ORIGINAL RESEARCH

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

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Background: Cardiac rehabilitation (CR) is a proven model of secondary prevention, but new sites, providing quality care, are needed in low-resource settings. This study (1) described the development of International Council of Cardiovascular Prevention and Rehabilitation's (ICCPR) Program Certification and (2a) tested its implementation, considering (b) appropriateness of quality standards for these settings.

Methods: The Steering Committee finalized 13 standards, requiring 70% be met. They are assessed initially through International CR Registry (ICRR) program survey and patient data; if Certification appears possible, a two-hour virtual site assessment is arranged to corroborate. Standard operating procedures for Assessor training were developed. A multi-method pilot study was then undertaken with a quantitative (description of quality indicators) and qualitative (focus groups on MS Teams) component. ICRR sites with post-program data by April 2022 were invited to participate. Two team members independently analyzed focus group transcripts, using a deductive-thematic approach with NVIVO.

Results: Five CR programs from the Eastern Mediterranean, South-East Asian and American regions participated. Upon application, with some data cleaning, initially four programs were eligible to proceed to virtual site assessment. Ultimately, all five programs were certified, each meeting a minimum of 12/13 standards (peak MET increase and program completion rate were not met by some centres). Four themes resulted from the two focus groups of 13 site data stewards: motivation and benefits (eg, international recognition, additional program resources), logistics (eg, communication, cost, site visit process), the standards and their assessment (eg, balance of rigor and feasibility), and suggestions for improvement (eg, website).

Conclusion: ICCPR's Program Certification has been demonstrated to be feasible, rigorous, and acceptable. Standards are attainable in low-resource settings. Certified programs reap benefits including additional resources. This first international Certification is suitable for low-resource settings, to complement that from the American and European CR Societies.

Keywords: quality of care, Certification, cardiac rehabilitation, low- and middle-income countries, registries, cardiovascular diseases

Introduction

Cardiovascular diseases (CVD) continue to be a leading burden of mortality and morbidity, which is much higher in lowand 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.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

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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).⁵ 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.⁶ However, there are differences in the nature of CR programs when compared to high-income countries (eg, dose, setting, comprehensiveness, multidisciplinary team), and they are more often privately funded.⁵ Therefore, a mechanism is needed to not only promote proliferation of CR in LMICs,^{7,8} but to support quality of these services. Indeed, greater quality of care can result in better patient outcomes.⁹ 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.

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), as well as York University (e2020-147).¹⁰

ICCPR Program Certification Development

ICCPR's Program Certification was developed in a rigorous fashion, by a steering committee comprised 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.^{11,12}

The purpose of the Certification is to recognize CR programs in resource-poor settings,¹³ who meet a minimum quality standard with regard to program structure, processes, and patient outcomes.¹⁰ Program certification is a peer-reviewed process designed to assess CR programs for adherence to quality standards of the ICCPR, also recognized other professional societies. 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 longestrunning one by the British Association of Cardiovascular Prevention and Rehabilitation (BACPR; <u>http://www.cardiacreh</u> <u>abilitation.org.uk/</u>),^{14,15} as well as that of the American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR; <u>https://www.aacvpr.org/Program-Certification</u>),^{16,17} and the European Association of Preventive Cardiology (EAPC;<u>https://www.escardio.org/Education/CareerDevelopment/Accreditation/EAPC-centre-accreditation</u>).¹⁸ A review of quality indicators of the major CR societies informed decisions on the quality standards,^{3,8,18–22} with consideration of feasibility based on what is assessed in ICRR's program survey and variable list.¹¹ Proposed standards were then discussed by the Program Certification steering committee, for approval to pilot test.

ICCPR's program certification is based on meeting 3 mandatory (ie, comprehensive program that offers at least initial assessment and structured exercise, cardiac emergencies policy in place and minimum peak MET increase from pre to post-program) and \geq 70% overall of 13 quality indicators (eg, team comprised 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 (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 \geq 60 consecutive patients, and that the site is in good standing with ICRR data entry (ie, no completeness or other data quality issues).

	Quality Standard		Site I		Site 2		Site 3		Site 4		Site 5	
	(Туре [†])		Value	Met Standard?	Value	Met Standard?	Value	Met Standard?	Value	Met Standard?	Value	Met Standard?
1*	Comprehensive program (≥3/10 components [⇔]) (S)	Program survey Q26; corroborate d in site visit	8	Y	8	Y	8	Y	8	Y	8	Y
2	Multidisciplinary team (≥2/14 types [∞]) (S)	Program survey Q21; corroborate d in site visit	8	Y	10	Y	7	Y	8	Y	6	Y
3*	Cardiac emergencies policy (S)	Program survey Q23; corroborate d in site visit	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
4	Assessment of risk factors: tobacco (P)	Responses in ICRR V22; corroborate d 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; corroborate d by Program survey Q25 and site visit	149 (100%) patien ts	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
7*	Peak MET increase ≥.5 [§] (O)	Responses in ICRR VII; corroborate d in site visit	3.7 ± 1.9	Y	0.9 ± 1.2	Y	1.8 ± 1.1	Y	0.8 ± 0.9	Y	0.3 ± 0.3	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; corroborate d in site visit	2 (100%)	Y	123 (100%)	Y	92 (100%)	Y	88 (100%)	Y	57 (91.9%)	Y

Table I ICCPR Program Certification Quality Standards, and Pilot Program Assessment Results, N=5

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(Continued)

Table I (Continued).

	Quality Standard ^I (Type [†])	Source(s)**	Site I		Site 2		Site 3		Site 4		Site 5	
			Value	Met Standard?	Value	Met Standard?	Value	Met Standard?	Value	Met Standard?	Value	Met Standard?
11	Knowledge – lipids [§] (O)	Responses in ICRR V25; corroborate d 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; corroborate d 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; corroborate d 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

Notes: ¹operationalization of each standard, including any exclusion criteria for each (eg, coverage for medication), are shown at: https://globalcardiacrehab.com/Program-Certification under "CR Quality Standards" sub-section. *Mandatory standard. [‡]Scored out of 10 at the pre-CR and post-CR assessments. [§]In program completers only. [□]Initial assessment, exercise training, patient education, nutrition counselling, tobacco cessation, stress management, medication prescription / titration, vocational counselling, psychosocial counselling, post-program re-assessment. [®]Physician (cardiology, physiatry, internal medicine, psychiatry, other), nurse / nurse-practitioner, exercise specialist, physiotherapist, psychologist, social worker, dietitian, pharmacist, occupational therapist, community health worker, administrative assistant. Note that these disciplines are not necessarily working full-time with the CR program. **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-and-Data-Dictionary(22. Values presented as n (%; patients for standards 5–13) or mean ± standard deviation.

Abbreviations: [†]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.

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,¹¹ and patient data, and analyses the quality standards using developed SPSS syntax, entering results into the developed Applicant Assessment Form (<u>Supplementary item 1</u>). Then, based on whether there are further needed materials, and whether or not 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 (Supplementary item 2). ICRR sub-committee and ICCPR Program Certification committee members are eligible to serve, and must sign a conflict of interest and confidentiality form (Supplementary Item 3; 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.¹⁰

ICCPR Program Certification Process

As shown in Figure 1, 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 which are assessed in the program survey and

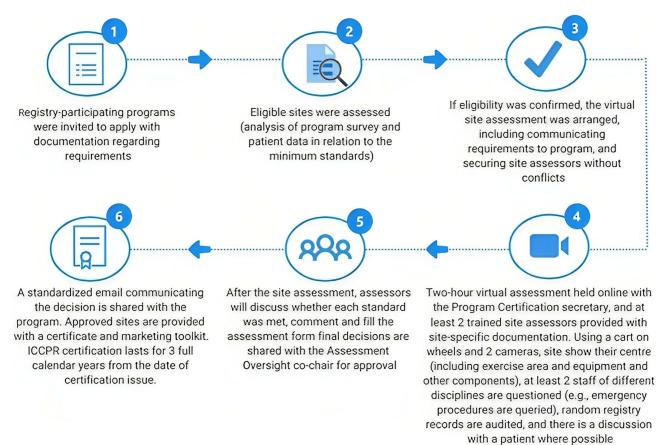


Figure I ICCPR Program Certification process.

Note: Reproduced from International Council of Cardiovascular Prevention and Rehabilitation (ICCPR). Copyright 2010. Available from https://globalcardiacrehab.com/ <u>Program-Certification</u>. Accessed October 31, 2023.²³

Abbreviation: ICCPR, International Council of Cardiovascular Prevention and Rehabilitation.

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 (Supplementary item 4), 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 (Supplementary item 5), 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, and decisions are shared with the Assessment Oversight co-chair for approval. Then, a standardized email communicating the decision is shared with the program (Supplementary item 6).

Where the decision is to certify, the program is provided a certificate (<u>Supplementary item 7</u>) 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.

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 last author (ICCPR Program Certification co-chair), and the first author (ICRR co-chair) and UE took notes and recorded non-verbal communication. 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 autotranscription 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.

Programs and Participants

Interested CR programs with ethics approval to participate in the registry and who met 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: <u>https://globalcardiacrehab.com/Program-Certification</u>). 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.

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 (<u>Supplementary item 8</u>). It assessed their perceptions of the application process, including communications, the virtual site visit and suggestions for improvement.

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 by UE. A deductive-thematic approach was used for analysis of the transcripts by the senior author and UE using NVIVO 1.5.1,²⁴ as outlined by Crabtree and Miller.^{25–27} Disagreements were reconciled with the first author. To ensure credibility, themes with sub-themes were then shared with all focus group participants to inquire whether they resonated, and requesting any input (ie, member checking).²⁸ 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).

Results

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

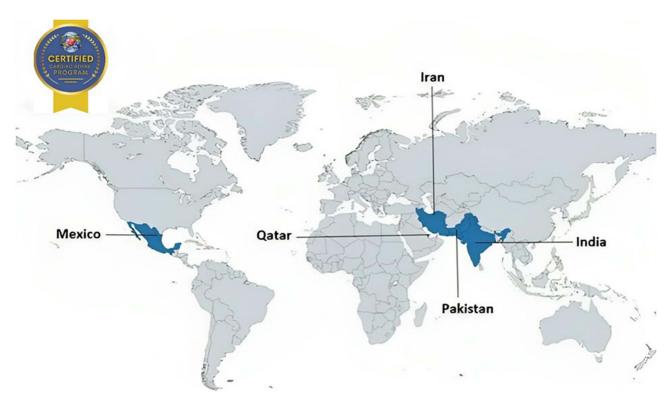


Figure 2 Map depicting cardiac rehabilitation programs which participated in pilot testing of ICCPR's Program Certification. Note: All sites were ultimately certified. **Abbreviation**: ICCPR. International Council of Cardiovascular Prevention and Rehabilitation.

	n (%) or Mean ± SD
Type of Institution*	
Referral / tertiary / academic site	4 (80%)
Private hospital	2 (40%)
Outside of a hospital	I (20%)
Funding for Program*	
Patient	4 (80%)
Government	I (20%)
Other	I (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	I (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

 Table 2 Characteristics of ICRR-Participating Pilot Cardiac Rehabilitation

 (CR) Programs, N=5

Notes: *More than one response could apply to each site. [†]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. [‡]See list of components in footnote of Table I (eg, vocational counselling).

Abbreviations: SD, standard deviation; ICRR, International Cardiac Rehabilitation Registry.

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 webcamera. At another point, it was difficult to view ICRR patient charts.

Results for quality standard assessment of each site are 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 (eg, heart failure, comorbidity).

Qualitative Perspectives on ICCPR's Program Certification

Characteristics of the 13 focus group participants are shown in Table 3. Most attended the 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 and corresponding illustrative quotes are shown in Table 4.

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 (ie, CR Foundations Certification; <u>https://globalcardiacrehab.com/Certification</u>), thus signalling the calibre of team members. 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. The

Participant Identification Number	Sex	Profession / Role
1	F	RN
2	F	Administrative secretary of CR program
3	F	РТ
4	F	РТ
5	F	Occupational therapist
6	М	MD/ Director of CR center
7	М	MD, Sports medicine specialist/ Head of CR center
8	М	Occupational therapy supervisor
9	F	Senior rehabilitation specialist
10	F	Assistant manager of CR program
П	F	Dietitian
12	F	Deputy general manager of CR program
13	F	Program Director

 Table 3 Focus Group Participant Characteristics

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

Table 4 Four Major Themes Regarding ICCPR's Program Certification, with Illustrative Quotes by Sub-Theme

Theme	Subtheme	Illustrative Quote (ID#)
Theme Motivation, benefits	Showcase quality at international calibre, pride	"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" – (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" – (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" – (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" – (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" – (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". – (8)
	Promotes program with patients, institutional leadership and policy-makers	"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" – (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". – (12) "We have placed the certificate in our offices as well our waiting area– in the prominent spaces of our institution" – (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" – (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; they were so happy about it. We printed it out. And we took a photo with the rest of the department; they were so happy about it. We printed it our social media. We even published it on our website" – (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". – (13) "We are planning to put the certification logo in our welcome letter for the patient upon joining" – (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" – (6)

(Continued)

Table 4 (Continued).

Theme	Subtheme	Illustrative Quote (ID#)					
	Lead to provision of program resources	"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" – (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". – (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" – (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" – (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" – (6)					
Logistics	Communication with ICCPR was clear, responsive, timely, and helpful to get through the process	"All the experience communicating about all the program certification- The online application- I support it. Everything. I think it's okay" - (6) "With the application process, I didn't find any difficulty. The [ICCPR] team was very much supportive" - (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" - (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" - (4) "We really received support and good comments also about our site" - (6)					
	Cost, including for re-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" – (6) "From our side, I think we will definitely we will [apply for re- certification in three years]" – (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" – (2) "Nothing of that sort [being judged]. In fact, the assessors were very neutral during the virtual assessment" – (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". – (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" – (2) "It was fair. They were very clear that it was meant to benchmark the practices, and imbibe certain best practices" – (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" – (2)					

(Continued)

Table 4 (Continued).

Theme	Subtheme	Illustrative Quote (ID#)					
Standards and their assessment	Discussion of finding the right balance between ensuring process is feasible for low-resource sites to participate, but also need to have rigor to ensure quality	"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 be ensure everything is fulfilled" – (6) "The people are paying from their own pocket, so our dropout rate is increasing day-by-day" – (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". – (2) "It was a quite in-depth audit. I was quite impressed that each and every component and aspect was investigated thoroughly" – (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" – (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" – (6) "Trying to make it more feasible for every [program] here because there are a lot of benefits" – (6)					
	Degree of difficulty of standards	"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" $-$ (12) "We think the peak METs increase of 0.5 from pre to post program is too low and should be changed" $-$ (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" $-$ (6)					
Areas for improvement	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" – (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" – (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" – (3)					
	Other	"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" – (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" – (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" - (12)					

Abbreviations: ICCPR, International Council of Cardiovascular Prevention and Rehabilitation; METs, metabolic equivalents of task; JCI, Joint Commission International.

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

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

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. 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.

The final theme pertained to potential areas for improvement, with the first sub-theme relating to the website organization. The second and final sub-theme grouped "other" suggestions, including being mailed a hard copy of the certificate, and ensuring multiple forms of payment (eg, Paypal is not available in Pakistan).

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 (eg, human resources). Finally, some areas for improvement were identified.

There have been several other studies on CR program quality assessment,^{19,29,30} and a few from the United Kingdom on CR program certification specifically,^{14,15} 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 show 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 \notin 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 ICCPRs. 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 1). 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.cal.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 <u>Supplementary items 4</u> and <u>6</u>). 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,³¹ 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.

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 that 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.

Abbreviations

CVD, Cardiovascular disease; LMICs, Low and middle-income countries; DALY, Disability adjusted life years; CR, Cardiac rehabilitation; ICCPR, International Council of Cardiovascular Prevention and Rehabilitation; ICRR, International Cardiac Rehabilitation Registry; BACPR, British Association for Cardiovascular Prevention and Rehabilitation; AACVPR, American Association of Cardiovascular and Pulmonary Rehabilitation; EAPC, European Association of Preventive Cardiology; METs; Metabolic equivalents of task; JCI, Joint Commission International.

Data Sharing Statement

The datasets generated and/or analysed during the current study are not publicly available. For the qualitative part, due to the small number of interviewees, participant identity could be identified. For the quantitative component, agreement to share data by participating sites in the ICRR was not obtained. Data are available from the corresponding author on reasonable request.

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Disclosure

AC serves on the Program Certification Steering Committee and also put his program forward for certification consideration. To mitigate any conflict, assessment of his site's data and the virtual site assessment were handled by other members of the committee without communication with AC until the decision had been reached. Two other authors were involved in this paper and their site was assessed, however they did not play a role in assessing their own site or have access to their certification data. Otherwise, the authors declare that they have no conflicts of interest.

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