IMPROVING CARDIAC REHABILITATION QUALITY THROUGH THE INTERNATIONAL CARDIAC REHABILITATION REGISTRY

FABBIHA RAIDAH, MD

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Abstract

Cardiovascular diseases are a leading burden of morbidity, particularly in low- and middle-income countries (LMICs). Cardiac rehabilitation (CR) is key to secondary prevention, though limited in LMIC. CR registries promote quality improvement (QImp), to support program augmentation. This thesis comprised a mixed-methods and a qualitative study assessing QImp within the International CR registry (ICRR) for LMIC. Descriptive and inductive-thematic analyses were applied. Study 1 focused on the development and implementation of ICRR's Program Certification in LMICs. Five/5 CR programs ultimately achieved certification, with feasibility demonstrated. Four themes emerged from a focus group with 13 ICRR data stewards: motivation/benefits, logistics, the standards and suggestions. Study 2 explored ICRR-participating programs' QImp needs and evaluated registry support. Focus group with nine participants and 4 respondents providing written input revealed three themes related to facilitators, barriers and supports. Overall, these studies emphasize the importance of CR registries in supporting the quality of CR in LMIC.

Dedication

I would like to dedicate this work to my dad, Dr. Md. Saifuddin Khaled, my mom, Lulu Tasneem, and my husband, Dr. Tanvir Chowdhury. Your unconditional love, support, prayers, and commitment helped me complete this journey successfully.

Mom and Dad, without you in my life, I would not have come this far. Tanvir, I am blessed that I have you as my soulmate.

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Firstly, I extend my gratitude to the Almighty for the myriad blessings bestowed upon me throughout the entire journey of completing my degree.

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Last but not least, I am also indebted to my parents, husband, in-laws, family members, and friends and well-wishers. Your ongoing encouragement, unconditional love, and guidance have been the pillars of my success. I would like to convey special thanks to Dr. Taslima Mamataz. I am lucky to have you as a senior member of the lab. You have always guided me in the best possible way. You are my guardian angel in the lab and have always been there through thick and thin.

Table of Contents

List of Figures

List of Tables

List of Acronyms

Sl. No.*	Acronym	Full form
1	CVD	Cardiovascular diseases
2	LMICs	Low- and middle-income countries
3	HICs	High income countries
4	DALY	Disability-adjusted life years
5	CR	Cardiac rehabilitation
6	ICCPR	International Council of Cardiovascular Prevention and Rehabilitation
7	BMI	Body mass index
8	ICRR	International Cardiac Rehabilitation Registry
9	QImp	Quality Improvement
10	QIs	Quality indicators
11	PDSA	Plan-Do-Study-Act
12	WHO	World Health Organization
13	SPSS	Statistical Package for the Social Sciences
14	BACPR	British Association of Cardiovascular Prevention and Rehabilitation
15	AACVPR	American Association of Cardiovascular and Pulmonary Rehabilitation
16	EAPC	European Association of Preventive Cardiology
17	MET	Metabolic equivalents of task

18	MS	Microsoft
19	ID#	Identification number
20	CEO	Chief executive officer
21	JCI	Joint Commission International
22	USD	United States Dollar
23	DASI	Duke Activity Status Index

*The serial no. of the acronyms is based on their appearance in the thesis

CHAPTER 1: OVERVIEW

Cardiovascular diseases (CVD) continue to be a leading burden of mortality and morbidity, which is much higher in low- and middle-income countries (LMICs) than high- income ones [1]. Eighty percent of CVD mortalities occur in LMICs, of which nearly 40% are classified as premature whereas it is 19% in high income countries (HICs) [1]. Here, premature death refers to death at a younger age than 70 years [1]. Half of the world's population lives in LMICs, where a disproportionate 57% of global cardiovascular deaths and 59% of disability-adjusted life years (DALY) losses occur [2].

Most CVDs are either preventable or treatable if they occur [1], particularly with secondary prevention as delivered comprehensively in cardiac rehabilitation (CR) [3]. In LMICs, a lack of capacity to diagnose and provide the corresponding treatment contributes to the rapid emergence of advanced complications [1]. Despite its' affordability and cost-effectiveness [4], the first global audit explored about CR 1) availability; 2a) volumes served and capacity; and b) the factors associated with greater volume; 3) density; and 4) barriers to a broader delivery and this audit was led by the International Council of Cardiovascular Prevention and Rehabilitation's (ICCPR) [5]. This audit revealed a gross dearth of CR capacity in LMICs, with only one CR "spot" available per year for every 66 incident ischemic heart disease patients (compared to 3.4 in high-income countries) [6]. Clearly, there is an urgent need for the rapid increases in CR capacity in LMICs, a mission to which ICCPR is dedicated (https://globalcardiacrehab.com/The-Charter).

CR is shown to be highly effective, when it is available and delivered in LMICs [7]. However, there are differences in the nature of CR programs when compared to high-

income countries (e.g., dose, setting, comprehensiveness, multidisciplinary team), and they are more often privately-funded [6]. For instance, CR programs in LMICs were found to employ physicians mostly, while HICs were more likely to have nurses, dietitians, social workers, pharmacists, and administrative assistants as part of their CR teams compared to LMICs [6]. Furthermore, stress tests were used more frequently in LMICs as initial functional capacity test, whereas HICs offered depression screening, nutrition counselling, stress management, tobacco cessation interventions, return-to-work counselling, and primary care provider communication [6]. According to the purchasing power parity, the median cost of a complete program for patients was US$338.29 in LMICs and US$244.86 in HICs, excluding transportation costs and loss of income due to time off work [6]. Therefore, a mechanism is needed to not only promote proliferation of CR in LMICs [8,9], but to support quality of these services. Indeed, greater quality of care can result in better patient outcomes [10]. Therefore, ICCPR has recently developed a Registry and Program Certification targeted to resource-poor settings. It was found by Zyl et al. that the term "low-resource setting" refers to nine main ideas: (1) financial pressure, (2) suboptimal healthcare service delivery, (3) underdeveloped infrastructure, (4) paucity of knowledge, (5) research challenges and considerations, (6) restricted social resources, (7) geographical and environmental factors, (8) human resource limitations, and (9) the influence of beliefs and practices, whether the setting is an LMIC or an HIC [11]. The objectives of this thesis are to: (1) describe the development of ICCPR's program certification, and (2a) test implementation of the certification, considering also (b) appropriateness of quality standards to programs in resource-poor settings, and (3) understand ICRR-participating CR program perceptions of the utility of their quality

improvement (QImp) initiatives.

CHAPTER 2: LITERATURE REVIEW

2.1 Burden of CVD in LMICs and CR as an effective intervention

CVD encompasses a range of diseases affecting the heart and blood vessels, including stroke, heart failure, hypertensive heart disease, rheumatic heart disease, peripheral arterial disease, and various other vascular and cardiac conditions [12]. CVD is the world's leading cause of death [13]. While the number of deaths from CVD has not changed considerably in high-income nations [14] since 1990, in LMICs, the number of deaths has grown by roughly 66% [13]. LMICs struggle with the burden of CVD while working under the constraints of constrained infrastructure, resources, and professional health personnel capacity [13]. It is anticipated that by 2030, more than 80% of cardiovascular-related disability and death will occur in the 139 LMICs [15].

CR is a comprehensive outpatient model of secondary preventive care delivered by a multidisciplinary team [16]. The fundamental components of CR are internationally agreed upon by national and international CR Societies, including the American Association of Cardiovascular and Pulmonary Rehabilitation and the European Association of Preventive Cardiology as well as by HICs and LMICs [16]. They include an initial assessment of patients to identify cardiovascular risk factors and comorbidities, prescribed exercise training, nutritional counselling, patient education, management of risk factors (e.g., dyslipidemia, hypertension, obesity, diabetes mellitus, and tobacco use), as well as psychosocial interventions and counselling [16]. Given acute treatments for CVD often only address certain areas of the vasculature, CR is key in to stabilizing and even possibly decelerating or regressing CVD [17].

Clinical guidelines for a wide range of cardiac diagnoses - such as acute coronary syndrome, heart failure, coronary revascularization (percutaneous coronary intervention and coronary artery bypass graft[13]) - strongly recommend referral to CR. Over the past 20 years, the benefits of CR have been demonstrated through rigorous research, in enhancing patient's quality of life and health outcomes [15], and reducing morbidity and mortality[5]. The most recent Cochrane meta-analysis was conducted in 2021, which focused on "Exercise-based Cardiac Rehabilitation for Coronary Heart Disease" [18]. According to this meta-analyses of clinical trials, participation in CR reduces (CVD) mortality and morbidity by approximately 20%, including costly revascularizations and re-hospitalizations, while also improving quality of life and remaining cost-effective [18].

Most trials included in this Cochrane review stem from high-income countries, which was 75% [18]. The context in LMICs is much different, and therefore the effects of CR should be examined. Public sources reimburse CR more commonly in high income countries (HICs) than in LMICs, where patients commonly pay out-of-pocket for care [19]. CR in LMICs is delivered at a substantially lower cost than in HICs, likely largely due to lower salaries paid for healthcare personnel, but also the lower dose of CR delivered, and that programs are often less comprehensive [19]. While very affordable – particularly when compared to acute CVD care – the cost of providing CR in LMICs exceeds the average health expenditure per capita [19]. For these reasons, Mamataz et al. undertook a systematic review and meta-analysis of 26 randomized controlled trials in 8 LMICs including 6380 patients with acute coronary syndrome or heart failure. The effects and effect sizes observed were comparable to those observed in high-income countries [7]. According to this review, CR was shown to make significant improvements in functional capacity,

quality of life, and reductions in blood pressure, lipids, and body mass index (BMI) compared to control groups [7]. However, the certainty of these improvements is considered low to moderate due to trial bias [7]. Moreover, due to the sample sizes and short duration of the trials, the assessment of CR on mortality and non-fatal outcomes, including hospital admissions was limited in this review [7]. In addition, cost-effectiveness findings in two of the included trials were focused on home-based CR, which aligns with other studies on CR in LMICs [7].

Despite proven CR benefits, CR is grossly under-available globally. According to the systematic review conducted by Ragupathi et al., CR is available in 68% of high-income nations, 28% of middle-income nations, and only 8% of low-income nations [20]. The availability of CR is the lowest where the prevalence of CVD is the greatest, with only one spot for every 66 incident ischemic heart disease patient per year in LMICs, whereas there is one spot for 3.4 ischemic heart disease patient per year in HICs [6]. With a vision of promoting CR particularly in LMICs, the ICCPR was founded in 2010 to unite associations dedicated to advance CR globally and collaboratively [21]. For example, ICCPR developed a consensus statement on how to deliver all core CR components in feasible and affordable ways in LMIC [9].

More recently, ICCPR developed the International Cardiac Rehabilitation Registry (ICRR) to support development of new CR programs in LMIC that are of high quality [22]. Let's digress a bit to look into ICRR's organizational structure (https://globalcardiacrehab.com/ICRR-Governance). The ICCR Steering Committee is led by an Executive Committee, which consists of a user subcommittee, a research subcommittee, and an ad hoc group comprised of representatives of other willing CR

registries internationally. The steering committee consists of a chair, treasurer, secretary, chair of the user subcommittee, chair of the research subcommittee, and other representatives. Other than chair and secretary, the user sub-committee also has co-chair of Quality Improvement (QImp), patient partner, and other representatives. In the research subcommittee, in addition to the chair and the secretary, there are co-chairs of data quality, statisticians, knowledge users, and other representatives. A rigorous process was followed to develop the ICRR, including an international Delphi for variable selection and definition [23]. Participating programs enter data anonymously on their participants pre- and post-program, as well as annually. There are some patient-reported outcomes as well. Among these, formal education, emotional support from someone, co-morbidities, anxiety about having money to meet basic needs, coverage for medicines, etc. are pre-program intakes only. In both pre- and post-programs, patients report quality of life/subjective well-being, depressive symptoms, fruit and vegetable intake per day, physical activity per week on average, tobacco use, medication adherence, current work status, etc. Patients also report their knowledge of controlling heart disease and if they did any part of cardiac rehab online or via phone, which is post-program intake only. Real-time dashboards are built in so programs can compare their performance on 12 indicators in relation to other programs, as well as in their own site performance over time. The ICRR user sub-committee is tasked with supporting programs in quality assessment and improvement where desired.

2.2 Quality & Quality Improvement

Health care quality encompasses safety, equity, evidence-based medicine, promptness of care, efficiency, and patient-centeredness (https://www.ihi.org/). While

there is a rising but still modest emphasis on efficiency and equity of treatment, current measurements generally have an emphasis on effectiveness and safety, with some consideration for timeliness and patient-centeredness [24]. Providing consumers with a clear quality framework increases their appreciation of a broader range of quality indicators (QIs), allowing them to recognize the importance of safe, effective, and patient-centered care and comprehend how these measures relate to their personal healthcare concerns [25]. They are assessed generally by structure, process and outcome indicators [26].

To define care quality in CR, the international CR community has developed QIs. For instance, the Canadian Cardiovascular Society's [27] are considered the most rigorously developed, with the following "top five" indicators: a) In-patients referred to a CR program, b) CR wait time from referral to enrollment, c) Patient self-management education, d) Increase in exercise capacity, e) Emergency response strategy. A field test was also performed. The American Association of Cardiovascular and Pulmonary Rehabilitation has published "performance measures" --indicators suitable for public reporting, external comparisons, and are advocating for pay-for-performance [28].The British Association for Cardiovascular Prevention and Rehabilitation published updated Standards for CR in 2023, and use them to assess programs as part of their national audit [29]. In Australia, a modified Delphi method was used to develop 11 QIs (QIs) for CR, with subsequent pilot testing [30]. Similarly, China, Japan, the European Society of Cardiology, and New Zealand have developed QIs for CR [31–34].

QImp is defined as the effort to enhance the extent to which health services increase the likelihood of desired health outcomes [35]. There are several commonly used

approaches such as Plan-Do-Study-Act (PDSA) cycles (Figure 1), or lean six sigma [36]. Plan-Do-Study-Act enables teams to select and experiment with interventions to attain their objectives [36]. This is a four-step iterative model that involves developing, implementing, studying, and evaluating plans. The outcomes of this process inform decisions regarding the adoption, adaptation, or abandonment of interventions [36]. Another example is 'audit and feedback'; this is a method of providing healthcare professionals with data on their clinical performance to enhance their adherence to intended practice. A Cochrane review demonstrated that this technique significantly improved processes, but with a minimal effect on patient outcomes [37].

Cardiovascular care was one of the initial fields in medicine to implement nationwide standardized quality measurement [38]. Quality measures in cardiovascular care focus on improving patient care and outcomes, such as reducing mortality rates, minimizing hospital readmissions, and enhancing patient experience [38]. The relationship between quality measures and tangible outcomes has been inconsistent, which presents difficulties for policymakers and clinical leaders aiming to use these measures to enhance cardiovascular care [38]. Singh et. al. observed that most strategies showed variable efficacy and inconsistent primary research results, which were probably caused by variations in outcome definitions, measurement techniques, and effect size calculations [39]. Reviews demonstrate that QImp interventions can lead to improvements in health care [40]. For example, the review by Lee et al. showed short-term QImp programs enhanced the quality of cardiovascular treatment in low- and middle-income countries, particularly for chronic conditions administered at the patient/provider level [13]. However, long-term monitoring of the implementation and effectiveness within specific practice settings

might be of greater importance [39]. M.M.H. de By et al. undertook a systematic review to examine the causal relationship between the utilization of registry data and the enhancement of clinical outcomes [41]. It has been shown in this study that collaboration, benchmarking, and feedback all result in quantifiably better results [41].

2.3 Cardiac Rehabilitation Quality and Quality Improvement

The ability to quantify the quality of health care is contingent on the availability of systems capable of accurately capturing how care is delivered and patient outcomes [42]. Several high-income countries, including the United States, the United Kingdom, and Europe, have established clinical quality registries to effectively assess the actual provision of healthcare services and registries have the potential to enhance care quality and improve return on investment [42]. A 2019 narrative review on quality assessment in CR revealed few studies [35]. CR quality had only been audited across the United Kingdom [29], the Netherlands [43], and Canada [44,45]. In these HICs, areas of low quality were identified. The first-ever global survey of CR programs was conducted by Supervía Pola et al., which assessed the type of patients served, professionals on the team and components delivered; note this only assessed structure and process indicators (no patient level data) [46]. This cross-sectional study surveyed CR programs globally online, and national cardiac associations or local champions helped identify programs where available [46]. Generalized Estimating Equations were used to analyze and compare the results by World Health Organization (WHO) region [46]. According to this global survey, despite clear evidence of the therapeutic and economic benefits of CR, just 50% of the countries have access to it [46]. There is notable variance in the quality of CR programs around the world, which may have an impact on patient outcomes [46].

Pack et al. conducted a nationwide survey in the United States to assess the assessment of quality by CR programs as well as implementation of strategies to improve quality [47]. 290 (71%) programs reported measuring program enrollment and completion rates in the past 5 year, with 249 (60%) programs implementing an associated QImp initiative to address enrollment and completion rates in the same time period [47]. According to this study, a survey of 812 program directors revealed that the majority of the patients initiate CR within 3-4 weeks following discharge and 50% of the programs offer telephone reminders to facilitate enrollment [47]. The referral process at the primary hospital is familiar to 89% of program directors, while 75% have knowledge of referral process at the primary clinic [47]. Certain directors encountered difficulties when attempting to measure referral, enrollment, and completion rates [47]. The study found a correlation between the measurement of participation rates and QImp projects [47]. It was observed that only 30% of eligible patients in the current U.S systems complete CR [47]. Moreover, a weak correlation was observed between QImp projects and program-reported participation rates [47]. In addition, a mere 29% of programs employed all three inpatient referral techniques (Phase 1 program, Systematic referral, and Liaison), whereas 4.7% programs did not use any of these techniques [47].

There have been a few studies of QImp interventions in the CR field. Most have tested interventions to improve indicators of CR utilization [48–52], including some in LMICs [53]. Results of the Cochrane review showed that these interventions are successful.

CHAPTER 3: OBJECTIVES

As previously described, ICCPR has developed the first global registry for low-resource settings (ICRR), through which CR program quality can be assessed and potentially improved. Moreover, ICRR's user sub-committee is analyzing registry data to determine where quality is low and implement QImp strategies with participating centres. These types of activities have never been undertaken before.

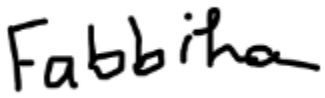
The objectives of the first manuscript were to: (1) describe the development of ICCPR's program certification, and (2a) test implementation of the certification, considering also (b) appropriateness of quality standards to programs in resource-poor settings. The objective of the second manuscript was to understand the QImp needs of ICRR-participating programs, and their perceptions of the registry's QImp supports.

CHAPTER 4: MANUSCRIPT 1

Development and Evaluation of the International Council of Cardiovascular Prevention and Rehabilitation (ICCPR) Program Certification for Low-Resource Settings.

4.1 ATTESTATION

This letter attests that the candidate: (1) cleaned quantitative data; (2) analyzed quantitative data using SPSS (e.g., program characteristics, pilot program assessment for eligibility of virtual site visit); (3) quantitative write-up; (4) participated in the focus group, and (5) supported manuscript submission; (6) was responsible for knowledge translation for the ICCPR Program Certification Steering Committee, including implementation of recommended changes to certification.



January 29, 2024

Fabbiha Raidah Date

January 29, 2024

Sherry L. Grace Date

4.2 INTRODUCTION

Cardiovascular diseases (CVD) continue to be a leading burden of mortality and morbidity, which is much higher in low- and middle-income countries (LMICs) than high- income ones [1]. Eighty percent of CVD deaths occur in LMICs, of which nearly

40% are classified as premature [1]. Half of the world's population lives in LMICs, where a disproportionate 57% of global cardiovascular deaths and 59% of disability-adjusted life years (DALY) losses occur [2].

Most CVDs are either preventable or treatable if they occur [1], particularly with secondary prevention as delivered comprehensively in cardiac rehabilitation (CR) [3]. In LMICs, a lack of capacity to detect and treat these diseases contributes to the rapid emergence of advanced complications [1]. Despite its' affordability and cost-effectiveness [4], the International Council of Cardiovascular Prevention and Rehabilitation's (ICCPR) global CR Audit revealed a gross dearth of CR capacity in LMICs, with only one CR "spot" available per year for every 66 incident ischemic heart disease patients (compared to 3.4 in high-income countries) [6]. Clearly, we need rapid increases in CR capacity in LMICs, a mission to which ICCPR is dedicated (https://globalcardiacrehab.com/The-Charter).

CR as delivered where available in LMICs is shown to be highly effective [7]. However, there are differences in the nature of CR programs when compared to high-income countries (e.g., dose, setting, comprehensiveness, multidisciplinary team), and they are more often privately-funded [6]. Therefore, a mechanism is needed to not only promote proliferation of CR in LMICs [8,9], but to support quality of these services. Indeed, greater quality of care can result in better patient outcomes [10]. Therefore, given none was available, ICCPR developed Program Certification targeted to resource-poor settings. The objectives of this pilot study were to: (1) describe the development of ICCPR's program certification, and (2a) test implementation of the certification, considering also (b) appropriateness of quality standards to programs in resource-poor

settings.

4.3 METHODS

This is a multi-method study, incorporating qualitative (focus groups with data stewards) and quantitative (description of standards at pilot sites) methods. It was approved by the Institutional Review Boards of both Hamad Corporation and Qatar University (Protocol No: MRC 02-20-359, QU-IRB 1518-EA/21) and York University (e2020-147) [26].

4.2.1 ICCPR Program Certification Development

ICCPR's Program Certification was developed in a rigorous fashion, by a steering committee comprised of 8 geographically and disciplinarily diverse CR experts, mostly from a low-resource setting, with input from the ICCPR community. It is a complement to their International Cardiac Rehabilitation Registry (ICRR), development and testing of which have been described elsewhere [23,54].

The purpose of the Certification is to recognize CR programs in resource-poor settings [11], who meet a minimum quality standard with regard to program structure, processes and patient outcomes [26]. Program certification is a peer-reviewed process designed to assess CR programs for adherence to quality standards of the ICCPR, also recognized by other professional societies [9,35]. It was ultimately approved by ICCPR Executive and then Council in December 2021, including the quality standards, policies, procedures, and steering committee Terms of Reference (https://globalcardiacrehab.com/Program-Certification).

Development of the Program Certification was based on learnings from other CR certifications, chiefly the longest-running one by the British Association of

Cardiovascular Prevention and Rehabilitation (BACPR; http://www.cardiacrehabilitation.org.uk/) [29,55], as well as that of the American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR; https://www.aacvpr.org/Program) [28,56] and the European Association of Preventive Cardiology (EAPC; https://www.escardio.org/Education/Career-Development/Accreditation/EAPC-centre-accreditation) [37]. A review of QIs of the major CR societies informed decisions on the quality standards [3,9,30,33,35,57,58], with consideration of feasibility based on what is assessed in ICRR's program survey and variable list [23]. Proposed standards were discussed by the Program Certification steering committee, for approval to pilot test.

ICCPR's program certification is based on meeting 3 mandatory QIs (i.e., comprehensive program that offers at least initial assessment and structured exercise, cardiac emergencies policy in place and minimum peak metabolic equivalents of task (MET) increase from pre to post-program) and ≥70% overall of 13 QIs (e.g., team comprised of at least 2 different disciplines, assessment of tobacco use and blood pressure, at least 50% program completion rate, increase in quality of life post-program, as well as patient knowledge regarding medications, lipid control, diet and return to life roles), ascertained through analysis of the site's data entered into the registry and as demonstrated in a 2-hour virtual site visit should results of the former warrant (see Table 1). Application requirements are found elsewhere (https://globalcardiacrehab.com/Program-Certification), but include that at least one staff member holds ICCPR's provider certification (CR Foundations Certification; https://globalcardiacrehab.com/Certification), that a minimum of 4 months of post-

program data have been entered in the ICRR on ≥60 consecutive patients, and that the site is in good standing with ICRR data entry (i.e., no completeness or other data quality issues).

A standard operating procedure was created for the Secretary and Applicant Assessment Oversight co-chair to process received applications. If requirements are met, the Secretary downloads the site's ICRR program survey [23] and patient data, and analyses the quality standards using developed SPSS syntax, entering results into the Applicant Assessment Form (Appendix A). Then, based on whether there were further needed materials, and whether minimum standards are met, a standardized, templated email is sent to the site. Where a virtual site visit is warranted, arrangements for securing site assessors (preferably with language ability matching the first language spoken of patients at the applying site where possible) and date are made.

A standard operating procedure for training virtual site assessors was also developed and approved by the Steering Committee (Appendix B). ICRR sub-committee and ICCPR Program Certification committee members are eligible to serve, and must sign a conflict of interest and confidentiality form (Appendix C, note potential conflicts must be declared for specific sites as well prior to any virtual site assessment). Potential site assessors are then sent details about the certification, arrangements are made to observe a virtual assessment, and then a one-on-one 45-minute video call is held with the Secretary and Assessment Oversight co-chair to ensure potential site assessor's knowledge of: the purpose, standards, and requirements for Certification, as well as on preparation for and execution of site visits, handling various scenarios, and post-site visit processes [26].

4.2.2 ICCPR Program Certification Process

As shown in Figure 2, registry-participating programs were invited to apply via email, attaching required documents. As per the standard operating procedures, the site was assessed as to meeting initial requirements, the 3 mandatory quality standards, and meeting a minimum of 9 of the 13 standards in the program survey and patient data. Once processed by the Secretary and eligibility was confirmed by the Assessment Oversight co-chair, standard email correspondence was sent to each program to arrange the virtual site assessment (Appendix D), with a reminder sent one week before. The Program Certification Secretary and at least 2 trained site assessors were in attendance at each virtual assessment, and were provided the site-specific results from ICRR analysis in relation to the standards, as well as five random patient registry identification numbers for the site in advance of the online assessment.

Assessments are held via an online web platform with videos on. Sites are asked to maintain the confidentiality of patient identity. As per the procedures on which site assessors are trained and which are shared with sites (Appendix E), first sites are asked to show the centre overall and where the various components are delivered, as well as functional capacity testing. Team members are questioned one-by-one, who explain their clinical role in the program, to confirm the multidisciplinary expertise, and also show emergency procedure policies and answer questions about it. Next the assessors confer with a patient where possible, to understand their care journey and education received. Finally, a review of random patient charts is undertaken, to confirm assessment of risk factors and program comprehensiveness.

Following the site assessment, assessors confer in camera about whether each

standard was met, with comments notated. They then reach consensus on a decision to: (a) certify, (b) potentially certify with specific remediation, (c) deny certification, or (d) request more information prior to rendering a decision. This is all documented in the Applicant Assessment form (Appendix A), and decisions are shared with the Assessment Oversight co-chair for approval. Then, a standardized email communicating the decision is shared with the program (Appendix F).

Where the decision is to certify, the program is provided a certificate (Appendix G) and marketing toolkit. ICCPR shares the news via their social media channels and website. CR programs will be ICCPR-certified for 3 full calendar years from the date of certification issue.

4.2.3 Procedure

After all pilot sites completed the Certification consideration process as outlined above, in December 2022, focus groups were held with eligible participants. All participants provided written informed consent included for publication of anonymized responses. The focus groups were led by the ICCPR Program Certification co-chair, and the ICRR co-chair and notes were taken, and non- verbal communication was recorded. Participants knew the co-chairs, and so to minimize bias, all participants were asked not to respond in a socially desirable manner in case this familiarity would impact their responses, being reminded that the goal was to receive as much constructive feedback as possible to ensure the utmost utility of the Certification program.

The focus groups were held via MS Teams. To facilitate communication despite several different languages, live auto-transcription was enabled, all parties had their cameras on, and the focus group guide was shared with participants in advance and on

the screen during the focus groups. Proceedings were video-recorded, again with consent.

4.2.4 Programs and Participants

Interested CR programs with ethics approval to participate in the registry and who meet criteria to apply for program certification at the time of the pilot (April-November, 2022) were considered eligible. The posted program certification application fee was waived for pilot programs (see: https://globalcardiacrehab.com/Program-Certification). Quality standards from these programs were considered. All program staff from the centres involved in the certification process, including application, any communications, and/or the virtual site visit, were invited to the focus groups. Those who expressed difficulty with spoken English were invited to submit written input.

4.2.5 Measures

Each Program Certification quality standard is listed in Table 1, along with the source to assess them. Full explanations of each are available elsewhere (https://globalcardiacrehab.com/Program-Certification).

The focus group guide for the data stewards was developed by the ICRR co-chairs, and input was sought from the Steering Committee (Appendix I). It aimed to support understanding of their perceptions of the application process, including communications, the virtual site visit and suggestions for improvement.

4.2.6 Analyses

A descriptive analysis of participating program characteristics was undertaken, using frequencies and percentages and means and standard deviations as applicable. Results for each quality standard were computed by site using descriptive statistics accordingly. Each quality standard was categorized as met or not met, and the percentage of met

quality standards was computed by site. SPSS v28 was used for descriptive analyses.

The focus group recording transcripts were cleaned to be verbatim and anonymized. A inductive-thematic approach was used for analysis of the transcripts using NVIVO 12 [59–62]. Disagreements were reconciled with the ICRR co-chair. To ensure credibility, themes with sub-themes were then shared with all focus group participants to inquire whether they resonated, and requesting any input (i.e., member checking) [63]. Each sub-theme was supported by illustrative quotations (note: where the respondent's first language was other than English, some minor edits were made to increase clarity where needed).

4.4 RESULTS

The first five ICRR-contributing programs across three World Health Organization regions agreed to be part of the pilot (Figure 3; 100% response rate). One was in a high-income country, but considered resource-poor given they were the sole program in the country. Program characteristics are shown in Table 2.

Upon application, some centres had outstanding data quality issues that needed to be rectified prior to analysis of ICCPR quality standards. While site assessments were in English, there were some challenges securing site assessors with proficiency in the primary first language of patients served at participating programs. For one site visit, the site was not prepared at the beginning of the assessment, the centre was not viewable, and no patient had been arranged. There was also the experience of patient education materials not being in English and not fully viewable via the web camera. At another point, it was difficult to view ICRR patient charts.

Results for quality standard assessment of each site is shown in Table 1. As shown, 4 of the 5 centres were eligible for virtual site visit based on the initial data analysis. One site did not meet the mandatory standard of a 0.5 Metabolic Equivalent of Task increase from pre to post- program, yet met all 12 other standards. A meeting of the Steering Committee was held, and it was decided to invite the program to provide context for the finding but to allow them to proceed to virtual site assessment, given evidence of many other areas of program quality.

Following site assessments, the decision for all applying centres was to certify; results for each standard are shown in Table 1. Based on the findings of the pilot and discussion with the Steering Committee, only one change was made to the standards. For the peak METs standard (#7), rather than a 0.5 MET increase overall, it now specified that at least 75% of program completers meet this threshold, given the short duration of some programs due to out-of-pocket patient cost, and the complexity of patients in these settings (e.g., heart failure, comorbidity).

4.3.1 Qualitative Perspectives on ICCPR's Program Certification

Characteristics of the 13 focus group participants are shown in Table 3. Most attended a first focus group, but a second was held with 3 participants who had conflicts or needed extra time due to language barriers. There were 4 main themes resulting from analysis of all the qualitative data: (1) motivation and benefits, (2) logistics, (3) standards and their assessment, and (4) areas for improvement. Sub-themes are shown in Figure x and corresponding illustrative quotes are shown below.

The first theme pertained to the motivations for programs to pursue ICCPR certification, and the benefits of doing so. The first sub-theme was to showcase their

quality at an international calibre, and the pride associated with certification. The 13 standards are publicly available, thus making it clear what level of quality a program meets. One of the standards relates to a staff member having also completed ICCPR provider certification (i.e., CR Foundations Certification; https://globalcardiacrehab.com/Certification), thus signaling the calibre of team members.

"If we are certified, then it adds value to what we are already doing. I mean, whatever practices we benchmark, getting to learn from the registry. and again putting it out saying, okay, this is what exactly it is and let the numbers speak for themselves" – (ID# 3)

"Having national certification really implies administrative, managerial and assistance processes that entail a lot of work; recognition is of great satisfaction. That is why, according to the new national registry of cardiac rehabilitation programs in our country, only a third of the registered centers are certified by our Society. You can imagine then that aspiring to be recognized now by the international authority of ICCPR is still a major challenge, but also an achievement of great proportions for all of us" – (ID# 6)

"We want to improve the quality of the treatment and care which we provided to the patient through this certification. We are able to improve the standard which were the, you know, criteria of the international society" – (ID# 9)

"Some standards, some benchmarks, we need just to see ourselves … where we are, where we are standing. So, this opportunity gave us a lot to improve… to check

ourselves, and to motivate more and more-- not only for ourselves, but our team members also want some international certification like ICCPR" – (ID# 10)

"Then once you, any program who got the certificate, definitely it increased their prestige. It increased their status, and increased their value. Because getting any international certification, it means a lot" – (ID# 12)

"Individual [ICCPR] provider certification was great already, but the program certification gave us more confidence to deliver this cardiac quality service to our patients." – (ID# 8)

The next sub-theme related to how the certification promoted the program with multiple stakeholders from patients, through institutional leadership and policy-makers. Recipients proudly displayed their certification on the walls of their gym, in welcome letters to new patients, in internal corporate communications, social media accounts and websites, and with national CR Societies.

"This achievement within my union of cardiac rehabilitators, surprised everyone and generated congratulatory reactions and great recognition, both among health professionals of our community and in social media" – (ID# 6)

"We have even placed the certificate in a very visible place in our institution. We have placed that certificate on our social media, and even in a newspaper advertisement we have shared our certification. Because now it's a source of pride for us too, that we are the only one [in our country] who is certified by any international body, and working within the international standards." – (ID# 12)

"We have placed the certificate in our offices as well our waiting area-- in the

prominent spaces of our institution" – (ID# 12)

"We have given this information about the certification to the newspaper on World Heart Day, and we have also placed this information on our website. We are planning to print on our stationary too" – (ID# 12)

"Our certificate, yeah, we shared it with the rest of the staff of the department; they were so happy about it. We printed it out. And we took a photo with the rest of the department. Yeah and we shared it in our social media. We even published it on our website" – (ID# 2)

"We're still taking pictures with the CEOs and the people and everyone's like, oh my God, you get the certificate, let's have a picture." – (ID# 13)

"We are planning to put the certification logo in our welcome letter for the patient upon joining" – (ID# 2)

"We were very happy because it's a hard process, you know, to achieve this; it's also very meaningful for us, and we shared this with all our community. I think maybe an opportunity here is to inform the Presidents of the national cardiac rehabilitation societies when we get certified. We shared this achievement with all the Society members…. It was received with a lot of joy and congratulations" – (ID# 6)

The final sub-theme related to how certification facilitated access to resources (e.g., funding, space) and even service expansion.

"Before we were certified we were struggling to expand our services in many hospitals and all over the country because we are the first cardiac rehabilitation program.

After the certification, there was a huge celebration, with the happy news coming from our Minister, the Minister of Health herself" – (ID# 13)

"They are all saying we're going to expand our Center. And we think that the cardiac rehabilitation certification by ICCPR has a lot of responsibility for this." – (ID# 6)

"Everything flipped. Like, we were struggling to have space and stuff. And [once certified] everyone looked at us and said 'whatever you need, we're going to give you'. We were struggling for 10 years and then just like that, in one month our life has changed" – (ID# 13)

"We did have the funds in order to expand, but we lacked proof of quality. So, with this certification, everyone thinks and sees our program as a very high-standard, qualified program. And so yes, now we will give you what you want in order to expand, and to achieve all the beautiful things" – (ID# 13)

"We're going to also capitalize on this. We are going to expand our center in the South, and we think that certification by ICCPR has a lot to do with this" –(ID# 6)

The second major theme related to the logistics of applying, ensuring their registry data quality was sufficient for assessment, communication with ICCPR, and the site visit itself. For the first subtheme, communication with ICCPR was perceived as timely, unbiased, private, and helpful, despite language and time differences.

"All the experience communicating about all the program certification-- the online application-- I support it. Everything.. I think it's okay" – (ID# 6)

“With the application process, I didn't find any difficulty. The [ICCPR] team was very much supportive” – (ID# 12)

“We all are convinced with the assessment, that all assessors have done a very fair assessment, and in fact supported us in in a lot of ways” – (ID# 12)

“The communication and the help from ICCPR has been very helpful and smooth; even being in different time zones, the [ICCPR] team was very helpful” – (ID# 4)

“We really received support and good comments also about our site”- (ID# 6)

Second, while pilot sites did not pay for certification in return for their involvement, they perceived the fees –including those for 3-year re-certification—to be reasonable. Note that one site noted challenges paying for the fee for one staff to complete ICCPR’s provider certification.

“I think the costs are reasonable… it's the work that it means for being certified; there's a lot of work and maybe people are [balancing] other priorities; that's the reality, but not costs. I think that is not the main reason here -- it's the work.”- (ID# 6)

“From our side, I think we will definitely we will [apply for re- certification in three years]” – (ID# 13)

“I think it will give us more confidence you know, when it comes to our patients that we are certified internationally. So I think it would be good to continue the certification after three years” – (ID# 2)

Finally, the site visit was perceived as rigorous, comprehensive, transparent,

objective, and fair. While preparation for the site was daunting, the technical rehearsal instituted alleviated this. While judgment was necessarily involved, the tone was supportive, unbiased, and confidential.

"Nothing of that sort [being judged]. In fact, the assessors were very neutral during the virtual assessment" – (ID# 3)

"There weren't any biases. And as far as the confidentiality was concerned, they were very clear that they didn't want to know the names of the patients, so that was good." – (ID# 3)

"We had an experience with a JCI audit in our hospital, and we didn't expect that it would be as at par with ICCPR's. As well, it was very detailed" – (ID# 2)

"It was fair. They were very clear that it was meant to benchmark the practices, and imbibe certain best practices" – (ID# 3)

"The [internet] connection during the virtual as a site, it is very important. And some of the team were a bit shy to be on the camera. We were happy with the questions because we got to show genuinely who we are and our every day work"- (ID# 2)

The third major theme pertained to the level of difficulty of the standards, considering the certification is geared towards resource-poor settings. For the first sub-theme, discussion centered on finding the right balance between ensuring the standards and process are feasible, but also needing to ensure rigor, to ensure quality and that certification is internationally- recognized as such. Participants spoke of the competing priorities; a lot of work was involved in entering data into the registry for several months to enable evaluation of candidacy for the virtual site assessment. Overall however,

programs considered the effort worthwhile.

“It should be hard in some sense, because there needs to be criteria. But the work in the database and the [virtual] examination .. it was a lot to ensure everything is fulfilled” - (ID# 6)

“The people are paying from their own pocket, so our dropout rate is increasing day-by-day” – (ID# 12)

“At the beginning we had difficulty following all the requirements. Actually, we even got lost sometimes, in following up, even in the registry. I think I would suggest, to make it much easier probably, you could come up with a book, a guideline, or something like that.” – (ID# 2)

“It was a quite in-depth audit. I was quite impressed that each and every component and aspect was investigated thoroughly” – (ID# 12)

“…being the part of the registry added a lot of burden, in terms of manpower, finances and all that. It is really hard for me to have a approval from my administration for establishing and managing this registry because it costs a lot” – (ID# 12)

“Being certificated or evaluated by you for being certificated, it's something like being judged. In fact, I think this is necessary, because in some things we maybe are doing wrong; something's wrong and we have to correct it” – (ID# 6)

“Trying to make it more feasible for every [program] here… because there are a lot of benefits” –(ID# 6)

The second sub- theme subsumed comments regarding the number of standards,

whether the appropriate areas were covered, and the feasibility of the benchmarks in resource-poor settings. While there were some challenges regarding the lipid knowledge indicator as many patients do not get tested due to cost, and some discussion about potentially adding other standards, there was overall consensus that the standards were highly appropriate.

“It was not difficult to meet all those standards except the the process outcome standard #6, which was about cholesterol. We are not asking our patients to have a cholesterol check regularly [because of the fee]. So, the question is always about this standard; We are always low” – (ID# 12)

“We think the peak METs increase of 0.5 from pre to post program is too low and should be changed” – (ID# 7)

“It's difficult sometimes to achieve all the criteria. But I think we really feel good, and we perceive that procedures and the way the standards were assessed were appropriate” –(ID# 6)

The final theme pertained to potential areas for improvement, with the first sub-theme relating to the website organization.

“Improve the line spacing so that the text does not appear to be too near with each other for ease of reading. And also another one is like, if it appears more appealing on the main page, like upon opening the website, I think like a photo or something like that will be more appealing than seeing all the text; Like, when you see all the text, oh, which one I will read or something like that” – (ID# 2)

"It's difficult. We are running all the time with a lot of stuff here, and maybe to

simplify the information it would be better for us" – (ID# 6)

"Add testimonials from the sites who are certified. So put my experience with the process or maybe how certification has helped me. So insights from those who have done it, that you know you could reach out to too, because it becomes a different scenario when you are on to the other side" –(ID# 3)

The second and final sub-theme grouped "other" suggestions, including being mailed a hard copy of the certificate, and ensuring multiple forms of payment (e.g., PayPal is not available in Pakistan).

"I think it would be also good to inform the program that they can apply for certification [when they start with the registry] instead of doing it in the middle, like after five months or something like that. I think it could have supported more preparation" – (ID# 2)

"We would not able to pay for the certification process because of the Paypal issue. So some options [for forms] of payment can be explored for these developing countries" – (ID# 12)

"We got the soft copy of the certificate, and we got it printed …. But you know, it was asked by our administration that it would be more valuable if they would send a hard copy directly to us" - (ID# 12)

4.5 DISCUSSION

Herein, development of the first international CR program certification was described, followed by pilot testing in five low-resource sites, establishing its' feasibility, rigor and acceptability. Results also establish the appropriateness and attainability of the

13 certification standards, with all sites ultimately achieving at least 12 of 13-- well above the required 70%. Analysis of the focus groups showcased the potential benefits for certified programs, as well as corroborated the appropriateness of the standards for resource-poor settings while also recognizing some logistical challenges (e.g., human resources). Finally, some areas for improvement were identified.

There have been several other studies on CR program quality assessment [35,64,65], and a few from the United Kingdom on CR program certification specifically [55,29], but all in high-resource settings to our knowledge. While program reports in the United States and Canada suggest sites are assessing quality, and those that elect to report similarly high quality, data from the BACPR's audit across the whole population of CR programs shows much more variation in quality, with many programs not meeting minimum standards.

Some barriers to CR program certification were identified during this research in the low-resource settings. The time to get approvals to participate in the registry was very lengthy, particularly in India. Securing time to enter registry data and the associated human resources required were considered challenging. Thus, it took considerable time to reach 60 patients to be eligible for Certification consideration. Also, preparation for the virtual site visit was considered daunting, to get the needed technical equipment ready.

There are three other CR program certifications available globally, also from well- reputed CR Societies, with BACPR's not available outside of the United Kingdom. The AACVPR has certified 1338 programs as of November 2022, and the most-recently initiated EAPC certification has certified 11 as of January 2023. As a single-country

association, the AACVPR certification is heavily based on American regulations, and costs more than ICCPR's at $960USD. There is an annual application window (others are rolling); application is facilitated by registry participation, but a documentation-only option is available. The EAPC requires a program be operational at least two years and that one staff be a paid member of EAPC. Similar to AACVPR, many documents are to be provided, following the patient journey, considering clinical and emergency scenarios, as well as regarding staff qualifications, infrastructure and equipment. There is a nominal application fee, with certification then requiring €5700, which would be out of reach for programs in LMICs.

In addition to the above differences between these certifications, there are some important differences with ICCPR's. These certifications are in English; English is the primary language for ICCPR's certification as well, but they do attempt to accommodate other languages through the use of translation of patient materials, securing bilingual virtual site assessors or interpreters where possible. There is a sliding scale of fees (for cost recovery only) to support ICCPR's certification, which is based on country income classification and funding source (private or public); while pilot sites did not perceive the nominal fee would be a barrier to application, one site did have a challenge paying the lower $100USD fee for provider certification of one staff member even to be eligible to apply. Inherently, lack of resources in LMICs will be a challenge to achieving broad reach of ICCPR's certification.

Based on the findings of this study, some changes and improvements were made to the Program Certification. Some clarifications were made to the website, and content broken down into sub-pages. Some photos from certified sites were added, as well as a

figure depicting the overall process (Figure 2). A first report of the ICRR was created, highlighting successes of the Program Certification, and including testimonials from participating programs.

In addition, registry-participating programs can now be informed about the availability of Program Certification option from inception, because it has been formally launched subsequent to this study. There was one small change made to one of the program standards (#7). The application process was made more explicit through the use of an online survey (https://yorkufoh.ca1.qualtrics.com/jfe/form/SV_0JPMyfAeXiArpZk), where required documentation can be uploaded.

Moreover, some clarifications and details were added to the email templates for communication with applicant programs at each stage of the certification consideration process (see Appendix D and Appendix F). For example, specifying two cameras on wheels may be needed and regarding languages of proficiency for the virtual site visit. The training and documentation to support site assessors during the virtual site visit were also improved, and a site visit recorded (with consent) for training purposes. A technical rehearsal step was added with the Secretary prior to the virtual site visit, to ensure for example stable internet connection, camera visibility, sound, and screen sharing.

In future, we will develop the policies and procedures for the three-year certification, which will not be reliant upon registry data entry. The Steering Committee is also contemplating a certification stream where registry participation is not required. We will also consider the logistics of mailing a token of certification to approved programs. Finally, quality improvement initiatives will be supported with interested

registry-participating programs; resulting webinars will be posted to ICRR's website.

Caution is warranted in interpreting these results. Given the limited sample size of a pilot study, results are not representative of all resource-poor CR programs, and thus generalizability of findings is unknown. Indeed, as outlined above, in comparison to data in the United Kingdom across the population of CR programs, there may have been a ceiling effect with some of the standards given the high-caliber of early ICRR-adopting programs. Second, with regard to measurement, as identified in the ICRR pilot study, there may be socially-desirable responding on the part of patients to the registry knowledge items. Even though some sites were commenting about low levels of cholesterol testing due to out-of-pocket cost, still most participants reported they knew their "cholesterol level and how to control it" (ICRR data dictionary, variable 25). Third, efforts were made prior to interviews and throughout the pilot period of study to minimize impacts of social desirability of program staff, but this may have skewed results to be more positive. Efforts were also made to ensure interviewer neutrality, and coding for all qualitative data included a non-ICRR chair. Finally, the nature of the design precludes causal conclusions.

4.6 CONCLUSION

In conclusion, ICCPR's first international CR Program Certification initiative has been developed, and pilot-tested in five centres in three regions. Results revealed it may be feasible, rigorous and acceptable to programs in low-resource settings, and improvements were made based on results. Thus, in line with our aim of promoting and recognizing quality CR services where they are needed most, the Steering Committee is now poised to accept applications. While there are some logistical challenges to

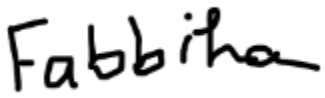
certification consideration in resource-poor settings, the many benefits of certification – including provision of more resources for delivery and expansion-- have been established.

CHAPTER 5: MANUSCRIPT 2

Promoting Cardiac Rehabilitation Program Quality in Low-Resource Settings: Needs Assessment and Evaluation of the International Council of Cardiovascular Prevention and Rehabilitation's Registry Quality Improvement Supports

5.1 ATTESTATION

This letter attests that the candidate: (1) supported implementation of the QImp initiative (e.g., communication with sites, arranging webinars and learning community sessions); (2) arranged the focus group (including inviting data stewards, securing informed consent) and documented non-verbal elements during it; (3) cleaned the focus group transcript, and analyzed it along with written responses received; as well as (5) undertook the write-up in the form of a peer-reviewed paper (original draft), and knowledge translation (i.e., implementation of any recommended changes to ICRR processes).



January 29, 2024

Fabbiha Raidah Date

January 29, 2024

Sherry L. Grace Date

5.2 INTRODUCTION

Cardiovascular diseases (CVD) are the leading burden of morbidity globally, particularly in low- and middle-income countries (LMICs) [1]. Cardiac rehabilitation (CR) is shown to effectively mitigate this burden [7]. However, there are differences in the nature of CR programs in LMICs when compared to high-income countries; these include more limited financial resources, differences in funding sources (i.e., more often privately-funded), having fewer staff (who have less opportunity for continuing education [66]), and patients receive fewer CR sessions [6]. This can impact program quality, which could lessen patient benefit from participation [10].

To enhance patient outcomes [67], the International Council of Cardiovascular Prevention and Rehabilitation's (ICCPR) CR Registry (ICRR) supports CR programs in low-resource settings [68] to assess and improve their quality of care [23,69]. Indeed, several CR registries offer quality improvement (QImp) support features such as benchmarking dashboards [70]. However, to our knowledge, there has been no evaluation of the needs of CR program staff to support them in undertaking QImp activities [35], nor evaluation of the utility and user-centeredness of QImp supports offered by registries. Therefore, the objective of this study was to understand the QImp needs of ICRR-participating programs, and their perceptions of the registry's QImp supports.

5.3 METHODS

5.2.1 Setting: ICRR QImp

Details of registry methods and the cohort are described elsewhere [23]. ICRR has several QImp features which are also described elsewhere, with some QImp education provided to on-boarding programs [71]. In brief, similar to other CR registries [70], ICRR-participating programs can monitor their quality on numerous internationally-agreed indicators [72] through real-time dashboards, benchmarking their performance over time

and in relation to other participating centres anonymously [23].

Moreover, the ICRR user sub-committee [23] actively supports QImp (see Appendix J for plans) through a learning community. Every six months, registry data are analyzed to determine where quality is low. With input from the ICRR community, a previously uncovered topic which is amenable to QImp (as per the literature review in the introduction) was selected. Each site was confidentially emailed about their performance for the quality area (Appendix N), as per best practices for registry feedback [73], and invited to a series of video calls. A "kick-off" webinar was held, presenting an overview of the importance of the topic. ICRR site stewards were invited to participate in 1-hour "QImp implementation chat" web meetings to discuss experiences related to quality improvement in the given area at their CR centres. The discussions covered the following: experiences considering quality level at their centre, how to secure resources for QImp activities (human, financial or otherwise as applicable), developing a plan to improve quality, implementation, and associated challenges, as well as measurement of progress. These were offered monthly on an as-desired basis for the 6 months of focus on the QImp area.

During these voluntary, confidential, and non-judgmental calls, applicable evidence as well as QImp best practices [65] and associated resources were presented, and change implementation challenges were discussed amongst stewards.

To date, ICCR decided on the first QImp topic of "engaging women in programs", given only ~17% of participants in the registry are female. The inaugural webinar was held in April 2023 (https://youtu.be/jAZpsO_Wnck). The first learning community chat was scheduled for June. The next topic for the fall was "reducing

barriers and increasing dose" which was held in October 2023 (https://www.youtube.com/watch?v=vPcjf4-PCNs). Participants in the registry were only receiving a mean of ~10 CR sessions, which may not be sufficient to reap the many benefits of CR as outlined in the introduction.

5.2.2 Design & Procedure

This was a qualitative study comprising primarily a focus group with ICRR data stewards. It was approved by York University's Office of Research Ethics (e2020-147), Canada. All participants provided written informed consent.

The focus group was held via MS Teams in November 2023, after two QImp topics [71]. To facilitate communication despite several different languages, live auto-transcription was enabled, all parties had their cameras on, and the focus group guide was shared with participants in advance and on the screen during the focus group. The ICRR chair led the focus group, with the Secretary and QImp lead of the user sub-committee supporting and notating. Proceedings were video-recorded.

5.2.3 Focus Group Guide

The ICRR Executive and User sub-committee developed a semi-structured question guide. The aim was to suppport understanding data steward's training and experience with QImp methods, CR QImp goals and barriers, familiarity with ICRR QImp supports, utility of ICRR QImp supports and how they can be improved, as well as further CR QImp needs.

5.2.4 Programs and Participants

All data stewards from CR programs [23] actively participating in the registry at the time of the focus group were invited to participate; there were 17 programs from across

all regions of the globe, with 40 stewards [22]. Those who expressed difficulty with spoken English were invited to submit written input in response to the focus group guide questions in their first language.

5.2.5 Analyses

The focus group recording transcript was cleaned verbatim and anonymized. Google Translate was used to enable analysis of received written responses in English.

A inductive-thematic approach was used for analysis of the data using NVIVO version 14[60–62]. Discrepancies were resolved through consensus discussion. To ensure credibility [61], themes with sub-themes were shared with all participants.

5.4 RESULTS

Nine stewards participated in the focus group, and written input was received from an additional four, with responses ultimately stemming from eight countries. Participant characteristics are shown in Table 5. Analysis of the focus group transcript was undertaken first, with the written feedback used thereafter to confirm saturation; this was agreed to be achieved by both coders.

Three main themes emerged through analysis; these are shown with sub-themes in Figure 4 and corresponding illustrative quotes are provided below. The first theme pertained to QImp facilitators. This included previous training of the data stewards, QImp requirements of their institutions, staff dedication to QImp for their patients, and leveraging of trainees for QImp in academic institutions.

"…… the program, the patient education, the insurance, the education of the staff, and the other associated staff, if we can take these as quality improvement initiatives, I'm

sure the program will take a leap." – (ID# 3)

"Basically, in quality improvement, we can help ourselves by improving our own skills so that we can give better treatment and outcomes to our patients." – (ID# 8)

Moreover, participants spoke about how the QImp features of the ICRR enabled them to realize their strengths and deficiencies, inciting team discussion and ultimately practice changes.

"When I studied physiotherapy, there were very few initiatives. Now that it's been almost 18–20 years, there are very, very few initiatives apart from somebody trying to help us out during our thesis …. I did my healthcare management and was a part of the healthcare management program. As working professionals, we were taught there. And again, I have done a cardiac rehab certification as well. So as a part of that, they have taught us about quality improvement initiatives, statistical methods, etcetera. I learned more about the quality of tools in healthcare management, and as far as the statistical part of it is concerned, I learned it in my master's." – (ID# 3)

"So basically, the QIs that we currently use in our institute are almost similar. We also use PDSA and Lean Six Sigma in our postgraduate and undergrad [degrees]. Also, a little more detailed are the biostats." – (ID# 8)

"We are competent enough to initiate quality improvement in our institution. It is a part of our system, so it is already there. So, what we are doing is like a continuous improvement, like a continual improvement that we've got to go through." – (ID# 3)

"They (the institution) ask us what we want to do, and they sit with us every quarter about the QIs that we submit and give us. Well, I push that initiative, that food

for thought on why we did better, why didn't we do better in certain areas, and what we could do to make the QIs smaller and better. That is the institutional part of it. As I said, our organization is into quality." – (ID# 3)

"But now our director makes it very important or gives the order to the doctors, to the surgeons, that they must send their patients for their cardiac rehab." – (ID# 5)

"She (the medical director) is strict about every one of our employees practicing on the clinical side and being active on the academic side because, well, all our employees are teaching." – (ID# 2)

"So, we have the International Classification of Functioning in the course curriculum, and that looks into participatory roles, activity limitations and restrictions, and social participation as well." – (ID# 4)

"We thought that we were doing things correctly and had many quality improvement initiatives or that the program was very good, but that has now given us food for thought on what things can and should be done." – (ID# 3)

"So, we are continuously working on those initiatives as to what we could do, what the best practices are, and what we should be doing to get there, or why is it that you are not on a benchmark?" – (ID# 3)

"Despite the little support from the hospital's senior management, we have a team that is very integrated into the care process, and we have already worked on some indicators." – (ID# 13)

"We thought we did a very good job, and we were doing a lot of patients, and we

had the patients coming, not maybe sustaining sessions, and just moving ahead. But the load that we had was tremendous, and probably that did not make us aware of or did not make me aware of what benchmarking and quality standards need to be until I joined the registry." – (ID# 4)

"It (ICRR) gave me the direction that this is what benchmarking is to be like, and these are the number of sessions, or this is the process in which we were doing everything. It was a comprehensive thing, but it was all in one, not as one unit that it was functional." – (ID# 4)

"When we started with the registry, we understood that everything needed to be marked and put to high-quality standards, and everything that concerned the organization, and the hospital was very huge." – (ID# 4)

"For the patient layout summary, we were removing it, and for those who had phones, we used to give them the PDF because, at times, it was not always possible to get a print of everything and pass it on. Then, as feasible, we removed the print and put it in the patient files, so that's how we have worked. So it was not possible to do it for everyone, but we could show it to the patients and tell them what it was." – (ID# 4)

"Yes, with participation in the ICRR, the team's responsibility for results has greatly improved. Before, the multidisciplinary team knew the importance of the work but now understands that "delivery" is very important, meaning the results can be measured and compared with other centres, and in this way, each professional seeks better results." – (ID# 13)

"We realized that the team today cares more about results and that the fact of

being monitored in some way arouses interest in achieving the individual goals of each participant. The results panels of our centre on the dashboard, although still small in quantity, already show the weak points and that we need to change the action strategy about the nutritional approach of our patients." – (ID# 13)

The second theme pertained to QImp barriers, which was comprised of three subthemes. First, staffing was an impediment – there were too few team members, and they had too little time for QImp activities. Participants also spoke about wanting to take advantage of one-on-one supports offered by ICRR's user sub-committee to engage in further QImp given they lacked skills in data analysis, and lack of time to spend with each patient to improve their care as desired.

"The only problem is that they (post-graduate students) rotate constantly, so if you have things in place properly, that's what you know after starting the registry. It has helped us to do it, so everybody is getting trained in it, and whoever comes next is trained in how it must be done. But the only thing is that turnover is very high because every two months they change So, every time the next person comes, I have to first sit down and train that person to completely explain everything and then take it. Alright? So, it's at a human resource level. Only the student resource staff I have only one staff member." – (ID# 4)

"There is no time to manage and execute our plan to improve the quality of the service due to a shortage of staff. I manage the service but lack continuous assistance, compromising progress in managing results." – (ID# 13)

The second barrier related to the international nature of the ICRR. While the QIs

were selected through a global Delphi process, in some cases they were not highly applicable locally (e.g., cultural relevance) or assessable in a CR registry (i.e., referral), or other indicators were perceived as key. Other barriers were language differences and the time difference for the synchronous QImp activities.

"This MET value that we get even if we perform a 6-minute walk test for the same person. The MET value when we do a DASI score makes a huge difference because the questions that are there for that skill are not very applicable to an Asian population." – (ID# 8)

"It's like some of the questions are very difficult to ask the Asian population. So, if you don't answer either, it is yes or no. So, one yes and one no makes a huge difference on the MET value, and when you compare both, the difference is that they're not coming closer, like it's not just like a 0.5 or something different. It's a huge difference." – (ID# 8)

"It is a very busy schedule for all of us because it's just late at night, although I would not say that this is a waste of time because in every webinar, we have learned a few things or the initiatives that the other sites have taken." – (ID# 2)

"Actually, it differs a little bit compared to what it is for the Western country, so we also are lacking with the .5 and we have struggled hard, literally changing our rehab and other techniques to improve their exercise capacity." – (ID# 8)

Last, were structural challenges related to their low-resource setting. For instance, it was difficult for programs to assess some QIs due to cost (e.g., lipids). Similarly some QImp changes would not be feasible for patients due to cost (e.g., increasing fruit and vegetable consumption; attending sessions despite lack of fee coverage by government;

and prohibitive distance for patients to travel due to lack of programs). Moreover, gender disparities and societal norms are factors that contribute to the higher dropout rates of women from CR sessions. Women often rely on men for transportation, which hinders their ability to attend these sessions alone. Additionally, men's work commitments further limit their availability to accompany women to these sessions.

"Now, when I'm looking at my problem, it was used to start with, Is that my patient? One of the causes is affordability, or it's vegetables and fruits. They can't afford fruits for more than one. The only fruit that they could afford was a banana. So how do I maintain quality standards when I'm talking about nutrition and perspective, and vegetarian food is like vegetables?" – (ID# 4)

"Unfortunately, because we belong to an area where the patients do not have good resources in terms of transportation and all, and because we are from a public sector organization, people who do not have money usually come to these organizations where they have to be dependent on the expenses, so somehow they are just unable to follow." – (ID# 2)

"But in terms of others and society as a whole, it (the webinar regarding engaging women) has worked, but only for women. I think again that when it comes to women, the obstacles are more prevalent in our society and our culture. The women take charge of everything. It's not that you're not actively participating in their household chores, their activities, or any kind of daily activity; she is sometimes more in a depressive phase. Ones who drop out more frequently than males, I guess, because in our culture, the female takes all the responsibility—the responsibility of the children and the home. So, this is the whole reason they quit; they drop out more frequently than males." – (ID# 2)

"Women are dropping out of our sessions because, in our society, women are more dependent on men. They can't come alone; most of them. Most of the men are working, so they have no time to bring them to the hospital to attend the cardiac session." – (ID# 5)

The final theme pertained to ICRR supports for QImp (Figure 6). Programs were very satisfied with the available ICRR supports, including using the dashboards to determine their readiness for ICCPR Program Certification application, and in particular hearing best practices from other programs. Participants reported that this gave them a sense they were not alone in their challenges, and in fact they desired further synchronous video sessions to further develop the ICRR QImp community. Future desired QImp topics included: return to life roles, patient education and mental health.

"I think having more and more such kinds of conversations with the other sites quarterly or every six months is important to see what they're doing and how they're improving. Whatever they're going through, I think that will help more." – (ID# 8)

"Whatever they said, this was a helpful thing when you know other people are also suffering, and you sometimes get a solution out. OK, they have been trying this, and you can also try and see if it works out for you. Maybe we can have more people from other sites also joining, and increasing the participation will help us most of the time." – (ID# 8)

"If we have someone from other sites, like other continents, who are part of the registry and they're coming up and sharing their experience and their rehab programs, how they are doing to improve their quality, and QIs, I think that will help all of this as

well." – (ID# 8)

"We suggest discussing new and creative methods of "patient education" that do not cause fatigue and demotivation of patients in training sessions." – (ID# 14)

"In our opinion, the following topics are of great importance: Different exercise protocols and their effectiveness in cardiac rehabilitation; Appropriate nutritional recommendations for patients according to the cultural and economic conditions of different countries; Improving the quality of life of patients in the field of mental health" – (ID# 14)

"In every webinar, we have learned a few things or the initiatives that the other sites have taken, and so different sites have different opinions and different strategies, which we took as a reflection, I guess, and this was helpful. It was not a waste of time, in my opinion; it was helping us to improve and to see what other people are doing on this site." – (ID# 2)

"I'll just add to this: you feel like you have people with you in the same boat, so it gives you that confidence." – (ID# 4)

"I feel that these problems are not mine alone. If they are being twisted in the same way the others are also facing, and you always have some learnings from other people's experience so you know small things that come in, then you know, OK, this can probably be tried and applied as a practice in our place and see if it works out or if it doesn't." – (ID# 4)

"I very well remember when we got that email for the MET from you that mentioned the quality of our six-minute walk test, but that helped us initially for five

months itself because then that forced us to brainstorm a little bit more, like why we are not able to achieve it or if we are achieving, how can we justify what we are doing? So that kind of five-month email helped us. Also, I remember you having one of your team members have a video call session with us and helping us out of the way out how to improve the QIs for other things like nutritional values." – (ID# 8)

"Yeah, I had received the email (5-month Quality improvement email), but then I wanted to first understand whether my site was matching those quality standards before I applied for CRFC because there is no funding. And as you said, we need to pay for it. So, I'm working into whatever other loopholes there are in the quality initiatives and trying to patch them up less." – (ID# 4)

"I believe that the greatest benefit will be after certification, which influences the creation of public policies for CR in our state. Strengthening our CR program to continue being a reference centre in the state and the country and working systematically in the training of new health professionals to expand and disseminate knowledge and take rehabilitation science to smaller cities to facilitate access for all citizens to a CR when necessary." – (ID# 13)

"In one-on-one support, I would want to understand certain aspects of the dashboard. I would want to understand what exactly we could do in each section or what the best practices are to be able to invite them and put them into practice." – (ID# 3)

"ICRR can support CR programs through cost-effectiveness studies of CR and optimization of economic resources in CR programs by country (taking into account the individual characteristics of the countries, as this would help to work with advocacy that

favours CR).” – (ID# 12)

5.5 DISCUSSION

Previous research on cardiac [41] and other [73] registries has established that the QImp features built in to ICRR such as benchmarking and feedback have quantifiable benefits for patient outcomes over time. While structural barriers are formidable in LMICs, CVD care QImp can be achieved in these settings [13]. This qualitative investigation of the QImp needs of CR programs and evaluation of ICRR QImp supports has identified barriers and facilitators to CR care improvement in low-resource settings.

Results compliment previous research findings regarding how to optimize usability and hence implementation of CR clinical quality registries [54,74]. Indeed, ICRR data quality improvement mechanisms [75] continue to be important to ensure utility of registry data for QImp purposes.

In response to this work, ICRR remains committed to providing and improving our QImp supports to participating programs. This will include leveraging translation software, and recording synchronous QImp activities so all programs can use the resources on-demand regardless of time zone. The next QImp topic of patient education is currently being planned, with provision of resources to help programs tailor associated care improvement activities to their local context. Further mechanisms to support CR programs to use the registry data to establish cost-effectiveness of their programs for resource advocacy would also be valuable.

Caution is warranted in interpreting these results. First, representative generalizability is not established through qualitative research, so the applicability of

these findings to other settings cannot be known. Second, the focus group lead was known to study participants. To minimize socially-desirable responding, participants were reminded that the goal was to receive as much constructive feedback as possible to enable the utmost utility of ICRR QImp initiatives.

5.6 CONCLUSION

In conclusion, this qualitative study has established the ways CR registries may be leveraged and optimized to support CR programs to assess and improve their care quality. This could not only optimize individual patient outcomes across programs, but the quality information can be leveraged by program leadership to demonstrate their excellence and impact, and hence advocate for further care resources to serve more patients.

CHAPTER 6: OVERALL CONCLUSIONS

Overall, these studies emphasize the significance of the ICRR and program certification in improving the quality of CR services. They illustrate how these endeavours can enhance patient outcomes and promote the allocation of resources to expand care, especially in settings with limited resources. This, in turn, advances the accessibility and effectiveness of cardiac rehabilitation programs on a global scale.

The ICCPR and ICRR are actively supporting ongoing QImp. The current focus of the ICCPR Program Certification Steering Committee is the development of a thorough 3-year re-certification process. This process aims to confirm programs uphold the ICCPR quality standards. In addition, the committee is considering the development of a non-registry pathway for certification, to accommodate a wider variety of CR programs who may not have the human resources to support registry participation.

In addition, the results of the studies herein raise directions for future research. For instance, to further validate the certification, it would be informative in future to compare patient outcomes between certified and non-certified CR programs. This analysis could offer valuable insights into the effectiveness of program certification. These investigations may encourage the development of new strategies for improving the quality and accessibility of CR services in various contexts, particularly for non-certified programs.

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Figure 1: The PDSA Cycle

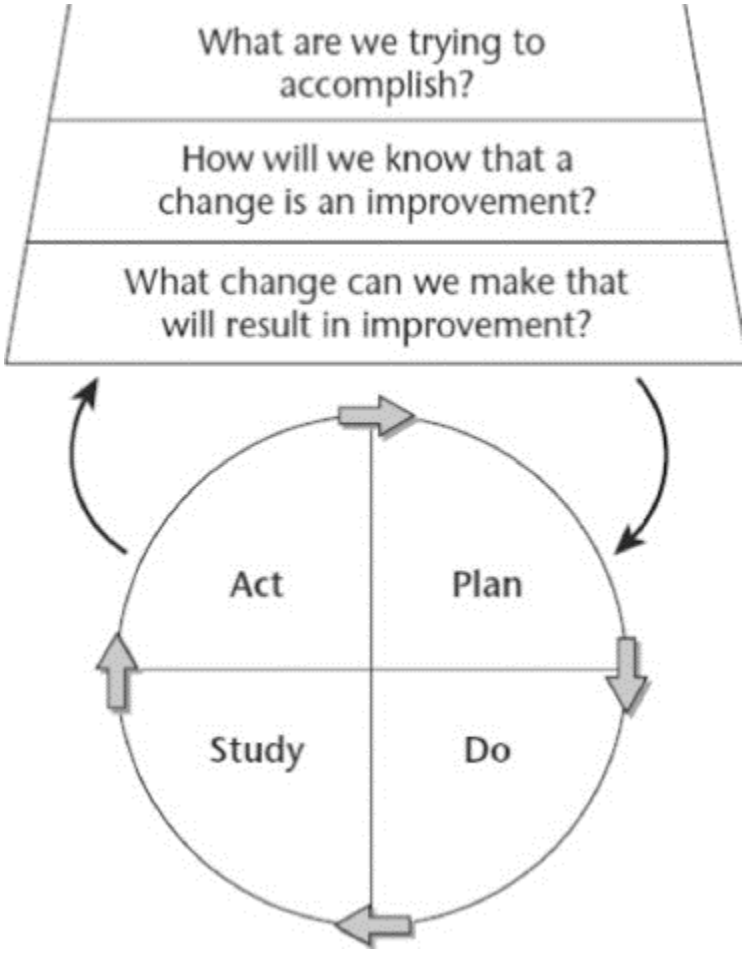


Figure caption: PDSA is shorthand for testing a change by developing a plan to test the change (Plan), carrying out the test (Do), observing and learning from the consequences (Study), and determining what modifications should be made to the test (Act) [72]

Figure 2: ICCPR Program Certification Process

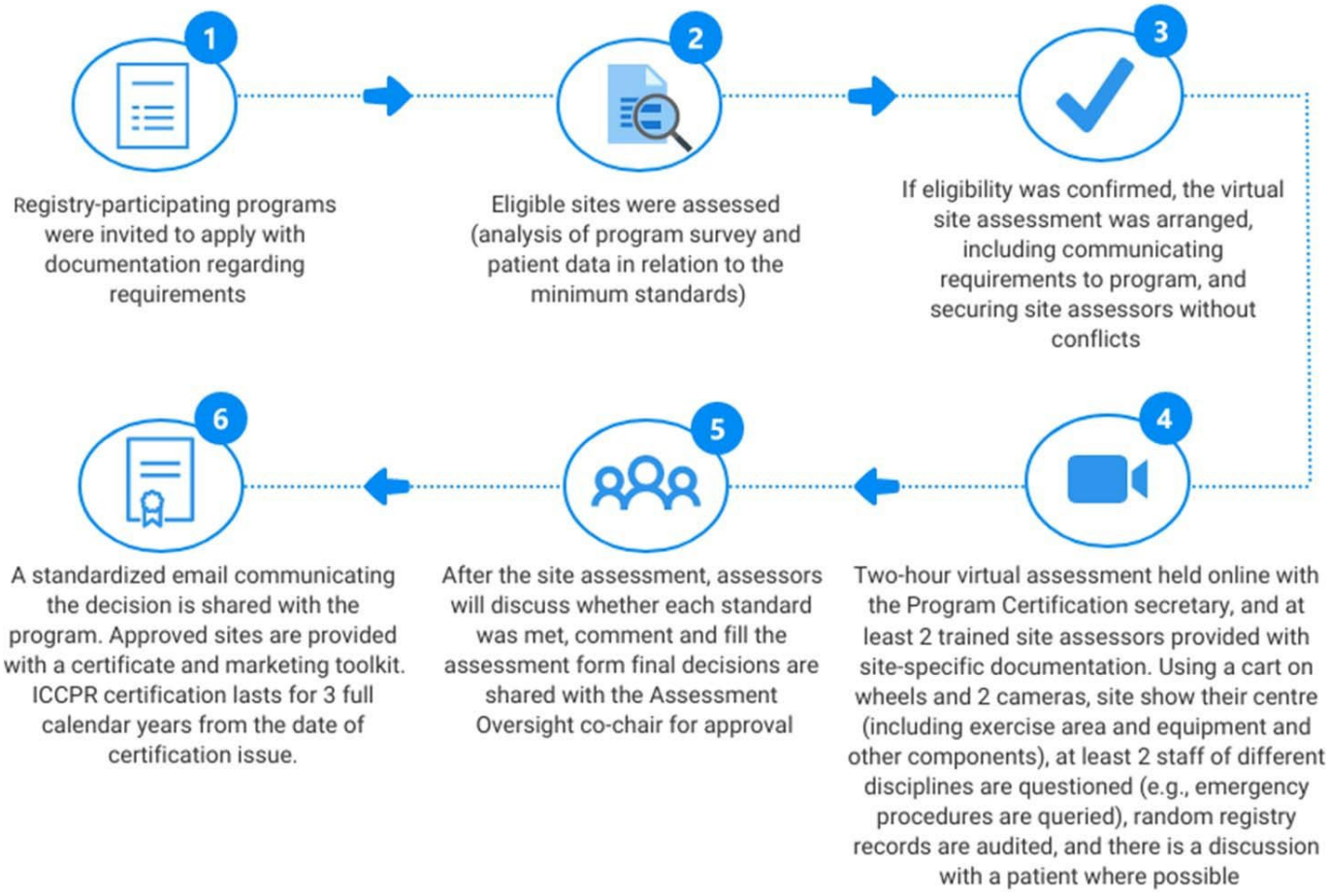
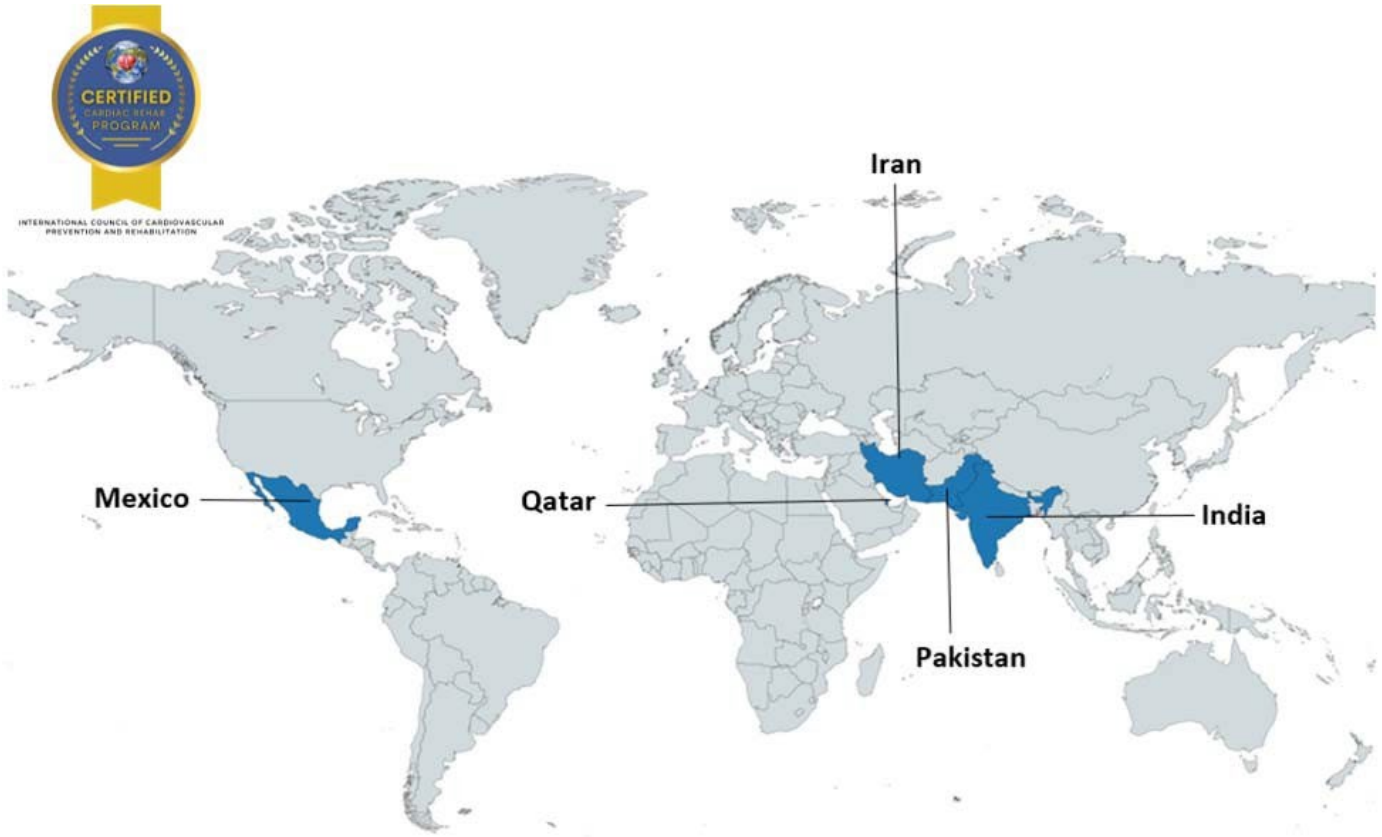
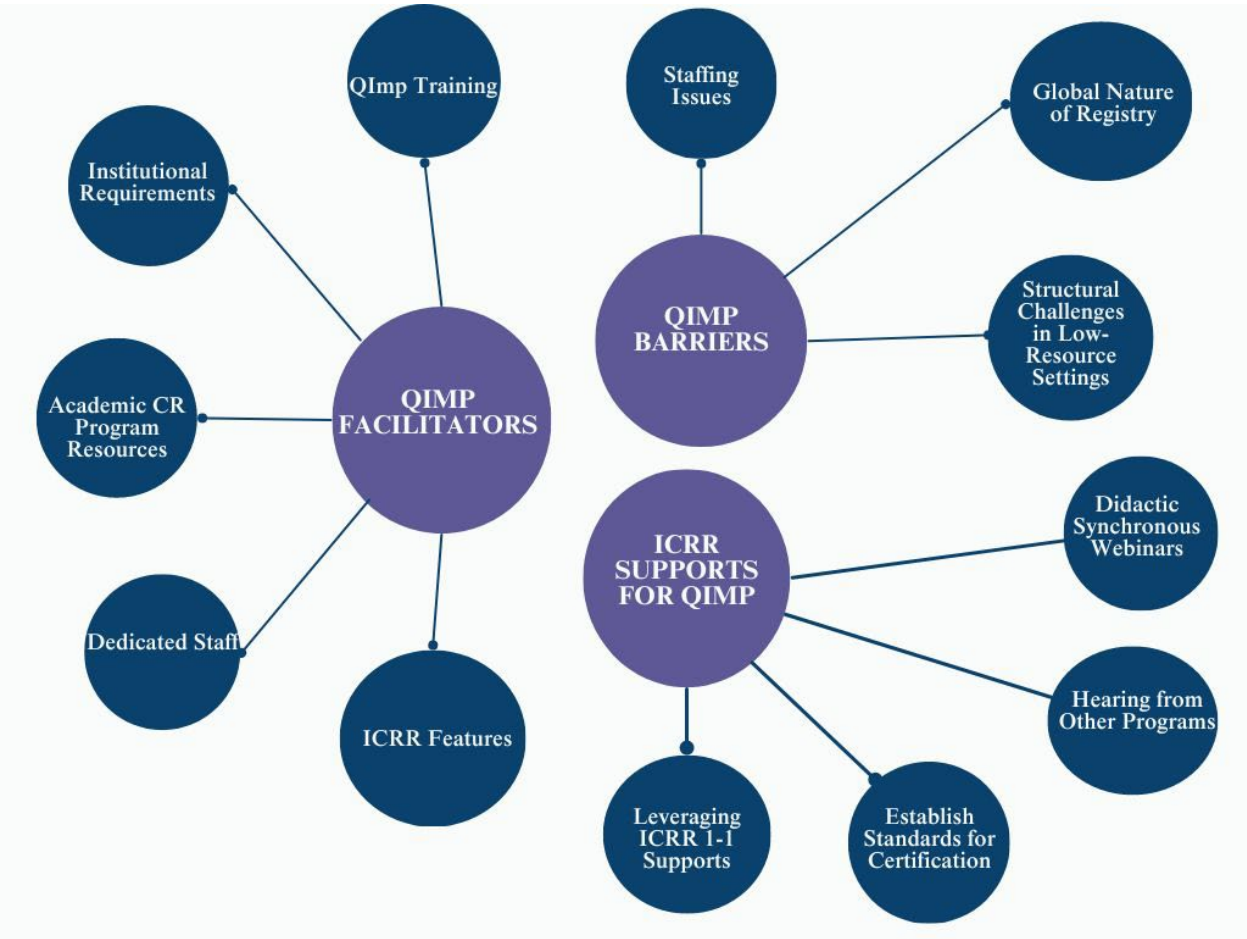


Figure 3: Map Depicting Cardiac Rehabilitation Programs Which Participated In Pilot Testing Of ICCPR's Program Certification



ICCPR, International Council of Cardiovascular Prevention and Rehabilitation Note: all sites were ultimately certified.

Figure 4: Three Main Themes With Corresponding Subthemes Regarding Cardiac Rehabilitation Program Quality Improvement Needs And Evaluation Of International Cardiac Rehabilitation Registry Improvement Supports



QIMP/QImp: Quality improvement; ICRR: International Cardiac Rehab Registry; CR: cardiac rehabilitation

Table 1: ICCPR Program Certification Quality Standards, And Pilot Program Assessment Results, N=5

			Site 1		Site 2		Site 3		Site 4		Site 5	
	Quality Standard ‖ (Type†)	Source(s)**	Value	Met standard ?	Value	Met standard ?	Value	Met standard ?	Value	Met standard ?	Value	Met standard ?
1*	Comprehensive program (/10 components) (S)	Program survey Q26; corroborated in site visit	8	Y	8	Y	8	Y	8	Y	8	Y
2	Multidisciplinary team (/14 types) (S)	Program survey Q21; corroborated in site visit	8	Y	10	Y	7	Y	8	Y	6	Y
3*	Cardiac emergencies policy (S)	Program survey Q23; corroborated in site visit	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y

			Site 1		Site 2		Site 3		Site 4		Site 5	
	Quality Standard ‖ (Type†)	Source(s)**	Value	Met standard ?	Value	Met standard ?	Value	Met standard ?	Value	Met standard ?	Value	Met standard ?
4	Assessment ofrisk factors: tobacco (P)	Responses in ICRR V22; corroborated by Program survey Q25 and site visit	149 (100%) patients	Y	486 (100%) patients	Y	94 (100%) patients	Y	184 (100%) patients	Y	90 (100%) patients	Y
5	Assessment of risk factors: blood pressure(P)	Responses in ICRR V22; corroborated by Program survey Q25 and site visit	149 (100%) patients	Y	483 (100%) patients	Y	94 (100%) patients	Y	184 (100%) patients	Y	89 (100%) patients	Y
6	Program completion rate (P)	Responses in ICRR V22	108 (81.2%)	Y	124 (36.3%)	N	93 (100%)	Y	92 (71.3%)	Y	62 (77.5%)	Y

			Site 1		Site 2		Site 3		Site 4		Site 5	
	Quality Standard ‖ (Type†)	Source(s)**	Value	Met standard ?	Value	Met standard ?	Value	Met standard ?	Value	Met standard ?	Value	Met standard ?
7*	Peak MET increase ≥.5§ (O)	Responses in ICRR V11; corroborated in site visit	103 (95.4 %)	Y	78 (63.4%)	Y	85 (92.4%)	Y	47 (52.8%)	N	13 (21.0%)	N
8	QoL increase from pre to post-program‡§ (O)	Responses in ICRR V18	1.3 ± 1.1	Y	2.3 ± 0.9	Y	1.6 ± 1.5	Y	8.5 ± 1.3	Y	2.1 ± 1.0	Y
9	Mins. MVPA ≥150/wk. post-program§ (O)	Responses in ICRR V21	350.4 ± 168.8	Y	305.4 ± 89.9	Y	126.0 ± 19.6	Y	251.26 ± 141.3	Y	207.5 ± 62.9	Y
10	Knowledge – medications§ (O)	Responses in ICRR V23; corroborated in site visit	2 (100%)	Y	123 (100%)	Y	92 (100%)	Y	88 (100%)	Y	57 (91.9%)	Y

			Site 1		Site 2		Site 3		Site 4		Site 5	
	Quality Standard ‖ (Type†)	Source(s)**	Value	Met standard ?	Value	Met standard ?	Value	Met standard ?	Value	Met standard ?	Value	Met standard ?
11	Knowledge – lipids§ (O)	Responses in ICRR V25; corroborated in site visit	2 (100%)	Y	122 (100%)	Y	92 (100%)	Y	88 (100%)	Y	57 (91.9%)	Y
12	Knowledge – diet§ (O)	Responses in ICRR V25; corroborated in site visit	104 (96.3%)	Y	122 (100%)	Y	92 (100%)	Y	88 (100%)	Y	62 (100%)	Y
13	Knowledge-return to life roles§ (O)	Responses in ICRR V25; corroborated in site visit	107 (99.1%)	Y	120 (100%)	Y	92 (100%)	Y	120 (100%)	Y	62 (100%)	Y
	Total		13 (100%)	Y	12 (92.5%)	Y	13 (100%)	Y	12 (92.5%)	Y	12 (92.5%)	Y

‖operationalization of each standard, including any exclusion criteria for each (e.g., coverage for medication), are shown at:https://globalcardiacrehab.com/Program-Certification under “CR Quality Standards” sub-section.

*mandatory standard

†S, structure, P, process, O, outcome

Y, yes; N, no; ICRR, International Cardiac Rehabilitation Registry; QoL, quality of life; MVPA, moderate or vigorous-intensity physical activity;METs, metabolic equivalents of task; ICCPR, International Council of Cardiovascular Prevention and Rehabilitation

Mins, minutes, wk, week

‡Scored out of 10 at the pre-CR and post-CR assessments.

§in program completers only.

**Q, question from ICRR program survey; V, variable from data dictionary entered into ICRR for each patient, operationalized as shown at:https://globalcardiacrehab.com/ICRR-Variables-&-Data-Dictionary(22).

Note: values presented as n (%; patients for standards 5-13) or mean ± standard deviation

Table 2: Characteristics of ICRR-Participating Pilot Cardiac Rehabilitation (CR) Programs, N=5

	n (%) or mean ± SD
Type of Institution*	
Referral / tertiary / academic site	4 (80%)
Private hospital	2 (40%)
Outside of a hospital	1 (20%)
Funding for Program*	
Patient	4 (80%)
Government	1 (20%)
Other	1 (20%)
Disciplines on CR Team*	
Administrative assistant	5 (100%)
Physiotherapist	4 (80%)
Any other type of exercise specialist	4 (80%)
Nurse	3 (60%)
Any physician	2 (40%)
Other	1 (20%)
Core Components Offered*†	
Patient education	5 (100%)
Resistance training	5 (100%)
Nutrition counselling	5 (100%)
Tobacco cessation sessions/ intervention	5 (100%)
Stress management / relaxation	5 (100%)
Prescription / titration of cardiac medications	4 (80%)
Other	4 (80%)
Program duration (weeks)	7.40 ± 2.97
Remote delivery available	5 (100%)

New patients served per month	18.33 ± 5.77

SD, standard deviation; ICRR, International Cardiac Rehabilitation Registry

*more than one response could apply to each site

†Note: participating sites must offer initial assessment and structured, aerobic exercise (supervised or unsupervised) hence they are not listed. They also must offer at least one other component.

Table 3: Focus Group Participant Characteristics

ID	Sex	Profession / Role
1	F	RN
2	F	Administrative Secretary of CR program
3	F	PT
4	F	PT
5	F	Occupational Therapist
6	M	MD/ Director of CR center
7	M	MD, Sports Medicine specialist/ Head of CR center
8	M	Occupational Therapy supervisor
9	F	Senior Rehabilitation specialist
10	F	Assistant manager of CR program
11	F	Dietitian
12	F	Deputy General Manager of CR program
13	F	Program Director

M: male; F, female; MD, medical doctor; PT, physiotherapist; CR, cardiac rehabilitation; RN,registered nurse

Table 4: Participant Characteristics of ICRR QImp Focus Group

Identification number	**Sex**	**Profession/Role**	**Country**
1	F	PT	India
2	F	PT	India
3	F	PT	Pakistan
4	F	PT	Pakistan
5	M	PT	Pakistan
6	F	PT	India
7	F	Cardiologist	Senegal
8	F	PT	Mexico
9	F	Medical Director	Pakistan
10	M	Medical Director	Czech Republic
11	F	Rehabilitation Scientist	Brazil
12	M	Cardiologist	Iran
13	F	Cardiologist	Colombia

APPENDICES

Appendix A: ICCPR Program Certification Application Assessment Form

INTERNATIONAL COUNCIL OF CARDIOVASCULAR PREVENTION AND REHABILITATION
PROGRAM CERTIFICATION
GLOBALCARDIACREHAB.COM/PROGRAM-CERTIFICATION

ICCPR Program Certification Applicant Assessment Form

SITE APPLICATION INFORMATION

[To be completed by the ICCPR Program Certification Secretary]

Date application received: Click or tap to enter a date.

Application # Click or tap here to enter text.(last digits year) Click or tap here to enter text. (consecutive numbering)

Site name: Click or tap here to enter text.

Site country: Click or tap here to enter text.☐ High-income ☐ middle ☐ low

Preferred assessment language: ☐English ☐other (please specify:Click or tap here to enter text.)

Funding source: ☐ private ☐ certain public ☐ uncertain public

SITE ELIGIBILITY

[To be completed by the ICCPR Program Certification Secretary w Consultation with Cttee Co-Chairs as Needed]

The following requirements need to be met to qualify for program certification

Linkage to ICCPR? ☐ Yes ☐ in process (describe: Click or tap here to enter text.) ☐ no (inform co-chairs)

CRFC certificate received? ☐ Yes ☐ No

All needed materials received? ☐ Yes ☐ No (specify what outstanding: Click or tap here to enter text.)

Applicable application fee received? ☐ Yes ☐ No (inform applicant, and do not inform co-chairs until received)

If above met, the following needs to be checked before commencing assessment of site data

Any data issues?

☐ no data quality or completeness issues ☐ outstanding issues

Number of patients with any post-program / progress data: ☐(must be ≥ 60)

Months where post-program / progress data have been entered: Click or tap here to enter text.(must be ≥ 4)

Assessment of Quality Standards using ICRR Data

[To be completed by the ICCPR Program Certification Secretary w Consultation with Co-Chair and Site Assessor]

If above met, the ICCR data can be used to initially determine whether programs meet the following quality standards (fill in pre-site visit / audit column and Assoc. comments):

	Quality Standard	Met pre-site visit?	Comments	Met during site visit?	Comments
1*	Comprehensive	☐ yes ☐ no		☐ yes ☐ no	
2	Multidisciplinary team	☐ yes ☐ no		☐ yes ☐ no	
3*	Cardiac emergencies policy	☐ yes ☐ no		☐ yes ☐ no	
4	Assmt tobacco	☐ yes ☐ no		☐ yes ☐ no	
5	Assmt BP	☐ yes ☐ no		☐ yes ☐ no	
6	Program completion rate	☐ yes ☐ no		n/a	
7*	Peak METs increase	☐ yes ☐ no		n/a	
8	QoL increase	☐ yes ☐ no		n/a	
9	Mins MVPA ≥150/wk post	☐ yes ☐ no		n/a	
10	Knowledge – meds	☐ yes ☐ no		☐ yes ☐ no	
11	Knowledge – lipids	☐ yes ☐ no		☐ yes ☐ no	
12	Knowledge – diet	☐ yes ☐ no		☐ yes ☐ no	
13	Knowledge- return to life roles	☐ yes ☐ no		☐ yes ☐ no	
Total		70%? ☐ yes ☐ no		70%? ☐ yes ☐ no	

*mandatory met? ☐ Yes ☐ No

MANDATORY MET & 70% (9/13) STDS PRE-SITE VISIT? ☐ yes (proceed to secure site assessor)

☐ no (communicate to site; they have 2 weeks to provide documentation for re-consideration they are met)

Date communicated to site: Click or tap to enter a date.

Comments re: response, if applicable (secretary to save all correspondence): Click or tap here to enter text.

VIRTUAL SITE ASSESSMENT TO CONFIRM QUALITY

Prior to Site Visit / Audit

[To be completed by the ICCPR Program Certification Secretary w Consultation with co-chair and site assessor]

Primary site assessor secured (first name, last name): Click or tap here to enter text.

Site assessor trainee (if applicable): Click or tap here to enter text.

Confirm no conflicts of interest? ☐ yes ☐ no

Confirm site assessor(s) training complete? ☐ yes ☐ no

Date of site visit: Click or tap to enter a date.

Date of technical rehearsal w Secretary: Click or tap to enter a date.

Any issues at technical rehearsal: Click or tap here to enter text.

Secretary present for site visit? ☐ yes ☐ no (why not?Click or tap here to enter text.)

5 random site patient IDs with some post data to be tested during site visit:

Virtual Site Visit / Audit

SITE ASSESSOR AND SECRETARY COMPLETE 2 FAR RIGHT COLUMNS IN ABOVE TABLE

Site visit completed successfully? ☐ yes ☐ no (please specify:Click or tap here to enter text.)

Any additional comments regarding site visit (save correspondence): Click or tap here to enter text.

Need for additional information from site before making decision? ☐ no ☐ yes (please specify: Click or tap here to enter text.)

If applicable: received? ☐ yes ☐ no

Need for 2nd site visit? ☐ no ☐yes (specify reason and what needs to be confirmed: Click or tap here to enter text.)

If applicable: Date of 2nd site visit: Click or tap to enter a date.

CERTIFICATION DECISION & COMMUNICATION

[To be decided Site Assessor after site visit, with Secretary. Can solicit input from ICCPR Certification Committee if required]

Site meet all requirements for certification? (select one of the following 5 options)

☐ yes

☐ no

☐ potential with remediation (please specify: Click or tap here to enter text.)

☐ could not be determined (please specify: need to observe pt)

☐ more information needed prior to decision (please specify: Click or tap here to enter text.)

Co-chair review and finalize certification decision: ☐ concur ☐ request for further information ☐ dissent

Certification Decision Communication with Site

Site informed of decision: Click or tap to enter a date.

If met: Site provided certificate and marketing materials? ☐ yes ☐ no

If met: site added to ICCPR website and announced on social media? ☐ yes ☐ no

If met: any issues during 3-year certification term with quality maintenance? ☐ no ☐ yes (please specify: Click or tap here to enter text.)

If met: end date for certification (end of 3rd calendar year): Dec 31, 20Click or tap here to enter text. (to trigger re-certification process)

If not met: program re-butt decision or provide contextual information that would lead us to change decision? ☐ no ☐ yes (date: Click or tap to enter a date.)

Rationale / materials received: Click or tap here to enter text.

Outcome: ☐ certified ☐ not certified

If not met: program request re-attempt? ☐ no ☐ yes (date): Click or tap to enter a date.

Re-attempt fee paid? ☐ yes ☐ no

Quality standards they will attempt to satisfy: #Click or tap here to enter text.; # Click or tap here to enter text.

Site visit required? ☐ yes ☐ no

Needed documentation received: ☐ yes ☐ no

Outcome based on communication of site assessor and co-chair: ☐ certified ☐ not

3-YEAR RE-CERTIFICATION

certified

Appendix B: Virtual Site Assessor Training - A Standard Operating Procedure For Training Virtual Site Assessors Was Also Developed And Approved By The Steering Committee

ICCPR Program Certification

Virtual Site Assessor Training SOP (for Secretary)

V1; February 14, 2022

1. When Secretary receives correspondence from new committee member (in future, reach out proactively via email when new members start terms using template email below) / interested site assessor, start a new row for them in the site assessor "training and roster" excel (dropbox "site assessors" subfolder)
    a. Ensure candidate currently or previously served on ICRR Steering or sub-committees or ICCPR committee (see excel files or website, or ask ICCPR secretary for confirmation), and meets the criteria of a site assessor (e.g., as per Steering Co Terms of Reference)
        i. If unsure check with steer co co-chairs
    b. complete all relevant columns (you may need info from member excel file in applicable governance subfolder of that committee)
2. Ensure ICCPR conflict of interest (CoI) & confidentiality form complete
    a. Save to dropbox "mtgs & governance" subfolder or "site assessor" subfolder with the forms,
    b. If not completed, ask the party to complete fully, and save in "site assessor" subfolder for completed forms in dropbox
    c. if any conflicts declared, alert co-chair and copy to "comments" column of the excel
3. Via email using the template below (scroll down), direct site assessor to review policies and procedures at https://globalcardiacrehab.com/Program-Certification, but provide them with Word version containing comments with the variables listed for each quality standard, and provide them the Assessment Application form template (dropbox).
4. Arrange for site assessor to observe a site assessment (if has, document date in excel)
    a. Check applicant tracking excel for dates of upcoming virtual site assessments. Let the potential assessors know of dates and confirm which one they can attend
    b. ensure candidate has no conflicts with the site to be assessed, and is not from country of site to be assessed.
        i. Document observation complete in the "training and roster" excel

    c. If there is no upcoming virtual site assessment and this training element needs to be met before an upcoming site assessment that we would like this assessor to lead for reasons of language for example, watching the recording of the site assessment will be sufficient; just notate that recording was observed in the training roster excel
5. Arrange 45-minute video call, and copy list of below things on which they will be quizzed so they prepare accordingly (this can be done before or after site assessment observation, but if after we recommend the site assessor watch the recording of a site assessment first)
    a. Once time is agreed, as per secretary SOP, send a calendar invite with time zone checked and link in the location
        i. If secretary will not be on the call, get the desired link from the program certification committee member leading the training
    b. During video call with their camera on (so you can check they have good quality connection and communicate clearly), question them on:
        i. What is the purpose of ICCPR's program certification
        ii. Describe some of the program-level standards, and how they are assessed
        iii. Describe some of the patient-level standards, and how they are assessed
        iv. Describe site requirements to qualify for a program certification site visit
        v. Describe what you would do to prepare for a site visit and how you would start the site visit
        vi. Walk us through the 6 aspects you will be assessing during the visit
        vii. How / what will you document from the site visit findings on the Assessment Application form section for the site visit (please share the file on your screen)
        viii. What would you say and do if the site is not prepared to show one of the elements required
        ix. Would you tell a site if they are meeting each standard or not? why or why not? And what would you do if the site asks whether they will be certified or not?
        x. What would you say at the end of the site visit to the site
        xi. What would you do after the visit? How would you handle if it was unclear if a quality standard was met or not?
    c. Clarify any areas where potential assessor doesn't have understanding
    d. Add any comments about the responses in the excel "comments" column
6. If you are concerned about the understanding of the site assessor or any other reason the candidate may not be a good assessor (e.g., sound, communication in English, video quality, respect of sites), confer with ICCPR Prog Cert co-chair via email to decide on remediation plan, or other
    a. When complete and if satisfactory, complete all remaining columns in "training and roster" excel in "site assessor" dropbox subfolder of "program certification" (ie. If no concerns, enter date assessor is approved to complete site assessments)

TWO TEMPLATE EMAILS:

TEMPLATE EMAIL TO ICCPR / ICRR COMMITTEE MEMBERS TO SOLICIT COI FORMS:

RE: Please complete ICCPR Program Certification CoI and Declaration form to initiate site assessor training process

Dear Member of the ICCPR / ICRR Community:

As part of your service, we ask that you volunteer to undertake ICCPR Program Certification virtual site assessments with the Secretary upon reasonable request. Kindly complete the attached conflict and declaration form and attach it in reply email.

We will then be in touch to arrange training accordingly.

Sincerely,

ICCPR Program Certification co-chair and Secretary

TEMPLATE EMAIL TO POTENTIAL SITE ASSESSORS TO MAKE ARRANGEMENTS:

RE: Arranging training for ICCPR program certification virtual site assessments

Dear Member of the ICCPR / ICRR Community:

Thank you for declaring your capacity and willingness to serve as a Program Certification site assessor. We have received your completed materials, and all is in order.

Please carefully review the policies and procedures at https://globalcardiacrehab.com/Program-Certification (see in particular the CR quality standards and virtual site visit assessment procedures section). FYI, I have also attached a file outlining the site visit process. I have also attached the Applicant Assessment form, which we use for each site visit to facilitate site assessment in accordance with these policies and procedures (the Secretary completes this, and would document your quality standard ratings there after any site visit). If you are interested, you can see the ICRR variables on which program quality pre-assessment is based here https://globalcardiacrehab.com/ICRR-Variables-&-Data-Dictionary. Please let us know if you have any questions.

To complete your training, you need to observe an assessment, and have a 45-minute call with us.

1. The following are dates of upcoming virtual site assessments: xxxxx. Please let us know if any of these dates suit.
    a. There is also a recording of a site assessment available here we suggest you watch: https://www.dropbox.com/s/bkbui0cm78czgmj/ICCPR_Prog%20Cert_virtual%20site%20assmt_recording4training_22.mp4?dl=0.

2. We also need to arrange a mutually-convenient time for a video call with your camera on (to ensure good connection and 2-way communication) where you will be asked the following:
    i. What is the purpose of ICCPR's program certification
    ii. Describe some of the program-level standards, and how they are assessed
    iii. Describe some of the patient-level standards, and how they are assessed
    iv. Describe site requirements to qualify for a program certification site visit
    v. Describe what you would do to prepare for a site visit and how you would start the site visit
    vi. Walk us through the 6 aspects you will be assessing during the visit
    vii. How / what will you document from the site visit findings on the Assessment Application form section for the site visit with they support of the Secretary (please share the file on your screen)
    viii. What would you say and do if the site is not prepared to show one of the elements required
    ix. Would you tell a site if they are meeting each standard or not? why or why not? And what would you do if the site asks whether they will be certified or not?
    x. What would you say at the end of the site visit to the site
    xi. What would you do after the visit? How would you handle if it was unclear if a quality standard was met or not?
    b. We recommend that if there is not an opportunity to view a virtual site assessment before this session, you watch the recording to help you prepare
    c. Here are some potential times; please let us know what works for you:

Sincerely,

ICCPR Program Certification co-chair and Secretary

Appendix C: Conflict of Interest and Confidentiality Form For Site Assessors

INTERNATIONAL COUNCIL OF CARDIOVASCULAR PREVENTION AND REHABILITATION
PROGRAM CERTIFICATION
GLOBALCARDIACREHAB.COM/PROGRAM-CERTIFICATION

ICCPR Program Certification

Conflict of Interest Disclosure

ICCPR's program certification scheme is to recognize cardiac rehabilitation (CR) programs in low-resource settings (includes in high-income countries) who meet a minimum quality standard with regard to program structure, processes and patient outcomes.

Given Name (First Name): **Surname (Last name):**

Thinking about relationships with any third party (e.g., industry, private foundation), financial or otherwise, or with members of ICCPR or ICRR governance committees (shown on our website):

Do you have any relevant or potential conflicts of interest related to your service on ICCPR's Program Certification Steering Committee?

- ☐ **No**
- ☐ **Yes**

If Yes, please specify:

Confidentiality & Integrity Declaration (for virtual site assessments)

If I am invited and accept to serve as an ICCPR Program Certification virtual site assessor, I shall maintain the confidentiality of the program(s) I assess, as well as the findings from the assessment in perpetuity. I shall undertake the virtual site assessment duties with integrity, while upholding the mission of the ICCPR.

If I have any potential conflicts of interest with any site for which I am asked to serve as a virtual site assessor at any time, I shall disclose this to the Program Certification Secretary and recuse myself from serving.

- ☐ **No**
- ☐ **Yes**

I can undertake site assessments in the following languages:

_____

Date: DD/MMM/ YYYY

Signature:

Appendix D: Email Template #1 – To Applicant Programs Upon Processing of Initial Application Materials (Standardized Email Correspondence Sent To Each Program To Arrange The Virtual Site Visit)

International Council of Cardiovascular Prevention and Rehabilitation (ICCPR)

ICCPR Program Certification

Email Template #1

to applicant programs upon processing of initial application materials (select appropriate template).

A. IF PROGRAM DID NOT PROVIDE ALL NEEDED INFORMATION

RE: ICCPR Program Certification Application- [COUNTRY] – needed materials

Dear Program:

Thank you for your interest in becoming an ICCPR-certified program. We are delighted to work with you to consider your program and associated materials.

At this point, unfortunately, we are not able to proceed with consideration of your program, for the following reason(s):

- ☐ We have not received your application fee
- ☐ We received the wrong amount for application, and $)____ is outstanding
- ☐ We have not received a Cardiac Rehab Foundations Certificate for a member of your program
- ☐ The ICRR has raised some issues around the quality of your contributed data, which need to be rectified before we could proceed in considering your program for certification
- ☐ You have not contributed at least 60 patients to the registry
- ☐ You have not yet provided the minimum of 4 months of post-program data to the registry
- ☐ We have not received 2 CR team member job descriptions of different disciplines who will be available to attend the virtual site visit, including documentation they

belong to their profession regulatory body in good standing. If this is not possible, then please provide evidence of their highest educational qualification.

Our Program Certification chair has recommended the following as a means to formally engage the CR community in your country / region with the ICCPR community:

_____

___

Kindly provide the necessary materials or a response within 2 weeks, and we would be happy to review them and potentially move forward in the certification consideration process. If you have any questions, consult our policies and procedures (https://globalcardiacrehab.com/Program-Certification), or ask.

Sincerely,

ICCPR Program Certification Secretary

B. IF PROGRAM DOES NOT MEET REQUIREMENTS TO BE CONSIDERED FOR CERTIFICATION

RE: ICCPR Program Certification Application- [COUNTRY] – meeting standards

Dear Program:

Thank you for your interest in becoming an ICCPR-certified program.

At this point, unfortunately, we are not able to proceed with consideration of your program, for the following reason(s):

- ☐ You do not meet 1 of the 3 mandatory quality standards
  - Comprehensive program
  - Cardiac emergency policy
  - Mean peak MET increase in completers from pre to post-program of ≥.5
- ☐ Based on program survey responses and/or patient data in the registry, you do not come close to meeting at least 70% of the 13 quality standards, as shown in the Table below (see https://globalcardiacrehab.com/Program-Certification for details on each standard)

Item	Quality Standard	Description	Data source	Met?
Program-level / Structure & Process Indicators				
1*	Comprehensive	*Comprehensive program, including (a) initial assessment, (b) structured exercise training (supervised or unsupervised) and (c) ≥1 other strategy to control CVD risk factors; evidenced based on program survey and during site visit (demonstration of at least one other component)	Program survey	□ yes □ no
2	Multidisciplinary team	Multidisciplinary team (i.e., ≥2 different regulated professions available to support patients at least on a part-time or referral basis)	Program survey, provision of current job descriptions with regulatory body membership (or equivalent)	□ yes □ no
3*	Cardiac emergencies policy	*Cardiac emergency policies in place	Program survey	□ yes □ no
4	Assessment of tobacco	Tobacco use is assessed	Program survey, responses in ICRR	□ yes □ no
5	Assessment of BP	Blood pressure is assessed	Program survey, responses in ICRR	□ yes □ no
Patient-level / Process & Outcome Indicators				
6	Program completion rate	Program completion rate: <50% of patients lost to follow-up / dropped out for non-clinical reasons other than return-to-work	ICRR data	□ yes □ no
7*	Peak METs increase	Mean peak METs increase of ≥.5 from pre to post-program, in program completers	ICRR data	□ yes □ no
8	QoL increase	Mean post-program quality of life score > pre-program score, in program completers	ICRR data	□ yes □ no
9	Mins MVPA ≥150/wk post	Mean minutes of moderate to vigorous-intensity activity per week post-program /progress ≥150, in program completers	ICRR data	□ yes □ no
10	Knowledge – meds	≥70% of patients reporting yes they know what heart pills they should be taking post-program, in program completers that have coverage for medication	ICRR data	□ yes □ no
11	Knowledge – lipids	≥70% of patients reporting yes they know their cholesterol level and how to	ICRR data	□ yes □ no

		control it post-program, in program completers		
12	Knowledge – diet	≥70% of patients reporting yes they know how to follow a heart-healthy diet post-program, in program completers	ICRR data	□ yes □ no
13	Knowledge-return to life roles	≥70% of patients reporting yes they have been supported to get back to their important life roles post-program, in program completers	ICRR data	□ yes □ no
Total	Total yes: _____ More than 70% (9 questions): □ yes □ no Mandatory* questions met: □ yes □ no			

We are happy to answer any questions you may have about which variables were used to calculate any of these standards. If you perceive we have made an error or oversight, kindly provide supporting materials or a response within 2 weeks. We would be happy to review them and potentially move forward in the certification consideration process.

If you have any questions, consult our policies and procedures (https://globalcardiacrehab.com/Program-Certification), or ask.

Sincerely,

ICCPR Program Certification Secretary

C. IF/WHEN PROGRAM READY TO PROCEED TO VIRTUAL SITE VISIT

RE: ICCPR Program Certification Application- [COUNTRY] – proceeding to site visit

Dear Program:

Thank you for your interest in becoming an ICCPR-certified program. Based on our review of your submitted materials, program survey responses and registry data (information on our analysis findings can be provided upon request), we are delighted to confirm you meet all the requirements to proceed to virtual site assessment.

The 2-hour virtual site assessment of your phase II program only will be held in English. Your site assessor, whom we have confirmed has no conflicts of interest is: _____ (cc'ed). Given your time zone and business hours there (as patients and staff must be present at the centre during the assessment), that of myself and the assessor, the best time of day for the site visit is: __:___ in your time zone.

Please confirm which of the following dates you, and other required parties as per the Program Certification policies and procedures, could be available:

Month, days…..
If these times cannot be accommodated, please inform us of your constraints, and we will work to find a mutually-convenient time.
Once you have confirmed the time, we shall send a confirmation calendar appointment with the zoom link.

The 6 elements to be assessed during the site visit can be found here: https://globalcardiacrehab.com/Program-Certification (scroll down to "virtual site visit assessment procedures and see table below). Be prepared to answer questions about the 6 elements.

Assess-ment	**Quality Standard/s**	**Evidenced by:**
1	• Comprehensive (1) • Assessment of tobacco (4) • Assessment of BP (5)	Show chart of randomly selected patient(s) from registry (site assessor to state registry IDs during site visit, and confirm correct patient chart pulled based on sex, age and initial assessment date), stored securely, documenting: a. Initial assessment (e.g., history, risk) b. the risk factors of tobacco use and blood pressure c. exercise prescription
2	• Comprehensive (1)	Show how other components of your CR program are offered (in addition to exercise at least 1 must be offered of the following: patient education [e.g., show materials], risk factor modification [e.g., show charting of cardiac medications], behavior change counselling [e.g., show charting of diet recommendations, tobacco cessation intervention] or stress management / psychosocial [e.g., show relaxation techniques recommended to patients])
3	• Multidisciplinary team (2)	Introduce us to 2 members of the team of different disciplines (can include applicant; corresponding to role descriptions provided at time of application), who will describe their clinical roles in the program (if the other person cannot be available, the site visit will need to be rescheduled upon payment of the re-attempt fee).
4	• Cardiac emergencies policy (3)	Show the policy / procedure binder / manual for handling cardiac emergencies, and summarize to Assessor (note: staff may be queried on scenarios); Show the means on-site to summon assistance in case of emergency to start life support (latter not applicable to fully remote programs), including equipment.
5	• Peak METs increase (7)	Show a patient functional capacity test, or if not possible, where / how performed at your program (can be virtual with patient with consent)

6	• Knowledge of meds (10), lipids (11), diet (12), return to life roles (13)	Show a patient education session (could be 1-1, virtual and/or group), and/or secure consent from a patient to speak with the site Assessor about their education received (e.g., about medications, lipids, diet, psychosocial).

Please be advised that if <u>all requirements from the policy and procedures are not met in the site visit or it does not start on time, the visit shall be terminated and the re-attempt fee shall apply</u>. For instance:

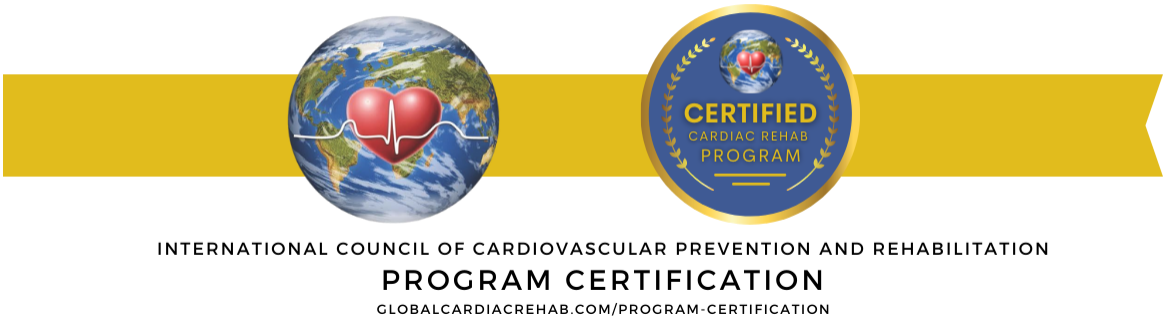
- ☐ You will need high-speed, wireless internet at your centre. Your device requires a functioning video camera (external USB web cam or integrated), and should be fully charged at the time of the site visit. Do not use a mobile phone.
- ☐ You and the team members will need to be in a fairly quiet space throughout the duration of the virtual site visit. Ensure good sound though the microphone and speaker.
- ☐ Ensure facilities and services can be observed (e.g., laptop on wheels to go to exercise machines, defibrillators as applicable).
- ☐ Ensure you can share documents on your screen in zoom.
- ☐ Ensure you are ready to show **<u>ALL</u>** required aspects of your program as per the elements above:
    a. randomly selected patient charts: be sure to have your file matching registry ID and name handy as we will provide some registry IDs and ask to view those patient charts (e.g., share screen)
        i. we will confirm it is the right patient by cross-referencing the year of birth, sex and initial assessment date for the patient.
        ii. if your charts are paper and/or not in English, this might be difficult to show us so try to think ahead how that could be achieved. But if electronic, show on shared screen
        iii. If your charts are not in English, please inform us as we will see about having someone on the call with that language proficiency.
    b. Introduce us to other professionals on your team (as per role descriptions sent at time of application) and we will ask them some questions. A minimum of 2 different disciplines must be present, but we prefer if as many members of your team can be present as possible. All staff should be on-site during the assessment.
    c. Show functional capacity testing and patient education (could include written materials) with the tablet on laptop on wheels
    d. Ensure at least 1 patient is available for us to question. The patient should be at the centre for a usual visit, but be willing to stay an extra 15 minutes and be willing to speak with us. Hopefully the patient can have some English-languge proficiency, but please remind us of their most common first languages so we can see if a site assessor with that expertise can be available if not.

A technical rehearsal will be arranged with the Secretary before the actual site assessment. As per the above requirements, at this time, we will confirm you are ready to proceed to the virtual site visit by observing you have the following capability: (1) good internet connection, visuals and sound for you, (2 a and b) able to communicate with (i.e., see and hear) a team member and patient (see point about language above); (3) show us you can share your screen with charts and /or patient education materials; (4) capability to take us on a tour of your centre to show us the various aspects; and (5) we will give you a random patient registry ID# and ask you to pull their chart, show it, and verify some of their information. This will then ensure you are ready to proceed to the actual site visit. The site visit will not proceed until this is met.
If you have any questions, consult our policies and procedures (https://globalcardiacrehab.com/Program-Certification), or ask.

Sincerely,

ICCPR Program Certification Secretary

Appendix E: Procedures for Virtual Site Assessors – Information to Support Site Assessors



Procedures for Virtual Site Assessments – Information to Support Site Assessors

TRAINING

The standards and policies are found here: https://globalcardiacrehab.com/Program-Certification

You will observe another virtual site assessment, and meet with the ICCPR Program Certification Exec to ensure you are prepared and answer any questions you may have. During this meeting we will also ensure you have a good internet connection, and good sound and video quality. Be sure you do not connect via a smartphone.

BEFORE ASSESSMENT

You will be asked to serve and declare any conflicts with the specific site. A mutually-convenient time will be selected.

When applying to the registry, programs complete a survey that contains many details about the site. The Secretary will send a PDF of those responses will be provided by the Secretary for you review so you have a sense of the program.

Then the results of the pre-assessment of program quality for the site will be shared with you using the below table (see grey shading). The program will have met at least 9 of the 13 standards or 70%. You can review any comments and ask any questions of the Secretary or co-chair.

	Quality Standard	Met pre-site visit?	Comments	Met during site visit?	Comments
1*	Comprehensive	□ yes □ no		□ yes □ no	
2	Multidisciplinary team	□ yes □ no		□ yes □ no	
3*	Cardiac emergencies policy	□ yes □ no		□ yes □ no	
4	Assmt tobacco	□ yes □ no		□ yes □ no	
5	Assmt BP	□ yes □ no		□ yes □ no	
6*	Program completion rate	□ yes □ no		n/a	
7	Peak METs increase	□ yes □ no		n/a	
8	QoL increase	□ yes □ no		n/a	
9	Mins MVPA ≥150/wk post	□ yes □ no		n/a	
10	Knowledge – meds	□ yes □ no		□ yes □ no	
11	Knowledge – lipids	□ yes □ no		□ yes □ no	
12	Knowledge – diet	□ yes □ no		□ yes □ no	
13	Knowledge- return to life roles	□ yes □ no		□ yes □ no	
Total	9/13 needed for certification	70%? □ yes □ no		70%? □ yes □ no	

Programs provide some supporting materials when they apply, as outlined on the website. They are saved on dropbox in the "applicants" folder, in a specific sub-folder for the site (e.g., job descriptions of the team members you will meet). If you do not have access to ICCPR's Program Certification dropbox and would like to see the materials, the Secretary would be glad to share them with you. Sometimes sites send additional information if we cannot secure a site assessor of the program's first language so they can be assessed ahead of the site visit and then discussed.

The secretary will have 5 random patient ID#s ready and you can use those during the site visit to pull charts randomly (use as many as needed until you feel confident you can determine whether the quality standard is met or not). The secretary will have access to the demographic information of the patient to confirm it is the right chart.

POINTS TO REMEMBER

Remember for many attendees on the call, English will not be their first language. So try to speak slowly. Make sure your mouth is visible in the screen. It might be advisable to share the steps of the visit on the screen when they are not sharing something so they can read it too, or even copy / paste into the chat box. You may need to use google translate for key information.

If the site is not ready on time, you cannot view clearly the program, the staff and patients are not available or any of the below 6 elements cannot be demonstrated the site visit should be ceased. The program certification working group will communicate to the site that they may re-attempt on paying the re-attempt fee. Note: a technical rehearsal with the site will be held with the Secretary in advance of the site visit to prevent issues.

During the site visit you are not to convey whether any of the standards are met or not or what the certification decision will be. That must be decided afterward with deliberation.

If you feel you cannot determine from the site visit proceedings whether a standard is met despite probing, you can discuss alternative ways to get the information after the site visit with the secretary (but this should not be communicated during the site visit). Only 9 of 13 need to be met, so it could be that it is not necessary.

The ICRR has separate quality improvement initiatives and they could work with the site separately on those where sites are interested. The purpose here is quality assessment only.

VIRTUAL SITE ASSESSMENT

Remember your confidentiality declaration and to treat the site with the utmost respect as an ICCPR representative.

Try to have the session flow as per the patient journey. We have also tried to order it by aspect of the site visit (i.e., seeing facilities; talking to staff; talking to patients; checking charts, as per left-hand column in table below).

During the 2-hour visit, you will ask the site to demonstrate the following 6 things (so you can estimate 20 mins each). The site knows to prepare accordingly (if some element cannot be done

by the site, you would be informed ahead; for instance patients may not speak in English). You can ask the program probing questions about each.

Start with introductions (assessors and their team). Let them know if you need a better view or to better hear.

Ask them to give an overview of their program and show you around.

Assess-ment Aspect	**Quality Standard/s**	**Evidenced by:**	**Met?**	**Comments** (observations, partially met, unable to determine, probing etc)
Intro / overview / showing the site overall	• Comprehensive (1)	Show how other components of your CR program are offered (in addition to exercise at least 1 must be offered of the following: patient education [e.g., show materials], risk factor modification [e.g., show charting of cardiac medications], behavior change counselling [e.g., show charting of diet recommendations, tobacco cessation intervention] or stress management / psychosocial [e.g., show relaxation techniques recommended to patients])	□ yes □ no	
Showing the centre	• Peak METs increase (7)	Show a patient functional capacity test, or if not possible, where / how performed at your program (can be virtual with patient with consent) *if can speak with patient at this point: Introduce yourself to the patient, and ask them about their journey to CR. Ask them to tell you about their experience in CR thus far.	□ yes □ no	
Talking to staff	• Multidisciplinary team (2)	Introduce us to 2 members of the team of different disciplines (can include applicant; corresponding to role descriptions provided at time of application), who will describe their clinical roles in the program (if the other person cannot be available, the site visit will need to be rescheduled upon payment of the re-attempt fee).	□ yes □ no	
Talking to staff	• Cardiac emergencies policy (3)	Ask the staff to show the policy / procedure binder / manual for handling cardiac emergencies, and summarize to Assessor; Show the means on-site to summon assistance in case of emergency to start life support (latter not applicable to fully remote programs), including equipment for example (e.g, defib machine).	□ yes □ no	

		You might want to ask for the records on maintenance of the crash cart, where applicable. You can ask which staff members have BCLS/ACLS, and one that has the latter you can ask them to show you how the cart is used. *As a site assessor, you should provide some scenarios and ask how they would deal with that (e.g., hypoglycemia, fall, patient has chest pain)		
Talking to patients where possible	• Knowledge of meds (10), lipids (11), diet (12), return to life roles (13)	Introduce yourself to the patient, and ask them about their journey to CR. Ask them to tell you about their experience in CR thus far. Ask about the education they have received. Show a patient education session or staff show materials (could be 1-1, virtual and/or group) about each of medications, lipids, diet, and psychosocial.	□ yes □ no	
Looking at program records / patient charts	• Comprehensive (1) • Assessment of tobacco (4) • Assessment of BP (5)	Ask staff to show chart of randomly selected patient(s) from registry (site assessor to state registry IDs during site visit, and secretary confirm correct patient chart pulled based on sex, age and initial assessment date with the site), stored securely, documenting: a. Initial assessment (e.g., history, risk) b. the risk factors of tobacco use and blood pressure c. exercise prescription	□ yes □ no	

You should make notes in the right-hand column of the above table during the visit privately.

At the end, thank the site and let them know we will be in contact about the outcome via email in due course.

AFTER SITE ASSESSMENT

Once you are certain the site has left the meeting, the Secretary will share screen with the applicant assessment form, so you can complete the site visit sections. You can make any comments to describe the site visit and anything that was lacking. Then she will show the first table above and you can discuss whether each of the standards were met during the site visit.

The site assessor may request additional information or documentation be provided after the virtual site visit if meeting of certain quality standards is unclear. During the debriefing conversation, needed information should be specified on the Secretary's form. In the case where there are some outstanding questions after the visit leading the Assessor(s) to have difficulty in making the certification recommendation, the ICCPR Program Certification committee may be consulted and/or a 2nd evaluation with a different Assessor may be arranged.

Ultimately, carrying forward the decision from registry data for variables that were not assessed during the site visit in the table, it can be determined whether 70% of the standards were met or not (i.e., <9/13=certified site).

You will be asked to give one of the following five recommendations for certification:

1. Yes
2. Perhaps, with some clarification or remediation (would need to be specified; note this decision should be used sparingly)
3. No
4. Could not be determined
5. More information needed prior to decision.

Once any outstanding information is received from the site if applicable, your role is complete. Thank you! The Secretary will communicate the outcome with the Program Certification cttee co-chair, and once confirmed, to the Site.

Appendix F: Email Template #2 – To Applicant Programs After Site Visit (Standardized Email Communicating The Decision To The Program)

International Council of Cardiovascular Prevention and Rehabilitation (ICCPR)

ICCPR Program Certification

Email Template #2

to applicant programs after site visit (select appropriate template).

A. WHERE CERTIFICATION REQUIREMENTS ARE MET

RE: ICCPR Program Certification Application- [COUNTRY] – decision

Dear Program:

Thank you for your interest in becoming an ICCPR-certified program. We are delighted to inform you that you meet the criteria for certification, and this decision has been finalized by ICCPR's Program Certification Chair. You can now officially call yourself "ICCPR-Certified!)

Your program is now certified through to December 31, 20xx. The corresponding certificate is attached.

Here is a summary of your program's performance for each quality standard:

Note ICRR's user sub-committee may be in touch to invite you to share some of your best practices with other programs, and is available to support you in any way with any areas where you may wish to develop quality further.

The good news will soon be shared on ICCPR's social media channels (TikTok, Instagram, Twitter, Facebook, LinkedIn) and website. If your staff or institution is on any of these channels, please feel free to provide the handle(s), and we can be sure to tag them. Please also share the posts widely in your circles and platforms.

Please find attached marketing materials you may use to advertise your certification. ICCPR is available to collaborate on any press releases you may wish to pursue. Certified programs are expected to at least maintain their practices throughout the certification term. ICCPR may conduct periodic audits at any time during the certification

period to ensure that the standards are still being met. This may include a site visit or a request for submission of materials related to certification standards.

You are invited to apply for re-certification in advance of the expiry of your term. Full details will be available on our website at https://globalcardiacrehab.com/Program-Certification.

Item	Quality Standard	Description	Data source	Met?
Program-level / Structure & Process Indicators				
1*	Comprehensive	*Comprehensive program, including (a) initial assessment, (b) structured exercise training (supervised or unsupervised) and (c) ≥1 other strategy to control CVD risk factors; evidenced based on program survey and during site visit (demonstration of at least one other component)	Program survey	□ yes □ no
2	Multidisciplinary team	Multidisciplinary team (i.e., ≥2 different regulated professions available to support patients at least on a part-time or referral basis)	Program survey, provision of current job descriptions with regulatory body membership (or equivalent)	□ yes □ no
3*	Cardiac emergencies policy	*Cardiac emergency policies in place	Program survey	□ yes □ no
4	Assessment of tobacco	Tobacco use is assessed	Program survey, responses in ICRR	□ yes □ no
5	Assessment of BP	Blood pressure is assessed	Program survey, responses in ICRR	□ yes □ no
Patient-level / Process & Outcome Indicators				
6	Program completion rate	Program completion rate: <50% of patients lost to follow-up / dropped out for non-clinical reasons other than return-to-work	ICRR data	□ yes □ no
7*	Peak METs increase	Mean peak METs increase of ≥.5 from pre to post-program, in program completers	ICRR data	□ yes □ no
8	QoL increase	Mean post-program quality of life score > pre-program score, in program completers	ICRR data	□ yes □ no
9	Mins MVPA ≥150/wk post	Mean minutes of moderate to vigorous-intensity activity per week post-program /progress ≥150, in program completers	ICRR data	□ yes □ no

Item	Quality Standard	Description	Data source	Met?
10	Knowledge – meds	≥70% of patients reporting yes they know what heart pills they should be taking post-program, in program completers that have coverage for medication	ICRR data	□ yes □ no
11	Knowledge – lipids	≥70% of patients reporting yes they know their cholesterol level and how to control it post-program, in program completers	ICRR data	□ yes □ no
12	Knowledge – diet	≥70% of patients reporting yes they know how to follow a heart-healthy diet post-program, in program completers	ICRR data	□ yes □ no
13	Knowledge-return to life roles	≥70% of patients reporting yes they have been supported to get back to their important life roles post-program, in program completers	ICRR data	□ yes □ no
Total	Total yes: _____ More than 70% (9 standards): □ yes □ no Mandatory* standards met: □ yes □ no			

Sincerely,

ICCPR Program Certification Secretary

B. WHERE CERTIFICATION REQUIREMENTS ARE NOT MET, BUT REMEDIATION COULD RECTIFY

RE: ICCPR Program Certification Application- [COUNTRY] – decision

Dear Program:

Thank you for your interest in becoming an ICCPR-certified program.

Following the virtual site visit, please find below a summary of our determination of your quality with regard to each of ICCPR's standards. Note you can find details regarding how each is operationalized on our website at: https://globalcardiacrehab.com/Program-Certification.

Item	Quality Standard	Description	Met?	Comments (if any)
Program-level / Structure & Process Indicators				
1*	Comprehensive	*Comprehensive program, including (a) initial assessment, (b) structured exercise training (supervised or unsupervised) and (c) ≥1 other strategy to control CVD risk factors; evidenced based on program survey and during site visit (demonstration of at least one other component)	□ yes □ no	
2	Multidisciplinary team	Multidisciplinary team (i.e., ≥2 different regulated professions available to support patients at least on a part-time or referral basis)	□ yes □ no	
3*	Cardiac emergencies policy	*Cardiac emergency policies in place	□ yes □ no	
4	Assessment of tobacco	Tobacco use is assessed	□ yes □ no	
5	Assessment of BP	Blood pressure is assessed	□ yes □ no	
Patient-level / Process & Outcome Indicators				
6	Program completion rate	Program completion rate: <50% of patients lost to follow-up / dropped out for non-clinical reasons other than return-to-work	□ yes □ no	
7*	Peak METs increase	Mean peak METs increase of ≥.5 from pre to post-program, in ≥75% of program completers	□ yes □ no	
8	QoL increase	Mean post-program quality of life score > pre-program score, in program completers	□ yes □ no	

Item	Quality Standard	Description	Met?	Comments (if any)
9	Mins MVPA ≥150/wk post	Mean minutes of moderate to vigorous-intensity activity per week post-program /progress ≥150, in program completers	□ yes □ no	
10	Knowledge – meds	≥70% of patients reporting yes they know what heart pills they should be taking post-program, in program completers that have coverage for medication	□ yes □ no	
11	Knowledge – lipids	≥70% of patients reporting yes they know their cholesterol level and how to control it post-program, in program completers	□ yes □ no	
12	Knowledge – diet	≥70% of patients reporting yes they know how to follow a heart-healthy diet post-program, in program completers	□ yes □ no	
13	Knowledge- return to life roles	≥70% of patients reporting yes they have been supported to get back to their important life roles post-program, in program completers	□ yes □ no	
	Total yes: _____ More than 70% (9 standards): □ yes □ no Mandatory* standards met: □ yes □ no			

As you will note, unfortunately you have not met the [70% threshold / mandatory standards] to be considered a certified program at this time.

However, should you perceive there has been any error or oversight, that there is a local context that renders one or more of the indicators inapplicable, or with some remediation some standard(s) could be met, you are welcome to work towards that in conjunction with us, upon payment of the re-attempt fee.

In particular, based on discussions, the following could be pursued to augment your quality, to meet certification standards:

_____

ICCPR remains dedicated to supporting programs to provide high-quality CR to patients in need, and this offer holds for one year. After that period, you are welcome to re-apply at any time.

It has been our pleasure to consider your program and to learn about all it has to offer. Sincerely,

ICCPR Program Certification Secretary

C. WHERE CERTIFICATION REQUIREMENTS ARE NOT MET, AND LIKELY NO CHANCE OF REMEDIATION

RE: ICCPR Program Certification Application- [COUNTRY] – decision

Dear Program:

Thank you for your interest in becoming an ICCPR-certified program.

Following the virtual site visit, please find below a summary of our determination of your quality with regard to each of ICCPR's standards. Note you can find details regarding how each is operationalized on our website at: https://globalcardiacrehab.com/Program-Certification.

Item	Quality Standard	Description	Met?	Comments (if any)
Program-level / Structure & Process Indicators				
1*	Comprehensive	*Comprehensive program, including (a) initial assessment, (b) structured exercise training (supervised or unsupervised) and (c) ≥1 other strategy to control CVD risk factors; evidenced based on program survey and during site visit (demonstration of at least one other component)	□ yes □ no	
2	Multidisciplinary team	Multidisciplinary team (i.e., ≥2 different regulated professions available to support patients at least on a part-time or referral basis)	□ yes □ no	
3*	Cardiac emergencies policy	*Cardiac emergency policies in place	□ yes □ no	
4	Assessment of tobacco	Tobacco use is assessed	□ yes □ no	
5	Assessment of BP	Blood pressure is assessed	□ yes □ no	
Patient-level / Process & Outcome Indicators				
6	Program completion rate	Program completion rate: <50% of patients lost to follow-up / dropped out for non-clinical reasons other than return-to-work	□ yes □ no	
7*	Peak METs increase	Mean peak METs increase of ≥.5 from pre to post-program, in program completers	□ yes □ no	
8	QoL increase	Mean post-program quality of life score > pre-program score, in program completers	□ yes □ no	

Item	Quality Standard	Description	Met?	Comments (if any)
9	Mins MVPA ≥150/wk post	Mean minutes of moderate to vigorous-intensity activity per week post-program /progress ≥150, in program completers	□ yes □ no	
10	Knowledge – meds	≥70% of patients reporting yes they know what heart pills they should be taking post-program, in program completers that have coverage for medication	□ yes □ no	
11	Knowledge – lipids	≥70% of patients reporting yes they know their cholesterol level and how to control it post-program, in program completers	□ yes □ no	
12	Knowledge – diet	≥70% of patients reporting yes they know how to follow a heart-healthy diet post-program, in program completers	□ yes □ no	
13	Knowledge- return to life roles	≥70% of patients reporting yes they have been supported to get back to their important life roles post-program, in program completers	□ yes □ no	
	Total yes: _____ More than 70% (9 standards): □ yes □ no Mandatory* standards met: □ yes □ no			

As you will note, unfortunately you have not met the 70% threshold to be considered a certified program at this time.

ICCPR remains dedicated to supporting programs to provide high-quality CR to patients in need. The user sub-committee would be happy to work with you and your program on quality improvement activities should you be interested. Please reply if you would like to take advantage of this. You are welcome to re-apply for certification at a later time once you have had a chance to successfully implement some quality initiatives.

It has been our pleasure to consider your program and to learn about all it has to offer.
Sincerely,

ICCPR Program Certification Secretary

Appendix G: ICCPR Program Certification Certificate

Appendix H: Consent Form for Focus Group (Study#1)

Informed Consent Form

Date: May 27, 2022

Study Name: Pilot of the International Cardiac Rehab Registry (ICRR)

Researchers: Sherry Grace, PhD; York University, Toronto, Canada (sgrace@yorku.ca) & Karam Turk-Adawi, PhD; Qatar University, Doha (kadawi@qu.edu.qa)

Purpose of the Research: To get input from participating cardiac rehabilitation programs on their experience on-boarding with the ICRR, contributing data to the ICRR, and being considered for program certification.

What You Will Be Asked to Do in the Research: You are invited to participate in a web-based focus group for approximately 2 hours.

Risks and Discomforts: We do not foresee any risks or discomfort from your participation in the research.

Benefits of the Research and Benefits to You: This information will be used to improve ICRR processes for future cardiac rehab programs interested in joining. This research could be of benefit to you if any of the changes improve current registry processes.

Voluntary Participation and Withdrawal: Your participation in the study is completely voluntary and you may choose to stop participating at any time. Your decision not to volunteer, to stop participating, or to refuse to answer particular questions will not influence the nature of the ongoing relationship you may have with the researchers or study staff, nor the nature of your relationship with ICCPR or the researcher's institutions either now, or in the future. Should you wish to withdraw after the study, you will have the option to also withdraw your data up until the analysis is complete.

Confidentiality: The interview recording will not be associated with identifying information. All information you supply during the research will be held in confidence and unless you specifically indicate your consent, your name will not appear in any report or publication of the research.

The focus group will be video-recorded and auto-transcribed digitally (any identifying information removed immediately afterwards), and the team will make handwritten notes without identifying information. Your data will be safely stored on a secure institutional server, and only research staff/research team members will have access to this information. The video-recordings will be destroyed once the resulting manuscript is accepted for publication, and the electronic transcripts and notes will be stored for 10 years and then destroyed by deletion. Confidentiality will be provided to the fullest extent possible by law.

This study will use MS Teams to collect data, which is an externally-hosted cloud-based service. When information is transmitted over the internet privacy cannot be guaranteed. There is always a risk your responses may be intercepted by a third party (e.g., government agencies, hackers). Further, while the researchers will not collect or use IP addresses or other information which could link your participation to

your computer or electronic devices without informing you, there is a small risk with any platform such as this of data that is collected on external servers falling outside the control of the research team. If you are concerned about this, we would be happy to make alternative arrangements (where possible) for you to participate, perhaps via telephone. Please contact Sherry Grace for further information.

Video recordings will be saved in a password-protected file to research team members' individual folders on the institutional server, not the cloud-based service.

Please note that it is the expectation that participants agree not to make any unauthorized recordings of the content of a meeting / data collection session.

Questions About the Research? If you have questions about the research in general or about your role in the study, please feel free to contact Prof. Sherry Grace either by telephone at (416) 892-3218 or by e-mail (sgrace@yorku.ca). This research has received ethics review and approval by the Human Participants Review Sub-Committee, York University's Ethics Review Board and conforms to the standards of the Canadian Tri-Council Research Ethics guidelines. If you have any questions about this process, or about your rights as a participant in the study, please contact the Sr. Manager & Policy Advisor for the Office of Research Ethics, 3rd Floor, Kaneff Tower, York University (telephone 416-736-5914 or e-mail ore@yorku.ca).

Legal Rights and Signatures:

I *( )*, consent to participate in *"Pilot of the ICRR"* conducted by *Sherry Grace*. I have understood the nature of this project and wish to participate. I am not waiving any of my legal rights by signing this form. My signature below indicates my consent.

Signature _____ **Date** _____
Participant

Signature _____ **Date** _____
Principal Investigator

Appendix I: Semi-Structured Interview Questions for Data Stewards (Focus Group Guide For Study #1)

ICCPR Program Certification Pilot

Semi-structured interview questions for data stewards

Start with welcome, and ask each attendee to state their profession.

Do a reminder around confidentiality, and how we will not reveal their identity in any publications. Any questions about the consent forms?

Reminder that we appreciate their candour in telling us what challenges they had, so we can improve the system for future programs joining ICRR.

PROGRAM CERTIFICATION

1. What would be the motivation for CR programs to be certified?
    a. What were the most important motivations at your centre?
2. ICRR sites are informed about the certification opportunity in an email at 5 months. Do you think this is best? Any ideas on better ways to do that?
3. Comments on webpage
    a. How do you think we could improve the program certification website, to better support interested sites?
4. What do you think about the 13 quality standards themselves?
    a. Did you feel clear about what each quality standard was?
    b. Could you understand how they were assessed?
    c. Did they all seem relevant in your setting?
    d. level of difficulty
        i. Any you think are too difficult to achieve as a low-resource setting?
        ii. Any for which you perceive the standard is too low?
        iii. Did the cut-offs seem fair and appropriate, given international standards and evidence?
    e. Any you think should be deleted as not important?
    f. Any standards you think are missing? An area of CR we have omitted?
    g. Any other ideas on how they could better be evaluated than as it is set up?
5. Describe your experience communicating with ICCPR about program certification.
    a. The online application (for those that used)
    b. Was the process clear and you knew what to expect?
    c. Did you feel supported through the process? Timely / responsive to your needs?
        i. Where standards were not met, did you feel judgment or support?
    d. What about communication about the initial standard assessment and
        i. certification decision?
            1. Did it feel transparent and clear whether you met each quality standard?
            2. Did the process feel fair, confidential and / or respectful?
6. Describe your experience during the virtual site assessment
    a. Was the process clear and you knew what to expect?
    b. Did you feel supported through the process? Or judged?
    c. Did you perceive the procedures appropriately assessed the standards?
        i. In what ways?

    d. How could it have been improved?
7. Upon certification decision
    a. were the marketing materials helpful? Did you use them? Which ones?
        i. Did you print and hang your certificate? Why or why not?
    b. Who did you share them with?
        i. Patients – level of service they can expect
        ii. institutional leadership?
        iii. Policy-makers / payers?
    c. Were you satisfied with the ways in which ICCPR shared the news of your social media on their website and social media accounts?
    d. What else would you like to support you in sharing the good news of your certification?
8. Were there any effects / impacts from your certification?
    a. Were your motivations to apply fulfilled?
    b. Did you use the results to make any program changes?
9. Do you think there should be a program certification option for programs that are not in the ICRR?
    a. Eg. AACVPR it is optional and EAPC there is no registry (all document uploads)
10. Given the fees,
    a. Do you perceive costs are reasonable?
    b. do you think you will apply for re-certification in 3 years? Why or why not?

11. Thanks for your time. Is there anything else you would like to tell us about your experience learning about and being a part of the registry or getting certified?

Appendix J: ICRR Quality Improvement (QImp) Plan

ICRR Quality Improvement (QI) Initiatives

V1; Aug 12/2021

The ICCPR's International Cardiac Rehab Registry (ICRR) includes as a primary objective assessing cardiac rehabilitation (CR) quality in low-resource settings (see protocol here: https://globalcardiacrehab.com/ICRR-Governance), with the ultimately aim of supporting programs to optimize quality in terms of structure, processes, and patient outcomes. ICRR governance includes the user sub-committee, with a mandate to support quality improvement (terms here: https://globalcardiacrehab.com/ICRR-Governance).

ICRR's quality initiatives were developed on the basis of evidence and best practices in CR and beyond. Data quality (trust in), intensity (e.g., frequency), timeliness, reach, confidentiality / non-judgmental tone, ease of implementation of QI approaches, and tailoring them to local context have all been considered. We endeavour to educate clinicians, provide support in analyzing and then improving processes, and to provide a fora for discussion on quality. Initiatives and processes will be responsive to program need, such that this will be a living document.

ICRR QI RESOURCES

The ICRR has several features to support quality assessment (see ancillary features information file for more detail): (1) the program survey completed prior to ICRR on-boarding which assesses many structural indicators, and (2) the dashboards displaying 12 process and outcome indicators selected through a delphi process, where (a) site performance is compared to itself over time (first 6 months vs thereafter), and (b) sites are compared to all other sites (there is also a patient-outcomes report where mean scores on 6 of the indicators are shown). Programs have access to this information at all times (i.e., timeliness). These comparisons provide easily-visible benchmarks for programs.

Moreover, (3) through the ICCPR Program Certification scheme (and also based on the program survey and ICRR patient data), 13 quality standards are delineated, based on ICCPR's consensus statement (Grace et al., Heart, 2016), and quality measures / standards from other professional CR societies. Some of these are simply met or not met, but others delineate degree of quality (e.g., % of patients knowing how to control their cholesterol post-program) and hence are of particular utility for our QI efforts. These then form the basis of our quality efforts.

PROGRAM OUTREACH:

The user sub-committee will espouse a "collaborative learning model", engaging programs in the QI process. All ICRR-participating programs are informed about the user sub-committee QI mission at their second on-boarding webcall, when training on post-program data entry is provided. All programs will be provided education about Plan-Do-Study-Act (PDSA) cycles once they have some post-program data entered, and hence the dashboard data are available to them for comparison, and invited to engage with the user sub-committee co-chair for QI at any time.

Once a minimum of 10 CR programs are contributing post-program data to the ICRR, biannually (April 1 and Oct 1), the user sub-committee QI co-chair will peruse the patient-reported outcomes report (values shown by site for administrators) or download the data to examine the other indicators or standards to see where either the greatest quality concern exists, or where there is wide site-to-site variability in quality. Or they will consider quality issues raised by sites following the invitation at the time of on-boarding. Ultimately, one area for QI will be identified twice per year; the user QI co-chair shall engage with the user sub-cttee including the patient partners, and ICRR exec/ steering to support prioritizing QI areas.

The co-chair will then do an environmental scan (including reaching out to liaison group of other CR registries) and literature search for resources to support programs in QI for this indicator. The highest-performing sites (number to be determined based on distribution of data) will be contacted via email by the ICRR Secretary and invited to share best practices with other programs; they will need to consent to sharing of any provided documents in the registry for any future participating programs and with the ICCPR community (they can de-identify them if they wish) and asked about their willingness to share best practices during a webinar on the topic.

The Secretary will then work with responding programs and the co-chair to identify a time to host the hour-long webinar. The webinar will be advertised to all-time ICRR participating programs (but a personal invitation will be sent confidentially by the co-chair to programs performing lowest on the indicator, with again the number to be determined based on the distribution of the data and the correspondence will be sent in a non-judgmental tone), and the ICCPR community, and recorded for subsequent posting on the ICRR website for those where the time zone is not suitable. All expressing interest will be provided the QI materials from the environmental scan and high-performing programs in advance of the webinar (e.g., evidence-based best practices algorithms, clinical pathways, standardized encounter forms, checklists, pocket cards, chart stickers, patient education materials). An expert in QI or the clinical area (as appropriate) will be invited to chair the webinar, and each program will have 5 minutes to share their best practices, and a Q&A will ensue.

After the webinar, all attendees will be asked to participate in monthly follow-up informal videocalls as a “community of practice” to support them in implementing new practices, tailored to their setting (e.g., translation). These will continue until the learning community has no further desire/need for discussion. The lower-performing programs will again be contacted confidentially, with the offer to have a 1-1 call, discuss strategies that could work in the local setting, and offer to review data for change at a subsequent call (over and above what can be seen in the dashboards).

QI activities will be summarized in ICRR reports, posted on the website among other dissemination avenues, and shared through ICCPR social media posts.

New programs contacting the user sub-committee regarding previously-covered QI areas will be provided all the materials and directed to the recorded webinar.

PATIENT OUTREACH:

The ICRR also has a patient lay summary, where post-program patients receive a summary of their progress and information on areas where further risk reduction and/or education may be needed. ICRR will not know the identity of patients, but will support programs to institute processes to follow-up with patients where guideline targets or education needs are not fulfilled by program completion, and to support patients in continued self-management post-program. This will be achieved by asking programs what would be of most help, doing an environmental scan and literature search, and reaching out to the ICCPR community for tools that can be shared. Likely, a webinar would be held and recorded.

Patients providing an email or mobile number may be contacted with lay ICRR summaries, but there is also a patient page of the registry where we can post materials for patients (https://globalcardiacrehab.com/ICRR-for-Patients). Through this, the user sub-committee could address some of the areas where the greatest gaps are identified, and encourage continued heart-health maintenance.

Appendix K: Email Template #3 – QImp and Program Certification Email To Be Sent To The Sites

RE: Supporting ICRR-participating programs in delivering high-quality CR (and program certification opportunity)

Dear ICRR-contributing program,

Thank you for your continued participation in the International Cardiac Rehabilitation Registry (ICRR) of the International Council of Cardiovascular Prevention & Rehabilitation (ICCPR). By now you will likely have entered in some post-program data, so you can finally view your program efficacy. This email serves to inform you of the ways the ICRR can support you to do that (see also: https://globalcardiacrehab.com/resources/Documents/ICRR_QI%20plan_v1-2.pdf), but of course your program quality always remains confidential.

To start, please familiarize yourself with quality improvement (QI), from a CR perspective, by watching this brief video overview at: https://globalcardiacrehab.com/ICRR-Quality-Improvement-Initiatives

DASHBOARDS & Pt-RELATED OUTCOMES REPORT

A training video on the quality features of the ICRR is found here: https://globalcardiacrehab.com/ICRR-Training (#3). You would have also received the "ancillary features" file when you on-boarded with the ICRR (also found under "documents" in the ICRR main screen menu). Therein, you can find information about accessing ICRR's dashboards, with 12 indicators (6 on each dashboard page) starting on page 5 of the document.

Recall at this point your data will be in the bar on the left, and data from all sites will be in bar on the right. Pay close attention to the units on the axes, as they do vary based on your data, so you have a sense of the degree of difference between your site and others; the difference may be just chance or measurement error or a true difference. If it is unclear, statistics can be used to test that, and we can show you how to do that upon request (e.g., enter your program mean and standard deviation [which you would need to compute by downloading/exporting your data as per that feature as also described in the "ancillary features" file] and that of all programs [we would need to provide] here: https://www.graphpad.com/quickcalcs/ttest1/?format=SD). Remember, you can also select to show only patients who completed the program in your dashboard figures (see instructions in "ancillary features" file).

Once you have been entering data over 6 months, the middle bar will populate on each dashboard figure, which will show data on more recent patients. Again, all this is outlined in the "ancillary features" file. You can also see mean pre and post-program for 6 of the indicators in the "pt-related outcomes report"

feature from the main menu. Finally, you can also export your data files, link the pre and post-data, to explore other variables (if needed, the sub-committee can support as resources permit).

If you are having trouble securing post-program data, perhaps from patients in unsupervised programs or who are no longer in the program, remember through the data dictionary there are suggestions on how to collect each variable without the need for an on-site visit if it is not feasible. The more follow-up data you enter (and the better quality it is), you will be in a better position to evaluate your program. You can also see how "complete" your data are in the "completeness report" feature from the main menu. If you are not yet taking advantage of direct patient report to optimize follow-up data collection but wish to, please reach out to us if we can be of support.

The "patient-related outcomes report" ancillary feature contains average scores pre and post-program for the 6 "patient-related outcomes" in the dashboard. See more details starting on page 8 of the "ancillary features" file.

Take the time to review the dashboard and patient-related outcomes report information with your team. Please remember even programs in the highest-resource countries struggle with quality and have areas to improve. Also remember you can't tackle everything at once; pick an area where quality improvement would be most feasible and impactful for patient outcomes to start!

QUALITY IMPROVEMENT INTIATIVES / PROGRAM OUTREACH

Please note this aspect of the registry is completely voluntary, confidential and non-judgmental. Consider this an invitation into a collaborative learning community!

As per ICRR's quality improvement plan, we actively work with sites on specific QI topics, upon analysis of patient outcomes in the registry. Previous and upcoming topics are listed on our website at: https://globalcardiacrehab.com/ICRR-Quality-Improvement-Initiatives. For each, you will see a webinar recording with some information on performance by ICRR-participating sites (in aggregate) and also recommendations on how to make improvements.

For future topics, you will be invited to the webinar and subsequent 1-hour "QI implementation chat" webmeetings to discuss:

- experiences considering your quality level at your centre,
- how you can secure resources (human, financial or otherwise as applicable),
- developing a plan to improve quality,
- implementation and associated challenges, as well as
- measurement of progress.

If you wish to pursue a quality improvement strategy that has not been covered, we can help you explore evidence-based strategies to address your issue. Here are some resources on the implementation process: https://globalcardiacrehab.com/ICRR-Quality-Improvement-Initiatives. See also attached example where this is applied to the problem of low CR referrals), and see too https://www.health.org.uk/sites/default/files/QualityImprovementMadeSimple.pdf). Remember that middle bar of the dashboard can help you assess whether your implemented strategies are having an impact!

The ICRR user sub-committee is here to help you improve the quality of your CR program, and we are happy to share resources and guide you through the process. Always feel free to contact us should you have any queries on improving the quality of your CR program.

OPTIONAL PROGRAM CERTIFICATION

ICRR-contributing sites also have the opportunity to apply for potential ICCPR Program Certification. While there is a fee associated with certification as outlined on our website (https://globalcardiacrehab.com/Program-Certification; sliding scale), once you have post-program or progress data on at least 60 patients in the registry, you are eligible to apply. We hope that you too will want to have your program recognized as "ICCPR-Certified" given all your efforts! Information on how to apply is found on our website; We then use your initial program survey as well as registry data to let you know your performance across the quality standards, and whether you meet at least 70% of them.

In closing, just a reminder as per ICRR policies in the site agreement, that when you feel you have achieved your goals with respect to your participation in the registry, you can let us know you will be ceasing entering new patients. Again, you are asked to follow-up annually on included patients as per the data dictionary, and again the direct patient report can facilitate that.

We commended you for your commitment to delivering the best-quality CR you can, to optimize your patient outcomes. ICRR remains available to support you in your efforts.

At ICRR, we measure up!

Sincerely,

ICRR User Sub-Committee Co-Chair for Quality Improvement, &
ICCPR Program Certification Steering Committee Co-Chair
iccpr.icrr@gmail.com

Appendix L: Consent Form for Focus Group on ICRR QImp activities (Study #2)

Informed Consent Form

Date: May 4, 2023

Study Name: Pilot of the International Cardiac Rehab Registry (ICRR) - Quality Initiatives Sub-Study

Researchers: Sherry Grace, PhD; York University, Toronto, Canada (sgrace@yorku.ca) & Karam Turk-Adawi, PhD; Qatar University, Doha (kadawi@qu.edu.qa)

Purpose of the Research: To get input from participating cardiac rehabilitation programs on their experience with quality improvement initiatives as part of the ICRR

What You Will Be Asked to Do in the Research: You are invited to participate in a web-based focus group for approximately 1.5 hours.

Risks and Discomforts: We do not foresee any risks or discomfort from your participation in the research.

Benefits of the Research and Benefits to You: This information will be used to improve ICRR processes for future quality improvement initiatives and for cardiac rehab programs joining in future. This research could be of benefit to you if any of the changes improve current registry processes.

Voluntary Participation and Withdrawal: Your participation in the study is completely voluntary and you may choose to stop participating at any time. Your decision not to volunteer, to stop participating, or to refuse to answer particular questions will not influence the nature of the ongoing relationship you may have with the researchers or study staff, nor the nature of your relationship with ICCPR or the researcher's institutions either now, or in the future. Should you wish to withdraw after the study, you will have the option to also withdraw your data up until the analysis is complete.

Confidentiality: The interview recording will not be associated with identifying information. All information you supply during the research will be held in confidence and unless you specifically indicate your consent, your name will not appear in any report or publication of the research.

The focus group will be video-recorded and auto-transcribed digitally (any identifying information removed immediately afterwards), and the team will make handwritten notes without identifying information. Your data will be safely stored on a secure institutional server, and only research staff/research team members will have access to this information. The video-recordings will be destroyed once the resulting manuscript is accepted for publication, and the electronic transcripts and notes will be stored for 10 years and then destroyed by deletion. Confidentiality will be provided to the fullest extent possible by law.

This study will use MS Teams to collect data, which is an externally-hosted cloud-based service. When information is transmitted over the internet privacy cannot be guaranteed. There is always a risk your responses may be intercepted by a third party (e.g., government agencies, hackers). Further, while the researchers will not collect or use IP addresses or other information which could link your participation to

your computer or electronic devices without informing you, there is a small risk with any platform such as this of data that is collected on external servers falling outside the control of the research team. If you are concerned about this, we would be happy to make alternative arrangements (where possible) for you to participate, perhaps via telephone. Please contact Sherry Grace for further information.

Video recordings will be saved in a password-protected file to research team members' individual folders on the institutional server, not the cloud-based service.

Please note that it is the expectation that participants agree not to make any unauthorized recordings of the content of a meeting / data collection session.

Questions About the Research? If you have questions about the research in general or about your role in the study, please feel free to contact Prof. Sherry Grace either by telephone at (416) 892-3218 or by e-mail (sgrace@yorku.ca). This research has received ethics review and approval by the Human Participants Review Sub-Committee, York University's Ethics Review Board and conforms to the standards of the Canadian Tri-Council Research Ethics guidelines. If you have any questions about this process, or about your rights as a participant in the study, please contact the Sr. Manager & Policy Advisor for the Office of Research Ethics, 3rd Floor, Kaneff Tower, York University (telephone 416-736-5914 or e-mail ore@yorku.ca).

Legal Rights and Signatures:

I *(fill in your name here),* consent to participate in *"Pilot of the ICRR – Quality Improvement*" conducted by *Sherry Grace*. I have understood the nature of this project and wish to participate. I am not waiving any of my legal rights by signing this form. My signature below indicates my consent.

Signature _____ **Date** _____
Participant

Signature _____ **Date** _____
Principal Investigator

Appendix M: Semi-Structured Interview Questions for Focus Group on ICRR QImp Activities (Study #2)

ICCPR ICRR QI Pilot

Semi-structured interview questions for data stewards

QUALITY IMPROVEMENT

Thanks for your input on the registry features that support quality. Now we would like to discuss with you how ICRR supports quality improvement, other than program certification.

1. Are you aware of QI and its methods?
    a. How familiar are you with it?
    b. what are you familiar with? (e.g., PDSA, lean, six sigma…)
    c. do you feel competent to initiate QI?
2. As a CR program, what does quality improvement mean to you?
    a. PROBES: what are your quality improvement needs?
    b. PROBES: do you feel you have capacity for quality improvement activities?
    c. PROBES: what resources do you need to support you in QI?
    d. PROBES: what benefits do you hope to achieve for your program?
3. Are you familiar with ICRR's quality improvement initiatives?
    a. PROBES: in what ways do you think ICRR supports you in quality improvement?
        i. E.g., they may mention dashboards, or patient-related outcomes report
        ii. PROBE: do you monitor how your program has changed (or not) over time on the dashboards?
            1. PROBES: if yes, was it helpful? How could it better meet your needs?
            2. IF NO: why not?
4. Have you looked at ICRR's quality improvement website?
    a. PROBES: reviewed any of the resources, including with overview video on what is QI for CR?
5. For those of you who have been in the ICRR for more than 5 months, do you remember receiving an email from us about the quality features in the registry?
    a. IF YES: was that useful in any way? How could it have been improved?
6. One of the quality initiatives is to analyze ICRR data to see where quality is lowest across sites, and then spend 6 months supporting programs to make improvements in one area. Do you remember the email we sent when we were arranging the first and/or second QI topics, which provided the results for all sites and your site?
    a. Was that helpful? How could that have been improved?
7. Which of you attended either quality improvement webinar?
    a. PROBE: engaging women in CR (Spr / 23)
    b. PROBE: reducing patient barriers and increasing dose / sessions attended (Fall / 23)
    c. did anyone watch the recordings?
    d. Tell us how useful that was?
        i. How could either have been improved?
        ii. PROBES: language barriers
    e. If no, why not?
8. Did you attend any of the confidential learning community discussions?
    a. If yes, where they helpful? How could they have been improved?

        i. PROBES: number, frequency, timing, duration
    b. If no, why not?
9. We are planning our next topic in the spring to be about improving patient education to increase patient knowledge and self-management
    a. What suggestions do you have for us to ensure it is as useful as possible to you?
10. We do look at the ICRR data to prioritize topics, what quality improvement areas are important to you?
    a. PROBES: would a mental health one be of interest to them (e.g., reducing depressive symptoms, improving quality of life scores on the ladder, return to life roles, social support, stress management knowledge)
11. Before we close, can you think of any other ways you would like ICRR to support you in program quality improvement?

Appendix N: Email Template #4 – To Sites Sharing Their Performance Confidentially

RE: ICRR's Quality Initiative – 2nd topic for Fall 2023 is CR barriers and session adherence

Dear ICRR-contributing program:

We appreciate having you as a part of our global community. We know from contributed data that patients at ICRR-participating sites are receiving high-quality care. However, there are always areas for improvement.

As one of the benefits of participating in ICRR, twice a year we have focused topics for quality improvement, as per: https://globalcardiacrehab.com/resources/Documents/ICRR_QI%20plan_v1-2.pdf. We hope you found value in our first QI topic of engaging women in CR.

Please note this aspect of the registry is completely voluntary, confidential and non-judgmental. Consider this an invitation into a collaborative learning community!

You can learn more about quality improvement in the context of CR here: https://globalcardiacrehab.com/ICRR-Quality-Improvement-Initiatives/. And here is a 15-minute video introduction regarding a hands-on "how to" for quality improvement by ICCPR's AACVPR representative Ann Gavic-Ottm MPA, RCEP, MAACVPR: *https://www.youtube.com/watch?v=stfcpqW91DM*.

NEXT TOPIC: PROGRAM DOSE

Based on ICRR data and/or site expressions of interest, the focus for the next 6 months will be on: **number of CR sessions patients attend and how to increase it**. Specifically, we aim to support interested programs to understand the average number of supervised sessions their patients are attending and consider barriers that may impede greater participation. ICCPR recently did a global survey of patient's CR barriers, and we found the top barriers – after not even being aware of CR and hence being able to enrol in our programs – were distance and cost.

For your information (confidentially), across the ICRR patients participate in an average of 11 supervised sessions (approximately 13 for program completers, and 8 for patients who do not); at your site, patients attend an average of YY sessions. Please note this does not include home or online sessions, as the registry does not capture the number of those sessions; at your site xx% of participants are shown to have done some online or phone-based sessions. Obviously, these sessions will also support your patients to achieve the improved outcomes associated with CR participation.

You and all the data stewards at your centre are invited to an optional **1-hour webinar** on October 18th at 8:30 AM Eastern; you should receive an electronic meeting invitation with a link to join (let us know if you do not). At this time, we will summarize overall performance in this area, and discuss ways to

improve. in case you cannot attend at that time due to the time difference or time conflict, the session will also be recorded and posted to ICRR's website at: https://globalcardiacrehab.com/ICRR-Quality-Improvement-Initiatives/.

All sites are invited to informal 1-hour "**QI implementation chat**" webmeetings to discuss:

- experiences considering your quality level at your centre,
- how you can secure resources (human, financial or otherwise as applicable),
- developing a plan to improve quality,
- implementation and associated challenges, as well as
- measurement of progress.
- Higher-performing sites are invited to share best practices

You and all your data stewards should receive electronic meeting invitations with a link to join these as well (let us know if you do not; the first one will be Nov 22 at 8:30am eastern). These meetings will not be recorded, and all attendees will be asked to keep the discussion confidential.

We look forward to our dialogue and activity over the next few months to augment CR quality. We are also available to speak individually with sites about questions or concerns, and solicit ideas to support you as needed.

At ICRR, we measure up!

Sincerely,

ICRR co-chair, Sherry Grace
ICRR QI lead, Dion Candelaria
ICRR Secretary, Fabbiha Raidah
Iccpr.icrr@gmail.com