercise capacity through the ISWT

| Name of centres, geographical distribution, types of professionals employed in the centres, number of patients included in CR programs | Not reported. | Not reported. | Not reported. | Not reported. |
### United States of America  
**AACVPR Outpatient Cardiac Rehab Registry**

- [www.aacvpr.org/Registry/Cardiac-Rehab](http://www.aacvpr.org/Registry/Cardiac-Rehab)

<table>
<thead>
<tr>
<th>Category</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demographics</td>
<td>Medical record ID, DOB, sex</td>
</tr>
<tr>
<td>Medical history</td>
<td>Admitting diagnosis, risk factors, comorbid conditions</td>
</tr>
<tr>
<td>Medication</td>
<td>All cardiovascular-related medications</td>
</tr>
<tr>
<td>Clinical</td>
<td>Lipids, glucose, BP, dietary outcomes, functional capacity</td>
</tr>
<tr>
<td>Anthropometric</td>
<td>Waist circumference, weight, height</td>
</tr>
<tr>
<td>Behavioural</td>
<td>Smoking status, exercise behaviour</td>
</tr>
<tr>
<td>Psychosocial measures</td>
<td></td>
</tr>
</tbody>
</table>

**Comprises of approx. 180 data elements including:**

- Referral, enrolment and discharge dates; healthcare utilisation including adverse and unexpected events
- Each participating program designates a principal user who is responsible for monitoring data integrity
- AACVPR own and operate the registry. Oversight is provided by the AACVPR Board of Directors and the AACVPR Registry Committee
- Privacy of included patients complies with the Health Insurance and Portability and Accountability Act. The program has a number of safeguards in place to protect the security of AACVPR data
- Benchmarking, quality assessment and improvement. Participating sites receive pre-configured reports at the individual, group and program level and enable the site to assess their performance in relation to guidelines

Each participating site is required to pay an annual fee to subscribe to the program. Multiple industry sponsors including: Janssen Pharmaceutical Companies, Quinton & ScottCare Cardiovascular.

### Audit of Cardiac Rehabilitation (NACR)

- [www.cardiacrehabilitation.org.uk](http://www.cardiacrehabilitation.org.uk)

<table>
<thead>
<tr>
<th>Category</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mental health measures</td>
<td>HADS-A, HADS-D</td>
</tr>
<tr>
<td>and associated staffing</td>
<td>Requirements per centre (e.g., types of staff, hours worked, no. staff per programme)</td>
</tr>
<tr>
<td>and associated staffing</td>
<td>Requirements per centre (e.g., types of staff, hours worked, no. staff per programme)</td>
</tr>
<tr>
<td>and associated staffing</td>
<td>Requirements per centre (e.g., types of staff, hours worked, no. staff per programme)</td>
</tr>
<tr>
<td>and associated staffing</td>
<td>Requirements per centre (e.g., types of staff, hours worked, no. staff per programme)</td>
</tr>
<tr>
<td>and associated staffing</td>
<td>Requirements per centre (e.g., types of staff, hours worked, no. staff per programme)</td>
</tr>
<tr>
<td>Health Sciences</td>
<td>Data Governance Committee.</td>
</tr>
<tr>
<td>NACR can seek annual approval</td>
<td>to use these data.</td>
</tr>
</tbody>
</table>
| patients and generate reports | Since the study in 2015 the NACR now supplies data to programmes as part of a National Certification Programme for Cardiac Rehabilitation.

**NACR can seek annual approval to use these data.**

Each participating programme aims to meet the following benchmarks:

- **Benchmarking**, quality assessment and improvement. Participating sites receive pre-configured reports at the individual, group and program level and enable the site to assess their performance in relation to guidelines.

Each participating site is required to pay an annual fee to subscribe to the program. Multiple industry sponsors including: Janssen Pharmaceutical Companies, Quinton & ScottCare Cardiovascular.
Acronyms: AGAKAR, Arbeitsgruppe für ambulante kardiologische Rehabilitation (Working group on out-patient cardiac rehabilitation); BP, blood pressure; HDL, high-density lipoprotein; LDL, low-density lipoprotein; HADS-A, Hospital Anxiety and Depression Scale – Anxiety component; HADS-D, Hospital Anxiety and Depression – Depression component; CR, cardiac rehabilitation; CCRR, Canadian Cardiac Rehabilitation Registry; QoL, Quality of life; COPD, chronic obstructive pulmonary disease; ROG, The Registry of Guideline-Based Therapy; TROL, Transparency Registry to Objectify Guideline-Oriented Risk Factor Management; DM, diabetes mellitus; CHD, coronary heart disease; LVEF, left ventricle ejection fraction; BMI, body mass index; ACE inhibitors, angiotensin-converting enzyme inhibitors; DPGR, German Society of Prevention and Rehabilitation; NACR, National Audit of Cardiac Rehabilitation; ISWT, incremental shuttle walking test; NHS, National Health Service; HSCIC, Health and Social Care Information Centre; AACVPR, American Association of Cardiovascular and Pulmonary Rehabilitation
3.4.8 **Barriers and enablers of implementation**

The included papers reported a number of barriers to establishing and maintaining CR registries. Barriers to the recruitment of sites included administrative hurdles such as collecting site agreement signatures, ensuring privacy standards and a lack of human resources for data entry. Data quality issues were reported such as incompleteness of data submissions as well as time delays with the reporting of data. Data gaps were also reported with regard to the inability to link to other datasets (e.g., in order to determine the proportion of eligible patients receiving CR, linkages to in-patient datasets is required). Furthermore, the maintenance of registries requires ongoing funding which was often reported as limited; the continuation of both the European and Canadian registries are uncertain due to lack of funding. Importantly, it was also noted that the presence of a registry does not guarantee quality improvement, but that a comprehensive approach is required including successful implementation of the registry, continuous data quality assurance, and transparent and timely feedback.

3.5 **Discussion**

This was the first systematic review of its kind to provide and synthesise evidence for existing national and international CR registries. Globally, we identified seven countries (3.26% of countries globally) that had established national CR registries and one international (Europe) registry. Of the identified registries, five are currently active (Austria\textsuperscript{85}, Canada\textsuperscript{138-140}, Denmark\textsuperscript{141}, the United Kingdom\textsuperscript{146} and the United States\textsuperscript{145}). The availability of CR programs is low worldwide; only 38.8\% of countries provide CR (68\% in high-income countries, 23\% in low and middle-income countries, and 8.3\% in low-income countries).\textsuperscript{150} This review demonstrates that systematic evaluation of these programs via registries is extremely limited. Apart from Mexico, all countries included in the review were high-income, which aligns with previous literature on CR programs being predominately
available in high-income countries even though 80% of CVD deaths now occur in low- and middle-income countries.\textsuperscript{150}

The limited number of active CR registries is likely due in part to barriers inherent in establishing and maintaining clinical registries. The AHA\textsuperscript{130} provides key recommendations for overcoming major challenges to developing CVD registries including; ensure high quality data, link clinical registries with clinical data, integrate clinical registries with electronic health records, safeguard privacy while reducing barriers to healthcare improvement, and secure adequate funding and develop business models to initiate and sustain clinical registries. Challenges identified within this review are discussed in further detail below and include; the heterogeneity of data collected across CR sites, challenges to ensuring quality of data entry and patient privacy, and lack of timely and transparent feedback.

The establishment of a CR registry largely depends upon consensus related to core minimum data and for these data to be routinely collected across sites in a regular and systematic way. Registries within this review most commonly collected data on: demographics; initiating event; clinical measures (e.g., blood pressure, blood glucose control); medical history and co-morbidities; anthropometrics; physical activity; and psychosocial measures. The registries provided a variety of top-down (e.g., Denmark which has mandated data entry and is funded by the Government) and bottom-up (e.g., Canada) approaches to develop consensus and uptake on these core minimal standards. The EuroCaReD\textsuperscript{147} registry demonstrates that it is feasible to make national comparisons when assessment methods and measures are consistent across countries.

Data linkage to administrative databases and health outcomes is crucial if registries are to determine service-level information (e.g., proportion of eligible patients receiving CR, inequalities in care provision) and long-term health indicators. As reported by Van de Veer
and colleagues\textsuperscript{151}, it is important that audit and feedback does not only include ‘outcome’ measures but also ‘process’ measures (e.g., adherence to guideline recommendations, time to treatment, referral processes, change in program delivery, and use of secondary prevention medication) as these are more easily modified by feedback. The effectiveness of feedback is further influenced by the participant’s trust in the quality of data as well as a range of personal and organisation factors (e.g., outcome expectation, motivation, leadership); as such a range of strategies are required to influence behaviour change and improve quality of care.\textsuperscript{151} The broader literature on disease registries recognises that data collection does not guarantee change in service provision and quality\textsuperscript{94, 130}; in-built feedback processes are important for facilitating improvements in quality of care. The National Audit of Cardiac Rehabilitation (United Kingdom) which is based on national guidelines\textsuperscript{146} provides one example of how a registry and auditing can be inter-linked.

Web-based applications to input data were a core feature of the majority of registries (n=6, 75\%) within this review and likely contributed to the success of the registry because such applications limit the need for double entry onto paper and then into a spread sheet. An additional benefit of web-based systems is their ability to generate site-specific reports, thereby providing timely information which sites can utilise for their own benchmarking and reporting. Tremendous opportunities will result from the increasing use of EMRs and advances in data scrapping techniques to extract data into registries. In Australia, the GRHANITE™ software system is being used to ethically extract patient information from primary care settings in a format that is record-linkable\textsuperscript{152} and authors of this review are currently investigating whether this approach can also be applied to CR.

The advancement of ‘big data’ methods could enable registries to be created from centralised systems rather than individual groups and associations developing their own disease-specific registries. Such methods have multiple benefits; it enables greater linkages
to other datasets, can track patients across the continuum of care, provides a platform for measuring co-morbidities, minimises the risks associated with individual associations establishing registries (e.g., maintaining funding), and reduces the burden on individual sites to manually enter data. However, use of electronic health records and centralised approaches do not remove the need for governance systems, or the challenges in ensuring appropriate data specifications and data quality.\(^\text{94}\)

This review had several strengths and limitations. The development of CR registries is a relatively new field of research so the number of included studies is small. Further, we recognise that health systems in many countries, particularly those in low- and middle-income settings may not offer structured, comprehensive CR and therefore are unlikely to monitor and evaluate CR programs. Further work is required to build capacity in such settings and for quality assurance that meets standardised, international standards to be central in its development. Only English language papers were extracted, potentially introducing selection bias. The included papers often lacked detail on: the registry process (e.g., time to enter patient’s record, how data input aligned with work flow), feedback received about the registry (e.g., from users, developers, recipients of feedback derived from the registry, or researchers), and the overall costs of running and maintaining a registry as well as methods to reduce costs. Further, long-term follow-up of patients was lacking.

However, the search was strengthened by the inclusion of a wide variety of study designs including grey literature and the independent assessment of studies by two reviewers with a high level of agreement. The use of the Covidence tool\(^\text{137}\) greatly assisted the management of the systematic review. Contact with authors of the included studies provided additional detail on registries and their expertise proved invaluable in identifying missed registries.
Further research is required to evaluate how audit and feedback could be integrated into the development of registries in order to influence system-level change. Additionally, data linkage studies are required to substantiate the impact of national registries on health systems and clinical outcomes.

3.6 Conclusions

Clinical registries play an important role in measuring healthcare delivery and supporting quality improvement for individuals with heart disease. Our findings show that very few countries have established CR registries. When properly integrated into the health system, CR registries have enormous potential to systematically collect CR data, provide timely and individualised feedback and improve the provision of care. Successful CR registries require the collection of uniform data (e.g., core minimum data) across sites; linkages to administrative databases to determine service-level information and long-term health indicators and utilisation of web-based applications to input data. Furthermore, CR registries are most useful when data collection is maintained over time and this requires adequate and sustainable funding sources. Well-managed CR registries have the potential to benefit service providers by tracking program performance, driving changes in guidelines, as well as assisting researchers in building an evidence base for the effectiveness of CR in reducing morbidity and mortality from CVD. Further, such data are critical for government funders and health policy-makers to better track CR expenditure and produce cost-effective policies. The results of this review inform the development of future CR registries to mitigate the burden associated with heart disease. Future research is required to evaluate the impact of national registries on health systems and clinical outcomes.
PHASE 3 & 4: Implement and evaluate

Apply plan in pilot settings

Collect data and analyse results to show what works and what does not
CHAPTER 4: UTILISING A DATA CAPTURE TOOL TO POPULATE A CARDIAC REHABILITATION REGISTRY: A FEASIBILITY STUDY
4 Chapter overview

The systematic review of CR registries (Chapter Three) highlighted important barriers to the development and sustainable use of CR registries including manual data entry. Successful registries used web-based data entry platforms, ensured data could be linked with other databases to determine health outcomes and provided timely feedback to sites. These lessons formed the foundation of this feasibility study which aimed to determine if an automated data capture software could reduce the burden of data entry on time-poor clinicians. Additionally, a web-based component using tailored software was developed to capture data not collected automatically. This protocol was implemented at a private and public CR service in Victoria.

4.1 Abstract

**Background:** Clinical registries are effective for monitoring clinical practice, yet manual data collection can limit their implementation and sustainability. The objective of this study was to assess the feasibility of using a data capture tool to collect CR minimum variables from electronic hospital administration databases to populate a new CR registry in Australia.

**Methods:** Two CR facilities located in Melbourne, Australia participated, providing data on 42 variables including: patient socio-demographics, risk factors and co-morbidities, CR program information (e.g., number of CR sessions), process indicators (e.g., wait time) and patient outcomes (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. Additionally, clinicians entered data on CR patients into a purpose-built web-based tool (REDCap). Formative evaluation including staff feedback was collected.

**Results:** The GRHANITE™ tool was successfully installed at the two CR sites and data from 176 patients (median age=67 years, 76% male) were securely extracted between September – December 2017. Data pulled electronically from hospital databases was limited to seven of the 42 requested variables. This is due to CR sites only capturing basic patient information (e.g., socio-demographics, CR appointment bookings) in hospital administrative databases. The remaining clinical information required for the CR registry were collected in formats (e.g., paper-based, scanned or Excel spreadsheet) deemed unusable for electronic data capture. Manually entered data into the web-tool enabled data collection on all remaining variables. Compared to historical methods of data collection, CR staff reported that the REDCap tool reduced data entry time.

**Conclusions:** The key benefits of a scalable, automated data capture tool like GRHANITE™ cannot be 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 patients, further investment is required in the digital platforms underpinning this approach.

4.2 Introduction

The ability to quantify healthcare quality relies on the implementation of appropriate systems that can accurately capture how care is being delivered. In a recent scientific statement, the AHA called for the systematic redesign of cardiovascular care to enable a ‘learning healthcare system’ which uses information technology and data infrastructures to enhance optimal healthcare delivery. In Australia, the ACSQHC promotes the use of clinical registries to systematically monitor healthcare, highlight variations in outcomes, and inform quality improvement efforts. Ischaemic heart disease ranks as the highest priority area identified by ACSQHC that would benefit from registry development due to the high burden of disease, serious consequences associated with poor quality care and strong clinical support. This follows the success of cardiac registries internationally including the Global Registry of Acute Coronary Events 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.

A key component of secondary prevention of heart disease is CR. Although CR is extremely effective in preventing cardiovascular recurrent events and complications and recommended in clinical guidelines, there is variability in program delivery and quality some of which stems from a lack of uniform data collection and monitoring systems. The need to develop quality indicators and implement systems that collect standardised CR outcome data are recognised by several national associations internationally including the ACRA (the Australian association of CR professionals). Specifically, ACRA recommend that all CR services collect a minimum set of data and report
on key performance indicators to promote continuous quality improvement of services and benchmarking. Despite these calls, quality indicator data from CR sites are, for the most part, not systematically collected or collated. One jurisdiction in Australia, Queensland, has recently established the Queensland Cardiac Outcomes Registry (QCOR) which includes the collection of CR quality indicator variables as part of the registry and will be the first state in Australia to systematically collect CR data. In the state of Victoria, the Victorian Cardiac Outcomes Registry collects data on cardiac patients across 35 hospitals on three modules (percutaneous coronary intervention, heart failure and the early treatment of acute MI). However, CR data are not included within this registry.

Globally, custodians of CR registries have noted challenges, common to any registry, such as site investment or ‘buy-in’, privacy and security considerations, as well as limited resources for contributing data. Indeed, sites are often required to manually enter data, which is time-consuming for clinical staff and increases the risk of data errors. Ideally, data collection should be automated and linked to administrative databases or electronic medical records (EMRs). With advances in technology, this is becoming more feasible. Automated data capture techniques using specially-designed software can be used to extract routinely-collected data. Such software can also incorporate automated safeguards built-in to the data entry systems to ensure privacy protection. This has been previously demonstrated within primary care and other settings in Australia using the GRHANITE™ (GeneRic Health Network Information for the Enterprise: 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) from CR sites and hospital administration databases using the GRHANITE™ automated data capture tool in order to populate a Victorian CR Registry (VCRR).
4.3 Methods

4.3.1 Overarching design of VCRR

This feasibility study consisted of a 3-month (September-December 2017) data collection period involving quantitative data capture from two pilot sites and formative evaluation of the process including feedback from CR clinicians. The design of the registry was guided by technical standards outlined by ACSQHC\textsuperscript{93}, as illustrated in a logic model (Figure 7).

![Clinical Quality Registries Information Model](image)

**Figure 7 Clinical Quality Registries Information Model**

Source: Australian Commission on Safety and Quality in Health Care\textsuperscript{93}

Reproduced with permission from *Logical Design for Australian Clinical Quality Registries*\textsuperscript{93}, developed by the ACSQHC, for use exclusively in Australia. ACSQHC: Sydney. 2012.

Acronyms: CQR: clinical quality registry; MBS: Medicare Benefits Schedule; PBS: Pharmaceutical Benefits Scheme
4.3.2 Selection of the minimum variables for the VCRR

The registry comprised a minimum set of variables selected from the New South Wales (NSW) ACRA association quality indicators and data dictionary which was based on expert consensus. The 42 selected data elements consisted of: demographic information (e.g., sex, age), disease/condition (e.g., principal referral diagnosis) risk factors and comorbidities (e.g., diabetes status, smoking status), intervention (e.g., number of CR sessions), process indicators (e.g., CR wait time) and individual patient outcomes (e.g., change in pre-post exercise capacity) (Table 9).

Table 9 Victorian Cardiac Rehabilitation Registry minimum variables

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

| Process indicators of evidence-based care | 27. CR wait time (CR commencement date – CR referral date) | 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 outcome measures | 41. Pre-post change in exercise capacity |
|                                    | 42. Pre-post change in waist circumference |

Acronyms: ACE-1: angiotensin-converting enzyme; ARB: angiotensin receptor blockers; CR: cardiac rehabilitation; CABG: coronary artery bypass grafting; PCI: percutaneous coronary intervention

### 4.3.3 Setting and Recruitment

In the state of Victoria in South East Australia, there are 136 CR programs, delivered across publicly and privately-funded hospitals and community health settings. ACRA (the national association of CR professionals) has a State-level directory of all CR facilities which was used to identify one public and one private site to invite to participate in the study. These sites were purposively selected to ensure sample representation of: funding sources (public and private), settings (acute hospital, rehabilitation hospital), and location (metropolitan and suburban). Site 1 was a large publicly-funded program, which runs a six-week CR program for approximately 40 outpatients per week. Site 2 was a private facility primarily funded through health insurance funds and the Department of Veteran Affairs, which runs a 12-
week program for approximately 15 outpatients per week. Participating sites were offered a stipend of AU$6,000 (USD$4700) to cover cost related to staff time for the set-up of automated data collection. Both CR sites agreed to participate.

4.3.4 **Ethics approval**

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

4.3.5 **Automated collection procedure (GRHANITE™)**

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 8.
4.3.6 Manual web-based data collection (REDCap)

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

4.3.7 Data extraction and linkage

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 scheduled to extract pre-determined variables on patients who participated in the CR program during the data collection period. GRHANITE™ enabled data to be extracted in a de-identified manner by incorporating advanced privacy-preserving hashing techniques to generate unique ‘signatures’. These data were then securely transmitted to the VCRR database based on the University of Melbourne’s server, with data stored in Microsoft SQL. Further details regarding data security and storage can be found in Appendix E.

4.3.8 Data quality

The system highlighted any GRHANITE™ 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) with number of patients manually entered into REDCap.
4.3.9 **Formative evaluation**

Semi-structured interviews were conducted within one week of the completed data collection period (December 2017) to ascertain any barriers or enablers to implementation of the CR registry. Individual interviews were held with clinical staff members involved with clinical data collection at the two pilot sites (N=3). The interviews were conducted by a member of the research team (ET). They were audio-recorded and then transcribed verbatim except to preserve anonymity.

The interview guide consisted of three parts: 1) historical approaches to data collection, 2) barriers to measuring and collecting variables and 3) recommendations for future registry implementation. Feedback provided by the clinicians was synthesised under the same three headings and identified barriers were coded in themes and sub-categories using content analysis.163

4.4 **Results**

4.4.1 **Characteristics of patients included in VCRR**

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

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

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

4.4.2 CR Quality

The minimum variables extracted were useful in informing assessment of CR site quality in many instances (Table 11). 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).
Table 11 Process indicators of evidence-based care

<table>
<thead>
<tr>
<th>Process indicator</th>
<th>SITE 1</th>
<th>SITE 2</th>
<th>Total</th>
<th>Unknown/missing*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Freq (%); Mean [SD]</td>
<td>Freq (%); Mean [SD]</td>
<td>Freq (%); Mean [SD]</td>
<td>Freq (%)</td>
</tr>
<tr>
<td></td>
<td>n=89†</td>
<td>n=26†</td>
<td>n=115†</td>
<td></td>
</tr>
<tr>
<td>CR wait time (days)</td>
<td>44.26 [22.53]</td>
<td>19.21 [19.46]</td>
<td>38.94 [24.13]</td>
<td>2 (1.74)</td>
</tr>
<tr>
<td>Screened for depression</td>
<td>48 (53.93)</td>
<td>24 (92.31)</td>
<td>72 (62.61)</td>
<td>43 (37.39)</td>
</tr>
<tr>
<td>Positive case for depression referred</td>
<td>1 (2.38)‡</td>
<td>2 (22.22)‡</td>
<td>3 (5.88)‡</td>
<td>43 (84.31)‡</td>
</tr>
<tr>
<td>No. of smokers</td>
<td>8 (8.99)</td>
<td>1 (3.85)</td>
<td>9 (7.83)</td>
<td>2 (1.74)</td>
</tr>
<tr>
<td>Smokers referred for cessation</td>
<td>0 (0)§</td>
<td>0 (0)§</td>
<td>0 (0)§</td>
<td>3 (33.33)§</td>
</tr>
<tr>
<td>Post-CR medications</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Antiplatelet</td>
<td>21 (23.60)</td>
<td>20 (76.92)</td>
<td>41 (35.65)</td>
<td>74 (64.35)</td>
</tr>
<tr>
<td>Beta-blockers</td>
<td>18 (20.22)</td>
<td>12 (46.15)</td>
<td>30 (26.09)</td>
<td>75 (65.22)</td>
</tr>
<tr>
<td>ACE-1/ARB</td>
<td>14 (15.73)</td>
<td>10 (38.46)</td>
<td>24 (20.87)</td>
<td>75 (65.22)</td>
</tr>
<tr>
<td>Lipid-lowering</td>
<td>21 (23.60)</td>
<td>13 (50.00)</td>
<td>34 (29.57)</td>
<td>75 (65.22)</td>
</tr>
<tr>
<td>Sublingual nitrate</td>
<td>11 (12.36)</td>
<td>5 (19.23)</td>
<td>16 (13.91)</td>
<td>75 (65.22)</td>
</tr>
<tr>
<td>Provided a symptom - management plan</td>
<td>48 (53.93)</td>
<td>22 (84.61)</td>
<td>70 (60.87)</td>
<td>45 (39.13)</td>
</tr>
<tr>
<td>Referred for ongoing care</td>
<td>44 (49.44)</td>
<td>24 (92.31)</td>
<td>68 (59.13)</td>
<td>47 (40.87)</td>
</tr>
</tbody>
</table>

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; †Denominator =
number of patient records entered into REDCap; † Denominator = number of patients screened positive for depression; ‡ Denominator = number of identified smokers

4.4.3  **CR Staff Perceptions of Data Capture Processes**

Feedback from the two sites revealed that the manual entry component was straightforward, easy to use, and quicker than traditional forms of data collection (i.e., clinician-selected variables entered into an Excel spreadsheet; Table 12). The training provided was perceived as sufficient and staff felt in-built features such as mandatory fields enabled them to feel more confident about the data quality. Staff expressed desire to have the capacity to search more easily for entered patient data (a feature that is available in REDCap but was not highlighted during the training session) and additional information about the rationale/evidence for some of the selected minimum variables. All interviewees wanted to continue using REDCap and preferred this approach over traditional methods; as described by the CR co-ordinator at Site 2 "I just can see that REDCap is the bright new future that we can start to get the cardiac rehab product out there with consistency between programs... Because at the moment we can all say that we are doing cardiac rehab and we can all be members of ACRA but I don't know what you're providing and you don't know what I am doing unless you are there".

Five main barriers were identified regarding historic methods of measuring and entering variables (see Supplementary file 3): 1) workload and competing responsibilities (e.g., time constraints); 2) environmental context and resources (e.g., information technology issues, and not having access to a quiet and secure space to enter data); 3) patient factors (e.g., patient needs/concerns conflicting with data collection requirements); 4) care delivery processes and co-ordination (e.g., referrals getting lost because sent via post/fax) and 5) outcome expectations (e.g., reduced confidence in data because of measurement errors).
Chapter 4 – Research article

Table 12 Feedback from sites on 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 are 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)

4.5 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 in Australia. While CR sites collected large amounts of clinical data, the majority of these data (i.e., 83% of the 42 variables) were not readily-available in an appropriate
electronic format rendering automated data extraction unfeasible. Until such time that the current infrastructure in public and private CR settings develops, the key benefits of scalable, automated data capture tools like GRHANITE™ will remain unrealised. While this approach remains promising for creating and maintaining a registry that monitors the quality of CR provided to patients, further investment is required in the digital platforms underpinning this approach including ensuring electronic platforms are: accessible to CR sites, fit for purpose, and capturing high quality data. In the interim, a web-based data collection tool housed on the REDCap system can enable standardised data to be collated from various CR sites with known limitations associated with manual data entry. These key findings are discussed further below.

Greater emphasis must be placed on ensuring CR staff have access to EMRs. In general, allied health and community-based settings have had low levels of adoption of electronic health infrastructure compared to acute settings and primary care. To ensure more timely access, national associations such as ACRA, the Cardiac Society of Australia and New Zealand (CSANZ) and the NHFA need to facilitate advocacy efforts at the local, state and 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; enhanced CR representation on state-based cardiac clinical networks could drive the issue at a state-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.

Future digital health investments will be driven by specific business needs and the identification and demonstration of local and system-wide benefits. 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 technology activities.  

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). In states where different EMR systems are being implemented, flexible tools like GRHANITE™ will be crucial in enabling interoperability of data across various systems (including public and private) whilst adhering to privacy and security concerns. This is the case in Victoria where the previous HealthSMART initiative aimed at reforming the IT ecosystem with a ‘one-size-fits-all’ approach’ was deemed unsuccessful and eventually abandoned after more than $300 million of investment. Consequently, the responsibility of developing digital solutions was placed back on health services providers resulting in a wide range of clinical information systems implemented to varying degrees across hospitals and health centres.

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

In the interim, CR data collection can be improved via the use of a standardised web-based tool housed on platforms such as the REDCap system. REDCap had multiple advantages including: 1) ease of implementation without any need for the sites’ IT departments, 2) usable at both public and private CR sites, 3) secure and password-protected access, 4) straight-forward and quick data entry, 5) in-built functions (e.g., mandatory fields, character
limits, drop down options, automated reports) to enhance data quality and completeness, 6) available for use at no costs for affiliated research institutes. Further, REDCap was supported by those entering the data who expressed an 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 can be more accurately documented. Additionally, unknown data requires additional clarification. For example, post-CR medication status had larger amounts of unknown responses than other 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.

4.5.1 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 generalisable 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.
4.5.2 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™. 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.
PHASE 5: Adjust

Use evidence to influence continual improvement
CHAPTER 5. DEVELOPING NATIONAL QUALITY INDICATORS FOR CARDIAC REHABILITATION IN AUSTRALIA: CONSIDERATIONS AND FUTURE DIRECTIONS
5 Chapter Overview

The previous chapter investigated how data could be collected from CR sites. This chapter examines what data should be collected. As identified in the previous chapter, staff at the CR sites questioned the rationale behind the inclusion of some of the requested data. Therefore, the aim of this chapter was to determine 1) which quality indicators are used internationally; and 2) important considerations for the development of national quality indicators for Australia. The top nine quality indicators collected internationally are reported (Table 14) and six considerations for the development of national quality provided (section 5.5).

A condensed version of these findings was published as a letter to the editor (Appendix B).

Citation: Thomas E, O’Neil A. Considerations for developing quality indicators for cardiac rehabilitation in Australia. Heart, Lung & Circulation, DOI: 10.1016/j.hlc.2018.11.009. [Letter to the editor]
5.1 Introduction

Care quality is an increasing focus of funders, providers and consumers of healthcare. Measuring and monitoring quality is important for ensuring accountability of healthcare providers, enhancing patient outcomes, minimising adverse events and aligning care with what patients want and the best available evidence.166 Quality indicators are explicitly defined statements that aim to measure adherence to aspects of evidence-based care that are deemed necessary for reaching optimal patient outcomes and provide a basis for quality improvement projects.153, 166 In Australia, the ACSQHC leads and coordinates key improvements in safety and quality in healthcare across the country and develops resources to enhance quality improvement projects (such as a Framework for Australian clinical quality registries167 and ACS clinical cares standards.168

Evaluation and quality improvement are core tenants of CR as outlined in the ACRA core components56. Although the core components provide a list of key performance indicators that should be collected, these are too numerous and time consuming and need to be reduced to be feasible for all sites to routinely complete. Further, as different states across Australia develop their own methods of monitoring CR, there is a risk that the collection of data will not be comparable across jurisdictions. Consequently, it is important that a set of national quality indicators are developed; however, at the time of this review it was unclear which quality indicators were the most important to collect.

Therefore, this chapter aims to review the current literature to identify: 1) which quality indicators are currently being collected internationally; 2) how these quality indicators relate to quality care standards and frameworks; and 3) recommendations for the development of a national set of quality indicators for CR in Australia.
5.2 Defining quality

The Institute of Medicine, in the United States defines high quality care as being safe, effective, patient-centred, timely, efficient and equitable.\textsuperscript{169} Quality indicators are well-defined, measurable elements of practice performance often translated from evidence-based recommendations and are used to generate review criteria and standards to quantify care quality.\textsuperscript{166} Multiple frameworks have been developed to conceptualise core aspects of care quality and can largely be categorised into three main groups\textsuperscript{170} including: 1) \textit{perspectives frameworks} encompassing the patient, healthcare provider and health manager perspectives (e.g., the client-orientated, provider-efficient services framework\textsuperscript{171}(COPE®)); 2) \textit{characteristics frameworks} comprising a set of characteristics such as health policies, infrastructure, referral systems and human resources (e.g., Maxwell’s 1992 characteristics of healthcare quality\textsuperscript{172}); and 3) \textit{system frameworks} in which quality comprises of distinct and measurable aspect of the health system including structure, processes and outcomes (e.g., Donabedian’s framework\textsuperscript{173}).

More recently, the WHO’s Quality of Care Framework\textsuperscript{174} has combined elements of all three types of frameworks described above into one model. While initially designed for maternal and newborn health, the framework is applicable to a wide-range of healthcare areas including CVD (Figure 9).
5.3 Importance of measuring quality within modern cardiac rehabilitation

The effectiveness of CR programs within contemporary cardiac management has recently been questioned by studies such as the RAMIT\textsuperscript{67}, which reported that comprehensive CR following MI had no important effect on mortality, morbidity, or health-related quality of life. While these negative effects did not impact the most recent Cochrane review by Andersen et al.\textsuperscript{19}, it has led to questions about the overall quality of care provided by CR.
programs in real-world settings and the importance of a minimum standard of care to be consistently delivered across sites.\textsuperscript{147}

Doherty et al.\textsuperscript{84} investigated whether CR programs in the United Kingdom met minimum standards using data from the NACR. Substantial variation between CR sites existed, with only 30\% of CR sites meeting criteria for high-performance; 18\% of sites were reported as having low performance; and a further 5\% failed to meet any criteria.\textsuperscript{84} Such variation in quality is of large concern as it highlights that many patients are not receiving optimal care, which, in turn may impact on their experience and outcomes. These results provide further evidence of the importance of continuously monitoring and evaluating CR programs and the quality of care provided.

### 5.4 Comparison to the international literature

#### 5.4.1 Search strategy

A literature review was conducted in August 2018 to identify quality indicators used to assess the delivery of CR internationally. The literature search involved two phases. First, the results from the systematic review of CR registries (Chapter Three) were used to identify countries that have national CR registries. Established registries where then reviewed to identify which countries had systematically (e.g., via a consensus-based approach) developed standardised quality indicators. Second, a general search of three databases (MEDLINE, PubMed and Google Scholar) was conducted to identify any other countries that had developed quality indicators not identified in the systematic review of CR registries, using the following search terms: “cardiac rehabilitation”, “acute coronary syndrome”, “secondary prevention”, “quality” “indicators”, and “standards”.
5.4.2 **Data extraction and synthesis**

For each identified country that collected quality indicators, the type (structural, process or outcome) and quality indicator were extracted. These were then synthesised into sections using the following aspects of care: 1) program model and structure; 2) referral, access and wait times; 3) assessment of risk factors; 4) self-management education; 5) psychosocial health; 6) post-CR assessment; 7) program completion; 8) discharge transition, linkage and communication; and 9) reporting and evaluation. Duplicates were removed, and similar indicators combined.

5.4.3 **Identified countries which had developed quality indicators for CR**

The systematic review of CR registries (Chapter Three) identified the following countries with national CR registries: Austria, Canada, Denmark, Germany, Mexico, the United States, the United Kingdom, and one regional registry for Europe. Of these, consensus-based quality indicators were available for Canada, Denmark, the United States, and the United Kingdom. An additional search of the literature revealed that the Netherlands and Japan had also undergone processes to develop quality indicators. The complete list of quality indicators collected by country can be seen in Table 13 and are contrasted against the New South Wales quality indicators used in our feasibility study (Chapter Four).
Table 13 Quality indicators collected internationally

<table>
<thead>
<tr>
<th>No.</th>
<th>Type</th>
<th>Quality Indicator</th>
<th>NSW178 Australia</th>
<th>Canada175</th>
<th>Denmark141</th>
<th>Japan177</th>
<th>Netherlands176</th>
<th>UK119</th>
<th>USA63</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td><strong>Program model and structure</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.1</td>
<td>Structure</td>
<td>Physician medical director providing program oversight</td>
<td>x</td>
<td></td>
<td></td>
<td>x</td>
<td>2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.2</td>
<td>Structure</td>
<td>Documented emergency response strategy and appropriately qualified staff</td>
<td>x</td>
<td></td>
<td></td>
<td>x</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.3</td>
<td>Structure</td>
<td>Appropriately qualified and component staff</td>
<td>x</td>
<td></td>
<td></td>
<td>x</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.4</td>
<td>Structure</td>
<td>Delivery of core components</td>
<td>x</td>
<td></td>
<td></td>
<td>x</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.5</td>
<td>Structure</td>
<td>Provision of a structured program within a defined pathway of care, which meets</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>x</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>the individual’s goals and is aligned with patient preferences and choice</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.6</td>
<td>Structure</td>
<td>Involvement of a multi-disciplinary team</td>
<td></td>
<td></td>
<td></td>
<td>x</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Referral, access, wait time</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.1</td>
<td>Process</td>
<td>In-patient referred to a CR program</td>
<td>x</td>
<td></td>
<td></td>
<td>x</td>
<td>x</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.2</td>
<td>Process</td>
<td>CR wait time from referral to enrolment</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.3</td>
<td>Process</td>
<td>CR enrolment/participation</td>
<td>x</td>
<td></td>
<td></td>
<td>x</td>
<td>x</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.4</td>
<td>Process</td>
<td>CR is offered to all priority groups</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>x</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>Assessment of risk factors</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.1</td>
<td>Process</td>
<td>Comprehensive assessment of modifiable cardiovascular risk factors</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2 Quality indicators that occur across four or more countries are highlighted in yellow
## Chapter 5 – Quality indicators

### Process Assessment of individual patient needs
- Assessment of current and past tobacco use: x 3
- Assessment of depression: x x x x x 5
- Assessment for anxiety: x 1
- Assessment of quality of life: x 1
- Assessment of diet: x x 2
- Assessment of adiposity: x x 3
- Screened for diabetes / blood glucose control (HbA1c): x x x 4
- Assessment of lipid control: x 2
- Assessment of blood pressure control: x 2
- Assessment of adherence to medications: x x 2

### Self-management education

#### Outcome
- Provision of self-management education
  - e.g., physical activity counselling, psychosocial education, dietary treatment, smoking cessation (if necessary): x x x 3
- Symptom-management education: x 1
- Prescribed exercise based on assessment of exercise capacity: x 1
- Current or recent smokers referred for smoking cessation advice/counselling: x x x 4
- Specialised education and intervention plan for patients with diabetes: x 1
- Specialised education and intervention plan for patients with hyperlipidaemia: x 1
- Specialised education and intervention plan for patients with chronic heart failure: x 1
| 4.8 | Process | Specialised education and intervention plan for patients with weight/composition measures above recommended goals |  |  | x | 1 |
| 4.9 | Process | Education on the importance of adherence to preventive medications that are described in guidelines |  |  | x | 2 |
| **Psychosocial health** |  |  |  |  |  |
| 5.1 | Process | Results of depression screener discussed with patient |  |  | x | 1 |
| 5.2 | Process | Primary care provider notified if clinical depression is suspected as result of screening |  |  | x | 1 |
| 5.3 | Outcome | Patients with suspected clinical depression referred for mental health management | x | x | x | 3 |
| 5.4 | Outcome | Patients with suspected clinical anxiety referred for mental health treatment | x |  | 1 |
| 5.5 | Process | Patients with high levels of stress referred to a stress management intervention | x |  | 1 |
| **Post-CR assessment** |  |  |  |  |  |
| 6.1 | Process | Patient needs |  |  | x | 1 |
| 6.2 | Process | Rehabilitation goals |  |  | x | 1 |
| 6.3 | Process | Cardiovascular risk profile (including: tobacco use, blood pressure control, lipid control, physical activity habits, weight management, diabetes, depression, exercise capacity, adherence to medications) |  |  | x | 2 |
| 6.4 | Process | Physical activity habits and the physical activity intervention plan |  |  | x | 2 |
| 6.5 | Process | Diabetes status and intervention plan reassessed (for those with diabetes at enrolment) |  |  | x | 1 |
| 6.6 | Process | Assessment of medical fitness to return to usual workplace during or following CR | x |  | 1 |
| 6.7 | Outcome | Improvement in exercise capacity | x | x | x | 4 |
| 6.8 | Outcome | Physical activity norms met (150 minutes of physical activity per week) | x |  | 2 |
## Chapter 5 – Quality indicators

<table>
<thead>
<tr>
<th>6.9</th>
<th>Outcome</th>
<th>Current or recent smokers at program enrolment not smoking at program completion</th>
<th>x</th>
<th>x</th>
<th>x</th>
<th>x</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.10</td>
<td>Outcome</td>
<td>Receiving antiplatelet treatment</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td></td>
<td>3</td>
</tr>
<tr>
<td>6.11</td>
<td>Outcome</td>
<td>Receiving statin/lipid lowering treatment</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td></td>
<td>3</td>
</tr>
<tr>
<td>6.12</td>
<td>Outcome</td>
<td>Receiving Beta blockers treatment</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td></td>
<td>3</td>
</tr>
<tr>
<td>6.13</td>
<td>Outcome</td>
<td>Receiving Angiotensin-converting enzyme / Angiotensin Receptor Blockers</td>
<td>x</td>
<td>x</td>
<td></td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>6.14</td>
<td>Outcome</td>
<td>Prescribed sub-lingual nitrate</td>
<td>x</td>
<td></td>
<td></td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>6.15</td>
<td>Outcome</td>
<td>LDL-cholesterol &lt;1.8mmol/L or a 50% decrease</td>
<td>x</td>
<td></td>
<td></td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>6.16</td>
<td>Outcome</td>
<td>Blood pressure below 140/90 mmHg</td>
<td>x</td>
<td></td>
<td></td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>6.17</td>
<td>Outcome</td>
<td>Improvement in quality of life</td>
<td>x</td>
<td></td>
<td></td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>6.18</td>
<td>Outcome</td>
<td>Time needed to start resumption of work</td>
<td>x</td>
<td></td>
<td></td>
<td></td>
<td>1</td>
</tr>
</tbody>
</table>

### Program completion

| 7.1 | Outcome | Percentage of patients enrolled in CR who completed the program | x | x | x | | 3 |
| 7.2 | Process | Reasons why CR patient did not complete the CR program (if applicable) | x | | | | 1 |
| 7.3 | Outcome | Percentage of prescribed CR exercise sessions completed by the patient | x | x | x | | 3 |

### Discharge, transition and communication

| 8.1 | Outcome | Provided an intervention to promote long-term physical activity post-CR | x | | | | 1 |
| 8.2 | Process | Patient received a discharge letter | x | | | | 1 |
| 8.3 | Process | Referred to ongoing care | x | | | | 1 |
| 8.4 | Process | Long-term patient outcomes are assessed | x | | | | 1 |
| 8.5 | Process | Documented communication/discharge summary between the CR program and healthcare providers (e.g., GP, cardiologist) | x | x | x | x | 4 |

### Reporting and evaluation
|   | Structure | Clinics perform internal evaluation and quality improvement |  |  | x | 1 
|---|-----------|-------------------------------------------------------------|---|---|---|---
| 9.2 | Structure | Patients participate in patient satisfaction research |  |  | x | 1 |
5.4.4 Most commonly collected quality indicators across countries

Quality indicators that were collected by a minimum of four countries were extracted into Table 14 to highlight the most common quality indicators collected across countries (shaded in yellow in Table 13).

Table 14 Most common quality indicators collected across countries

<table>
<thead>
<tr>
<th>No.</th>
<th>Type</th>
<th>Quality Indicator</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Process</td>
<td>In-patient referred to a CR program</td>
</tr>
<tr>
<td>2</td>
<td>Process</td>
<td>CR wait time from referral to enrolment</td>
</tr>
<tr>
<td>3</td>
<td>Process</td>
<td>Patient received a comprehensive assessment of modifiable cardiovascular risk factors*</td>
</tr>
<tr>
<td>4</td>
<td>Process</td>
<td>Patient screened for diabetes / blood glucose control (HbA1c)</td>
</tr>
<tr>
<td>5</td>
<td>Process</td>
<td>Patient assessed for depressive symptoms with a validated and reliable tool</td>
</tr>
<tr>
<td>6</td>
<td>Process</td>
<td>Patients who are current or recent smokers were referred for smoking cessation advice/counselling</td>
</tr>
<tr>
<td>7</td>
<td>Outcome</td>
<td>Current or recent smokers at enrolment in the program were not smoking at program completion</td>
</tr>
<tr>
<td>8</td>
<td>Outcome</td>
<td>Patient improved their exercise capacity during rehabilitation</td>
</tr>
<tr>
<td>9</td>
<td>Process</td>
<td>A documented communication/discharge summary was provided to healthcare providers (e.g., GP, cardiologist) from the CR program</td>
</tr>
</tbody>
</table>

*Including assessment of: tobacco use, blood pressure control, lipid control, physical activity habits, weight management, diabetes, depression, exercise capacity, adherence to medications.

5.5 Consideration for the development of national CR quality indicators in Australia

Campbell et al.\textsuperscript{166} purport that the development and application of quality indicators should include consideration of: 1) the available evidence; 2) what stakeholders’ perspective(s) the
indicators are intended to reflect; and 3) what aspects of care is being measured. Furthermore, for the development of Australian quality indicators and an accompanying data dictionary it is important to consider which data will be generated by applying the indicators, how the data aligns with Australian reporting standards and which processes can be used to enable national consensus on the indicators selected. These considerations are discussed below.

5.5.1 Consideration 1: What evidence is available?

Selected quality indicators should be those likely to impact on patient outcomes and therefore supported by a strong evidence base. Importantly, evidence-based practice does not only include research evidence but also clinician expertise and patient values combined with contextual understanding.\(^{179,4}\) For example, some areas of care may not be underpinned by research evidence such as RCTs but are strongly supported by clinicians and patients (e.g., providing discharge summaries to patients and care providers).

An important initial step is to review the empirical literature and summaries of the literature (e.g., guidelines, systematic reviews) to determine which recommendations have the strongest research evidence. These then need to be combined with clinical expertise, patient values and contextual understanding.

As part of a project with the NHFA, which aimed to develop a standardised curriculum for CR (see Appendix B for the full study details), the international CR literature was reviewed (with a focus on guidelines, Cochrane systematic reviews and other high-quality systematic reviews) and assigned levels of evidence to each component of care.\(^{160}\) An expert advisory group (including researcher, clinicians and a consumer representative) then rated each statement via a two-round modified-Delphi process to determine the areas of care that were ‘essential’ versus ‘desirable’ considering the strength of the evidence, contextual factors and
likely impact on the patient. The following 24 statements were determined as ‘essential’ aspects of care that should be measured, therefore providing a foundation for the development of quality indicators.

Table 15 Essential components of care for Australian CR programs as determined by modified-Delphi approach

<table>
<thead>
<tr>
<th>Initial assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 CR programs should undertake a comprehensive initial assessment that enables the needs of the CR participant to be understood and leads to an individualised care plan. The initial assessment should include:</td>
</tr>
<tr>
<td>• socio-demographic information</td>
</tr>
<tr>
<td>• clinical history</td>
</tr>
<tr>
<td>• exercise capacity</td>
</tr>
<tr>
<td>• lifestyle risk factors (physical activity, diet, smoking, alcohol)</td>
</tr>
<tr>
<td>• psychosocial health (depression, anxiety)</td>
</tr>
<tr>
<td>• medications.</td>
</tr>
<tr>
<td>2 Following the initial assessment, CR participants should be encouraged to set achievable goals with support from CR staff.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Heart education and self-management</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 CR participants should be provided with education on self-management strategies.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Medication education and review</th>
</tr>
</thead>
<tbody>
<tr>
<td>4 CR participants should be provided with medication education that includes basic indications and benefits of commonly prescribed medication therapy.</td>
</tr>
<tr>
<td>5 CR participants should be encouraged and supported to adopt strategies that lead to medication adherence.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Managing medical risk factors</th>
</tr>
</thead>
<tbody>
<tr>
<td>6 CR programs should provide education and skills for participants to self-manage or prevent hypertension.</td>
</tr>
<tr>
<td>7 CR programs should provide education and skills for participants to self-manage or prevent dyslipidaemia.</td>
</tr>
<tr>
<td>8 CR programs should provide education and skills for participants to self-manage or prevent diabetes.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Exercise training and physical activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>9 CR participants should be provided with a tailored, progressive and supervised exercise training program.</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>---</td>
</tr>
<tr>
<td><strong>10</strong></td>
</tr>
<tr>
<td><strong>Healthy eating &amp; weight management</strong></td>
</tr>
<tr>
<td><strong>11</strong></td>
</tr>
<tr>
<td><strong>12</strong></td>
</tr>
<tr>
<td><strong>Tobacco cessation and alcohol reduction</strong></td>
</tr>
<tr>
<td><strong>13</strong></td>
</tr>
<tr>
<td><strong>14</strong></td>
</tr>
<tr>
<td><strong>15</strong></td>
</tr>
<tr>
<td><strong>Psychosocial wellbeing</strong></td>
</tr>
<tr>
<td><strong>16</strong></td>
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<td><strong>17</strong></td>
</tr>
<tr>
<td><strong>18</strong></td>
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<tr>
<td><strong>19</strong></td>
</tr>
<tr>
<td><strong>Activities of daily living</strong></td>
</tr>
<tr>
<td><strong>20</strong></td>
</tr>
<tr>
<td><strong>21</strong></td>
</tr>
<tr>
<td><strong>Reassessment and completion</strong></td>
</tr>
<tr>
<td><strong>22</strong></td>
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<tr>
<td></td>
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<tr>
<td></td>
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<tr>
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</tbody>
</table>
• review of personalised goals set at beginning of program.

| CR participants should receive a review of goals set at the completion of the CR program |
| A discharge or summary letter should be provided to the CR participant and sent to their general practitioner and cardiologist. |

5.5.2  **Consideration 2: What stakeholder perspectives are the indicators intended to reflect?**

Healthcare impacts on a range of stakeholders (patients and their family, health professionals, managers and healthcare funders) who have different views about how care should be delivered and therefore, have different opinions on which aspect of care is most important to be measured. Careful consideration is required to determine whose perspective the indicators are intended to reflect and to ensure all appropriate stakeholders are included in the process.

Increasingly it is being recognised (such as by the WHO’s Quality of Care Framework\textsuperscript{174}) that quality of care encompasses not only the provision of care but also the *experience of care*. Consequently, it is important to ensure consumers or patient representatives are included in the development of quality indicators. Consideration of *how* the patient experience could be measured and reflected in the indicators is also required; this may be possible through the inclusion of patient reported outcome measures (PROMS) as well as patient reported experience measures (PREMS).

5.5.3  **Consideration 3: What aspects of care are being measured and what data will be generated by applying the quality indicators?**

Indicators can focus on different aspects of the healthcare system including the structure (e.g., personnel, organisation of resources and finances); outcomes (e.g., morbidity, mortality, health related quality of life); and processes (e.g., diagnosis, treatment, referral).
Most CR quality indicators collected internationally relate to processes and outcomes and very few relate to structural indicators (Table 13). This emphasis on process indicators is appropriate because improvement in process is often the primary aim of quality improvement projects. Policy-makers and funding bodies, however, are very likely to be interested in health outcomes and potentially how outcomes relate to structural factors (such as staffing levels and qualifications) so they can determine where funding is best invested. Consequently, development of national quality indicators should not overlook the inclusion of these aspects of care.

Quality indicators are defined and operationalised via the use of a data dictionary that defines the period of care, specifies the denominator and numerator and determines where the data should be collected from. Potentially the development of quality indicators can also be used to enhance the standardisation of the underlying tools used for measurement by encouraging the use of valid and reliable tools with appropriate options.

5.5.4 **Consideration 4: Do the indicators comply with reporting standards?**

The reporting of the quality indicators (and the data dictionary) needs to be sufficiently uniform to enable cross-jurisdictional comparisons and should therefore align with Australia’s national data reporting standards (the Metadata Online Registry (METeOR)). Ensuring data compliance with METeOR is an essential aspect of the development of clinical registries in Australia as delineated by the ACSHC.

5.5.5 **Consideration 5: How can the collected data be used for data linkage?**

Without data linkage, the impact of CR on long-term outcomes cannot be determined. The inclusion of identifiable variables (e.g., date of birth, Medicare number) is required to enable data linkage. While identifiable data necessitates additional ethical and security processes, Australian standards for the development of registries highlight data linkage wherever
possible. Consequently, in addition to the national quality indicators, variables must be included that would enable linkage to occur, a process that is supported by a waiver of consent.

5.5.6 **Consideration 6: What process is most appropriate to develop the national quality indicators and ensure the above considerations are met?**

An important consideration is whether the identified variables will provide a reliable and valid proxy of quality CR delivery. Systematic frameworks can be incorporated into consensus-based methods used to develop national quality indicators. For example, the framework proposed by the American College of Cardiology and the AHA (Figure 10), which assesses the usefulness, validity, reliability and feasibility of cardiovascular performance measures, could enable a transparent evaluation of suggested quality indicators and assist with the prioritisation of the most important indicators to include.
| Name of Measure: |  |
| Clinical Rationale: |  |
| Numerator: |  |
| Denominator: |  |
| Measure: |  |

<table>
<thead>
<tr>
<th>Rate this measure on the following criteria</th>
<th>Disagree</th>
<th>Moderate Agreement</th>
<th>Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Useful in Improving Patient Outcomes</strong></td>
<td>1 2 3 4 5</td>
<td>1 2 3 4 5</td>
<td>1 2 3 4 5</td>
</tr>
<tr>
<td>1. <strong>Evidence-based</strong>: The scientific basis of the measure is well established.</td>
<td>1 2 3 4 5</td>
<td>1 2 3 4 5</td>
<td>1 2 3 4 5</td>
</tr>
<tr>
<td>2. <strong>Interpretable</strong>: The results of the measure are interpretable by practitioners.</td>
<td>1 2 3 4 5</td>
<td>1 2 3 4 5</td>
<td>1 2 3 4 5</td>
</tr>
<tr>
<td>3. <strong>Actionable</strong>: The measure addresses an area that is under the patient's control.</td>
<td>1 2 3 4 5</td>
<td>1 2 3 4 5</td>
<td>1 2 3 4 5</td>
</tr>
</tbody>
</table>

| **Measure Design** |  |
|-------------------|  |
| 1. **Denominator**: The patient group to whom this measure applies (denominator) is clinically meaningful. | 1 2 3 4 5 |
| 2. **Numerator**: The definition of conformance for this measure is clinically meaningful. | 1 2 3 4 5 |
| 3. **Validity**: The measure appears to measure what it is intended to (face validity). | 1 2 3 4 5 |
| a. The measure captures most meaningful aspects of care (content validity). | 1 2 3 4 5 |
| b. The measure correlates well with other measures of the same aspect of care (construct validity). | 1 2 3 4 5 |
| 4. **Reliability**: The measure is likely to be reproducible across organizations and delivery settings. | 1 2 3 4 5 |

| **Measure Implementation** |  |
|----------------------------|  |
| 1. **Feasibility**: The data required for the measure is likely to be obtained with reasonable effort. | 1 2 3 4 5 |
| a. The data required for the measure is likely to be obtained at reasonable cost. | 1 2 3 4 5 |
| b. The data required for the measure is likely to be obtained within the period allowed for data collection. | 1 2 3 4 5 |

| **Overall Assessment** |  |
|-----------------------|  |
| Considering your assessment of this measure on all dimensions above, rate this measure overall for inclusion into the ACC/AHA Heart Failure Performance Measurement Set. | Do Not Include | Could Include | Must Include |
| 1 2 3 4 5 | 1 2 3 4 5 |

Figure 10 Sample rating form of indicators
Source: Spertus et al.\textsuperscript{153}, adapted from the Q-SPAN-CD collaboration\textsuperscript{182}

### 5.6 Future directions and challenges

The above recommendations were developed to be tabled at the national think tank on measuring CR effectiveness in September 2018 and to contribute towards discussions
regarding which indicators should be included in a set of Australian-wide quality indicators. The next step is to work towards the development and consensus of national CR quality indicators and an accompanying data dictionary to enable sites across jurisdictions to collect data in standardised manner. Further, next steps should include wide-scale consultation of the indicators including with state and territory departments of health. Further, it would be important to assess the accuracy of the data being collected and considerations for wide-scale benchmarking (e.g., development of risk-adjustment methods, outlier identification). Finally, the ultimate test of the selected quality indicators will be how useful they are for funders of CR programs; a key consideration for building sustainable business models and ensuring long-term implementation.

5.7 Additional studies

Since the meeting in September 2017, Moghei et al.\textsuperscript{183} have published a narrative review of CR quality indicators used internationally, which aligned with the results presented in Table 13.
PHASE 6: Disseminate

Share results to improve care for everyone
CHAPTER 6: IMPROVING THE MONITORING OF CARDIAC REHABILITATION DELIVERY AND QUALITY: A CALL TO ACTION FOR AUSTRALIA
6 Chapter overview

The South Australian Academic Health Science and Translation Centre (SA Translation Centre) offered to host a national think tank on CR effectiveness measurement on September 26th, 2018 with the aim to discuss state-based activities and future national directions. The NHFA and ACRA agreed to provide partnership for the event. This Chapter combines the outcomes and recommendations of the meeting in a ‘call to action’ and provides a collective voice of policy-makers, researchers and clinicians from across Australia drawing together key priority and recommendations for improvement.

A condensed version of this chapter has been published in Heart, Lung and Circulation (Appendix F) and the outcome of the national think tank was also disseminated via a communique (Appendix F).

6.1 Abstract

There is increasing momentum nationally and internationally to improve the monitoring of CR as a major pathway by which to enhance the quality of care delivered and outcomes for people living with heart disease. Many of the key challenges present twenty years ago regarding CR monitoring, including program structure and processes, utilisation rates and outcomes, remain today. Unlike other high-income countries such as Canada and the United Kingdom, Australia has no national registry or audit to monitor CR services. In September 2018, a national think tank was held to discuss current methods of monitoring the effectiveness of CR across states, and the next steps for implementing improved state and national evaluation systems. This discussion paper brings together the collective voice of policy-makers, clinicians and researchers within CR to provide clear recommendations to integrate current state-based initiatives within a national framework.

6.2 Introduction

In Australia, there are over 65,000 acute coronary events each year. Almost 625,000 people live with coronary heart disease (CHD). Improvements in acute treatment over recent decades (including advancements in risk-lowering medications and surgical interventions) have resulted in more people surviving a heart event and living with CHD. Among survivors, approximately 20% will suffer a second cardiovascular event in the first year.

Secondary prevention services, including CR, are a well-established, and effective form of preventing recurrent CHD events. There is strong evidence that greater uptake of CR can reduce the burden of disease and result in broader social and economic benefits. International and national guidelines have consistent recommendations on the importance of patient referral to CR based on the compelling evidence of the benefits
and return on investment. Despite this, referral rates of eligible Australian patients to CR is reported to as low as 30%\textsuperscript{189} due to range of barriers including at the system and service-level (e.g., lack of recommendation from doctors, lack of electronic referral systems). Other key issues, not unique to the Australian setting, include the fact that these programs are not well standardized and can be highly variable in their delivery and quality.\textsuperscript{84,157} The absence or dilution of positive effects of “real-world” CR trials (e.g., RAMIT\textsuperscript{67}), likely owing to such heterogeneity, highlight the need for mechanisms that promote fidelity such as minimum standards in the delivery of CR.

Unlike other high-income countries such as Canada, the United States, the United Kingdom and Europe, Australia has no national registry or auditing system by which to routinely monitor and evaluate CR service delivery.\textsuperscript{160} The CONCORDANCE registry\textsuperscript{190} does monitor evidence-based care of ACS in the acute setting (including referral to CR) across 41 Australian hospitals but does not monitor the quality of CR delivery. Ironically, twenty years ago, Australia was one of the very first countries to develop a comprehensive CR database, the Victorian Cardiac Rehabilitation Database (VCRD). This work provided a means of identifying patient participation rates\textsuperscript{191} and ascertaining long-term patient outcomes, including a 35% improvement in five-year survival.\textsuperscript{192} However, key barriers to platform maintenance, specifically with respect to resources, limited it sustainability.

Such challenges remain today. In addition, the quality of CR delivery and provision of evidence-based care (e.g., depression screening, optimal medical therapy) are not routinely evaluated, despite recommendations from the ACRA.\textsuperscript{56} In the past five years, multiple states across Australia have begun revisiting ways to routinely collect CR service data, independently working towards solutions. The NHFA, along with the Stroke Foundation, has recently been commissioned by the Commonwealth to develop a National Strategic
To capitalize on these national efforts, collaborative and cohesive national recommendations for CR are required.

In September 2018, a national think tank was held to discuss: current approaches to the monitoring and evaluation of CR services across different states, and identify and reach consensus on the next steps for implementing state and national evaluation systems. The meeting was hosted by the South Australian Academic Health Science and Translation Centre (SA Translation Centre), in partnership with ACRA and the NHFA. Australian researchers (N=9), clinicians (N=7), policy-makers (N=8), and consumer representatives (N=2) attended, with at least one representative from each State or Territory.

The aim of this discussion paper is to summarise the key outcomes of the think tank including: 1) the current state-based initiatives for monitoring the quality of CR delivery including quality indicators used and the possibility for existing initiatives or infrastructure to be used to capture CR; 2) threats and opportunities to these initiatives; and 3) consensus-based recommendations for national monitoring. We conclude by issuing a ‘call to action’ for a national approach that leverages off existing work undertaken in states and territories to enhance the quality and delivery of care for patients recovering from a cardiovascular event.

6.3 Inventory of current state-based initiatives monitoring the quality of CR

Representatives from each state and territory provided a summary of their respective approaches to measuring delivery and effectiveness of CR services (Table 16). Overall, progress varied widely. In two states state-level CR data are actively collected as part of routine care: (1) Queensland incorporates CR data into the Queensland Cardiac Outcomes
Registry (QCOR)\textsuperscript{194}, and currently captures data from 43/48 public hospital outpatient CR sites; (2) South Australia has had a minimum dataset and database\textsuperscript{195} since 2013, and has since conducted 3 state-wide audits comprising 24 rural and metropolitan services.\textsuperscript{195} Western Australia, the Northern Territory and Tasmania reported no methods in place for routinely capturing state-level CR data. It was reported that pilot studies were underway in New South Wales (including data from the Australian Capital Territory) and Victoria, both applying methods by which to extract data from sites using quality indicators developed by New South Wales.\textsuperscript{66}

Table 16 CR quality initiatives by relevant Australian states and territories

<table>
<thead>
<tr>
<th>State</th>
<th>Year</th>
<th>Initiative</th>
<th>Outcome</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>QLD</td>
<td>2015</td>
<td><em>Queensland Cardiac Outcomes Registry (QCOR)</em></td>
<td>43/48 outpatient sites included</td>
<td>Active</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Established by the Statewide Cardiac Clinical Network to collect and use clinical data to provide insights into the quality and safety of cardiac care across Queensland in public patients (and to include private providers soon)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• In 2017, QCOR added a CR module to the registry which captures CR referral, pre and post-CR assessments performed in sub-acute and community-based outpatient settings (e.g., change in exercise capacity, depression screening, risk factors). The two main outcome measures are 1) timely referral and 2) timely assessment.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NSW / ACT</td>
<td>2015</td>
<td><em>NSW Minimum Data Set Working Party</em></td>
<td>Development of quality indicators and a data dictionary, piloting data collection.\textsuperscript{66}</td>
<td>Piloting</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• NSW divisions of ACRA and NHF plus the NSW Agency of Clinical Innovation have developed a set of CR quality indicators and a data dictionary which are currently being piloting across 41 sites in NSW, ACT and Tasmania, collected via Excel spreadsheets</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Collected minimum data from 66 CR programs across Victoria; was linked to</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

150
outcome registries (Victorian Admitted Episodes Dataset and the Victorian Death Registry) later).

### 2017

**Victorian Cardiac Rehabilitation Registry feasibility study**

- Authors ET, AO, SG, RG and DC have re-examined the feasibility of establishing a Victorian CR registry using a data capture tool ‘GRHANITE’.
- Piloted use at two sites (public and private).

Data are largely unavailable in an appropriate electronic format. A web-based template (REDCap) enabled minimum CR data to be entered by clinicians and collated.

Pilot funding from University of Melbourne (ended Dec 2017)

### SA

- **2012**
  - Development of a minimum CR dataset

- **2015**
  - Introduction of a central, web-based database with uniform, standardised data entry used by metropolitan and country clinicians as part of routine practice.

### 2018

- State-wide data linkage program
  - Developed state-based quality indicators

Quality indicators to be built into the Department of Health’s ACS dashboard which will facilitate monitoring of the effectiveness, appropriateness and efficiency of care provided during the ACS patient journey.

### TAS

- **2017**
  - Contributed data towards the NSW pilot data collection.
  - Regular, ongoing state-wide audits and service level reports.

Active since 2012

Funded by SA Health, local health networks Department of Cardiology, Flinders University, SA Translation Centre. Future sustainable funding is not confirmed.

<table>
<thead>
<tr>
<th>Acronyms: ACT: Australian Capital Territory; CR: cardiac rehabilitation; NSW: New South Wales; QLD: Queensland; SA: South Australia; TAS: Tasmania; WA: Western Australia; n/a: not applicable</th>
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<th></th>
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<tbody>
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</tbody>
</table>
6.3.1 Scan of Australian CR quality indicators

An absence of a uniform set of quality indicators (including process and outcome quality indicators) was noted. The ACSQHC have developed clinical care standards for ACS\textsuperscript{168} which has one indicator (Indicator 6) that refers to referral to CR, however, the standards do not extend beyond discharge from the in-patient setting. A comprehensive set of >70 indicators were developed back in 2015 as part of a CR core components initiative\textsuperscript{56}, however, these were not rigorously developed. Further, it was deemed infeasible to collect this volume of data, with a clear imperative to identify a minimum data set of essential indicators for monitoring and evaluation. A key output was mapping the quality indicators that are being used across the four currently active jurisdictions (Table 17).

Table 17 Quality indicators currently collected across Australian jurisdictions

<table>
<thead>
<tr>
<th>Area of care</th>
<th>Quality indicator collected across states</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>NSW/ACT</td>
</tr>
<tr>
<td>Referral to CR</td>
<td>X</td>
</tr>
<tr>
<td>Timely commencement of CR</td>
<td>X</td>
</tr>
<tr>
<td>Assessment of adiposity</td>
<td>X</td>
</tr>
<tr>
<td>Assessment of depression</td>
<td>X</td>
</tr>
<tr>
<td>Assessment of smoking status</td>
<td>X</td>
</tr>
<tr>
<td>Assessment of diabetes</td>
<td>X</td>
</tr>
<tr>
<td>Assessment of physical activity level</td>
<td></td>
</tr>
<tr>
<td>Assessment of alcohol consumption</td>
<td></td>
</tr>
<tr>
<td>Quality of life</td>
<td></td>
</tr>
<tr>
<td>Adherence to medication prescription</td>
<td></td>
</tr>
</tbody>
</table>
### Assessment of medication adherence

<table>
<thead>
<tr>
<th>Item</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assessment of medication adherence</td>
<td>X</td>
</tr>
<tr>
<td>Referral of patients screened positive for depression</td>
<td>X</td>
</tr>
<tr>
<td>Referral/counselling for smokers</td>
<td>X</td>
</tr>
<tr>
<td>Change in exercise capacity</td>
<td>X</td>
</tr>
<tr>
<td>Unplanned hospital admissions of a cardiac cause within 30 days and 12 months</td>
<td>X</td>
</tr>
<tr>
<td>Program completion</td>
<td>X</td>
</tr>
<tr>
<td>Discharge communication</td>
<td>X</td>
</tr>
<tr>
<td>Referral to ongoing care</td>
<td>X</td>
</tr>
</tbody>
</table>

**Acronyms:** ACT: Australian Capital Territory; CR: cardiac rehabilitation; NSW: New South Wales; QLD: Queensland; SA: South Australia; WA: Western Australia

### 6.3.2 Implementing and scaling up a national approach to improving CR quality and monitoring

Established Australian registries that could potentially be expanded to incorporate CR data were identified. These included the Victorian Cardiac Outcomes Registry ([https://vcor.org.au/](https://vcor.org.au/)) which collects clinical and quality of care information for specific cardiac diagnoses / interventions in the in-patient setting (percutaneous coronary intervention, management of acute STEMI in regional and rural centres) and one module in the out-patient setting (heart failure) in Victoria. Additionally, the Australian Rehabilitation Outcomes Centre (AROC: [https://ahsri.uow.edu.au/aroc/index.html](https://ahsri.uow.edu.au/aroc/index.html)) is the custodian of a national registry focused on rehabilitation outcomes, and includes data from a range of conditions including stroke, spinal injuries, and amputation.

Lessons can also be applied from diseases that have established quality monitoring and improvement programs. For example, the quality of stroke care delivery in Australia is assessed via two complementary national programs that use the same integrated data...
management system (Australian Stroke Data Tool) to avoid duplication of data entry for overlapping variables: the Australian Stroke Clinical Registry (http://www.auscr.com.au/) and the Stroke Foundation audit program (https://informme.org.au/en/stroke-data). These complementary programs are used to routinely assess adherence to national clinical guidelines with the audit being a cross-sectional comprehensive audit in a small number of cases with information on organisational resources also collected, whereas the registry is continuous and includes PROMs three to six months post-index event and long-term survival from linkage with the national death index.

6.4 Threats and opportunities to CR quality initiatives in Australia

Assessing and improving CR services requires the implementation of system-wide innovations with developed governance structures, infrastructure and sustained financial investment. To enhance developments in these areas, during the think tank we identified the following key gaps and opportunities to advance the monitoring and quality of CR services across Australia.

Governance

A well-developed strategic plan and a governance committee will be crucial to the success of a quality CR registry. Formal governance structures are required to oversee a clinical registry's operations according to the ACSQHC\textsuperscript{93} which recommends that Australian clinical registries make clear, publicly-available statements about governance structures including data ownership and custodianship. It was agreed that the national governance committee should involve representation from the NHFA, ACRA, clinicians entering data, researchers and consumers.
6.4.1 **Champions and Advocacy**

Initiatives that support the delivery of high-quality CR require champions at high levels of medicine and policy. Cardiology is a highly influential discipline, and members of this discipline, along with the allied health and nursing community are critical to the success of sustainable CR initiatives at the national level. The European Association of Cardiovascular Prevention and Rehabilitation has made efforts to combine acute cardiology care and allied health-led secondary prevention together under the umbrella of 'preventive cardiology' with the aim of developing a comprehensive model of care with a long-term focus on cardiovascular health. It is important that national associations such as ACRA and CSANZ continue to foster strong inter-disciplinary collaboration regarding CR in Australia. Further, these activities need to be translated into initiatives that monitor service delivery and quality (e.g., registries) to ensure the whole continuum of care is captured.

Another opportunity for advocacy is the representation of CR professionals and advocates on state-based cardiac government health policy and cardiac clinical networks. Queensland has been very effective in working with cardiac networks to implement their cardiac registry, an approach that could be applied in other states.

National organisations and professional societies and associations are well placed to advocate the importance of CR services in Australia. The NHFA has been a long-standing champion for increased availability of, access to and participation in CR. It has long endorsed the collection of uniform quality performance measures for this purpose. The NHFA's presence in every state and territory as well as its engagement with the federal government and state and territory governments provides it with a platform to advocate for national coordination. ACRA, as a peak body, also has state and national governance committees enabling a coordinated voice for CR health professionals.
6.4.2 Disparate data collection

State-wide data collection has progressed more easily and rapidly in jurisdictions that have centralised data systems (e.g., South Australian Health) and/or high connectivity across in-patient and out-patient care (e.g., via the Queensland Health information and technology infrastructure available in Queensland). An absence of this overarching infrastructure requires more flexible data collation formats (e.g., web-based tools that collate data from across disparate health systems).

Globally, eight countries have developed quality indicators for CR. Across Australia, some states (e.g., Queensland, New South Wales and South Australia) have independently developed quality indicators. Working in silos has resulted in some inconsistencies, including heterogeneity or lack of operationalisation of key variables (Table 2). This has limited comparability of data across jurisdictions. The development of a national CR registry that reports on nationally developed quality indicators in a consistent format would enable standardised data to be collected and reported across Australia in-keeping with metadata reporting standards (METeOR; https://www.aihw.gov.au/about-our-data/metadata-standards).

6.4.3 Auditing of CR quality

Systematic reviews provide evidence that auditing clinical practice, when combined with timely feedback, is an effective way of improving care quality. The NHFA have recognised that a national CR audit is a key action required to tackle heart disease; the requirements of which should be considered and importantly, a business case developed. A national CR registry or audit would enable national quality indicators to be reported upon which would provide a foundation for quality improvement initiatives.
6.4.4 Data entry burden

Collection of CR data beyond the site-level (e.g., a state-based or national registry or audit) requires the recruitment of individual sites, and the completion of high-quality patient data entered in a timely manner.

Technology-based innovations, such as web-based tools can improve the data entry process in registries by providing secure log-ins, standardised templates with drop-down options, mandatory fields (to reduce missing data) and real-time feedback via automated reports. To reduce the data entry burden on sites with limited resources and capabilities, options can be provided on the amount of data they provide (e.g., minimum data only or maximum data). A ‘traffic light’ system has been successfully used in the Australian Stroke Data Tool for the audit and registry programs, enabling sites to use discretion about collecting data beyond the minimum data set. The developers of the Canadian Cardiac Rehabilitation Registry have developed a purpose-built, clinician management and data collection software called ‘Cardiologica’. This platform enables mobile and tablet-based information to be uploaded, therefore enabling patients to enter some of their own data directly as a time saving mechanism.

Where possible, data may also be able to be automatically filled from hospital administrative databases to reduce the data entry burden. A flexible, automated data capture tool such as what has been used widely in primary care (e.g., GHRANITE™) may have significant potential to pre-fill data in the future as CR sites transition to more electronic forms of data collection. Further, a free, online system for research and practice, the REDCap system has been widely available in public hospitals and universities across Australia and used internationally. REDCap provides a cost-effective option for standardised data collection and has been integrated into EMRs in some Australian hospital settings.
Carefully devised incentives for data entry also need to be considered. Queensland has used a Quality Improvement Payment system within QCOR. For the CR module this provided financial payments to acute care sites who enter CR referral data within three days of eligible patients being discharged from hospital, and a further payment to CR sites if the referred patient attends an initial assessment within 28 days. This quality improvement payment was successful in encouraging data collection and has now been withdrawn with the data now included within mandatory reporting requirements of the hospitals. Conversely, one-off fixed term payments to health departments, which have been tried in Western Australia and Victoria, were not effective. A key difference is that Queensland embedded financial incentives into the data collection process, rewarding the CR site directly where possible (rather than incentives being directed at the health service, more broadly). Such an approach may be useful for initial buy-in but does not appear sustainable in the long term. Consequently, non-financial incentives need to be considered such as incorporating data entry into improved clinician management systems which have additional benefits for clinicians such as the ability to deliver automated reports at the service-level (e.g., service participation rates, adherence to quality indicators like 30-day wait times) and the individual-level (e.g., patient discharge reports).

6.4.5 Data linkage

Access to patient admission databases would help determine the denominator (the total population eligible to attend CR (i.e., ACS ± revascularisation, heart failure), and data linkage would further enable assessment of the clinical impact of the service (long-term patient outcomes (e.g., hospital readmissions, mortality)). An essential requirement for data linkage is a reliable linkage variable. The development of the My Health Record, a federal government initiative to provide an online, secure summary of all Australian’s health information, and the accompanying development of an Individual Healthcare Identifier will likely prove useful for data linkage purposes in the future. Linkages between new and
existing registries and administrative data as well as other clinician databases such as pathology and imaging records, will further increase the value of the available cardiac information, provide an evidence base for research and model of care development, and improve the effectiveness of service performance monitoring. Departments of Health across states and territories have expertise in data collection and linkage which can potentially be accessed via cardiac clinical networks. One barrier to accurate data linkage is the lack of a consistent ‘cardiac rehabilitation code’ used across health service reporting; a potential solution lies in the use of an International Classification of Disease “cardiac rehabilitation” code (code ‘z50.0’ in ICD-10 Australian Modification\textsuperscript{201}; code QB95 in the ICD-11 Version 2018\textsuperscript{202}). Utility of this code within the outpatient setting would need to be assessed.

6.4.6  \textit{Electronic Health Infrastructure}

EMRs have potential to enhance CR data collection yet remain under-utilised. To ensure more than 'electrifying' of the current workload, eHealth needs to be viewed as a platform to enable innovation in care delivery (i.e., dual use of data for clinical and quality purposes). During this time of technology transition, it is important to clearly define the desired uses and outcomes of the technology, rather than the outcomes being defined \textit{by} the technology. The gold standard of EMR systems is ‘integrated care’ whereby data collected on a patient across the continuum of care is collated. For instance, Queensland Health has heavily invested in their integrated-EMR system which is being rolled out across hospital sites enabling integration of pathology, vital signs (e.g., pulse, blood pressure), pharmacy and administrative data. Such an integrated model holds potential for increasing timely access for clinicians to accurate medical information, reducing variation in care processes and enhancing the coordination of patient care across the continuum from prevention through to end-stage care.
6.4.7 National guidelines

Clinical practice guidelines provide evidence-based recommendations regarding what constitutes quality CR delivery. In 2004, the NHFA released a Recommended Framework for CR and ACRA released a core components document in 2014. Both are widely utilised by clinicians however neither are clinical guidelines. Recently, the NHFA and the CSANZ developed national clinical guidelines for ACS, atrial fibrillation and heart failure. Other countries have rigorously developed CR guidelines that are continually being updated; for example, the American guidelines are currently under review. Although we acknowledge the complexity and cost of their development, there remains a pressing need to revisit this issue. Developing specific Australian clinical guidelines for CR to establish what constitutes quality CR delivery within the Australian context will be critical for promoting evidence based best practice.

6.4.8 Sustained funding

While high-quality registries provide a good return on investment, securing funding for the establishment, broad-scale adoption, and long-term sustainability of registries is notoriously challenging. This is likely why many CR registries have not been maintained. Opportunities for funding exist with research funding sources, commercial industries and government health departments. The recent creation of health research translation centres (https://nhmrc.gov.au/research-policy/research-translation-and-impact/recognised-health-research-and-translation-centres) across the country provide additional possibilities for this work. Funding proposals need to be developed within a broader strategy that incorporates an understanding of the current political environment and an acute understanding of the key beneficiaries of accurate CR data.
6.5 Consensus-based recommendations

After discussion of the threats and opportunities of CR initiatives, national think tank participants unanimously agreed to develop national quality indicators that assess CR quality. Consensus was reached on the establishment of a national taskforce with representation from the NHFA, ACRA, and the key CR state-wide initiatives outlined in Table 1 (including a representative from South Australia, Queensland, Victoria and New South Wales). The taskforce’s primary responsibility is to develop a set of national quality indicators and an accompanying data dictionary (aligned with the Australian reporting standards) for CR that can be consistently collected and reported across states and territories. Drafted indicators will be disseminated for feedback to the remaining members of the think tank along with other identified stakeholders (e.g. cardiologists, policy-makers, those with expertise in registries) as well as CR clinicians via ACRA networks.

The growing momentum across jurisdictions suggests it is timely to capitalise on the past and ongoing activities in CR monitoring to improve outcomes for people living with heart disease. Authors of this ‘call to action’ have provided the following recommendations and suggested plans for implementation to further capitalise on state-based initiatives and improve the quality of cardiac care across Australia (Table 18).

<table>
<thead>
<tr>
<th>Issues</th>
<th>Recommendations</th>
<th>Suggested plans for implementation</th>
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<tbody>
<tr>
<td>Lack of national governance</td>
<td>Develop an overarching body for CR measurement</td>
<td>Establish a national steering committee with representation from the NHFA, ACRA and key leaders working on CR quality initiatives</td>
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<td></td>
<td>Optimize the broader advocacy capacity of the steering committee (e.g., to state and territory health departments, government, national associations like CSANZ, and clinicians via ACRA)</td>
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<tr>
<td></td>
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<td>Ensure early communication to key stakeholders that a</td>
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</table>
quality indicator taskforce has been established

Develop a plan for and appropriate sub-committees for the development of a national registry and quality improvement projects.

| Lack of clinical champions for CR | Determine key champions for improving monitoring of CR | Identify leading clinicians (e.g., cardiologists, surgeons) willing to champion CR quality indicators to be included in broader cardiac outcome registries
Disseminate lessons learnt from states (e.g., QLD, NSW) that have successfully championed for CR through clinical cardiac networks
Maximize advocacy potential of NHF/ACRA |
| Disparate data collection within and across states and territories. | Develop a national cardiac registry that collects a minimum dataset of CR variables | Support the national taskforce to develop CR quality indicators and an accompanying data dictionary that can be uniformly reported across jurisdictions. Apply for funding to combine standardised data collected across states and territories into a national CR registry |
| Data entry burden | Use technological innovations to reduce data entry requirements | Promote the use of web-based data entry tools and automatic pre-filling of data to reduce data entry errors, time / staff burden and cost |
| Limited data linkage/integration | Ensure systematically collected CR data can be linked to administrative data (e.g., death registries, hospital admissions) | Determine minimum requirements/variables to enable data linkage across datasets
Consider integration with other well-established registries (e.g., VCOR, AROC) |
| E-Health infrastructure under-developed | Improve access to EMRs within CR settings | Scoping exercise of best software options
Develop a business plan for enhanced EMRs, which defines the desired outcomes of EMRs within CR
Implement |
| Limited reporting requirements at the state/national level |Enhance state-based reporting of CR | Explore potential of applying for an MBS item code for CR
Explore whether QLD’s quality incentive payment scheme would be effective in other states |
<p>| No recent national evidence-based CR guidelines, with applicability to | Develop a business case for CR guidelines |</p>
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<tr>
<th><strong>guidelines for CR</strong></th>
<th><strong>Australian setting</strong></th>
<th><strong>Determine if CRA, NHF and other key associations will endorse</strong></th>
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</table>
| **Limited funding** | Secure sustained investment into CR monitoring initiatives | Complete a scan of potential funding options  
Use collected data to show variation in clinical practice and the value of improved and standardised reporting on the delivery and quality of CR |

**Acronyms:** ACRA: Australian Cardiovascular Health and Rehabilitation Association; AROC: Australian Rehabilitation Outcome Centre; CR: cardiac rehabilitation; CSANZ: Cardiac Society of Australia and New Zealand; NHF: National Heart Foundation; NSW: New South Wales; MBS: Medicare Benefits Scheme; QLD: Queensland; VCOR: Victorian Cardiac Outcomes Registry

### 6.6 Conclusions

In summary, a national approach, that leverages work already undertaken in states and territories, is required to enhance the quality and delivery of care for patients recovering from a heart or circulatory event. This ‘call to action’ brings together the collective voice of policy-makers, clinicians and researchers within CR and provides clear recommendations to integrate current state-based initiatives within a national framework. Since the think tank, a national taskforce has been developed and is working towards the development of national CR quality indicators to enable standardised reporting of CR across jurisdictions.
CHAPTER 7: DISCUSSION AND CONCLUSIONS
7 Chapter overview

In this chapter a summary of the main research findings from the preceding chapters are outlined, as well as the strengths and limitations of the research. Additionally, implications for policy and practice are discussed and recommendations for future research are highlighted.
7.1 Summary of findings

The overarching aim of this thesis was to investigate feasible methods to improve the monitoring of CR quality and delivery across Victoria, Australia. The work was guided by the rapid-learning healthcare system model and four research objectives were addressed, as follows:

**Objective 1:** To determine whether attendance of a CR program is associated with reduced hospital readmissions post-discharge in Victoria.

In Chapter Two, evidence was presented demonstrating that in a Victorian ACS population, CR attendance was not associated with all-cause hospital readmission. However, CR attendance was associated with reduced frequency of hospital admissions and length of stay in the 24 months following ACS. Given the majority of healthcare costs post-ACS are driven by hospitalisations, reductions in frequency and length of stay have the potential to reduce CVD healthcare expenditure and offset the cost of delivering CR. These results corroborate studies by Canyon and Meshgin\textsuperscript{103} as well as Zwisler et al.\textsuperscript{109}, which demonstrated the benefits of CR in regard to length of stay but no significant benefits in overall unplanned hospital admissions. Other studies with larger sample sizes\textsuperscript{104} and longer follow-up periods\textsuperscript{116} appear to have more pronounced findings. Further reduction in hospital admissions may be possible with enhanced delivery of CR (e.g., dose\textsuperscript{88}, delivery of a ‘comprehensive’ program targeting more than six risk factors\textsuperscript{74}) and quality (e.g., ensuring CR is provided in a timely manner, evidence-based content is delivered, risk factors are screened, ongoing coordination of care is provided and communicated\textsuperscript{84}). This study provides further evidence for the impact of CR on readmissions rates in a contemporary ACS population.
In the systematic review (Chapter Three), it was identified that seven national CR registries and one international (Europe) registry had been established globally. Of the identified registries, five were active (Austria85, Canada138-140, Denmark141, the United Kingdom146 and the United States145). As such, systematic evaluation of CR programs via registries was demonstrated to be in the early stages of development. Since the completion of this review, no further registries have been identified, although via personal communication it is believed that CR teams in China have begun work on establishing a CR registry (currently no published record of this work is available in English). Successful CR registries were reported to: 1) collect uniform data (e.g., core minimum data); 2) ensure collected data are of interest to all stakeholders (e.g., CR clinicians, funders of services) to enhance engagement; 3) enable linkages to administrative databases to determine service-level information and long-term health indicators; 4) use web-based applications to import data and pull from EMRs where possible; 5) embed continuous data quality checks into the registry design; 6) provide timely feedback; and 7) have adequate and sustainable funding sources. When well-developed, registries have enormous potential to enable the systematic collection of CR data, provide timely and individualised feedback and improve the provision of care.

This study is the first of its kind to provide a synthesis of evidence for national and international CR registries. Similar efforts have been undertaken regarding stroke registries.133 Identified barriers and facilitators of this review aligned with the broader literature on CVD registries.94,130 The findings of this study were important for guiding the development of the VCRR feasibility study (Chapter Four) by providing the ability to determine the most commonly collected data in CR registries internationally, and the

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**Objective 2:** To identify and describe how CR programs are monitored and evaluated internationally.
methods used for data collection. Further, the review contributes to the international literature by highlighting the barriers and facilitators to the establishment and ongoing sustainability of CR registries.

Clinical registries play an important role in measuring healthcare delivery and supporting quality improvement. Australia and other countries appear set for an increase in the establishment of registries in prioritised health areas as the reporting of the quality and safety of care increases. Consequently, this review provides an important contribution to the literature to ensure the true potential of these tools for CR are achieved.

**Objective 3:** To investigate the feasibility of implementing a CR registry in Victoria.

Once it was identified that comparable countries are successfully auditing CR programs via registries, the focus of the thesis shifted to the determination of how this could be done in Victoria. Findings from the systematic review (Chapter Three) were used to inform the feasibility study presented in Chapter Four. This study was designed to assess the feasibility of using a data capture tool and web-based platform to collate data from a CR public and private site in Victoria.

Evidence from the feasibility study showed that while a data capture tool has promise in settings with well-designed EMRs, electronic health infrastructure at the pilot sites was not sufficiently developed to the level that could support this approach. As an interim solution, a web-based data entry platform (e.g., REDCap) enabled variation in practice to be manually captured and was supported by those entering the data. Data collection via the REDCap platform shows promise as an approach that should be explored further given it is accessible, easy to use and affordable to use, and could enable the monitoring of CR quality across the private and public sectors.
The transition to digital health systems holds great potential for enhancing clinical care within the CR setting. 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. The findings highlight important recommendations to enhance the viability of automated data-capture technologies in the future, reducing the burden of data collection placed on time-poor CR clinicians.

**Objective 4:** To provide recommendations for improving the monitoring of CR delivery and quality.

In Chapter Six, a 'call to action' is presented incorporating outcomes from a national think tank on improving CR measurement across Australia. This chapter provides collective recommendations from policy-makers, clinicians and researchers from across Australia. The establishment of a national CR registry requires the development of agreed quality indicators and a standardised data dictionary, carefully established governance structures, and enhanced advocacy efforts to ensure sustained funding. Additionally, the development of CR guidelines and enhanced use of technology (including access to EMRs) is required to improve the quality and delivery of care for patients with CVD. Progress towards these recommendations has begun via the development of a CR Quality Indicator Taskforce (of which I am a member) that is developing standardised national quality indicators for CR. A summary of recommendations to integrate current state-based initiatives within a national framework is provided in Table 19.

### Table 19 Summary of the call to action recommendations

<table>
<thead>
<tr>
<th>Recommendations for improving the monitoring and delivery of CR across Australia</th>
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Chapter 7 – Discussion and conclusions

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<tr>
<td>3</td>
<td>Improve access to EMRs within CR settings</td>
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<tr>
<td>4</td>
<td>Develop evidence-based CR guidelines, with applicability to Australian setting</td>
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<tr>
<td>5</td>
<td>Secure sustained investment for CR monitoring initiatives</td>
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**Registry-specific recommendations**

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<tbody>
<tr>
<td>1</td>
<td>Develop a national cardiac registry that collects a minimum dataset of CR variables</td>
</tr>
<tr>
<td>2</td>
<td>Use technological innovations to reduce data entry requirements</td>
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<tr>
<td>3</td>
<td>Ensure systematically collected CR data can be linked to administrative data (e.g., death registries, hospital admissions)</td>
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<tr>
<td>4</td>
<td>Investigate incentive to enhance state-level reporting of CR</td>
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**7.2 Implications of findings**

**7.2.1 Implications for a Victorian state-wide CR registry**

The findings of this thesis support the roll out of a web-based platform that enables standardised data to be collated at the state-level with potential broader application. In order to collate CR data, CR clinicians have indicated a need for: 1) standardised quality indicators to assist with knowing what data are the most important for collection; 2) an easy to use, web-based software program that would enable quick and high-quality data collection; and 3) a software program that would also assist with daily patient management tasks such as writing discharge summaries. Development of national quality indicators and use of more advanced software systems (e.g., such as the Canadian CR registry software, Cardiologica) appear to be appropriate endeavours to undertake to enable reliable national, and potentially international, comparison of CR data. Implementation of a CR registry provides the potential to track and enhance referrals to CR, capture the patient reported outcomes and experience measures, link to health outcomes such as readmissions, and
benchmark care delivery, thereby enhancing the access and quality of secondary prevention care received by patients with heart disease.

7.2.2  Improving Victoria’s digital health infrastructure

Future digital health investments will be driven by specific business needs and the identification and demonstration of local and system-wide benefits. 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.

In Victoria, the previous HealthSMART initiative was aimed at reforming the IT ecosystem with a ‘one-size-fits-all approach’ but was deemed unsuccessful and eventually abandoned after more than $300 million of investment. Consequently, the responsibility of developing digital solutions was placed back on health services providers resulting in a wide range of clinical information systems being implemented to varying degrees across hospitals and health centres in Victoria. Therefore, flexible tools like GRHANITE™ will be crucial in enabling interoperability of data across various systems (including public and private), while adhering to privacy and security concerns.

A first step for CR services, however, is ensuring CR data are collected in electronic formats and transition away from paper and scanned medical records. To enable this, electronic platforms need to: 1) be accessible to CR sites, 2) be fit for purpose, and 3) capture high quality data. In general, allied health and community-based settings have had low-levels of adoption of electronic health infrastructure compared to acute settings and primary care and greater emphasis must be placed on ensuring CR staff have access to EMRs. However, data collected in any electronic database are only as good as the information that is entered;
therefore, routine quality checks are required and design features incorporated to reduce missing data or entry errors (e.g., mandatory fields).

Better linkages between new and existing data registries (e.g., the Victorian Admitted Episodes Database) will further increase the value of the available information, provide an evidence base for research and improve the effectiveness of service performance monitoring. The use of an individual healthcare identifier such as that being proposed via the My Health Record initiative (a federal government initiative currently being rolled out across Australia that aims to provide a secure online summary of an individual’s health information; www.myhealthrecord.gov.au) may prove useful in this area. The ability of data capture tools such as GHRANITE to import data from centralised databases (i.e., My Health Record) requires additional exploration.

7.2.3 **Implications for a national CR registry**

In Queensland and South Australia there are already state-wide registries/audits of CR sites. New South Wales is currently piloting methods of data collection from their CR sites and are also including data from the Australian Capital Territory and Tasmania. Therefore, if data collection of CR sites in Victoria can be advanced and aligned with the other states, there would be large potential for data to be aggregated at the national level. Further, the enhancement of a web-based tool, such as REDCap or Cardiologica, that enables the collection of nationally-agreed quality indicators may also be useful for other states and territories (e.g., Western Australia and the Northern Territory) that currently have no means to collect or monitor data beyond the individual site level.

A national CR registry would require carefully developed governance structures, policies and processes that align with the standards set by the ACSQHC. The work of this thesis, in particular the call to action (Chapter Six), has provided a foundation for engaging different
stakeholders including consumers and end-users from different jurisdictions to come together; as demonstrated by the development of a national taskforce on quality indicators for CR.

Additionally, an Australian Cardiac Outcomes Registry has previously been attempted that was to include data for a range of cardiac interventions and outcomes. This national registry has not been successfully established. However, the Commonwealth government appears to be invested in the re-establishment of a national cardiac registry. This follows the ACSQHC report\textsuperscript{154}, which ranked ischaemic heart disease as the highest priority area that would benefit from registry development due to the high burden of disease, serious consequences associated with poor quality care and strong clinical support. While the government is currently engaged in this issue, it is important that those working within CR are organised and ready to capitalise if a national program of work does eventuate. CR variables would need to have been prioritised and defined, ready to be included in a cardiac registry that encompasses the whole continuum of care.

7.2.4  \textit{The role of state government (Department of Health and Human Services)}

As the major funder and overseer of the Victorian public health system, the DHHS has a large role to play in the collection of state-level data that aims to improve care quality and reduce care variation. The DHHS currently has a renewed focus on care quality and safety due to a cluster of avoidable infant deaths that occurred at a Victorian hospital between 2013 and 2014. This event resulted in an external review of the DHHS’s processes culminating in the Targeting Zero report\textsuperscript{206}, which found that the DHHS had neither adequate oversight, (including systems and information) to ensure the Victorian hospital system was providing consistently safe and high-quality care, nor adequate processes to support hospitals to efficiently and effectively strengthen care. As a result of the recommendations within the
report, the DHHS made safety and quality improvement a core goal and established an office (Safer Care Victoria) solely focused on driving state-wide quality improvement.

Regarding cardiac care, the DHHS has delineated its priorities in the *Design, service and infrastructure plan for Victoria’s cardiac system* (the ‘cardiac plan’).\(^9\) Embedding an innovative data collection and patient management tool into routine CR service delivery, will facilitate the achievement of the following priority themes of the cardiac plan: 1) developing a system-wide plan for improved CR; 2) improving data collection across the continuum of care and developing key performance indicators to monitor service effectiveness (including patient experience and outcomes and system performance such as benchmarking between hospitals to drive service improvement); and 3) improving data collection systems to strengthen the capacity of researchers to access useful data in a collaborative way. Therefore, the DHHS is an important stakeholder and potential funder of the scale-up of this work. Currently, the DHHS has committed to funding 20 clinical quality registries including VCOR, and early discussions have commenced for the CR registry following on from the pilot work within this thesis.

The DHHS also has an important role regarding data linkage as it is currently involved in the collection of multiple state-level databases and has specific expertise in data linkage via the Victorian Agency of Health Informatics. Opportunities for data linkage are growing. The national- and state-based infrastructure for supporting greater data linkages across a range of administrative datasets is planned to expand significantly. With appropriate consent, those working in CR, can take advantage of this infrastructure to have more data to enhance our understanding of the effect of CR on various subgroups of the population, or the longer-term adherence to secondary prevention medication, hospital readmissions, or frequency of accessing primary care services through interrogation of various Medicare Benefits Scheme claim items e.g., use of chronic disease management plans.
7.2.5 The role of national associations or organisations

National associations such as ACRA, CSANZ and the NHFA have important roles in advocating for improved monitoring or CR via registries and/or audits at the national level. The thesis highlights important challenges of monitoring the effectiveness of CR across all states and territories and provides clear, consensus-based recommendations (Chapter Six) that can now be used by these associations to enhance advocacy efforts in upcoming national strategies (e.g., the Heart and Stroke Action Plan that is currently being developed).

Further, these associations have built strong relationships with important stakeholders and can engage champions such as policy-makers and health service providers to promote the work and garner momentum in this effort. Additionally, ACRA and the NFHA have been important stakeholders in the development of national CR quality indicators and currently co-chair the taskforce committee. These associations could also use their well-established positions to advocate for standardised reporting of CR (such as via the use of the International Classification of Disease ‘cardiac rehabilitation’ code). As these associations have representatives in every state and territory, they are extremely instrumental in drawing together cohesive projects and strategies at the national level.

7.2.6 The future of cardiac registries and the international context

Expansion of registries globally. In a statement on the future of registries by the American College of Cardiology and the AHA it is stated that over the past decades in delivering medical care two developments are particularly noticeable: “1) an increasing emphasis on measuring and improving the quality and efficiency of medical care; and 2) the proliferation of clinical registries designed to understand care and outcomes in ‘real-world’ settings”.94(p1927) The development and use of registries in the United States and other countries such as Sweden (that has established more than 100 clinical registries) is much further advanced than in Australia. However, it does appear that Australia is set for a large
increase in the measurement and reporting of care safety, efficiency and quality. The focus of organisations such the ACSQHC, which has developed standards for establishing clinical registries in Australia and a framework for their use,\textsuperscript{93} highlights the growing focus on registries in the future.

\textit{Registries in the era of electronic health records.} The advancement of ‘big data’ methods could enable registries to be created from centralised systems rather than individual groups and associations developing their own disease-specific registries. An advantage of centralised data is the possibility of tracking patients across the continuum of care. The Ministry of Health in Singapore has established a National Registry of Disease Office that amalgamates data on major non-communicable diseases into one central place (see \url{https://www.nrdo.gov.sg/}). This approach has multiple benefits: it enables greater linkages to other datasets, provides a platform for measuring co-morbidities, minimises the risks associated with individual associations establishing registries (e.g., maintaining funding), and reduces the burden on individual sites to manually enter data. However, reliable data linkage at an individual level continues to be a challenge for many countries that must ensure robust systems that meet both confidentiality and security standards for the projection of the individual.\textsuperscript{207}

Integrated EMRs are a burgeoning tool and are being incorporated into clinical practice all over the world. Queensland Health is currently upgrading their EMR system to enable integration of EMRs with patient monitoring devices that automatically upload vital signs and observations (e.g., temperature, heart rate and blood pressure; see: \url{https://www.health.qld.gov.au/clinical-practice/innovation/digital-health-initiatives/queensland/integrated-electronic-medical-record-iemr}). The system enables further integration with pathology data, pharmacy information systems, pathology and administrative databases. This development has large possibilities for the Queensland

In relation to Victoria’s ICT infrastructure, a ministerial review\(^9^1\) recommended that rather than seeking fully integrated EMRs, the immediate focus should be on the progressive development of interoperable electronic health records that are focused on achieving critical business requirements and improving patient care.

*Challenges with implementation of digital health innovations.* Difficulties in digital health implementations have been experienced all around the world. Even the most advanced health systems face challenges relating to interoperability, uniform coding of patient information, and dealing with privacy and security concerns.\(^1^6^4\) Given healthcare is a complex adaptive system, an ongoing, practice-driven approach to implementation is required. Such an approach has been illustrated by a 19-year process of development and improvement of the Rheumatology Quality Registry in Sweden.\(^1^5^5\) The rapid learning healthcare system model used to guide the process undertaken throughout this thesis enables such an iterative process to occur. An advantage of this model is that it enables those at the point of care to consistently improve an innovation over time, gradually leading to system-wide change.

### 7.3 Strengths and limitations

Important strengths of this body of work include the salience of the research to policy and practice continuum, the use of a learning healthcare systems model to direct each stage of development, and the collaboration and engagement with CR clinicians, researchers (nationally and internationally), national associations (ACRA and the NHFA) and government (the DHHS). Much ground-breaking work has been completed which forms the platform for ongoing capacity building and innovation for CR registries.
Several study limitations were observed and were discussed in detail in Chapters Two, Three and Four. A summary of these limitations across this body of work is outlined in the following sections.

7.3.1 Determining the impact of CR on hospital readmissions from cohort study data

The use of the ADVENT study cohort data for assessing the association between CR and readmissions had inherent limitations. First, there was selection bias, in that 27% (n=99) of the eligible cohort did not attend CR. To account for this, we adjusted for baseline differences between CR attenders and non-attenders and propensity to attend CR.

Second, there were measurement issues. CR attendance was self-reported, which has known limitations, and referral to CR was not confirmed in patients’ medical records. As previously discussed, Australia does not have consistent methods of monitoring CR (e.g., a CR registry), making cross-checking of CR attendance across multiple sites difficult. However, self-report of CR attendance has previously been found to have very high concordance with objective chart reports. Data linkage of the ADVENT study with the Victorian Admitted Episodes Database and the Victorian Death Index is currently underway but was outside of the scope of this thesis.

7.3.2 Generalisability of results from the feasibility study

Due to the small sample size and Victorian setting, results from the feasibility study (Chapter Four) may not be generalisable 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.
7.3.3 **Limitations of registries**

Much of this thesis has laid the foundation work for the establishment of a Victorian CR registry and the efforts to achieve a national registry. While there is general consensus that well-developed registries are valuable for understanding care practices and providing a mechanisms by which care quality can be monitored\(^{94}\), it should be noted that registries have multiple limitations. These limitations (as discussed in section 4.4.8) include the high cost of establishment, barriers regarding privacy and ethical requirements, challenges in recruiting sites, human resource barriers for data entry, challenges ensuring data quality and completeness, as well as ongoing funding and overall maintenance and sustainability issues. Importantly, the systematic review (Chapter Three) also noted that the presence of a registry does not guarantee quality improvement, but that a comprehensive approach is required including successful implementation of the registry, continuous data quality assurance, and transparent and timely feedback.

Further, despite the prevalence of clinical quality registries internationally, there is a paucity of evidence regarding the direct benefits of the establishment of a registry on health outcomes.\(^{151}\) Registries can define clinical characteristics and outcomes of patients undergoing various interventions, benchmark service compliance to guideline recommendations, and be used to evaluate quality improvement projects. They have also been shown to positively influence process of care measures; however, evidence of effectiveness on outcomes such as morbidity and mortality is limited. In Australia, a case study of five established clinical registries showed that each registry improved clinical practice at a relatively low cost resulting in a net positive return on investment.\(^{205}\)

### 7.4 Next steps and recommendations for future research

The following recommendations and next steps are proposed:
• **Scale-up the use of a web-based tool to collate data across CR sites in Victoria.** Although the gaps in the provision and delivery CR appear to be numerous (e.g., under-utilisation of CR programs, low-level of CR referrals, variability in program delivery), this thesis argues that the most appropriate starting place to improve CR across Victoria is with the standardised and systematic collection of data. To achieve standardised collection of data, this work has proposed that a web-based tool should be implemented in a phased manner across Victorian public and private CR services. Linkage to state-level administrative datasets (e.g., the Victorian Admitted Episodes Database, Victorian Death Index) is then required to determine CR attendance of eligible Victorians with CVD and the impact of CR on health outcomes.

• **Embed the development of a registry within a cycle of quality.** Second, the collected data must be used in a meaningful way, to not just monitor the provision of care, but to systematically enhance the quality of care provided. The effectiveness of a registry is hypothesised to be enhanced when embedded within a quality improvement cycle. Authors who examined 13 clinical registries from five countries suggested that registries that transparently reported outcome data and enabled clinicians to engage in continuous learning had the greatest impact on outcomes. However, there is limited empirical evidence on which specific feedback strategies have the greatest effect on driving improvements. In the broader literature, audit and feedback has been the quality improvement strategy evaluated most rigorously and has been shown to result in small but important improvements in clinical care (depending on baseline performance and how the feedback is delivered). Documentation of why usual care was not followed should also be considered. Potentially, the exceptions to the rules can provide valuable insights and contributions to guideline development as has previously been seen in the
Standardized Clinical Assessment and Management Plans program. Further research is required to evaluate how various feedback strategies could be integrated into the development of registries to influence the quality of care.

- **Incorporate the patient experience within the registry.** Further focus is required on truly understanding the experience of people with heart disease in Australia and how they wish to be supported in managing their condition and maintaining healthy behaviours. Like many chronic disease registries, CR registries internationally are not typically capturing the patient experience of CR or using this information to shape care delivery. Recently, some disease registries have evolved to be ‘patient centred learning health systems’ in which patients, clinicians and researchers co-produce the development of registries, integrating patient reported and clinical data to support care decisions. An exemplar of this approach is the Swedish Rheumatology Quality Registry, which reported that participating services experienced a 50% decrease in inflammatory activity among patients with rheumatoid arthritis. Such an approach could be applied to CR, and some web-based tools (e.g., Cardioligica used by the Canadian CR registry) have the capability to build in a platform accessible to patients so they can upload their own personal data (e.g., objective measures of physical activity) and share with care providers (e.g., their general practitioner) to assist with shared decision making. The usefulness of CR registries is likely to lie in our ability to successfully engage with patients to co-design a monitoring platform that truly enables the patient experience to be captured and drives change in care that aligns with patient needs.

- **Enable CR data to be incorporated into a national CR registry.** To enable CR data to be aggregated at the national level, standardised quality indicators are required; the
development of these is the primary goal of the CR Quality Indicator Taskforce. Beyond the quality indicators, a national registry will require: governance structures; a range of policies to be developed (e.g., a data custodian policy, data security policy and data sharing policy); appropriate ethical approval to enable data to be aggregated; and the development of a data management team (including strong statistical and data linkage support). Greater efficiencies in coordination via a national approach is preferably better than each state duplicating these various aspects which also increases costs. However, if determined to be more feasible, it is also possible that if data collection was standardised, aggregated data collected at the state-level could be included within a national repository.

- **Evaluate the impact of registries on health outcomes.** Additional studies are required to substantiate the impact of national registries on health systems and clinical outcomes. Non-randomised trials, for example in diabetes care, have shown that the implementation of a registry can significantly improve both care processes and health outcomes (e.g., HbA1c, LDL, cholesterol) for patients exposed to services that had at least a medium level of registry utilisation\textsuperscript{21}; potentially suggesting the level of registry use positively impacts on outcomes. This hypothesis requires further investigation.

## 7.5 Translation into practice

Relationship building and stakeholder engagement has been a major strength of this PhD. This has included strong links with the NHFA, ACRA, clinicians working within CR across Victoria, other research institutes (namely Deakin University), the DHHS, Safer Care Victoria, and the Victorian Cardiac Clinical Network as well as international colleagues and researchers working in CR (including from Canada, the United Kingdom and Denmark).
Through regular attendance of events, seminars and conferences, the findings of this thesis have been used to advocate for the inclusion of a CR registry as a priority within CVD research (e.g., at the Heart and Stroke National Action Plan consultation meeting), engage clinicians in the need to enhance the monitoring of CR programs (e.g., at the Victorian ACRA Education Day) and discuss with the DHHS how the findings of this thesis align with their Cardiac Plan.

As a consequence of the relationship building and advocacy of this work described above, I was invited to submit a grant to the DHHS to embed a web-based tool across Victorian public hospital sites. Additionally, the private hospital that participated in the feasibility study has requested information regarding how they could use REDCap in the long term to monitor their CR programs.

Further, as the Victorian representative on the National Taskforce for the Development of CR Quality Indicators, I have contributed to the development of national CR quality indicators to improve the consistency of reporting of CR programs across jurisdictions. Currently the agreed quality indicators include 11 variables. A data dictionary that defines each variable and provides clear methods for how to collect data in adherence with national reporting standards is currently being progressed in collaboration with a range of experts.

### 7.6 Concluding remarks

Rising unplanned hospital admissions associated with CVD provide a continuing challenge to the Australian healthcare system. Improving the delivery and utilisation of CR holds great potential for keeping Australians with heart disease healthier and out of hospital. This thesis demonstrates how a learning healthcare system approach could be used to develop and then apply innovative methods to improve the monitoring of CR within the context of Victoria (Australia). The feasibility of using a web-based tool to capture CR quality indicator
information was demonstrated in both private and public CR services. Based on this work and other initiatives across Australia with a range of experts and colleagues, collective and consensus-based recommendations were developed to enhance the monitoring of CR programs nationally. Through embedding these recommendations within a national strategic plan, there is potential that the delivery of CR will be improved resulting in better outcomes (such as reduced unplanned admissions) for people with heart disease in Australia and potentially elsewhere.
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Appendix A: Contributions to the ADVENT and VCRR studies
## ADVENT STUDY

<table>
<thead>
<tr>
<th>Date</th>
<th>Task Completed (2015-2019)</th>
</tr>
</thead>
</table>
| Feb 2016 & 2017 | **ETHICS**  
Submitted project annual report to the University of Melbourne system                                                                                                                                         |
| Sept 2015 – Dec 2016 | Submitted ethics amendments for inclusion of new staff members                                                                                                                                                  |
| Sept 2015 – Dec 2016 | **PROJECT MANAGEMENT**  
Transferred documents and equipment from Monash University to the University of Melbourne, set up interview room, updated and maintained the project protocol, re-organised project shared drive.  
Managed Time Point 2 (TP2) data collection (n=365 participant phone interviews) including the supervision of two research assistants (RAs).  
Provided staffing cost estimates for project budgeting when required  
Ensured appropriate storage of electronic and paper-based participant files |
| Oct 2016        | **STAFF TRAINING / SUPPORT**  
Trained up staff member (KR) in TP2 data collection  
- CATI/CIDI training; training in data management, data storage; protocols and reporting of severely depressed participants |
| Dec 2015        | Trained up staff member (SB) in TP2 data collection  
- CATI/CIDI training; training in data management, data storage; protocols and reporting of severely depressed participants |
| Dec 2015 – Dec 2016 | Providing de-briefing support to RAs when required for difficult phone interviews and ensured correct processes were followed (e.g., reported to project CIs, GPs contacted and informed of severely depressed participants, appropriate service hotlines provided) |
| Sept 2015 – Dec 2016 | **DATA COLLECTION**  
Completed training of how to use the CIDI instrument  
Personally conducted (or managed the withdrawal of) 121 participant computer assisted phone interviews; each phone interview took approximately 1.5 hrs (1hr interview; 30 mins admin). If mental health measures led to concerns, followed-up with the project CIs and sent a letter to the patients GP. |
| Sept 2015 – Dec 2016 | **PROJECT TEAM COMMUNICATION**  
Attended fortnightly ADVENT project team meetings | Provided fortnightly updates on TP2 data collection |
| Sept 2015 – Mar 2016 | Arranged fortnightly meetings, agenda, minutes, room bookings |
| Mar 2016 – Jan 2019 | Attended ad-hoc project meetings |
| Sept 2015 – Dec 2016 | **PARTICIPANT COMMUNICATION**  
Reviewed/edited quarterly participant newsletter  
Organisation of the ‘Community Forum’  
- gathered expressions of interest from participants, assisted with arrangements and planning of the forum, edited the PowerPoint presentations, prepared resources for participants |
| Sept 2015 – Dec 2016 | Updated participant contact details and addresses as required |
| **DATA CLEANING** |                                                                 |
### Appendix A - Contributions

<table>
<thead>
<tr>
<th>Date</th>
<th>Task Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jan 2017 – Mar 2018</td>
<td>Combined and cleaned data from the data management system, hard copy forms (BDI-II), and readmission data into one dataset in Stata 13.</td>
</tr>
<tr>
<td>Jan – Sept 2018 Dec 2018</td>
<td>Updated data as required if inconsistencies or data entry errors noted. Cross-checked hard copy files for outlier / missing data.</td>
</tr>
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</table>

### PUBLICATIONS/ACADEMIC OUTPUTS

- **Dec 2018**

- **Nov 2018**

### PRESENTATIONS

- **Mar 2019**

- **Aug 2018**

- **Aug 2018**

- **Dec 2017**

- **Aug 2017**

- **May 2017**

- **June 2016**
  - **Thomas E**. ADVENT study: Reflections and themes on cardiac rehabilitation. National Heart Foundation, Melbourne, June 2016. [Invited presentation]

### PARTNER/CI COLLABORATION ACTIVITIES

- **June 2016**
  - Attended a meeting at the National Heart Foundation’s Victoria office to discuss qualitative data from TP2 regarding cardiac rehabilitation.
Appendix A - Contributions

Mar 2015
Attended broad project team writing day | Assisted with preparation of meeting

Nov 2015

VCRR STUDY

<table>
<thead>
<tr>
<th>Date</th>
<th>Task Completed (2017-2019)</th>
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<tr>
<td>Mar – May 2017</td>
<td>ETHICS Co-ordinated and co-wrote ethics applications for:</td>
</tr>
<tr>
<td></td>
<td>• University of Melbourne HEAG standard project review (Ref #1748609 Approved 08/05/2017)</td>
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<tr>
<td></td>
<td>• University of Melbourne HESC standard project review (Ref #1748609 Approved 08/05/2017)</td>
</tr>
<tr>
<td></td>
<td>• St John of God Low and Negligible Risk Ethics Committee (Ref #1142 Approved 12/04/2017)</td>
</tr>
<tr>
<td></td>
<td>• Western Health Low and Negligible Risk Ethics Committee (Ref #LNR/17/WH/57 Approved 15/06/2017)</td>
</tr>
<tr>
<td>Mar 2017</td>
<td>PROTOCOL DEVELOPMENT</td>
</tr>
<tr>
<td></td>
<td>Attended face-to-face meeting at Western Health with HaBIC, and project PI.</td>
</tr>
<tr>
<td>Apr 2017</td>
<td>Attended face-to-face meeting at SJOG, Frankston with HaBIC, and project PI.</td>
</tr>
<tr>
<td>May 2017</td>
<td>Attending teleconferences with project CIs</td>
</tr>
<tr>
<td>Mar – May 2017</td>
<td>Attended monthly meetings at HaBIC for ongoing protocol development</td>
</tr>
<tr>
<td>July 2017</td>
<td>Competed REDCap training at the University of Melbourne</td>
</tr>
<tr>
<td>Aug 2017</td>
<td>Developed REDCap data collection templates and developed step-by-step guides for data collection for participating sites</td>
</tr>
<tr>
<td>Aug 2017</td>
<td>PROJECT IMPLEMENTATION</td>
</tr>
<tr>
<td></td>
<td>Trialled data collection templates at sites</td>
</tr>
<tr>
<td>Mar – Aug 2017</td>
<td>Liaised with participating sites IT departments and HaBIC to ensure successful installation of GHRANITE™ at participating sites</td>
</tr>
<tr>
<td>Aug 2017</td>
<td>Trained staff in the collection of data using REDCap, arranged staff access to the REDCap templates</td>
</tr>
<tr>
<td>Sept- Dec 2017</td>
<td>Provided on-going communication with participating sites to ensure successful data entry during the study period</td>
</tr>
<tr>
<td>Dec 2017</td>
<td>Completed data quality checks with HaBIC and participating sites</td>
</tr>
<tr>
<td>Dec 2017</td>
<td>DATA CLEANING</td>
</tr>
<tr>
<td></td>
<td>Cleaned 10-year data at Site 2 to enable successful data extraction</td>
</tr>
<tr>
<td>Jan – Mar 2018</td>
<td>Cleaned and analysed data for main publication</td>
</tr>
<tr>
<td>Date</td>
<td>Event</td>
</tr>
<tr>
<td>----------</td>
<td>-------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Nov 2018</td>
<td>Thomas, E., O'Neil, A. Considerations for the development of quality indicators for cardiac rehabilitation in Australia, <em>Heart, Lung &amp; Circulation</em>. [Letter to the Editor] [Accepted 19.11.2018]</td>
</tr>
<tr>
<td></td>
<td><strong>PRESENTATIONS</strong></td>
</tr>
<tr>
<td>Mar 2018</td>
<td>Thomas, E. Technology in cardiac rehabilitation.</td>
</tr>
<tr>
<td>Dec 2017</td>
<td>Thomas, E. Developing a cardiac rehabilitation registry – the early days.</td>
</tr>
<tr>
<td>Mar 2017</td>
<td>Thomas E. Developing a Victorian Cardiac Rehabilitation Registry utilising a data scraping technique.</td>
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For period September 2015 – Jan 2019

Name: Associate Professor Adrienne O’Neil

Position: Chief Investigator (VCRR), Investigator (ADVENT)

Signed: Adrienne O’Neil

Date: 15.02.2019
Appendix B: Relevant additional publications
Seeking best practices for cardiac rehabilitation registries in Europe

Constantinos H Davos

Cardiac rehabilitation has been established as a core component of secondary prevention in cardiovascular diseases (CVDs). Its beneficial effects have long been proved by clinical trials and meta-analyses which show a clear reduction in morbidity and mortality in patients after an acute coronary event. This worldwide accepted intervention is challenged in everyday clinical life as the demography of population changes, increasing the complexity of cardiac conditions while novel invasive and pharmacological approaches appear. In this variable medical environment it is of apparent importance that cardiac rehabilitation is being delivered effectively to all patients according to clinical practice guidelines through high quality services.

A well accepted research instrument which helps us to evaluate cardiac rehabilitation programmes so as to improve their efficiency is national and international registries and Poffley et al. in their recent systematic review report on all available cardiac rehabilitation registries. The authors provide us with very useful insights regarding the design and execution of these registries as well as barriers, limitations and enablers of implementation. They mention that “well-designed and well-executed registries capture data that reflect ‘real-world’ clinical practice, helping us to evaluate patterns of care and disparities”. This claim immediately raises the question of how we can have a well-design and well-executed cardiac rehabilitation registry so as to gather solid and conclusive data that will help us improve cardiac rehabilitation programmes. Based on this review we may be easily disappointed by the heterogeneity of the registries, which is mainly due to differences in cardiac rehabilitation structure, legislation, funding and national guidelines. But if we take a closer look we easily find out that many registries converge to some certain points which seem to be important for all registry designs. They all, or most of them, collect data on demographics, medical history, anthropometrics, clinical and psychosocial measures, and medication. They use a web-based data-entry method which is an easy and quick way for data collection and may be further improved by technology improvements and novel ‘big data’ methods. The majority collect data at cardiac rehabilitation enrolment and cardiac rehabilitation completion, they are governed by national cardiac rehabilitation working groups within associations and securing patients’ privacy is indisputable.

Apart from these similarities these registries show significant differences which are important and affect their quality. Service-level data and process methods were poorly reported thus affecting the use of registry results in audit and feedback. Follow-up data are missing and evaluation of cardiac rehabilitation outcomes was limited. A universal rule for collecting individual participants’ information without the need of a signed informed consent while securing patients’ privacy is needed and it would certainly increase enrolment. Incentives related to national legislation, to programme certification and reimbursement or benchmarking and auditing seem to be more effective compared with voluntary participation. Funding is crucial and seems to be a major barrier in conducting and retaining a cardiac rehabilitation registry. Securing funding from the government or research funding bodies may be preferred since industry sponsorship of cardiac rehabilitation activities is somewhat difficult.

Even if we combine all the above mentioned requirements, we still cannot guarantee a successful implementation of a registry, excellence in data quality and the translation of registry results into immediate changes in cardiac rehabilitation practices, especially when there is no interaction between registry and audit. It is also disputable whether registry reports may affect national health systems by increasing the availability of cardiac rehabilitation programmes, which remain unacceptably low in most European countries. To overcome problems and challenges in developing CVD registries in Europe, the creation of specific recommendations by
European Associations and countries with long experience in maintaining cardiac rehabilitation registries, is an emerging need. The first efforts with the Carinex Survey and the European Cardiac Rehabilitation Inventory Survey were recently improved by the European Cardiac Rehabilitation Registry and Database (EuroCaReD), which is a significant proof that a multi-national cardiac rehabilitation registry in European countries is feasible. This registry has created a tool for putting together information on the clinical status of cardiac rehabilitation across Europe. Although EuroCaReD is a primary international registry it shows almost the same advantages and limitations as the rest of the registries presented by Poffley et al. It is, therefore, important to maintain the continuity of this effort because it offers to the cardiac rehabilitation community a unique opportunity to improve the quality of standardized data collection, increase motivation for participation and provide sufficient data which can be used as a benchmark throughout European countries.

Declaration of conflicting interests
The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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References
Considerations for developing quality indicators for cardiac rehabilitation in Australia

Citation: Emma Thomas and Adrienne O'Neil. Considerations for developing quality indicators for cardiac rehabilitation in Australia. Heart, Lung and Circulation; 2019. DOI: 10.1016/j.hlc.2018.11.009

To the Editor

We read with interest Zecchin et al's [1] paper on the development of cardiac rehabilitation (CR) quality indicators (QIs) for Australia and agree with the authors’ advocating a set of national QIs. In considering the wider implementation of these QIs across Australia, we have the following suggestions.

Firstly, when moving towards national QIs, it is important to consider how ‘quality’ will be defined and from whose perspective. Increasingly it is being recognised (such as in the World Health Organisation’s Quality of Care Framework [2]) that quality of care encompasses not only the provision of care but also the experience of care. Consequently, it is important to consider how PREMs can be included and used to enhance the utilisation of CR services.

Second, it is important to determine whether the identified variables will provide a reliable and valid proxy of quality CR delivery. The authors recognise that the current QIs developed in one state may not be generalisable. In the next iteration, we suggest the identified QIs are systematically assessed by national stakeholders using the framework [3] proposed by ACA/AHA which assesses the usefulness, validity, reliability and feasibility of cardiovascular performance measures.
Third, the reporting of the QIs needs to be sufficiently uniform to enable cross-jurisdictional comparisons. There is no mention that the QIs align with Australia’s national data reporting standards (METeOR). The QI data dictionary should comply with these standards to enhance comparability.

Fourth, without data linkage, the proportion of eligible patients receiving CR and the impact of CR on long-term outcomes cannot be determined. The authors mention this as a limitation, and report being constrained by the lack of data in the EMRs. However, this could be largely overcome by the inclusion of identifiable variables (e.g., date of birth, Medicare number). While identifiable data necessitates additional ethical and security processes, Australian standards [4] for the development of registries highlight data linkage wherever possible. Consequently, national QIs must include variables that would enable linkage to occur, a process that is supported by opt-out consent.

Next steps should include an assessment of data accuracy and considerations for wide-scale benchmarking (e.g., development of risk-adjustment methods, outlier identification). Finally, the ultimate test of the QIs will be how useful they are for funders of CR programs; a key consideration for building sustainable business models and ensuring long-term implementation.

Development of a standardised program of content for cardiac rehabilitation using a modified-Delphi process

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(*co-first authors)

1. Institute of Physical Activity and Nutrition (IPAN), Deakin University, Melbourne, VIC, Australia
2. Melbourne School of Population and Global Health, University of Melbourne, VIC, Australia
3. National Heart Foundation of Australia, Melbourne, VIC, Australia
ABSTRACT

Objective: To develop a core standardised program outline for cardiac rehabilitation (CR) programs in Victoria.

Design: Using the RAND/UCLA Appropriateness Method (RAM), a two-phase process was undertaken to develop and validate core content of a standardised CR program.

Participants: An invited multidisciplinary Expert Advisory Group (EAG; n=18) including CR health professionals (nurses, allied health professionals, cardiologist), academics, policy makers, representation from the Australian Cardiovascular Health and Rehabilitation Association and consumers, provided oversight of the literature review and assisted with development of best practice statements. Twelve members of the EAG went onto to participate in the modified Delphi process rating the necessity of statements in two rounds on a scale of 1 (not necessary) to 9 (essential).

Main outcome measure: Best practice statements that achieved a median score of ≥8 on a nine-point scale were categorised as “essential”; statements that achieved a median score of ≥6 were categorised as “desirable” and statements with a median score <6 were omitted.

Results: 45 best practice statements were developed from the literature across ten areas of care within four education domains (CR foundations, developing heart health knowledge, psychosocial health and life beyond CR). At the end of a two-round validation process 24 statements were rated as essential, 23 as desirable and one statement was omitted.

Conclusions: For the first time in Australia, an evidence-based and consensus-led standardised program outline for Phase II CR has been developed that can be provided to all cardiac patients regardless of the mode of CR program delivery.
Strengths and Limitations

- The RAND/UCLA Appropriateness Method involved an in-depth review of the international clinical guidelines in combination with a two-round modified-Delphi rating process. The two-round process enabled in-depth discussion with the participants at the conclusion of each round. This allowed the participants a chance to hear other perspectives to take into consideration for the next rating round. This process has been used successfully in other areas of care and has been shown to be useful where clinical guidelines are lacking.
- A diverse group of participants were represented on the Expert Advisory Group who undertook the modified Delphi process. This included cardiac rehabilitation clinicians, academics, policy makers, representation from the Australian Cardiovascular Health and Rehabilitation Association and a consumer.
- End users (cardiac rehabilitation clinicians) were given the opportunity to provide feedback on draft documents in relation to the content, how the final document would be produced (hard copy versus online) and where it could be accessed.
- The literature review was not systematic and therefore may not be exhaustive. However, the most recent and relevant international guidelines were reviewed in addition to high levels of evidence (where available) to formulate the best practice statements.
- While the best practice statements are derived from the international literature, they have been refined for the Australian healthcare context and may require some adaptation to be applicable to other settings.
INTRODUCTION

In Australia, almost 70,000 people experience an acute coronary syndrome (ACS) event each year\(^1\) and approximately 20,000 people die annually from coronary heart disease (CHD)\(^2\); making heart disease the single leading cause of death. Although mortality rates have declined in recent decades\(^3\), the prevalence of those living with CHD has increased. As modifiable risk factors account for approximately 80% of CHD\(^4\) and up to 50% of CHD admissions are repeat events\(^5\), it is imperative that people with heart disease are educated in long-term self-management strategies to reduce the risk of further cardiac events, hospital readmissions and premature death.\(^5\)

Long term self-management strategies are developed in cardiac rehabilitation (CR) programs. These secondary prevention programs are a multi-component intervention delivered by an interdisciplin ary team that aim to halt the progression of disease and optimise functioning. This is achieved via exercise sessions and lifestyle change education that focus on regaining or maintaining physical capacity, wellbeing, medication compliance, and social and vocational participation.\(^6\)–\(^8\) Research evidence demonstrates that exercise-based CR can significantly reduce the risk of cardiovascular mortality\(^7\), improve health-related quality of life and decrease hospital admissions.\(^9\) However, the ‘real-world’ effectiveness of CR programs is dependent upon a range of factors including program delivery (e.g., dose and content). Recent evidence demonstrates that ‘comprehensive’ CR programs (e.g., targeted six or more risk factors) have a larger effect on all-cause mortality than less comprehensive programs.\(^10\)

In many countries (including Australia\(^10\)) the expansion of CR programs has occurred organically, with programs replicated from model sites but not standardised; national associations have since tried to implement quality standards retrospectively. Consequently, standardised CR programs are limited, and when they do exist are largely implemented at the health organisation level rather than at the national level. Currently in Australia, considerable heterogeneity exists in the delivery of programs nationally. This has been demonstrated in several national cross-sectional surveys investigating program characteristics\(^11\), screening practices for CVD risks and measurement tools used\(^6\), and exercise training characteristics.\(^13\) At the global level, heterogeneity in the delivery of CR programs has impacted upon the ability to assess the effectiveness of CR with multiple authors of meta-analysis calling for internationally accepted standards of CR delivery and
evaluation.\textsuperscript{14-17} For example, a leading health facility in Canada has developed the Cardiac College (https://www.healtheuniversity.ca/en/CardiacCollege), which provides a standardised patient education guide to CR. Further, researchers in Germany have developed a standardised inpatient CR program which, compared to usual care, was shown to improve illness knowledge and physical activity.\textsuperscript{18}

In 2004, a Framework for Cardiac Rehabilitation\textsuperscript{19} was developed by the National Heart Foundation of Australia and the Australian Cardiovascular Health and Rehabilitation Association (ACRA). The Heart Foundation is a charity dedicated to the prevention of heart disease and improving the heart health and quality of life of all Australians through work in prevention, support and research. This framework was further expanded upon in 2014 by the ACRA and involved a set of core components consisting of five elements of cardiovascular disease secondary prevention and CR.\textsuperscript{6} The core components for quality delivery and outcomes of services include: (1) equity and access to services, (2) assessment and short-term monitoring, (3) recovery and longer-term maintenance, (4) lifestyle/behavioural modification and medication adherence, and (5) evaluation and quality improvement.\textsuperscript{66666} While the core components provide broad overarching guidance, clinicians are still required to interpret and implement these within their daily clinical practice.

Therefore the aim of this study was to develop a standardised program outline for the education component of CR. Specific aims included ensuring the program outline was evidenced based, standardised but with flexibility to provide individualised education for clients, culturally aware, person centred and built on the existing ACRA Core Components.\textsuperscript{6} The aim was to have standardised content that would be applicable across a range of delivery modes (face-to-face, telehealth, web, or mobile phone). This work was undertaken by the National Heart Foundation of Australia in partnership with researchers (Deakin University) and was funded by Safer Care Victoria.

\textbf{METHODS}

\textbf{Design}

The RAND/UCLA Appropriateness Method (RAM)\textsuperscript{20} was used to guide the development of the program outline (Figure 1). This approach has previously been used in the development of statements in pharmacy\textsuperscript{21} and aphasia care.\textsuperscript{22} The RAM method involves two main steps;
1) a comprehensive review and synthesis of the literature and 2) a two-round modified-Delphi process.

**Figure 1**: Overview of the RAND/UCLA Appropriateness Method adapted from Finch et al.\textsuperscript{20}
**Literature review and synthesis of evidence**

In February 2018, a review of literature was undertaken in three phases. The first phase involved a review of national and international CR guidelines and core component documents in addition to organisation and association websites known to provide these publications. CR and ACS guidelines and core components were included if they were from comparable high-income countries and regions to Australia (United Kingdom, United States of America, Canada, New Zealand, Europe) and published in English. To ensure guidelines aligned with recent evidence, only documents published after the year 2000 were included. Guideline data were extracted into an online spreadsheet which was accessible to all authors for review and discussion. Synthesis of these data informed the basis for identifying core areas for the CR program content.

The second phase of the literature review involved searching The Cochrane Library (2000 – 2018) for overviews and systematic reviews of identified CR program content (e.g., exercise training, nutrition education, smoking cessation). Where no Cochrane systematic reviews were available for content areas, the third phase of the literature review was undertaken. Search terms (Supplementary file, Table 3) were developed for each content area and applied to the following databases: PubMed, TRIP database (www.tripdatabase.com), MEDLINE and Google Scholar between the years 2000 – 2018. Study designs were limited to the highest level of evidence available (systematic reviews, followed by randomised controlled trials [RCTs]). In addition, we also searched the reference lists of clinical practice guidelines and systematic reviews (identified in phase one and two) to identify other appropriate and high-quality evidence (Figure 1).

**Participants - Expert Advisory Group**

An expert advisory group (EAG) (Table 1) was formed to provide input for this program of work. Membership of the EAG was guided by the authors in consultation with ACRA. The aim of the EAG membership was to have interdisciplinary representation from the majority of Australian states and territories where possible. Specific roles of the EAG included; 1) assistance in identifying appropriate and relevant literature or documents in addition to the authors search, 2) guidance on the overall direction and format of the program outline, 3) review of each developed module, providing feedback to the authors, 4) participation in a modified Delphi process to determine what content should be included in the CR program outline. In addition to the working group, the EAG was comprised of 16 members and met five times via scheduled teleconferences with one face-to-face meeting. Members of the EAG
had the option to contact the authors and the Heart Foundation project managers at any time with feedback.

**Table 1**: Expert Advisory Group members including working group (n=6) and Delphi Participants (n=12)

<table>
<thead>
<tr>
<th>Member</th>
<th>Organisation (at time of project)</th>
<th>Professional role</th>
<th>Expertise</th>
<th>State / Country</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Working group</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dr Sue Forrest</td>
<td>National Heart Foundation of Australia</td>
<td>Managerial, policy</td>
<td>Chair</td>
<td>Victoria</td>
</tr>
<tr>
<td>Professor Ralph Maddison</td>
<td>Deakin University</td>
<td>Research</td>
<td>Academic Chair Working group</td>
<td>Victoria</td>
</tr>
<tr>
<td>Dr Susie Cartledge</td>
<td>Deakin University</td>
<td>Research</td>
<td>Working group</td>
<td>Victoria</td>
</tr>
<tr>
<td>Emma Thomas</td>
<td>Deakin University &amp; University of Melbourne</td>
<td>Research</td>
<td>Working group</td>
<td>Victoria</td>
</tr>
<tr>
<td>Kerry Hollier</td>
<td>National Heart Foundation of Australia</td>
<td>Policy</td>
<td>Working group</td>
<td>Victoria</td>
</tr>
<tr>
<td>Roni Beauchamp</td>
<td>National Heart Foundation of Australia</td>
<td>Policy</td>
<td>Working group</td>
<td>Victoria</td>
</tr>
<tr>
<td><strong>RAND/UCLA Modified Delphi Participants</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A/Professor Adrienne O'Neil</td>
<td>University of Melbourne</td>
<td>Research</td>
<td>Mental health</td>
<td>Victoria</td>
</tr>
<tr>
<td>A/Professor Nicholas Cox</td>
<td>Western Health &amp; University of Melbourne</td>
<td>Clinical, research</td>
<td>Cardiologist</td>
<td>Victoria</td>
</tr>
<tr>
<td>Emma Boston</td>
<td>St John of God, Frankston Rehabilitation Hospital</td>
<td>Clinical President, ACRA Victoria</td>
<td>Nursing</td>
<td>Victoria</td>
</tr>
<tr>
<td>Kim Gray</td>
<td>Austin Health</td>
<td>Clinical</td>
<td>Physiotherapy Incoming President, ACRA National</td>
<td>Victoria</td>
</tr>
<tr>
<td>Professor Robyn Gallagher</td>
<td>University of Sydney</td>
<td>Research</td>
<td>Nursing ACRA National President</td>
<td>New South Wales</td>
</tr>
<tr>
<td>Cate Ferry</td>
<td>National Heart Foundation of Australia</td>
<td>Managerial, policy</td>
<td>National Heart Foundation of Australia</td>
<td>New South Wales</td>
</tr>
<tr>
<td>Stephen Woodruffe</td>
<td>West Morton Hospital and Health Service</td>
<td>Clinical</td>
<td>Physiotherapy, Rehabilitation Medicine and Cardiology</td>
<td>Queensland</td>
</tr>
<tr>
<td>Beth Meertens</td>
<td>National Heart Foundation of Australia</td>
<td>Policy</td>
<td>Dietitian</td>
<td>Queensland</td>
</tr>
</tbody>
</table>
Development of program outline modules

Following Phase I of the literature review, best practice statements referring to what should be included in CR programs from the identified clinical guidelines were extracted by authors (SC, ET) into an Excel spreadsheet. Extracted information was synthesised under content areas (e.g., exercise training, nutrition, psychosocial health) and included: the guideline reference(s), an overall recommendation, National Health and Medical Research Council (NHMRC) level of evidence, and the underlying reference/rationale for the recommendation. Similar best practice statements were synthesised along with the highest level of evidence. These best practice statements, the NHMRC level of evidence and rationale formed the basis of each ‘module’. The EAG then provided guidance on what additional information should be provided to enable implementation of the best practice statements at each site and included: a module aim, example content of how each recommendation could be implemented, and resources (i.e., Action plans, websites, phone applications). Modules were then then drafted (SC, ET, RM) with input from content experts (EAG or external where required i.e., smoking cessation, pharmacology). The content experts provided guidance on how the best practice statements could be implemented within a CR setting and the most appropriate resources available. For example, broad nutritional education best practice statements on making healthy dietary choices to reduce cardiovascular risk was expanded by providing the five principles of the Heart Foundations’ Eating for Heart Health Position Statement, along with tips, resources and additional links.

Once the modules were in full draft, they were also reviewed by end-users – CR coordinators. Members of the local state chapter of ACRA were invited to a public forum (14 September 2018) where modules were reviewed in a workshop format. Feedback from attendees was collated and then incorporated into the modules where appropriate. The modules were then finalised by the working group.
Validation of best practice statements

We used the RAND/UCLA modified Delphi method\textsuperscript{20} to validate the best practice statements and to determine which statements would be classified as essential to deliver within a program versus desirable. The Delphi method involves a group of experts led by a facilitator, to determine the appropriateness of clinical procedures, or in this case, the appropriateness of content to be included in CR programs.\textsuperscript{20}

Following the RAM guidelines\textsuperscript{20}, the modified Delphi process consisted of two rating rounds. Prior to rating rounds, all members of the EAG were briefed on the procedure, provided with a timeline for the process and an opportunity to ask questions. Rating rounds were conducted via an online survey platform (Qualtrics, Provo, UT, Version 10-11/2018) distributed via email. The online rating survey consisted of the best practice statements, rationale with accompanying references and NHMRC level of evidence. While all best practice statements were deemed appropriate as they were derived from the comprehensive literature review, participants were asked to rate each best practice statement on a scale of necessity. The provided scale was from one to nine, where nine indicated that it would be improper clinical judgment not to provide the intervention and one indicated that although the intervention is appropriate, it was not necessary. As per the RAND manual, prior to rating each recommendation the EAG participants were asked to consider a ‘typical’ CR site (i.e., with average patients, clinicians and in a typical setting) and they were specifically requested not to consider cost implications when making their judgements.

Each round was followed with a teleconference with the EAG to discuss results, provide clarification if necessary and achieve consensus. In addition, once round one was complete, all participants were provided with an individualised scoring results sheet that indicated both their own scores and scores from all participants, for their review. At the conclusion of round two, all participants were sent an overall scoring sheet with the calculated median for each best practice statement.

This modified Delphi method with group discussion has been demonstrated to achieve results that are valid\textsuperscript{24} and reliable.\textsuperscript{20,25} Additionally, we used an experienced facilitator during group discussions (SF), which has been shown to control for bias, and a panel facilitator who was familiar with Delphi methodology (ET).\textsuperscript{20}
Analysis
Rating scores were reviewed and descriptively summarised after each round according to RAM Delphi protocol. Initial analysis involved calculating the median score for each statement and assessing the dispersion of scores. There were no a priori cut off scores to determine if best practice statements would be essential or desirable—scoring cut offs were determined once the data were reviewed and the dispersion of rating scores could be assessed.

RESULTS
Literature review
In total, eight clinical practice guidelines were identified that related to CR in six countries (Australia, New Zealand, the United Kingdom, the United States of America, the Netherlands, and Canada) one region (Europe) and one international guideline (from the World Health Organisation) (Supplementary Table 1). The identified Australian guideline was related to the care of patients with ACS generally and provided only brief mention of CR. Additionally, seven core component documents were identified (Supplementary Table 2).

Common areas of content identified from the guideline synthesis were: exercise training, smoking cessation, psychological and psychosocial interventions, education (physical activity, diet, weight control, blood pressure, medication adherence, cholesterol/lipids), education—disease management (anatomy and physiology, chest pain management, cardiopulmonary resuscitation training), vocational rehabilitation.

A search of Cochrane Library identified one overview and 11 reviews that were applicable to our criteria. Where information for the module development could not be sourced from these reviews, a separate search was undertaken to find the highest level of evidence. The education categories identified in the guideline review provided the basis for formulating the final ten developed modules (Table 2), which consists of a total of 47 best practice statements.
Table 2. Final structure of program outline

<table>
<thead>
<tr>
<th>Education categories</th>
<th>Module title</th>
<th>Number of best practice statements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiac rehabilitation foundations</td>
<td>1. Initial assessment and goal setting</td>
<td>12</td>
</tr>
<tr>
<td></td>
<td>2. Heart education and self-management</td>
<td>2</td>
</tr>
<tr>
<td>Developing heart health knowledge</td>
<td>3. Medication education and review</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>4. Managing medical risk factors</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>5. Exercise training and physical activity</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>6. Healthy eating and weight management</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>7. Tobacco cessation and alcohol reduction</td>
<td>4</td>
</tr>
<tr>
<td>Psychosocial health</td>
<td>8. Psychosocial wellbeing</td>
<td>9</td>
</tr>
<tr>
<td>Life beyond cardiac rehabilitation</td>
<td>9. Activities of daily living</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>10. Reassessment</td>
<td>2</td>
</tr>
</tbody>
</table>

**RAM Round 1**

In October of 2018, 12 members (67%) of the EAG participated in RAM Round one of the Delphi process. Overall, the majority of statements rated very highly, with little dispersion. As a result, we used stringent criteria to determine the definition of agreement (all responses falling between 7 – 9) and best practice statements as essential (median ≥ 8). These decisions were guided by the RAM Delphi protocol.20

The high level of agreement was the basis of our discussion in the scheduled teleconference following this rating round. In response to this, the EAG were asked to consider which best practice statements should be compulsory part of CR programs versus which statements would be good additions to programs, where there was capacity to deliver them. Inconsistent scoring within module categories (ie. one medical management best practice statement scored highly, but the others did not) was also discussed. All discussion points during the teleconference were for EAG members to consider during the second rating round.

**RAM Round 2**

The same 12 EAG members participated in RAM Round two of the Delphi process. Greater dispersion of scores was observed in round 2 compared to round 1, however there was still clear consensus on which statements would be essential, desirable or inappropriate.
The discussion during the round two teleconference, focussed on best practice statements which had inconsistent scoring within module categories. During these discussions all participants in the teleconference had an opportunity to discuss scoring and content experts were also asked to comment. Based on discussions, four statements were increased to an essential rating – this was a result of omitting a singular outlier score of below 7 and with consensus from the group. The other topic of discussion was ensuring this work was in line with other national work on quality indicators and minimum data sets. Our aim was to ensure the program outline was consistent with the indicators and minimum data set requirements. Again, we took the same approach for those statements of omitting a singular outlier score and ensuring group consensus.

At the completion of round two, final scoring resulted in 22 essential best practice statements, 23 desirable and one inappropriate (Table 3). The final two best practice statements from the “reassessment and completion” module were developed once the “initial assessment” module had been finalised through the Delphi process. This was to ensure the final two statements were appropriate and mirrored statements from the first module. While these statements did not go through the Delphi process, they were approved by the EAG via email correspondence.

Table 3. Finalised best practice statements

<table>
<thead>
<tr>
<th>Number</th>
<th>Best Practice Statement</th>
<th>Round median score/9</th>
<th>2 Essential (E) or desirable (D)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>Initial assessment module</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.1</td>
<td>The initial assessment should include socio-demographic information</td>
<td>9</td>
<td>E</td>
</tr>
<tr>
<td>1.2</td>
<td>The initial assessment should include clinical history</td>
<td>9</td>
<td>E</td>
</tr>
<tr>
<td>1.3</td>
<td>The initial assessment should include exercise capacity</td>
<td>9</td>
<td>E</td>
</tr>
<tr>
<td>1.4</td>
<td>The initial assessment should include adiposity (waist circumference)</td>
<td>7.5</td>
<td>D</td>
</tr>
<tr>
<td>1.5</td>
<td>The initial assessment should include medical risk factors (blood pressure, lipids, blood glucose)</td>
<td>9</td>
<td>D</td>
</tr>
<tr>
<td>1.6</td>
<td>The initial assessment should include lifestyle risk factors (physical activity, diet, smoking, alcohol)</td>
<td>9</td>
<td>D</td>
</tr>
<tr>
<td>1.7</td>
<td>The initial assessment should include psychosocial health (depression, anxiety)</td>
<td>9</td>
<td>E</td>
</tr>
<tr>
<td>1.8</td>
<td>The initial assessment should include medications</td>
<td>9</td>
<td>D</td>
</tr>
<tr>
<td>1.9</td>
<td>The initial assessment should include return to activities of daily living</td>
<td>8</td>
<td>D</td>
</tr>
<tr>
<td>1.10</td>
<td>The initial assessment should include sleep</td>
<td>7.5</td>
<td>D</td>
</tr>
<tr>
<td>1.11</td>
<td>Following the initial assessment, CR participants should be encouraged to set achievable goals with support from CR staff.</td>
<td>9</td>
<td>E</td>
</tr>
<tr>
<td></td>
<td><strong>Heart education and self-management module</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.1</td>
<td>CR participants should be provided with education, tailored where possible to their condition about anatomy and physiology of the heart; return to activities, risk factors, chest pain management or heart failure management plan.</td>
<td>8.5</td>
<td>D</td>
</tr>
<tr>
<td>2.2</td>
<td>CR participants should be provided with education on self-management strategies</td>
<td>8.5</td>
<td>E</td>
</tr>
</tbody>
</table>

Medication education and review module
3.1 CR participants should be provided with medication education that includes basic indications and benefits of commonly prescribed medication therapy.  
3.2 CR participants should be encouraged and supported to adopt strategies that lead to medication adherence.  
3.3 CR staff (pharmacist where possible) should review CR participants medications to ensure optimisation of cardio-protective medications.

### Managing medical risk factors module

| 4.1 | CR programs should provide education and skills for participants to self-manage or prevent hypertension | 8 | D |
| 4.2 | CR programs should provide education and skills for participants to self-manage or prevent dyslipidaemia | 8 | D |
| 4.3 | CR programs should provide education and skills for participants to self-manage or prevent diabetes | 8 | E |

### Exercise training and physical activity module

| 5.1 | CR participants should be provided with a tailored, progressive and supervised exercise training program. | 9 | E |
| 5.2 | CR participants are provided with education and strategies to increase general physical activity and reduce sedentary behaviour. | 9 | E |

### Healthy eating & weight management module

| 6.1 | The focus of advice should be on making healthy dietary choices to reduce total cardiovascular risk. | 9 | E |
| 6.2 | If resources allow, offer individualised consultation with a trained health professional to discuss diet including understanding the CR participant's current eating habits and provide personalised advice that is sensitive to culture, needs, socio-economic status, and capabilities. | 8 | E |
| 6.3 | Patients with additional co-morbidities leading to more complex dietary requirements should be assessed and managed by an Accredited Practising Dietitian. | 8 | D |
| 6.4 | Education and advice should be provided on the importance of maintaining a healthy weight for heart health. For CR participants who are overweight or obese, develop an individualised, achievable plan working towards an initial goal of losing 10% of body weight and a longer-term goal of achieving a body mass index below 25. | 8 | D |
| 6.5 | Referral to weight-loss programmes delivered by experts should be considered for patients requiring assistance with weight management. | 7 | D |

### Tobacco cessation and alcohol reduction module

| 7.1 | A brief intervention for smoking cessation by a CR clinician should be provided to CR participants who smoke using the Ask, Advice and Help model. | 9 | E |
| 7.2 | CR participants should be encouraged to use a combination of nicotine replacement products (patch plus gum or spray or lozenge or inhalator) or “stop smoking medications” (varenicline, bupropion) to assist to quitting. | 9 | E |
| 7.3 | CR participants who are excessive drinkers should be offered brief advice/counselling to encourage reduction of alcohol intake. | 8.5 | E |
| 7.4 | Consider referring CR participants who are alcohol dependent to specialised services and notify their general practitioner. | 8 | D |

### Psychosocial wellbeing module

| 8.1 | CR participants should be screened for depression and anxiety at the beginning and end of the CR program using a validated tool. | 9 | E |
| 8.2 | An assessment of the social support available to the CR participant is recommended and should aim to determine the social support needs of the CR participant. | 7 | D |
| 8.3 | CR programs should provide participants with an opportunity to discuss the typical emotional response to a heart event. | 8 | E |
| 8.4 | CR programs should provide education around the signs and symptoms of depression and other mood disorders. | 8 | E |
| 8.5 | CR programs should assist CR participants to respond appropriately to ongoing psychological symptoms including when to seek help. | 8.5 | E |
| 8.6 | CR programs should discuss the importance of social support on heart health recovery and encourage participants to reflect on how they can enhance or better utilise their social support networks. | 7.5 | D |
| 8.7 | CR programs should consider how social networks can be enhanced for their participants who have low levels of perceived social support. | 6 | D |
| 8.8 | Cardiac rehabilitation programmes should consider the contributions family members and carers can make to a participants’ recovery. | 8 | D |
| 8.9 | Specific carer support groups may be considered to focus on the issues partners or carers may encounter in coping with their family member's cardiac condition. | 6.5 | D |

### Activities of daily living module

| 9.1 | Clinicians should discuss driving restrictions with CR participants and provide guidance on where further information can be sought. | 9 | E |
| 9.2 | If an individual is unable to drive, explore alternatives to assist with independence. | 6 | D |
| 9.3 | CR programs should include vocational guidance to facilitate graded return to work | 7 | D |
and discuss any barriers an individual may face returning to work.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th>9</th>
<th></th>
<th>E</th>
</tr>
</thead>
<tbody>
<tr>
<td>9.4</td>
<td>CR participants should have an opportunity to discuss any concerns they have relating to resuming sex after their cardiac event.</td>
<td></td>
<td>9</td>
<td>E</td>
</tr>
<tr>
<td>9.5</td>
<td>CR participants should have an opportunity to discuss and/or train in cardiopulmonary resuscitation (CPR).</td>
<td></td>
<td>8</td>
<td>D</td>
</tr>
</tbody>
</table>

Reassessment and completion module

<p>| | | | | |</p>
<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>10.1</td>
<td>CR participants should receive a review of goals set at the completion of the CR program.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10.2</td>
<td>A discharge or summary letter should be provided to the CR participant and sent to their general practitioner and cardiologist.</td>
<td></td>
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</tr>
</tbody>
</table>

*these statements did not undergo the Delphi process but were approved by the Expert Advisory Group

**DISCUSSION**

The RAND/UCLA Appropriateness method enabled us to combine best current evidence with expert consensus and end user participation to develop a standardised program outline for Phase II CR. Specifically, 24 essential and 23 desirable best practice statements across four education categories were developed and validated. While the program outline aligns with the content and guidelines from similar international populations, it was important to develop a context specific program outline for Australia, guided by local experts. This outline will prove to be an important and up-to-date guiding document for CR programs across Australia.

Importantly, the content outline provides direct guidance on what content to implement, with useful resources, links and examples on how essential aspects of a CR program can be delivered. Given the implementation science literature has consistently reported on a failure to translate evidence into practice, it is crucial that research and clinical knowledge is synthesised and translated into usable tools to ensure patients can benefit from optimal healthcare. This is particularly important for the CVD community where optimal preventative care (i.e., prescription of preventative medications, lifestyle advice and referral to CR) is estimated to occur in only 25% of the Australian cardiac population. Poor secondary prevention of cardiac populations occurs globally; in the United Kingdom recent data suggests that only 50% of eligible patients are referred to CR (despite Class 1 recommendations) and in the United States, a third of the ACS population are readmitted to hospital within 30 days, and over 60% are readmitted within one year.

The effectiveness of CR programs within the contemporary cardiology setting has recently been questioned by studies such as the Rehabilitation After Myocardial Infarction Trial (RAMIT). This study reported that comprehensive CR following MI had a neutral effect on mortality, morbidity, or health-related quality of life, however there are questions about the generalisability of the RAMIT results to the wider population and the variable dose of CR
compared to other trials.\textsuperscript{15} While these negative effects did not impact the most recent Cochrane review by Anderson et al,\textsuperscript{7} it has led to questions about the overall quality of care provided in CR programs in real-world settings and the importance of minimum standard of care to be consistently delivered across sites.\textsuperscript{60} Doherty et al.\textsuperscript{61} investigated whether CR programs in the United Kingdom met minimum standards using data from the National Audit of Cardiac Rehabilitation (NACR). Substantial variation between CR sites existed, with only 30\% of CR sites meeting criteria for high-performance; 18\% of sites were reported as having low performance; and a further 5\% failed to meet any criteria.\textsuperscript{61} Such variation in quality is of large concern as it highlights that many patients are not receiving optimal care which may impact on their experience and outcomes. These results provide further evidence on the importance of continuously monitoring and evaluating CR programs and the quality of care provided.

An additional benefit of standardisation includes eliminating unnecessary work for clinicians to determine what content their program should be delivering. This was voiced by local CR coordinators during the end-user forum, who wished to see more guidance provided for an Australian CR context. Standardisation allows clinicians more time to spend with participants, and to tailor and individualise the care within the standard pathway. It is also essential that CR programs are delivering all required components of prevention. As highlighted previously, a systematic review and meta-analysis of contemporary CR randomised controlled trials\textsuperscript{14}, found that only programs which addressed six or more risk factors reduced all-cause mortality, demonstrating the need to standardise programs to ensure they are comprehensive. Standardisation, paired with data can then measure the quality of care provided, allow for other processes such as benchmarking and provide further specific data to guide treatment plans for patient sub-groups.

Care quality is an increasing focus of funders, providers and consumers of healthcare. Currently in Australia, there is recognition of the importance of quality in CR, as several states are in the process, or have developed, quality indicators.\textsuperscript{50–54} There is now work underway to create national quality indicators.\textsuperscript{62} However, Australian CR has many steps to realise standardisation and quality of CR at state or national levels. The CR model in the United Kingdom has multiple components at the health system level working towards care reform of secondary prevention services including: minimum standards (as defined by the British Association for Cardiovascular Prevention and Rehabilitation), clinical guidance (provided by the National Institute for Health and Care Excellence) and a National
Certification Programme for CR. Priorities for quality improvement of Australian CR would be to use the research underpinning this program outline and feed it into national CR guidelines. These could be stand-alone or could be a supplement to existing ACS, heart failure and atrial fibrillation guidelines. Additionally the development of state based registries and national quality indicators also need to be actioned.

**Strengths and limitations**

The strengths of our program of content for Australian CR programs include using an extensive literature search, paired with a robust method to validate best practice statements using local experts. We also followed RAND criteria closely by ensuring members of the team had conducted the RAND/UCLA process before as the manual strongly advocates the process of “seeing one” before “doing one”.

There are however some limitations of this methodology where the participants of the RAND/UCLA process may not be able to extend their vision to the wider context of the problem. We did try and balance this however with the presence of consumers within the EAG, and specifically consulted them when panel discussions could not easily be resolved. Secondly, the literature review was not systematic and therefore it is possible that studies, guidelines or core components may have been missed from our review. Performing a systematic review was outside of the scope of this project, however we aimed to ensure the review was comprehensive by searching multiple databases, checking reference lists of included studies and documents and consulting with the EAG. Finally, this study was conducted in one state of Australia, however the membership of the EAG was national in order to give wider perspective and so that this work can be implemented on a national scale in the near future.

**Future directions**

The next phase of this work is underway and includes the development of a web-based resource. The final resource will be assessed by end-users to ensure it is appropriate, acceptable and easy to use for CR coordinators and staff. In addition, ideally the future online resource will be dynamic, enabling updates to occur as new evidence becomes available and defray the costs of reprinting hard copy publications. Resources will then be rolled out to end-users, initially in Victoria through the Heart Foundation, Safer Care Victoria and the ACRA state chapter. The resource should make it easy for current CR programs to assess whether the education component of their program meets our best
practice statements, especially in terms of ensuring they meet best practice statements classed as essential. Importantly, to aid in translation, future work with end-users via ACRA and Heart Foundation networks is planned (webinars, seminar etc.)

Implications
While this work has been focussed in the state of Victoria, dissemination of the outlines is planned nationally. It is anticipated that this would be the starting point toward national standardisation, which aligns closely with the current work being undertaken with CR quality indicators in Australia. The process of developing this standardised program of content outline has been invaluable for reinforcing critical links within the Australian CR landscape (Heart Foundation, government, ACRA). This work has also assisted with driving the momentum of CR advancement in Australia to aid with increasing consistency and quality. This is important not only for the traditional face to face programs, but for new and emerging methods of CR delivery such as mobile health. The next logical step is to then investigate the best way for this content to be delivered, so guidance can also be developed for the optimum delivery of this content.

CONCLUSION
We have developed an evidence-based, expert consensus driven standardised program outline of content for CR in Australia comprising of 47 best practice statements within 10 modules. In light of the absence of Australian CR clinical guidelines, this program outline provides an essential resource for CR program coordinators and staff.

ACKNOWLEDGEMENTS
We wish to acknowledge the Expert Advisory Group for their input and guidance in the development of this project. Additional expert advice was also sought from Sarah White (QUIT Victoria) and Cia Connell (Heart Foundation). We would also like to acknowledge Eugene Lugg (Heart Foundation) for ongoing assistance with translation of this work.

FUNDING STATEMENT
This work was supported by Safer Care Victoria.
REFERENCES


## Supplementary Material

### Table 1. Identified guidelines

<table>
<thead>
<tr>
<th>Country/Author</th>
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<th>Title</th>
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<tbody>
<tr>
<td><strong>Australia</strong></td>
<td>2016</td>
<td>National Heart Foundation of Australia and Cardiac Society of Australia and New Zealand (Chew, Scott, Cullen et al.)</td>
<td>National Heart Foundation of Australia and Cardiac Society of Australia and New Zealand: Australian clinical guidelines for the management of acute coronary syndromes 2016</td>
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<tr>
<td>Scotland</td>
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<td>Scottish Intercollegiate Guidelines Network (SIGN)</td>
<td>Cardiac rehabilitation: A national clinical guideline</td>
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<td>Europe</td>
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<td>The sixth joint task force of the European Society of Cardiology and other societies on cardiovascular disease prevention in clinical practice</td>
<td>European guidelines on cardiovascular disease prevention in clinical practice</td>
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<td>Netherlands</td>
<td>2013</td>
<td>Achtten, Staal, van der Voort et al.</td>
<td>Exercise-based cardiac rehabilitation in patients with coronary heart disease: a practice guideline</td>
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<td>United Kingdom</td>
<td>2013</td>
<td>National Institute for Health and Care Excellence (NICE)</td>
<td>Myocardial infarction: cardiac rehabilitation and prevention of further cardiovascular disease</td>
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<td>Canada</td>
<td>2009</td>
<td>Canadian Association of Cardiac Rehabilitation</td>
<td>Canadian guidelines for cardiac rehabilitation and cardiovascular disease prevention: Translating</td>
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<td>New Zealand</td>
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<td>Best Practice Evidence-based guideline Cardiac Rehabilitation</td>
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Table 2. Identified core components/scientific statement documents

<table>
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<td>Australian Cardiovascular Health and Rehabilitation Association (ACRA) Core Components of Cardiovascular Disease Secondary Prevention and Cardiac Rehabilitation 2014</td>
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<td>Australia &amp; New Zealand</td>
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<td>National Heart Foundation of Australia and the Cardiac Society of Australia and New Zealand.</td>
<td>Reducing risk in heart disease an expert guide to clinical practice for secondary prevention of coronary heart disease</td>
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<td>Australia</td>
<td>2004</td>
<td>National Heart Foundation of Australia and Australian Cardiac Rehabilitation Association</td>
<td>Recommended Framework for Cardiac Rehabilitation '04</td>
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<td>American Heart Association</td>
<td>Cardiac Rehabilitation and Secondary</td>
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<td>USA</td>
<td>2010</td>
<td>American Association of Cardiovascular and Pulmonary Rehabilitation  (Hamm, Sanderson, Ades et al.)</td>
<td>Prevention of Coronary Heart Disease.</td>
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<td>Europe</td>
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<td>Cardiac Rehabilitation section of the European Association for Cardiovascular Prevention and Rehabilitation  (Piepoli, Corra, Adamopoulous et al.)</td>
<td>Core competencies for Cardiac Rehabilitation/Secondary Prevention Professionals: 2010 update.</td>
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<td>UK</td>
<td>2017</td>
<td>British Association for Cardiovascular Prevention and Rehabilitation (BACPR)</td>
<td>Secondary prevention in the clinical management of patients with cardiovascular diseases. Core components, standards and outcome measures for referral and delivery.</td>
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**Table 2.** Results from the Cochrane Library of Systematic Reviews, N=12

<table>
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<th>Year</th>
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<tr>
<td>Home-based versus centre-based cardiac rehabilitation</td>
<td>Delivery method</td>
<td>Anderson et al.</td>
<td>2017</td>
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<td>Patient education in the management of coronary heart disease</td>
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<td>Anderson et al.</td>
<td>2017</td>
</tr>
<tr>
<td>Topic</td>
<td>Description</td>
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</tr>
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<td>Psychological interventions for coronary heart disease</td>
<td>Psychological interventions</td>
<td>Richards et al.</td>
<td>2017</td>
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<td>Exercise-based cardiac rehabilitation in heart transplant recipients</td>
<td>Exercise – special population</td>
<td>Anderson et al.</td>
<td>2017</td>
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<tr>
<td>Exercise-based cardiac rehabilitation for adults with atrial fibrillation</td>
<td>Exercise – special population</td>
<td>Risom et al.</td>
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<td>Sibilitz et al.</td>
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<td>Exercise-based cardiac rehabilitation for coronary heart disease</td>
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<td>Anderson et al.</td>
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<td>Internet-based interventions for the secondary prevention of coronary heart disease</td>
<td>Delivery method</td>
<td>Devi et al.</td>
<td>2015</td>
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<td>Cardiac rehabilitation for people with heart disease: an overview of Cochrane systematic reviews</td>
<td>Overview (review of systematic reviews)</td>
<td>Anderson et al.</td>
<td>2014</td>
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<td>Promoting patient uptake and adherence in cardiac rehabilitation</td>
<td>Uptake and adherence</td>
<td>Karmali et al.</td>
<td>2014</td>
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</tbody>
</table>
**Table 3. Search terms used to find additional module evidence**

Search terms searched between Feb - June 2018

**Overview terms**

CVD: "cardiovascular disease" or "cardiac" “rehabilitation” or "secondary prevention"

**AND**

**Module specific search terms**

<table>
<thead>
<tr>
<th>Module</th>
<th>Search terms</th>
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<tr>
<td>1. Initial assessment and goal setting</td>
<td>Guideline and core component documents used for this module.</td>
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<tr>
<td>5. Exercise training and physical activity</td>
<td>“physical activity”, “exercise”, “sedentary behaviour”, “exercise intervention”, “exercise training”</td>
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<td></td>
<td>Healthy eating and weight management</td>
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<tr>
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<td>------------------------------------</td>
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<tr>
<td>7.</td>
<td>Tobacco cessation and alcohol reduction</td>
</tr>
<tr>
<td>8.</td>
<td>Psychosocial wellbeing</td>
</tr>
<tr>
<td>9.</td>
<td>Activities of daily living</td>
</tr>
</tbody>
</table>
A Pathway to Phase II Cardiac Recovery: A Quick Guide

- This Quick Guide summarises the evidence-based Best Practice Statements that are recommended for delivery in a cardiac rehabilitation program.

- The clinician is able to prioritise which content to provide in their service, as the Best Practice Statements have been assessed as 'essential' or 'desirable' by a cardiac rehabilitation expert advisory group.

- **Essential** (Red shade) The content presented in this Best Practice Statement should be prioritised for delivery in all cardiac rehabilitation programs.

- **Desirable** (Blue Shade) The content presented in this Best Practice Statement should be considered for delivery in cardiac rehabilitation programs, based on capacity and resources.

- For further information, example content and supporting resources, please refer to the full resource, A Pathway to Cardiac Recovery: Standardised Program Content for Phase II Cardiac Rehabilitation on the Heart Foundation website www.heartfoundation.org.au

<table>
<thead>
<tr>
<th>Initial assessment</th>
</tr>
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<tbody>
<tr>
<td>Comprehensively assess the CR participant’s needs and develop an individualised care plan. This initial assessment should include:</td>
</tr>
<tr>
<td>• socio-demographic information</td>
</tr>
<tr>
<td>• clinical history</td>
</tr>
<tr>
<td>• exercise capacity</td>
</tr>
<tr>
<td>• lifestyle risk factors (physical activity, diet, smoking, alcohol)</td>
</tr>
<tr>
<td>• psychosocial health (depression, anxiety)</td>
</tr>
<tr>
<td>• medications.</td>
</tr>
</tbody>
</table>

| Desirable initial assessment features to consider: |
| • adiposity (waist circumference) |
| • medical risk factors (blood pressure, lipids, blood glucose) |
| • ability to return to activities of daily living |
| • quality of life. |

- Following the initial assessment, encourage and support participants to set achievable goals.
Heart education and self-management

- Educate CR participants about self-management strategies.
  
  Give CR participants education (tailored to their condition, if possible) about:
  
  - the anatomy and physiology of the heart
  - how to return to activities of daily living
  - risk factors modification for secondary prevention in heart disease
  - chest pain management or a heart failure management plan.

Medication education and review

- Give CR participants medication education that includes basic indications and benefits of commonly prescribed medication therapy.

- Encourage and support participants to adopt strategies that lead to medication adherence.

- CR staff (including a pharmacist, if possible) should ensure CR participants are receiving optimal cardio-protective medications.

Managing medical risk factors

- Equip CR participants with the skills to self-manage or prevent hypertension.

- Equip participants with the skills to self-manage or prevent dyslipidaemia.

- Equip participants with the skills to self-manage or prevent diabetes.

Exercise and physical activity

- Give CR participants a tailored, progressive and supervised exercise training program.

- Educate participants about strategies to increase general physical activity and reduce sedentary behaviour.

Healthy eating & weight management

- Focus advice on making healthy dietary choices to reduce total cardiovascular risk.

- If resources allow, offer individualised consultation with a trained health professional to discuss diet. The goals are to understand the CR participant's current eating habits, and give personalised advice that is sensitive to culture, needs, socio-economic status, and capabilities.

- An Accredited Practising Dietitian should assess and manage CR participants with complex dietary requirements due to co-morbidities.

- Provide education and advice on the importance of maintaining a healthy weight for heart health. For participants who are overweight or obese, develop an individualised, achievable plan working towards an initial goal of losing 5–10% of body weight and a longer-term goal of achieving a body mass index (BMI) below 25.

- Consider referring participants requiring assistance with weight management to weight loss programs delivered by experts.

NEARLY 1 in 3 heart attacks ARE REPEAT EVENTS

**Tobacco cessation and alcohol reduction**

- Give CR participants who smoke a brief intervention for smoking cessation, using the Ask, Advice and Help model.

- Encourage participants who continue to smoke to use a combination of nicotine replacement products (patch plus gum or spray or lozenge or inhalator) and/or to visit their doctor to discuss other “stop smoking medications” to assist quitting.

- Offer participants who are excessive drinkers brief advice/counselling to encourage reduction of alcohol intake.

- Consider referring alcohol-dependent CR participants to specialised services and notify their general practitioner.

**Psychosocial wellbeing**

- Screen CR participants for depression and anxiety at the beginning and end of the CR program using a validated tool.

- Give participants an opportunity to discuss the typical emotional response to a heart event.

- Educate participants about the signs and symptoms of depression and other mood disorders.

- Assist participants to respond appropriately to ongoing psychological symptoms including when to seek help.

- Assess the social support available to CR participants and determine their social support needs.

- Discuss the importance of social support to heart health recovery, and encourage participants to reflect on how they can enhance or better utilise their social support networks.

- Consider how social networks can be enhanced for participants who report low levels of social support.

- Consider the contributions family members and carers can make to participants’ recovery.

- Consider encouraging partners or carers to join specific carer support groups to help them to cope with their family member’s cardiac condition.

---

**Cardiac rehabilitation can reduce unplanned cardiac readmissions by up to 18%**


**Patients are >2x as likely to participate in cardiac rehabilitation if a health professional discusses it with them before they leave hospital**

Source: Heart Foundation Heart Attack Survivor Survey, June 2018
### Activities of daily living

- Discuss driving restrictions with CR participants and help them to find further information.
- Give participants an opportunity to discuss any concerns related to resuming sex after their cardiac event.
- If a CR participant is unable to drive, explore alternatives to assist with independence.
- Include vocational guidance to facilitate graded return to work and discuss any barriers an individual may face returning to work.
- Give CR participants an opportunity to discuss and/or train in cardiopulmonary resuscitation (CPR).

### Reassessment and completion

The post-program assessment should include, at a minimum:

- exercise capacity
- lifestyle risk factors (physical activity, diet, smoking, alcohol)
- psychosocial health (depression, anxiety)
- medications

If possible and applicable, reassess CR participants’:

- adiposity (waist circumference)
- medical risk factors (blood pressure, lipids, blood glucose)
- quality of life
- success in returning to activities of daily living.

- Review CR participants’ goals at the completion of the program.
- Give the participant and their general practitioner and cardiologist a discharge or summary letter.
Appendix C: Chapter Two supplementary material
15 October 2015

Prof Brian Oldenburg
Melbourne School of Population and Global Health
The University of Melbourne

Dear Prof Oldenburg

Project title:  The ADVENT study (Anxiety Depression & Heart Rate Variability in cardiac patients: Evaluating the impact of negative emotions on functioning after Twenty four months)

Researchers:  Professor I Meredith, Mr M S Alharbi, Professor C Taylor, Professor D Clarke, Dr A Fisher, A/Prof A Forbes, Dr S Zavarese, Dr D McKenzie, Prof D L Hare, Dr J Oldroyd, Associate Professor K Sanderson, Dr A O’Neil, Prof B F Oldenburg, Dr A Dheerasinghe, Dr T Pathirane, Ms E Thomas

Ethics ID:  1441737

I am pleased to advise that the amendment 1441737.3 dated 30 September to this Project has been approved by the Health Sciences Human Ethics Sub-Committee.

Please note it is your responsibility to ensure that all people associated with the Project are made aware of the amendment.

Yours sincerely

Ms Hilary Young
Secretary, Health Sciences HESC
Phone: 03 8344 8595, Email: hilary.young@unimelb.edu.au
10th September 2015
Ms Julie Geptart
HREC Coordinator
Research Support Services
Level 2, I Block
Monash Medical Centre
Clayton Victoria 3168

Dear Julie

Amendments to the project - The ADVENT study (Anxiety Depression & Heart Rate Variability in cardiac patients: Evaluating the impact of negative emotions on functions after twenty four months

I wish to inform the ethics committee that three new post graduate students have joined the ADVENT study) from 1st of September 2015. Here with I have attach the HREC amendment form for the approval of the Health Science Human ethics committee.

Thank you

Professor Brian Oldenburg
BSc,MPsychol,PhD
Chair of Noncommunicable Disease Control
Director, Centre for Health Equity
Melbourne School of Population & Global Health
The University of Melbourne, Victoria 3010
Phone: +61-419025692
email: brian.oldenburg@unimelb.edu.au
http://www.pgh.unimelb.edu.au
# HREC Amendment Form

Where an ethically approved research project requires amendment, this form should be submitted to the reviewing HREC that approved the research by the Coordinating Principal Investigator.

If a multi-site research project, principal investigators (PI(s)) will be responsible for sending a copy, to their site's Research Governance Office.

## Research Project Details

<table>
<thead>
<tr>
<th><strong>HREC Reference Number</strong></th>
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<tr>
<td><strong>Coordinating PI/PI</strong></td>
<td>Brian Oldenburg</td>
</tr>
<tr>
<td><strong>Project Title</strong></td>
<td>The ADVENT (Anxiety and Depression &amp; heart rate variability in cardiac patients: Evaluating the impact of negative emotions on function after twenty four months)</td>
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<tr>
<td><strong>Date of this submission</strong></td>
<td>10th of September 2015</td>
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<tr>
<td><strong>HREC Approval Date</strong></td>
<td>19th October 2012</td>
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<td><strong>Site Name (Organisation)</strong></td>
<td>Monash University</td>
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## What changes have occurred or are intended?

Please note that these could include changes in procedure or direction of the project, in the source or manner of recruitment, in the number of participants or changes to research personnel. (max 200 words. Please attach an additional sheet, if required)

Three post-graduate students (two medical doctors and a PhD student with a clinical health background) have joined the study from 1st of September 2015 until 1st September 2016 to assist with aspects of data collection.

## Please explain the reason for these changes

Please include a comment on the impact of the changes on the project and in particular on the research participants (if any) at sites for which the HREC is responsible. (max 200 words. Please attach an additional sheet, if required)

All three have experience in enacting medical research and are trained health professionals. They will be trained by the Project Manager, overseen by the Chief Investigators, to execute the data collection protocol, thus this amendment is unlikely to impact on the research study.
HRRC Amendment Form

Do these changes raise any ethical issues?  ☑ Yes  ☐ No

If Yes, please identify any ethical issues. (Note: 100 words. Please attach an additional sheet, if required.)

Documents

List the amended documents that are to be reviewed for this amendment, including version date.

E.g. Participant Information and Consent Form  Version Date: X May 2008  

Have you provided one (1) copy of all amended documents with all changes clearly indicated?  ☑ Yes  ☐ No

Did a commercial sponsor initiate this amendment?  ☑ Yes  ☐ No

If Yes, please provide the following details:

Sponsor Name

Contact Person

Email Address/s

Note: Investigators should check with their Research Governance Officer to determine whether a site specific amendment is required including any fee payment that may apply (indicate the fee below).

CTN

If this is a drug/device research project, does the amendment include additional and/or different drugs/devices or involve a new indication for any drug/device from that approved in the original project?  ☑ Yes  ☐ No  ☑ N/A

Consultative Council for Human Research Ethics

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HREC Amendment Form

Does this amendment impact the type or frequency of service provided by a supporting department at participating sites?  

☐ Yes  ☑ No

If yes, provide written approval from the relevant departments to your own Research Governance Officer.

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<thead>
<tr>
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<th>Anatomical Pathology</th>
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<td>Other (specify):</td>
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Are all participating sites affected by this amendment?  

☑ Yes  ☐ No

If no, please list those sites that are affected

Please note: Amendments to ethically approved research may also impact the Site Specific Assessments. Research Governance Officers at the affected sites (named above) must be notified by the CPI/PI to determine if the SSA needs to be amended. Final approval to implement an amendment at individual sites will be issued by that site’s RGO.

Declaration

I confirm that this project is being conducted in keeping with the conditions of approval of the reviewing HREC and subject to any changes subsequently approved. I confirm that the project is being conducted in compliance with the NHMRC National Statement on Ethical Conduct in Human Research (NHMRC, 2007) or as amended. I confirm that I have not received any information in any form from anyone involved in the trial to suggest this report does not accurately reflect the progress of the project at the above site(s).

[Signature]

Signature of Principal Investigator:

Date: 09.07.2016

<table>
<thead>
<tr>
<th>CPI/PI Name</th>
<th>Brian Oldenburg</th>
<th>Trial Coordinator</th>
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<tr>
<td>Email</td>
<td><a href="mailto:brian.oldenburg@unimelb.edu.au">brian.oldenburg@unimelb.edu.au</a></td>
<td>Email</td>
</tr>
<tr>
<td>Phone Number</td>
<td>0419025652</td>
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STROBE Statement—Checklist of items that should be included in reports of *cohort studies*

<table>
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<th>Title and abstract</th>
<th>Recommendation</th>
<th>Author check</th>
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<tbody>
<tr>
<td>1</td>
<td>(a) Indicate the study’s design with a commonly used term in the title or the abstract</td>
<td>✓</td>
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<tr>
<td></td>
<td>(b) Provide in the abstract an informative and balanced summary of what was done and what was found</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Background/rationale</td>
<td>Explain the scientific background and rationale for the investigation being reported</td>
<td>✓</td>
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<tr>
<td>3</td>
<td>Objectives</td>
<td>State specific objectives, including any prespecified hypotheses</td>
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<tr>
<td>4</td>
<td>Study design</td>
<td>Present key elements of study design early in the paper</td>
<td>✓</td>
</tr>
<tr>
<td>5</td>
<td>Setting</td>
<td>Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection</td>
<td>✓</td>
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<tr>
<td>6</td>
<td>Participants</td>
<td>(a) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up</td>
<td>✓</td>
</tr>
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<td></td>
<td></td>
<td>(b) For matched studies, give matching criteria and number of exposed and unexposed</td>
<td>N/A</td>
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<tr>
<td>7</td>
<td>Variables</td>
<td>Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable</td>
<td>✓</td>
</tr>
<tr>
<td>8*</td>
<td>Data sources/measurement</td>
<td>For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group</td>
<td>✓</td>
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<td>9</td>
<td>Bias</td>
<td>Describe any efforts to address potential sources of bias</td>
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<td>10</td>
<td>Study size</td>
<td>Explain how the study size was arrived at</td>
<td>Ref provided for ADVENT protocol</td>
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<td>Quantitative variables</td>
<td>Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why</td>
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<td>Statistical methods</td>
<td>(a) Describe all statistical methods, including those used to control for confounding</td>
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<tr>
<td></td>
<td></td>
<td>(b) Describe any methods used to examine subgroups and interactions</td>
<td>✓</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(c) Explain how missing data were addressed</td>
<td>✓</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(d) If applicable, explain how loss to follow-up was addressed</td>
<td>✓</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(e) Describe any sensitivity analyses</td>
<td>✓</td>
</tr>
<tr>
<td>13*</td>
<td>Results</td>
<td>(a) Report numbers of individuals at each stage of study—e.g. numbers potentially eligible, examined for</td>
<td>✓</td>
</tr>
</tbody>
</table>

* indicates items that are specific to randomized controlled trials.
### Appendix C – STROBE checklist

**Eligibility**
- Confirmed eligible, included in the study, completing follow-up, and analysed
- Give reasons for non-participation at each stage
- Consider use of a flow diagram

<table>
<thead>
<tr>
<th>Descriptive data</th>
<th>14*</th>
</tr>
</thead>
<tbody>
<tr>
<td>(a) Give characteristics of study participants (e.g. demographic, clinical, social) and information on exposures and potential confounders</td>
<td>✓</td>
</tr>
<tr>
<td>(b) Indicate number of participants with missing data for each variable of interest</td>
<td>✓</td>
</tr>
<tr>
<td>(c) Summarise follow-up time (e.g. average and total amount)</td>
<td>✓</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Outcome data</th>
<th>15*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report numbers of outcome events or summary measures over time</td>
<td>✓</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Main results</th>
<th>16</th>
</tr>
</thead>
<tbody>
<tr>
<td>(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (e.g. 95% confidence interval). Make clear which confounders were adjusted for and why they were included</td>
<td>✓</td>
</tr>
<tr>
<td>(b) Report category boundaries when continuous variables were categorized</td>
<td>✓</td>
</tr>
<tr>
<td>(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period</td>
<td>N/A</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Other analyses</th>
<th>17</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report other analyses done—e.g. analyses of subgroups and interactions, and sensitivity analyses</td>
<td>✓</td>
</tr>
</tbody>
</table>

**Discussion**
- Summarise key results with reference to study objectives

<table>
<thead>
<tr>
<th>Key results</th>
<th>18</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias</td>
<td>✓</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Limitations</th>
<th>19</th>
</tr>
</thead>
<tbody>
<tr>
<td>Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence</td>
<td>✓</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Interpretation</th>
<th>20</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discuss the generalisability (external validity) of the study results</td>
<td>✓</td>
</tr>
</tbody>
</table>

**Other information**
- Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based

*Give information separately for exposed and unexposed groups.

Cardiac rehabilitation on 24-month all-cause hospital readmissions

Supplementary File 1: Sensitivity analysis

Table 1. Sensitivity analysis: Association between attending CR and number of hospital readmissions [1, 2, 3, 4, 5, 6] \(^a\) (No. of observations = 406 including imputed data)

<table>
<thead>
<tr>
<th></th>
<th>OR</th>
<th>95% CI</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unadjusted</td>
<td>0.61</td>
<td>0.40, 0.93</td>
<td>0.025</td>
</tr>
<tr>
<td>Model 1*</td>
<td>0.60</td>
<td>0.39, 0.92</td>
<td>0.022</td>
</tr>
<tr>
<td>Model 2†</td>
<td>0.53</td>
<td>0.32, 0.86</td>
<td>0.011</td>
</tr>
<tr>
<td>Model 3‡</td>
<td>0.53</td>
<td>0.31, 0.90</td>
<td>0.018</td>
</tr>
</tbody>
</table>

*Model 1: Linear regression adjusting for covariates
†Model 2: adjusted for propensity to participate in CR
‡Model 3: used inverse probability treatment weighting

Table 2: Association between attending CR and length of stay \(^a\) (No. of observations = 406 including imputed data)

<table>
<thead>
<tr>
<th></th>
<th>Coef.</th>
<th>95% CI</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unadjusted</td>
<td>-0.93</td>
<td>-1.83, -0.03</td>
<td>0.042</td>
</tr>
<tr>
<td>Model 1*</td>
<td>-0.94</td>
<td>-1.88, -0.008</td>
<td>0.048</td>
</tr>
<tr>
<td>Model 2†</td>
<td>-1.29</td>
<td>-2.37, -0.20</td>
<td>0.020</td>
</tr>
<tr>
<td>Model 3‡</td>
<td>-1.29</td>
<td>-2.62, 0.41</td>
<td>0.057</td>
</tr>
</tbody>
</table>

*Model 1: Linear regression adjusting for covariates
†Model 2: adjusted for propensity to participate in CR
‡Model 3: used inverse probability treatment weighting
Appendix D: Chapter Three supplementary material
Appendix D – Search strategy

PubMed
(((((acute coronary syndrome[MeSH Terms]) OR myocardial infarction[MeSH Terms]) OR percutaneous coronary intervention[MeSH Terms]) OR coronary artery disease[MeSH Terms] "cardiac") AND (rehabilitation))) AND (((registrier*) OR audit) OR data)) AND ((english[Language])

MEDLINE
exp acute coronary syndrome/
exp myocardial infarction/
exp percutaneous coronary intervention/
exp coronary artery disease/
"cardiac".mp.
1 or 2 or 3 or 4 or 5
Exp rehabilitation/
6 and 7
"registrier".mp.
"audit".mp.
"data".mp.
9 or 10 or 11
8 and 12
Limit 13 to (english language)

CINAHL
"cardiac rehabilitation"
AND
registry
OR
audit
AND
English
AND
national

Google Scholar
"cardiac rehabilitation", "NATIONAL registry", audit, data
### PRISMA CHECKLIST

<table>
<thead>
<tr>
<th>Section/topic</th>
<th>#</th>
<th>Checklist item</th>
<th>Reported on page #</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>TITLE</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Title</td>
<td>1</td>
<td>Identify the report as a systematic review, meta-analysis, or both.</td>
<td>53</td>
</tr>
<tr>
<td><strong>ABSTRACT</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Structured summary</td>
<td>2</td>
<td>Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.</td>
<td>54</td>
</tr>
<tr>
<td><strong>INTRODUCTION</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rationale</td>
<td>3</td>
<td>Describe the rationale for the review in the context of what is already known.</td>
<td>55-56</td>
</tr>
<tr>
<td>Objectives</td>
<td>4</td>
<td>Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).</td>
<td>57-58</td>
</tr>
<tr>
<td><strong>METHODS</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Protocol and registration</td>
<td>5</td>
<td>Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.</td>
<td>N/a</td>
</tr>
<tr>
<td>Eligibility criteria</td>
<td>6</td>
<td>Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.</td>
<td>57-58</td>
</tr>
<tr>
<td>Information sources</td>
<td>7</td>
<td>Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.</td>
<td>57</td>
</tr>
<tr>
<td>Search</td>
<td>8</td>
<td>Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.</td>
<td>Appen D</td>
</tr>
<tr>
<td>Study selection</td>
<td>9</td>
<td>State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).</td>
<td>57-58</td>
</tr>
<tr>
<td>Data collection process</td>
<td>10</td>
<td>Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.</td>
<td>58-59</td>
</tr>
</tbody>
</table>
### Data items
11 List and define all indicators for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made. 58-59

### Risk of bias in individual studies
12 Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis. n/a

### Summary measures
13 State the principal summary measures (e.g., risk ratio, difference in means). n/a

### Synthesis of results
14 Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., $I^2$, for each meta-analysis). 59

---

<table>
<thead>
<tr>
<th>Section/topic</th>
<th>#</th>
<th>Checklist item</th>
<th>Reported on page #</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risk of bias across studies</td>
<td>15</td>
<td>Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).</td>
<td>n/a</td>
</tr>
<tr>
<td>Additional analyses</td>
<td>16</td>
<td>Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.</td>
<td>n/a</td>
</tr>
</tbody>
</table>

### RESULTS

<table>
<thead>
<tr>
<th>Study selection</th>
<th>17</th>
<th>Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.</th>
<th>60, Fig 6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study characteristics</td>
<td>18</td>
<td>For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the papers.</td>
<td>Table 7</td>
</tr>
<tr>
<td>Risk of bias within studies</td>
<td>19</td>
<td>Present data on risk of bias of each study, and, if available, any outcome level assessment (see item 12).</td>
<td>n/a</td>
</tr>
<tr>
<td>Results of individual studies</td>
<td>20</td>
<td>For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.</td>
<td>Table 7,8</td>
</tr>
<tr>
<td>Synthesis of results</td>
<td>21</td>
<td>Present results of each meta-analysis done, including confidence intervals and measures of consistency.</td>
<td>n/a</td>
</tr>
<tr>
<td>Risk of bias across studies</td>
<td>22</td>
<td>Present results of any assessment of risk of bias across studies (see Item 15).</td>
<td>n/a</td>
</tr>
<tr>
<td>Additional analysis</td>
<td>23</td>
<td>Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).</td>
<td>n/a</td>
</tr>
</tbody>
</table>

### DISCUSSION
### Summary of evidence
24 Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).

### Limitations
25 Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).

### Conclusions
26 Provide a general interpretation of the results in the context of other evidence, and implications for future research.

### FUNDING
27 Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.

---


*For more information, visit:* [www.prisma-statement.org](http://www.prisma-statement.org)
Appendix E – Uni Melb ethics

08 May 2017

Dr Adrienne O’Neil
Melbourne School of Population and Global Health
The University of Melbourne

Dear Dr O’Neil

I am pleased to advise that the Health Sciences Human Ethics Sub-Committee approved the following Project:

Project title: The Victorian Cardiac Rehabilitation Registry (VCRR) project: Phase 1
Researchers: Dr W Keech, A/Prof D J Boyle, Professor N Cox, Dr L Neubeck, Dr A E O’Neil, Dr J E Manski-Nankervis, Ms E Thomas, E Boston, Professor R Gallagher, P S Grace
Ethics ID: 1748609

The Project has been approved for the period: 08-May-2017 to 31-Dec-2017

It is your responsibility to ensure that all people associated with the Project are made aware of what has actually been approved.

Research projects are normally approved to 31 December of the year of approval. Projects may be renewed yearly for up to a total of five years upon receipt of a satisfactory annual report. If a project is to continue beyond five years a new application will normally need to be submitted.

Please note that the following conditions apply to your approval. Failure to abide by these conditions may result in suspension or discontinuation of approval and/or disciplinary action.

(a) Limit of Approval: Approval is limited strictly to the research as submitted in your Project application.

(b) Variation to Project: Any subsequent variations or modifications you might wish to make to the Project must be notified formally to the Human Ethics Sub-Committee for further consideration and approval. If the Sub-Committee considers that the proposed changes are significant, you may be required to submit a new application for approval of the revised Project.

(c) Incidents or adverse effects: Researchers must report immediately to the Sub-Committee anything which might affect the ethical acceptability of the protocol including adverse effects on participants or unforeseen events that might affect continued ethical acceptability of the Project. Failure to do so may result in suspension or cancellation of approval.

(d) Monitoring: All projects are subject to monitoring at any time by the Human Research Ethics Committee.

(e) Annual Report: Please be aware that the Human Research Ethics Committee requires that researchers submit an annual report on each of their projects at the end of the year, or at the conclusion of a project if it continues for less than this time. Failure to submit an annual report will mean that ethics approval will lapse.

(f) Auditing: All projects may be subject to audit by members of the Sub-Committee.

If you have any queries on these matters, or require additional information, please contact me using the details below.

Please quote the ethics registration number and the title of the Project in any future correspondence.

On behalf of the Sub-Committee I wish you well in your research.

Yours sincerely

Ms Hilary Young - Secretary
Health Sciences HESQ
Phone: 03 8344 8595, Email: hilary.young@unimelb.edu.au

RESEARCH, INNOVATION & COMMERCIALISATION
Incorporating Uniti Commercial Ltd and the School of Melbourne Cutsor Programs
The University of Melbourne, Victoria 3010, Australia
E: info@unimelb.edu.au T: 13000 73070 W: unimelb.edu.au/mba

262
12 April 2017

Dr Adrienne O’Neil
University of Melbourne
Lvl 4, 207 Bouvier St
CARLTON VIC 3010

Dear Dr O’Neil,

Re: (VCRR) The Victorian Cardiac Rehabilitation Registry Project (Our ref: 1142)

Thank you for forwarding the above pilot registry for review by the St John of God Health Care (SJGHC) Human Research Ethics Committee (HREC) (“the Committee”).

I am pleased to advise that the Committee has granted ethical approval of your study via an expedited review process as per section 5.1.7 of the National Health and Medical Research Council’s National Statement on Ethical Conduct in Human Research (NHMRC, 2007) (“the National Statement”). Specifically, the Committee has approved for this registry a waiver of consent as per section 2.3.9/10 of the National Statement.

This ethical approval is inclusive of the documents attached to your submission dated 27 March 2017, and is subject to receipt of ethical approval from the University of Melbourne HREC.

The HREC approval period is from 12 April 2017 to 31 December 2017. Should an extension of this timeframe be required, you must seek continued approval from the Committee before the expiry of this time period.

In accordance with NHMRC guidelines, the Participating Site/Principal Investigator is responsible for:

1. Notification to the HREC of any adverse events or unexpected outcomes that may affect the continuing ethical acceptability of the study;
2. The submission of any proposed amendments to the study or previously-approved documents;
3. The submission of an annual progress report for the duration of the study which is due on the anniversary of HREC approval;
4. Reporting of any protocol deviations or violations, together with details of the procedure(s) put in place to ensure the deviation or violation does not recur;
5. Notification and reason for ceasing the study prior to its expected date of completion (if applicable);
6. The submission of a final report and translation of results (including publications) upon completion of the study.

The St John of God Health Care Human Research Ethics Committee is constituted and operates in accordance with the National Health and Medical Research Council’s National Statement on Ethical Conduct in Human Research (2007).
WESTERN HEALTH LOW RISK HUMAN RESEARCH ETHICS PANEL
APPROVAL TO CONDUCT RESEARCH AND
SITE SPECIFIC ASSESSMENT (SSA) AUTHORISATION

15 June 2017

Professor Nicholas Cox
Cardiology
Sunshine Hospital
176 Furlong Road
St Albans VIC 3021

Dear Prof Cox,

LREP Project Number: LNR/17/WH/57

Project Title: Victorian Cardiac Rehabilitation Registry (Phase 1)

LREP Approval Date: 14 June 2017 SSA Approval Date: 15 June 2017

Principal Investigator/s: Dr Adrienne O’Neill & Prof Nicholas Cox

I am pleased to advise that the above project has been given ethics approval by the Western Health Low Risk Ethics Panel (LREP). The LREP confirms that your proposal meets the requirements of the National Statement on Ethical Conduct in Human Research (2007).

This project has also been issued with site specific approval to be conducted at Western Health.

Ethics & Governance approval for this project applies at the following sites:

- Sunshine Hospital

Conditions of Ethics Approval and Governance Authorisation:

You are required to submit to the LREP:

- The actual start date of the project at Western Health.
- An Annual Progress Report (that covers all sites listed on approval) for the duration of the project. This report is due on the anniversary of LREP approval date. Continuation of ethics approval is contingent on submission of an annual report, due within one month of the approval anniversary. Failure to comply with this requirement may result in suspension of the project by the LREP.
- A comprehensive Final Report upon completion of the project.
- Submit to the LREP for approval any proposed amendments to the project including any proposed changes to the Protocol and Participant Information and Consent Form/s.
- Notify the LREP of any adverse events that have a material impact on the conduct of the research.
- Notify the LREP of your inability to continue as Principal Investigator.
- Notify the LREP of the failure to commence the study within 12 months of the LREP approval date or if a decision is taken to end the study at any of the sites prior to the expected date of completion.
- Notify the LREP of any matters which may impact the conduct of the project.
Approved/Noted Documents:

<table>
<thead>
<tr>
<th>Document</th>
<th>Version</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low &amp; Negligible Risk National Ethics Application Form (LNR NEAF); AU/13/693D216</td>
<td></td>
<td>14 April 2017</td>
</tr>
<tr>
<td>Western Health LNR Risk Assessment Form</td>
<td>1</td>
<td>11 April 2017</td>
</tr>
<tr>
<td>Western Health Site Specific Form</td>
<td></td>
<td>24 April 2017</td>
</tr>
<tr>
<td>Protocol</td>
<td>3</td>
<td>02 June 2017</td>
</tr>
<tr>
<td>Appendix A: List of Variables for each site</td>
<td>1</td>
<td>11 April 2017</td>
</tr>
<tr>
<td>Appendix B: GRHANITE Data Security Information Sheet</td>
<td>2.1</td>
<td>11 April 2017</td>
</tr>
<tr>
<td>Appendix C: Western Health Participant Information Sheet</td>
<td>2</td>
<td>02 May 2017</td>
</tr>
<tr>
<td>Appendix D: Western Health Consent Form</td>
<td>2</td>
<td>02 May 2017</td>
</tr>
<tr>
<td>Appendix H: Brochure for CR session rooms and waiting areas</td>
<td>1</td>
<td>02 June 2017</td>
</tr>
<tr>
<td>Statement of Approval – Cardiac Outpatient Rehabilitation Services</td>
<td></td>
<td>24 April 2017</td>
</tr>
<tr>
<td>Curriculum Vitae &amp; WH Researchers code of Conduct</td>
<td></td>
<td>12 April 2017</td>
</tr>
<tr>
<td>• Adrienne O’Neil</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research Collaboration Agreement between Western Health and The University of Melbourne</td>
<td></td>
<td>15 June 2017</td>
</tr>
</tbody>
</table>

The Office for Research may conduct an audit of the project at any time.

The Office for Research Western Health wishes you and your colleagues every success in your research.

Yours sincerely,

Ms Virginia Ma
Research Governance Officer
On behalf of the Western Health Low Risk Ethics Panel
Western Health Office for Research
Email: ethics@wh.org.au
Expanded Methods (GRHANITE™)

Data Extraction

GRHANITE™ operates within the institutional boundaries of the collaborating hospital or clinic. Data extracted utilising GRHANITE™ is by pre-arrangement with IT departments. The GRHANITE™ development team work with the IT department to define what data are available and to determine how it may be accessed. GRHANITE™ is then configured to operate in conjunction with the local IT requirements, permitted data formats and data sets. For this study, patient identifying information was removed prior to transmission.

Data security

All communications are secured via GRHANITE™ end-point public/private key encryption. The study data are further encrypted separately utilising one of 10,000 randomly assigned Rivest-Shamir-Adleman (RSA) key pairs and 256-bit Advanced Encryption Standard (AES) encryption. The keys that allow the study data to be decrypted are located solely on the project designated secure data repository and are ultimately decrypted using GRHANITE™ Databank software.

Data storage

The encrypted data was securely transmitted to secure Virtual Servers hosted on the National ResearchCloud Infrastructure (hosted by The University of Melbourne). These data are kept separately from any other data. Data will be kept for 5 years, or the lifecycle of the registry in its original or larger form (pending future ethics approval).
Expanded Methods (REDCap)

The REDCap tool was developed by Vanderbilt University and is a secure web application designed to enable researchers to design and build their own surveys and data capture forms.

Data Security

The REDCap surveys for this project were hosted on ResearchCloud at The University of Melbourne. Users required a registered login and were only able to access projects they had been granted permission for by the project owner. Within each project, user rights were further restricted to specific data capture forms (e.g., researchers were unable to view the first form which contained patient identifying data). REDCap also has a “Data Access Group” (DAG) function which ensures data collected from multi-site studies is only accessible to the appropriate users (e.g., clinicians from Site 1 could only view data from Site 1). This user rights security and DAG feature ensured that the research team were unable to view any patient identifiable data, the clinical staff at each hospital could only see their patient’s data, and enabled the capture of key demographic information to ensure patient linkage was able to be achieved between the GRHANITE extracted data from the hospitals administrative data systems and the captured REDCap data.

Data extraction

Reports could be run easily by the clinical staff to ensure that the collected REDCap data was de-identified, through exporting the custom-built reports into a Comma Separated Values (CSV) file at each site. GRHANITE was then used to extract the data.

Data quality

As the REDCap surveys were custom built, the research team could define each required variable response. Essential data was set as “mandatory” and the data form could not be completed without such data being entered. Responses also had set word of character lengths (e.g., patient
Medicare numbers were set to 10 digits) to help ensure data quality. Drop down lists or check boxes were incorporated to ensure consistent responses where appropriate.
Appendix E – Semi-structured interview questions

Semi-structured interview questions with CR clinical staff

SITE: __________ INTERVIEWEE: ______________________________

Introduction
As part of the Victorian Cardiac Rehabilitation Registry VCRR (Phase 1) study we are collecting information from your CR site. We are interested in exploring the factors that may impact the collection of data and reasons behind why data may vary across sites (e.g., variations in the patient population, staffing ratios, length of program).

You do not have to answer every question and can cease the interview at any time. Before we start do you have any questions?

Background information
1. How many CR programs does your health services run? Across how many locations?
___________________________________________________________________________
___________________________________________________________________________

2. Approximately, how many patients attend the CR sessions per week/month? How many in each group?
___________________________________________________________________________
___________________________________________________________________________

3. How many sessions are included in each CR program?
___________________________________________________________________________
___________________________________________________________________________

4. How many funded staff members support the running of the CR program/s? What are their roles?
___________________________________________________________________________
___________________________________________________________________________

5. How is the program funded?
___________________________________________________________________________
___________________________________________________________________________
Utilising the REDCap online forms to collect CR data

Prior to using the REDCap system:

• How did your CR program collect information on the CR program?

• Who would enter this information and what other duties/competing responsibilities do they have?

• Did you routinely collect information on each of the following indicators?

1. CR wait time (Length of time from date of hospital discharge or referral to commencement of CR program)

2. Assessment of adiposity (Delta change of waist circumference at post-program)

3. Assessment of exercise capacity (Delta change in METS of 6MWT)

If not, what were some of the barriers to collecting this information?
If not, what were some of the barriers to collecting this information?
___________________________________________________________________________
___________________________________________________________________________

4. **Assessment of depression & referral to mental health management if ≥ moderate depression**
___________________________________________________________________________
___________________________________________________________________________
If not, what were some of the barriers to collecting this information?
___________________________________________________________________________
___________________________________________________________________________

5. **Current or recent smokers referred to smoking cessation advice/counselling**
___________________________________________________________________________
___________________________________________________________________________
If not, what were some of the barriers to collecting this information?
___________________________________________________________________________
___________________________________________________________________________

6. **Assessment of evidence-based medications (pre/post)** *(Medication prescription status at pre- and post-assessment of patients with principal diagnosis of ACS and or CHF)*
___________________________________________________________________________
___________________________________________________________________________
If not, what were some of the barriers to collecting this information?
___________________________________________________________________________
___________________________________________________________________________

• Were there any incentives/disincentives to collecting CR data?
___________________________________________________________________________
Appendix E – Semi-structured interview questions

- Were there sufficient resources to collect CR data?

- What were the main barriers to collecting CR data?

- How was the CR data used?

Using the REDCap system:

- How frequently did you enter data into REDCap? (Daily, weekly, monthly)

- How would you describe the data entry process? (Easy, somewhat easy, average, somewhat difficult, difficult)

Were you provided with enough training and support to be able to enter the CR data into REDCap?

- On average, how much time (mins) did it take to enter one patient file into the REDCap system?

Did any other duties/competing responsibilities interfere with entering the REDCap data?

Did you see entering CR data into REDCap as part of your role?

- Were any of the items in the REDCap tool ambiguous or difficult to answer?
Appendix E – Semi-structured interview questions

- How confident are you that you entered data into REDCap correctly?

- Did entering data into REDCap have any influence on the delivery of the CR program?

- In your opinion, why did your site decide to partake in this study to assess the feasibility of establishing a Victorian Cardiac Rehabilitation registry?

Future use of the REDCap system:

- Would you like to continue collecting CR data through the REDCap system? Why/why not?

  Do you have any suggestions on how the data entry process could be improved?

  Would the use of the automated reports generated through REDCap be of benefit to you?

Is there anything else about the CR program that you would like to mention that is not already covered?

THANK YOU VERY MUCH FOR YOUR TIME
### Supplementary table: Barriers to measuring and entering data and illustrative quotes

<table>
<thead>
<tr>
<th>Barrier theme</th>
<th>Barrier sub-category</th>
<th>Process indicator</th>
<th>Example quote</th>
</tr>
</thead>
<tbody>
<tr>
<td>Workload and competing responsibilities</td>
<td>Clinical responsibilities and time constraints</td>
<td>All</td>
<td>“Challenges to entering CR data] is time management when there is pressure to see and do something acute” (CRC3)</td>
</tr>
<tr>
<td></td>
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<td></td>
<td>“If there were barriers it would be time if anything” (CRC3)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>“Sometimes there’s been difficulties getting that [entering CR data] done in a timely manner because of time constraints”</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>“As a senior clinical nurse specialist, you can be pulled all over the place” (CRC1)</td>
</tr>
<tr>
<td>Environmental context and resources</td>
<td>Information technology systems and access</td>
<td>All</td>
<td>“The main problem has been the clunkiness of the IT system – using Excel spreadsheets it jumps around and misbehaves” (CRC1)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>“I don’t have access to my laptop on the ward” (CRC1)</td>
</tr>
<tr>
<td></td>
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<td></td>
<td>“Ideally, I’d be entering it on an I-Pad then and there so you are entering it once and not going back twenty times” (CRC1)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>“We are still transitioning from a very paper-based sort of system to electronic and ... ideally we would have moved to something we can pull [electronically] but we are still having to enter manually” (CRC2)</td>
</tr>
<tr>
<td></td>
<td>Having a quiet, secure space to enter data</td>
<td>All</td>
<td>“Being in a very cramped office, I can be here and could have four other people, talking on the phone... I found that very distracting trying to put the data in” (CRC1)</td>
</tr>
<tr>
<td>Patient factors</td>
<td>Patient health (e.g., cardiac signs or co-morbidities) may restrict</td>
<td>Exercise capacity</td>
<td>“The only time it’s [exercise capacity] not done would be functionally there is an issue with the patient, they are exhibiting some cardiac...”</td>
</tr>
</tbody>
</table>

274
<table>
<thead>
<tr>
<th>Topic</th>
<th>Domain</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ability to perform outcome measures</td>
<td>flags such as ischemic chest pain, dizziness, not feeling well (CRC1)</td>
<td></td>
</tr>
<tr>
<td>Patient has not provided requested information e.g., medication list or returned completed assessment of depression</td>
<td>Ax. of depression, Ax. of medications</td>
<td>“It can be very hard to get patients to bring in their information and follow-up” (CRC1)</td>
</tr>
<tr>
<td>Conflict between patient needs and data collection requirements</td>
<td>All</td>
<td>“Individual patients might be focused on other things in an assessment and because we have set timeframes coming into the program, if they are spending most of their time talking about their medications you may not get to every other bit of information” (CRC2)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>“When you are assessing a patient your presented with a whole group of issues often and you need to prioritise and so waist circumference may not get done” (CRC1)</td>
</tr>
<tr>
<td>Care delivery processes and coordination</td>
<td>CR wait time</td>
<td>“A lot of organisations are still faxing it [CR referral] or putting it in the post … that can take 14 days or longer to get to me” (CRC1)</td>
</tr>
<tr>
<td>Accuracy of data impacted by patient attendance of the initial assessment</td>
<td>CR wait time</td>
<td>“If they declined or failed to attend [the initial assessment] there is a higher likelihood of them not being entered” (CRC2)</td>
</tr>
<tr>
<td>Lacking post-CR data on patients who do not complete CR or decline to attend</td>
<td>Exercise capacity</td>
<td>“Post-CR data has more anomalies – people may stop at session 4 or 5, or not complete or decline” (CRC2)</td>
</tr>
</tbody>
</table>
| Outcome expectations (perceived importance, beliefs about consequences) | Not part of what is historically done | Referring smokers, depression screening | “We advise about quit lines but we don’t actively refer” (CRC3)

“It [depression screener] is measured but not recorded on our Excel spreadsheet. Our spreadsheet was developed 10 or so years ago or greater and wasn’t something that we measured at the time it was developed” (CRC2)

Reduced confidence in the data due to measurement errors | Ax. of adiposity | “Because if someone is taking a measurement around the waist it can be so arbitrary” (CRC1)

“I think some clinicians think some data is more important than others ... so at the moment like with waist circumference, I know it is done by one nurse and not the other” (CRC2) |
Appendix F: Chapter Six supplementary material
Improving the Monitoring of Cardiac Rehabilitation Delivery and Quality: A Call to Action for Australia

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*fTranslational Public Health and Evaluation Division, Stroke & Ageing Research, Department of Medicine, School of Clinical Sciences at Monash Health, Monash University, Clayton, Vic, Australia
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Keywords
Registry • Cardiac rehabilitation • Audit • Quality indicators

In Australia, there are over 65,000 acute coronary events each year and 625,000 people living with coronary heart disease (CHD). Among survivors, approximately 20% will suffer a second cardiovascular event in the first year. Secondary prevention services, including cardiac rehabilitation (CR), are well-established and effective forms of preventing recurrent cardiovascular events. There is strong evidence that greater uptake of CR can reduce the burden of disease and result in broader social and economic benefits. Despite this, referral of eligible Australian patients to CR is as low as 30% (although the exact rates cannot be ascertained), due to a range of barriers at the provider and system levels (e.g., lack of recommendation from doctors, lack of electronic referral systems). Other key issues, not unique to the Australian setting, relate to lack of standardisation in content, delivery, and quality.

There is increasing aspiration nationally and internationally to improve the monitoring of CR, as a means to enhance the quality of care delivered and outcomes for people living with CHD. However, the ability to quantify healthcare quality relies on the availability of appropriate systems that can accurately capture how care is being delivered and patient outcomes, and this could be strengthened in Australia. In contrast, other high-income countries such as the United States, the United Kingdom and Europe have clinical quality registries to provide a vehicle for measuring the ‘real-world’ delivery of care. Such registries can promote improvement in care quality, and hence increase return on investment. Australia urgently needs to meet international standards through developing a national registry or auditing system to monitor and evaluate CR service delivery.

In the past 5 years, multiple states and organisations across Australia have been independently working towards solutions to these issues with a focus on the routine collection of CR service data. Further, Commonwealth support is...
increasing for a national cardiac registry, following the report released by the Australian Commission on Safety and Quality in Health Care [10], which ranked ischaemic heart disease as the highest priority condition that would benefit from registry development given the burden of disease, serious consequences associated with poor quality care and strong clinical support. Further, in May 2019 the Department of Health opened consultation on the Draft National Clinical Quality Registry Strategy [12].

To capitalise on these initiatives and the growing momentum across jurisdictions, it is timely to develop collaborative recommendations to enhance monitoring of CR across Australia to improve outcomes for people living with heart disease.

Accordingly, in September 2018, a national roundtable meeting was held to discuss: i) current approaches to the monitoring and evaluation of CR services across different states, as well as ii) identify and reach consensus on the next steps for implementing national evaluation systems. The meeting was hosted by the South Australian Academic Health Science and Translation Centre (Health Translation SA), in partnership with the Australian Cardiovascular Health and Rehabilitation Association (ACRA) and the National Heart Foundation of Australia (NHFA). Australian researchers (N = 9), clinicians (N = 7), policy-makers (N = 8), and consumer representatives (N = 2) attended, with at least one ACRA representative from each State or Territory.

Current Approaches to CR Monitoring and Evaluation in Australia

Representatives from each state and territory provided a summary of their respective approaches to measuring delivery and effectiveness of CR services (Table 1). Status varied widely. Queensland incorporates CR data into the Queensland Cardiac Outcomes Registry (QCOR) [13], and currently captures data from 43/46 public hospital outpatient CR sites. In South Australia there has been a minimum dataset and database since 2012, with three state-wide audits comprising 24 rural and metropolitan services conducted [14]. Western Australia, the Northern Territory and Tasmania reported no systematic approach in place for routinely capturing state-level CR data. It was reported that pilot studies were

<table>
<thead>
<tr>
<th>State</th>
<th>Year</th>
<th>Initiative</th>
<th>Outcome</th>
<th>Status</th>
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<tbody>
<tr>
<td>QLD</td>
<td>2015-</td>
<td>Queensland Cardiac Outcomes Registry (QCOR)</td>
<td>43/48 outpatient sites included</td>
<td>Active</td>
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<td></td>
<td></td>
<td>• Established by the Statewide Cardiac Clinical Network to collect and use</td>
<td></td>
<td>Funded by QLD Health and</td>
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<td>clinical data to provide insights into the quality and safety of cardiac</td>
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<td>the Statewide Cardiac</td>
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<td></td>
<td></td>
<td>care across Queensland in public patients (and to include private providers)</td>
<td></td>
<td>Clinical Network</td>
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<td>• In 2017, QCOR added a CR module to the registry which captures CR</td>
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<td>referral, pre and post-CR assessments performed in sub-acute and</td>
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<td>community-based outpatient settings (e.g. change in exercise capacity,</td>
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<td></td>
<td></td>
<td>depression screening, risk factors). The two main outcome measures are 1)</td>
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<td>timely referral and 2) timely assessment.</td>
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<tr>
<td>NSW/ACT</td>
<td>2015</td>
<td>NSW Minimum Data Set Working Party</td>
<td></td>
<td>Piloting</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• NSW branch of ACRA and NHF plus the NSW Agency of Clinical Innovation</td>
<td></td>
<td>Partial funding from the</td>
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<tr>
<td></td>
<td></td>
<td>have developed a set of CR quality indicators and a data dictionary which</td>
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<td>NSW NHF</td>
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<td></td>
<td></td>
<td>are currently being piloted across 41 sites in NSW, ACT and Tasmania,</td>
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<td>collected via Excel spreadsheets.</td>
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Table 1 CR quality initiatives reported by Australian states and territories.
underway in New South Wales (including data from the Australian Capital Territory and Tasmania) and Victoria, both applying methods by which to extract data from sites using quality indicators developed by New South Wales [15]. An absence of a uniform set of quality indicators (including process and outcome indicators) was identified.

**Recommendations to Achieve National CR Monitoring and Evaluation**

During the roundtable the following key gaps and opportunities to advance the monitoring and quality of CR services across Australia were identified (Table 2). The NHFA and ACRA recognise that a national CR registry (or audit) is a key action required to tackle CHD [18]; the requirements of which should be considered and importantly, a business-case developed. The development of a national CR registry that reports on nationally developed quality indicators in a consistent format would enable standardised data to be collected and reported across Australia and would provide a foundation for quality improvement initiatives.

As part of these recommendations, it was unanimously agreed that the development of national quality indicators to measure CR quality is required as first step. Consensus was reached on the establishment of a national taskforce with representation from the NHFA, ACRA, and the key CR statewide initiatives (including a representative from South Australia, Queensland, Victoria and New South Wales). The taskforce’s primary responsibility will be to develop a set of national quality indicators and an accompanying data collection template.
Acknowledgements

ET is supported by a Postgraduate Scholarship (APFI113920) from the National Health and Medical Research Council, Australia and AD is supported by a Future Leader Fellowship (#101160) from the Heart Foundation, Australia.

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[18] National Heart Foundation. Six actions the next Australian Government must take to tackle our biggest killer. Heart Disease; 2018.
IMPROVING CARDIAC REHABILITATION MEASUREMENT IN AUSTRALIA THINK TANK

COMMUNIQUE

On 26 September 2018 the SA Academic Health Science and Translation Centre (the SA Translation Centre) Cardiac Rehabilitation Priority Project jointly hosted a national forum in Adelaide – The National Improving Cardiac Rehabilitation Measurement Think Tank.

The purpose of the forum was to:
- share state-based activities on measuring the effectiveness of Cardiac Rehabilitation (CR) services;
- progress the development of a minimum dataset of national quality indicators; and
- determine the next steps to progress the measurement of CR across Australia.

This Think Tank was supported through funding from the Medical Research Future Fund Rapid Applied Research Translation Program and was a partnership between the SA Translation Centre, the Australian Cardiovascular Health and Rehabilitation Association (ACRA) and the National Heart Foundation of Australia (NHFA). It included consumer, clinician, researcher, data, health and policy promotion leaders representing Northern Territory, Western Australia, South Australia, Tasmania, Queensland, Victoria and New South Wales.

Why measure cardiac rehabilitation and secondary prevention in Australia?

In 2014-15, nearly 625,000 Australians (2.7%) reported having long term heart disease, causing 160,000 hospitalisations and costing 1.5 billion of the annual health budget. Survivors of a heart attack or threatened heart attack have >20% risk of a repeat event within 2 years, some of which are fatal. Cardiac rehabilitation services are proven to assist patients to reduce their risk factors (high blood pressure and/or cholesterol, smoking, diabetes and depression) and can prevent another heart event. National, expert guidelines recommend referral to CR.5,6

Despite the evidence, referral rates in Australia remain poor (approx. 45%) and once referred, attendance and completion rates remain low (approx. 20-60%). Barriers include a combination of psychological, social and system factors. Importantly contemporary Australian data on referral, attendance and completion rates are lacking. CR services also vary widely in terms of program content, structure and delivery.

Measuring the quality of CR services can improve patient experience and outcomes. Further, aggregated data from multiple health services can support comparisons and identify areas for improvement. High quality data are needed to monitor service effectiveness. Consequently, clinicians and decision makers are informed of the evidence and value proposition of CR services.

What happened at the Think Tank?

Following presentations on the current evidence on global CR registries and a national environmental scan, services from each state provided a status update on their service measurement activities. Of note New South Wales, Queensland, South Australia and Victoria are already progressing significant bodies of work to measure CR services. A workshop was facilitated to conceptualise and determine the way forward.

Consumer members spoke to the importance of focusing on the measurement of patient experiences and outcomes. There was support for pre- and post-patient assessments as the best way of measuring program effectiveness, highlighted by an improvement in risk factors and quality of life. The Think Tank was an example of how collaboration can be harnessed to progress an initiative across the country.
IN-PRINCIPLE RECOMMENDATIONS

- Progress the establishment of a national set of quality indicators for CR service measurement which state/territories can use where feasible.
- Use the common quality indicators for CR that have been identified in SA, QLD and NSW to form the basis of a national minimum set of indicators. These include:
  - Referral to cardiac rehabilitation
  - Wait times to commence a service
  - Guideline medications at discharge and on service completion
  - Completion of a CR service
  - Pre and post assessments to measure change in risk factors including: depression, smoking, HBA1C, cholesterol, blood pressure, physical activity and waist circumference and quality of life.

By the end of the day there was agreement to:

- Establish a Taskforce that will meet at least twice before the end of 2018 to progress the development of the above quality indicators.
- The Taskforce will develop the detail on each indicator and work towards compiling a data dictionary.
- Barriers and enablers to collecting data should be outlined against each quality indicator.
- Where states have already progressed this work, information outlining the processes, barriers and enablers could be collated, written up and published with the aim of sharing learnings with others.

Acknowledgement goes to the following people for their attendance and contributions:

- SA Translation Centre - Wendy Keech, Meghan Douglass
- Heart Foundation - Rachelle Foroman, Julie-Anne Mitchell, Alex Clark, Cate Ferry, Sabine Drilling, Natasha Schranz
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- Uni WA - Tom Briffa
- Healthy Living NT - Chrissie Inglis
- SA Health - iCCnet Claudine Clark

Carolyn Astley, Project Lead, Cardiac rehabilitation MRFF project, SA Translation Centre, SAHMRI.

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