First report of the International Council of Cardiovascular Prevention and Rehabilitation's Registry (ICRR)

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Abstract

Objectives: Cardiac rehabilitation-- programs comprehensively delivering outpatient secondary prevention-- is under-available and under-studied in the resource-poor settings where it is needed most. This report summarizes the governance, participating sites, patient characteristics and outcomes, as well as knowledge translation activities during first year of operation of ICCPR's registry, namely the International Cardiac Rehab Registry.

Methods: A pilot study was undertaken with five centres, demonstrating feasibility, satisfaction with the on-boarding processes, as well as data quality.

Results: Fourteen centres have been engaged from all regions but Europe; Data have been entered on >1000 patients (18.1% female; mean age=57.6), of whom 62.4% completed their programs and 19.9% dropped out for work or clinical reasons. Post-program, completers had significantly better work status, functional capacity, medication adherence, physical activity levels, diet, as well as lower tobacco use than non-completers (all $p<0.05$). A site Certification program was developed and piloted, with five centres now recognized for their quality, given they met over 70% of the 13 internationally-agreed standards based on Registry data and a virtual site assessment.

Conclusion: Annual assessments have started. Quality improvement activities will soon be underway. We continue to invite new programs, supporting development in resource-poor settings to the benefit of patients served.

Protocol registration: www.clinicaltrials.gov identifier is https://clinicaltrials.gov/ct2/show/NCT04676100

Keywords: Cardiovascular diseases, cardiac rehabilitation, Registries, Secondary prevention, developing countries, Certification, quality of health care, outcome and process assessment, health care

1.0 INTRODUCTION

Due to economic development and corresponding demographic transitions, cardiovascular disease (CVD) incidence is currently greatest, or projected to increase at the greatest rate, in low and middle-income countries (LMICs)[1] . It is the leading cause of mortality globally[2], although where acute care can be accessed, there are many people living chronically with CVD, for whom secondary prevention can greatly improve quality and quantity of life[3].

Cardiac rehabilitation (CR) is a standardized outpatient model of secondary prevention, proven clinically- and cost-effective[4]. Unfortunately however, it is least available in LMICs, where need is greatest[5,6]. Indeed, over 14 million more CR “spots” are needed per year to treat indicated incident patients. Therefore, as per their mission the International Council of Cardiovascular Prevention and Rehabilitation (ICCPR) – an umbrella organization of the World Heart Federation bringing together CR-related Societies globally – works towards addressing this gap[7]. Towards this aim, they have developed an International Cardiac Rehab Registry (ICRR;[8]), which launched in the Fall of 2021[9].

The rigorous process of developing the ICRR is reviewed elsewhere[9], but in brief involved liaising with other CR registries[10,11], forming committees, an inclusive Delphi process to select and define variables, usability testing[12], and a pilot study with five centres[13]. In our first year, 14 centres have joined, entering data on approximately 1,000 patients. Thus, it is timely to provide an update on the implementation of the ICRR post-launch, including a description of participating centres, patients entered, and the development of Program Certification.

2.0 GOVERNANCE

The international representation of ICRR committee members and diversity of disciplines represented are shown in Figure 1. The Executive committee, and the Steering Committee to which it is accountable, met regularly as per its' Terms, for oversight, as well as financial and ethical (XXX University Office of Research Ethics #e2020-359) stewardship[9]. There was liaison with other CR registries, such as meetings with the Danish and Swedish CR registries, and joint symposia at conferences as well[14,15]. We have engaged seven graduate students to serve with the ICRR to develop their skills as well as capacity around CR tailored to resource-poor settings to date.

The user sub-committee was closely involved in the pilot study, which assessed the implementation of the ICRR with regard to patient eligibility appropriateness, completeness / generalizability of patient volumes entered, time to enter data, variable completeness, patient retention at follow-up and data accuracy, as well as site experience joining and participating in the registry, and patient's experience alike[13]. Learnings were used to improve the on-boarding process, and indeed now 14 centres were on-boarded, involving one-on-one 1.5-hour training regarding pre-program data entry, and a subsequent training session on follow-up data entry as well as using registry features. Training videos were also shared and are available for all future sites on-demand regarding using the features of the ICRR to support quality, as well as annual data entry that is now beginning and in future the process to end ICRR participation when a participating program so chooses[16]. ICRR materials were translated to 8 other languages, although the electronic materials remain only in English at this time. A standard operating procedure for site off-boarding was finalized. Only one patient request for access to data has been received to date.

The research sub-committee, which was also involved with the pilot study, actively monitored data quality and completeness as programs contributed data. Standardized emails were sent to participating programs where some initial data issues were identified, with a request for rectification and response within three weeks, which has been well-received. In line with ICRR's data quality policy, procedures to enact the more formal data quality audit process were finalized[17].

3.0 PARTICIPATING CENTRES

At the time of launch, an ICCPR webinar was held to introduce the opportunity to interested programs. As outlined above, 14 centres to date have secured approvals to join ICRR, from the American, African, Eastern Mediterranean, South-East Asian, and Western Pacific regions (all but Europe; Figure 2). One centre has requested and been granted an ethical waiver to participate to date (was not applicable to pilot sites), as is the norm for other CR registries and is appropriate given the registry is anonymous, but other requests are currently under consideration. Indeed, approximately 10 other centres have applied to join the ICRR and are working to secure the necessary institutional approvals.

Characteristics of the participating centres are shown in Table 1, and clearly show ICRR is attracting the intended types of programs they seek to support. Based on annual volumes, the pilot study revealed centres are entering approximately 90% of patients in to the ICRR, with almost all patients approached agreeing to participate[13]. Variable completeness was good, but retention for follow-up assessments varied based on patient program completion status, with less than 50% of non-completing patients having any follow-up data entered. Sites reported being satisfied with the time required to enter data, and found the data entry process to be user-friendly, particularly given the training provided.

4.0 COHORT CHARACTERISTICS, CR OUTCOMES AND PROGRAM CERTIFICATION

Characteristics of entered participants as of October 2022 are shown in Table 2, which again are concordant with target population.

Overall, 848 of the 954 participants had some follow-up data. Two-thirds (n=529; 62.4%) completed their program. Only 54.2% (n=169) of non-completers were truly drop-outs, as many patients had to return to work (n=57, 18.3%), or had a new cardiovascular (n=9, 2.9%) or non-cardiac (n=40, 12.8%) issue that precluded participation. One participant died. Program completers participated in a mean of 14.8±9.4 sessions, while non-completers participated in 7.1±6.1.

All available outcome variables are shown by program completion status in Table 3. As shown, there were significant improvements in work status, functional capacity, quality of life, physical activity, diet, as well as reductions in tobacco use, body mass index, blood pressure, and depressive symptoms from pre to post-program among completers, with a trend for lower lipids (likely limited by power). Post-program, completers had significantly better work status, functional capacity, medication adherence, physical activity levels, fruit and vegetable intake, as well as lower tobacco use than non-completers, with a trend towards lower depressive symptoms. Post-program knowledge is shown in Figure 3. This supports the benefits of CR as delivered in LMICs, in line with randomized trial data[18].

Also upon request from ICCPR Council, a corresponding Certification program was developed [19-20]. The steering committee for this initiative was constituted during the initial year of ICRR operation (Figure 1). Certification requires demonstration of staff training[21], and meeting ≥70% of 13 quality standards, agreed based on performance measures established by CR Societies[22] and informed by the Delphi process for variable selection[9]. A pilot study of the certification program was also undertaken; five centres went through the application process, with subsequent analysis of their ICRR data (program survey for structural indicators and registry data for outcome indicators; process indicators also assessed through both), followed by a two-hour virtual site assessment, with two trained and impartial site assessors. Assessor training, conflict declaration and site assessment procedures are described elsewhere[20]. To date, five pilot centres earned certification, and this has led to institutional and governmental greater resource provisioning as well as satellite site development at some centres[20].

5.0 KNOWLEDGE TRANSLATION

To summarize, as outlined herein, since inception peer-reviewed ICRR articles have been published regarding development[9], usability testing[12], a pilot study[13], and soon regarding the Program Certification[20]. The registry has also been presented at major CR meetings globally, among other venues, with 6 conference citations to date[14-15,23-27]. ICRR has yet to receive data access requests, but the research sub-committee remains poised to receive them. They will consider them in line with our established policies and procedures, thus growing the research and advocacy impact of the ICRR as intended[9].

ICRR also has a quality improvement mandate in addition to the Certification[28], whereby twice per year we will focus on areas where quality is low based on ICRR data[29]. Participating programs with success in these areas will be asked to share resources supporting their best practices and will be invited to a webinar, with other speakers regarding related quality improvement evidence. Following the webinar, interested ICRR-participating programs will be invited to meet monthly as a learning community to implement and monitor changes in their setting. Our first efforts will focus on engaging women in CR.

Finally, we support ongoing communication amongst our Sites to promote engagement, regarding any training needs as outlined above, as well as with updates on the overall progress of the registry and the successes it facilitates. As an example, a more “lay” version of this report was prepared for our participating CR sites (see online Appendix).

6.0 THE FUTURE OF THE ICRR

We continue to engage more centres to join the ICRR, given the many benefits of participating, including benchmarking, automatic generation of a lay progress summary for each patient, real-time access to site data, program recognition and potential certification, as well as opportunities for research involvement. There is information on our website about joining for interested programs, along with an orientation video[16]. Given centres that elect to participate may be dedicated to care quality and hence provide higher-quality care, the user sub-committee shall approach more diverse centres to invite them to join.

As outlined above, ICRR has marked its one-year anniversary, and hence annual patient follow-ups for our initially-participating programs have begun. Participating program data stewards have been provided training to initiate the first annual data collection for other participants. Electronic surveys support patient report of all but vital status (where patients have agreed and are proficient in the English-language). Programs are asked to continue annual follow-ups until patients pass away, are too ill to complete assessments, or of course express unwillingness to continue where possible.

7.0 CONCLUSIONS

This report has established that, despite the ongoing SARS-CoV-2 pandemic, in its’ first year, ICCPR’s new registry has successfully engaged 14 centres who entered approximately 1000 patients. The characteristics of participating programs and patients are in line with those we endeavour to serve, and patient outcomes are shown to be improved with CR participation. ICRR continues to welcome new programs, and will support them in entering data of the highest quality as well as retaining patients for follow-up data collection. We aim to provide a future report, where we hope we will be summarizing ICRR successes in achieving our goals supporting program development in resource-poor settings to the benefit of patients served.

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**There are few training or certification opportunities for cardiac rehabilitation professionals from learned institutions, and until this paper on ICCPR's, none had been formally evaluated.

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Table 1: Characteristics of ICRR-Participating Cardiac Rehabilitation (CR) Programs in 2022, N=14

	n (%) or mean ± SD
Type of Institution*	
Referral / tertiary / academic centre	9 (81.8%)
Private hospital	3 (27.3%)
Outside of a hospital	2 (18.2%)
Funding for Program*	
Patient	8 (72.7%)
Government	4 (36.4%)
Other	2 (18.2%)
Disciplines on CR Team*	
Physiotherapist	10 (90.9%)
Nurse	9 (81.8%)
Administrative assistant	9 (81.9%)
Any physician	4 (36.4%)
Any other type of exercise specialist	4 (36.4%)
Other	2 (18.2%)
Core Components Offered*†	
Patient education	14 (100%)
Prescription / titration of cardiac medications	14 (100%)
Resistance training	14 (100%)
Nutrition counselling	13 (90.9%)
Tobacco cessation sessions/ intervention	13 (90.9%)
Stress management / relaxation	13 (90.9%)
Program duration (weeks)	8.11 ± 3.1
Remote delivery available	9 (81.8%)
New patients served per month	11.11 ± 8.1

SD, standard deviation; ICRR, International Cardiac Rehabilitation Registry
*more than one response could apply to each centre
†Note: participating centres 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 2: Pre-program characteristics of participants entered in the International Cardiac Rehabilitation Registry, N=954

	n (%) or mean ± SD
Sociodemographic	
Sex (n, % female)	210 (18.1)
Age (years)	57.6 ± 11.6
Education (years)	13.5 ± 5.6
Work Status	
Full or part-time for pay (includes self-employment)	308 (32.3)
Disability (sick leave) or modified duties at work	217 (22.7)
Retired	199 (20.9)
Not employed	141 (14.8)
Other	49 (5.1)
Worry about having enough money to meet basic needs, including health and care	
Not at all	422 (44.2)
Sometimes	368 (38.6)
Often	129 (13.5)
Pay for heart pills or medicines out-of-pocket (n, % yes)	747 (78.3)
Clinical	
Referral Diagnoses*	
Acute coronary syndrome	432 (51.6)
Stable coronary artery disease or stable angina	262 (27.5)
Heart failure	59 (6.2)
Other cardiac	74 (7.8)
Referral Interventions*	
Percutaneous coronary intervention	460 (48.2)
Coronary artery bypass surgery	289 (30.3)
Valve surgery or intervention	39 (4.1)
Rhythm device	16 (1.7)
Ablation	2 (0.2)
Other	37 (3.9)
None	56 (5.9)
Risk Factors	
LDL (mmol/L)	4.3 ± 2.4
BMI (kg/m^2)	27.8 ± 4.8
SBP (mmHg)	122.1 ± 15.6
DBP (mmHg)	73.5 ± 9.8
Comorbidities*	
Diabetes	125 (20.9)
Musculoskeletal issues	18 (3.0)
Lung disease	4 (0.4)
Cancer	4 (0.4)

Peripheral vascular disease / claudication	4 (0.4)
Stroke / transient ischemic attack	3 (0.3)
Cognitive issues	1 (0.1)
Heart-Health Behaviors	
Peak METs	4.8 (3.1)
Physical activity (minutes / week at least moderate intensity)	114.5 (109.1)
Fruit and vegetable intake (servings / day)	3.2 (1.7)
Tobacco Use	
Never	526 (55.1)
Current	141 (14.8)
Former	247 (25.9)
Medication adherence (/5)	1.7 ± 1.0
Psychosocial	
Quality of Life (/10)	5.8 ± 1.3
Social Support (/5)	1.8 ± 0.9
Depressive symptoms (PHQ-2)	1.4 ± 1.5
Positive screen (≥3)	117 (10.6)

CRT: Cardiac resynchronization therapy; ICD: Implantable cardioverter-defibrillator; LDL: Low-density lipoprotein; BMI: Body mass index; SBP: Systolic blood pressure; DBP: Diastolic blood pressure; METS: Metabolic equivalent of task; PHQ-2: Patient Health Questionnaire-2
Note: higher scores are better for medication adherence and quality of life, whereas lower scores are better for depressive symptoms and social support.
*select all that apply.

Table 3: Retained Patient’s Outcomes, N=848‖

	Pre-Program		Post-Program		*P for change in completers from pre to post*	*P for difference by completion status at post*
Outcome	*Program Completers*	*Non-Completers*	*Program Completers*	*Non-Completers*		
Work Status					<0.001	<0.001
Full or part-time	238 (47.5%)	22 (13.2%)	243 (47.2%)	56 (18.2%)		
Disability or modified duties	83 (16.6%)	63 (37.7%)	88 (17.1%)	102 (33.2%)		
Retired	98 (19.6%)	32 (19.2%)	102 (19.9%)	67 (21.8%)		
Not employed	55 (11.0%)	38 (22.8%)	55 (10.7%)	61 (19.9%)		
Other	27 (5.4%)	12 (7.2%)	27 (5.2%)	21 (6.8%)		
Risk Factors						
LDL (mmol/L)	4.5±1.9	4.4±1.7	4.3±2.0	4.7±3.0	0.07	*
BMI (kg/m^2)	27.4±4.7	27.1±3.9	27.1±4.6	26.3±4.4	<0.001	0.25
SBP (mmHg)	121.5±16.3	120.7±12.9	119.7±16.6	120.9±13.4	<0.01	0.45
DBP (mmHg)	73.4±10.4	71.1±8.7	70.8±9.2	70.5±7.9	<0.001	0.73
Heart-Health Behaviors						
Peak METs	5.9±3.2	2.6±2.4	7.2±3.8	5.1±0.7	<0.001	<0.001
Physical activity (minutes / week at least moderate intensity)	120.0±113.7	100.8±95.3	245.3±139.2	193.7±98.8	<0.001	<0.001
Fruit and vegetable intake (servings / day)	3.8±1.7	3.2±1.3	4.8±1.4	4.3±1.2	<0.001	<0.001
Tobacco Use					<0.001	0.001
Never	293 (56.0%)	93 (53.8%)	293 (60.4%)	93 (56.1%)		
Current	50 (9.6%)	42 (24.3%)	40 (7.6%)	30 (17.3%)		
Former	166 (31.7%)	35 (20.2%)	167 (31.9%)	46 (26.6%)		
Medication adherence‡ (/5)	1.3±0.9	2.5±1.2	1.3±0.6	1.1±0.4	0.14	<0.01
Psychosocial						

Quality of Life (/10)	5.7±1.4	5.8±1.1	7.5±1.3	7.4±1.1	<0.001	0.24
Depressive symptoms (PHQ-2; /6)	1.3±1.4	1.5±1.7	1.3±1.4	1.5±1.7	<0.001	0.06

Note: n (%) or mean ± standard deviation shown

LDL: Low-density lipoprotein; BMI: Body mass index; SBP: Systolic blood pressure; DBP: Diastolic blood pressure; METS: Metabolic equivalent of task; PHQ-2: Patient Health Questionnaire-2

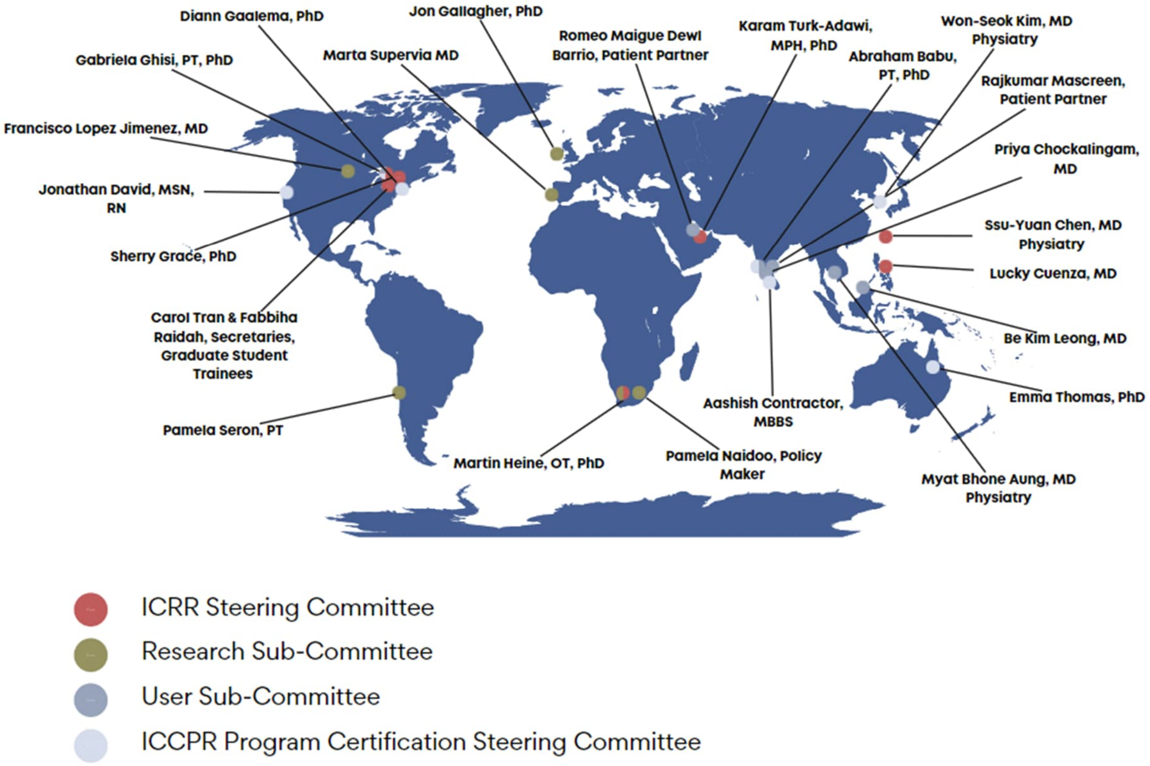
Note: higher scores are better for medication adherence and quality of life, whereas lower scores are better for depressive symptoms.

*cell sizes too small for inferential testing.

‖varies by outcome due to missing data.

‡in those who have medication coverage only.

Figure 1: ICRR Committee Members



ICRR, International Cardiac Rehabilitation Registry; ICCPR, International Council of Cardiovascular Prevention and Rehabilitation

Figure 2: ICRR Participating Sites, with Certification Status, N=14

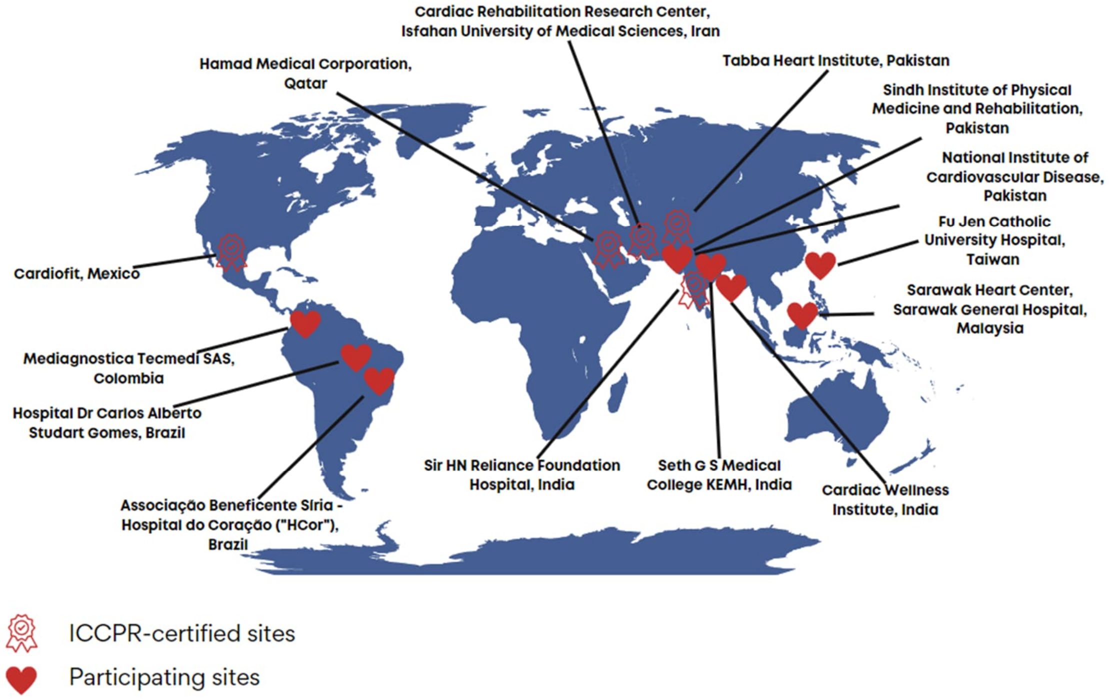


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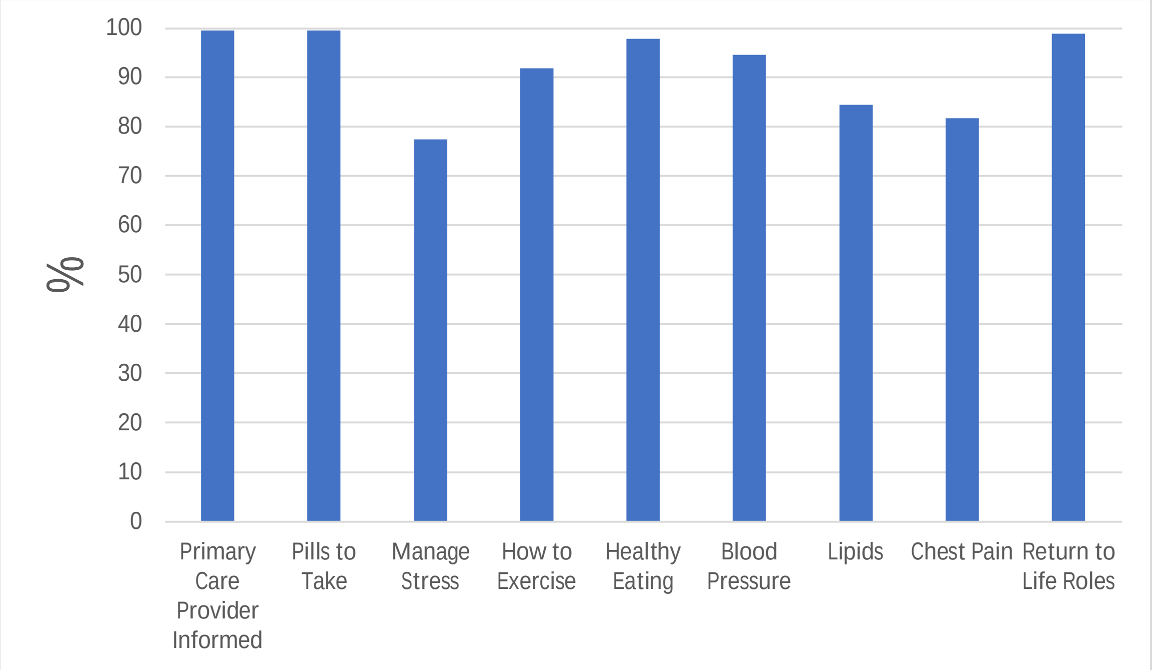
Figure 3: Knowledge Post-Program, in Program Completers



Variable 25 from data dictionary, available at: https://globalcardiacrehab.com/ICRR-Variables-&-Data-Dictionary