Costs of Cardiac Care: Patient Burden and Rehabilitation Delivery

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A Dissertation Submitted to the Faculty of Graduate Studies in Partial Fulfillment of the Requirements for the Degree of

Doctor of Philosophy

GRADUATE PROGRAM IN KINESIOLOGY AND HEALTH SCIENCE
YORK UNIVERSITY
TORONTO, ONTARIO

July 2019

ABSTRACT

Background: Cardiac rehabilitation (CR) reach is minimal globally, primarily due to financial factors. This study characterized CR funding sources, cost to patients to participate, cost to programs to serve patients, and the drivers of these costs.

Methods: In this cross-sectional study, an online survey was administered to CR programs globally. Cardiac associations and local champions facilitated program identification. Costs in each country were reported using purchasing power parity (PPP). Results were compared by World Bank country income classification using generalized linear mixed models.

Results: 111/203 (54.68%) countries in the world offer CR, of which data were collected in 93 (83.78% country response rate; N=1082 surveys, 32.0% program response rate). CR was most-often publicly funded (more in high-income countries [HICs]; p<.001), but in 60.20% of countries patients paid some or all of the cost. Funding source impacted capacity (p=.004), number of patients per exercise session (p<.001), personnel (p=.037), and functional capacity testing (p=.039). The median cost to serve 1 patient was $945.91PPP globally. In low and middle-income countries (LMICs), exercise equipment and stress testing were perceived as the most expensive delivery elements, with front-line personnel costs perceived as costlier in HICs (p=.003). Modifiable factors associated with higher costs included CR team composition (p=.001), stress testing (p=.002) and telemetry monitoring in HICs (p=.01), and not offering alternative models in LMICs (p=.02).

Conclusions: Too many patients are paying out-of-pocket for CR, and more public funding is needed. Lower-cost delivery approaches are imperative, and include walk tests, task-shifting, and intensity monitoring via perceived exertion.

ACKNOWLEDGEMENTS

I would like to thank my supervisor Dr. Sherry Grace, for her continuous support, guidance and encouragement throughout my PhD. I will always be grateful to have had the opportunity to train under your supervision.

I would also like to thank my wonderful lab mates for their support and friendships.

Finally, thanks to my family for all the love, support and patience during the past few years. I would not be where I am today without you.

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INTRODUCTION

Cardiovascular disease (CVD) is among the leading burdens of disease and disability globally.[1] Due to advances in acute treatment, there are many patients living chronically with CVD. They are at risk for recurrent events and require long-term follow-up and management. This includes regular visits with specialists, testing of their cardiovascular risk factors and function, taking on average 3-4 classes of medications, and participating in cardiac rehabilitation (CR).

The costs of CVD to the healthcare system have previously been characterized,[2–4] and are substantial. CVD is the costliest of any health condition. However, there has been little consideration of the costs (not only out-of-pocket [OOP] costs, but also time-related costs) to patients to attend visits for tests and treatments, as well as for medications.[5] These have been characterized in cancer patients, who also require ongoing monitoring and management. [6] In a publicly-funded healthcare system or one with a good system of private healthcare insurance, costs to patients would certainly be lower than in systems without such coverage. In Canada for example, healthcare services are generally covered, but there is limited coverage of medications for those <65 years old. These patients must pay OOP, if they do not have a benefit plan through an employer or purchased privately.

Moreover, patients may miss paid work due to disability or need to pay OOP for household assistance. They may need to go on long-term disability or retire. This also has important financial ramifications for patients.

CR is a chronic disease management program that successfully prolongs quality and quantity of life,[7] and hence clinical practice guidelines recommend CVD patients participate.[8,9] Most patients attend supervised programs located in academic hospitals;[10] on average patients

attend 2-3 times per week for 5 months.[11] There is wide variation around the world however in terms of whether these services are reimbursed (by government or private insurers), or whether patients must pay OOP. Moreover, efforts to promote sustained exercise in CR grads are necessary, but little is known about the costs to deliver these services. Indeed, the costs to programs and to patients to participate in CR and transition to self-management have been scantly characterized[12–14].

Through this dissertation, patient costs for cardiac care will be characterized, including consideration of loss of productivity, and participation in CR. The costs to deliver CR (including post-program maintenance interventions), how it is reimbursed, and the degree to which financial resources are barriers to delivery will be characterized around the globe.

REVIEW OF LITERATURE

CVD is a class of diseases that involve the heart or blood vessels. It is recognized as the leading cause of death worldwide[15] and among the leading causes of death and disability in Canada[16]. In 2013, 32% of global deaths were attributable to CVD[15]. In Canada, CVD makes up 25% of the national burden of disease[17]. One in every 20 Canadians reports being diagnosed with a CVD, but the actual number with undetected heart disease is much higher[18].

In addition to health impacts, CVD also poses a major economic burden on patients, their families and society. This is due to productivity loss and costs of care[19]. Evidence suggests that CVD pushes approximately 10% of affected families into poverty in low and middle-income countries where there is limited public healthcare[20]. Furthermore, due to disability caused by CVD, individuals may require assistance with activities of daily living, which are costly, as well as financial support if they cannot work[19].

In Canada, CVD is the largest health-related economic cost, with major direct (i.e. hospital care, drugs, physician care, other institutional care) and indirect (i.e. mortality, and short and long-term disability) costs. This cost has increased over recent years and now amounts to CAD$22 billion per year, with 3 of the top 4 most expensive health conditions in Canada being CVDs.[18,21] On a global level, it is predicted that by 2030, the total cost of CVD will rise to a staggering US$1,044 billion (from US $863 billion in 2010)[22].

Secondary Prevention of Cardiovascular Disease

While CVD mortality has been declining in Canada due to advances in acute treatment, there are many Canadians living chronically with CVDs. These patients are at high risk of recurrent events. As a result, secondary prevention is crucial. This includes follow-up with cardiac specialists, regular testing to monitor disease status, and on-going treatment. Diagnostic tests include X-rays, electrocardiograms, blood and urine tests, CT scans, echocardiograms and stress tests. Treatment consists of approximately 5 medications and may include repeat revascularization, among other therapies.

The time and OOP costs for cardiac patients to attend these visits, have these tests and undergo recommended treatments are not well characterized, particularly in high-income countries (HICs) such as Canada and those with public healthcare. While one would assume costs under public healthcare would not be prohibitive, this should be understood, particularly because there are socioeconomic disparities. In India, OOP expenditures for CVD treatment have been shown to have a major economic burden on patient households[23,24].

A study in Ontario cancer patients suggests that time and OOP costs for survivor care can represent a substantial burden, particularly for lower-income patients[6] where total costs represent 10% of income for these patients. Some patients had higher costs than others, namely those with

radical prostatectomy, younger age, poor urinary function, current androgen deprivation therapy and recent cancer diagnosis, however, only urinary function significantly affected total cost.

Cardiac Rehabilitation

CR is a comprehensive chronic disease management program model designed to reduce risk in patients with established CVD. Due to its' established benefits[7], CR is recommended for outpatients with CVDs. [25–27] CR services are provided through an interdisciplinary approach to promote cardiovascular risk reduction, and heart-healthy behaviour. The core components of CR include: risk factor assessment, patient education, lifestyle risk factor management (physical activity and weight management, diet and smoking cessation), psychosocial health, and medical risk factor management.[28–30]

Unfortunately, CR is grossly under-used[31]. While there are factors at the patient-level[32], much of the reason for this relates to lack of financial resources, be it for personnel or space for example. Indeed, surveys of CR programs in Australia and New Zealand[33], China[34], Japan[35], Scotland[36], Spain[37], Latin America and the Carribbean[38], South America[39], Mexico[40] Arab Region and Canada[41] report financial issues as a primary barrier to broader delivery of services.

Cardiac Rehabilitation Cost

Little is known about the costs to deliver CR around the world. Recently, the International Council of Cardiovascular Prevention and Rehabilitation (ICCPR) surveyed countries around the globe regarding CR delivery costs as well as reimbursement sources and policies. When asked who reimburses CR in their country (respondents were asked to check all that apply), 61% reported the government, 55% reported patients pay OOP, and 52% reported

insurance companies[19]. These findings suggest that many patients pay OOP for CR services and thus a better understanding of these costs is needed, given the likely impacts on utilization rates.

Traditional CR consists primarily of supervised exercise sessions delivered in an outpatient setting, such as a hospital or clinic. Overall, delivering the traditional model of CR carries with it costs associated with personnel, equipment and other supplies, space and other operating costs[12,13,42]. Only a handful of studies have reported all costs to run a program per patient. For example, the study by Oldridge et al. in Canada reported direct costs for a 16-session supervised program were: space $290CAD (1987; Purchasing Power Parity PPP$506 in 2016 dollars), overall personnel $148 (PPP$258), equipment $64 (PPP$112), and resource literature $5 (PPP$9), for a total of $PPP884[13].The study by Whittaker et al. reported the costs of 6-week supervised program were overall $1845AUD (2013; PPP$1,312), comprised of facility $595 (PPP$423), administration $450 (PPP$320), coaching and mentoring $225 (PPP$160), assessment $195 (PPP$139), gymnasium $180 (PPP$128), communications $125 (PPP$89), technology $40 (PPP$28) and education $35 (PPP$25) costs[12]. Clearly, delivery costs will vary greatly based on the density of patients served per session, whether patients are monitored during exercise using telemetry or other less-expensive means, the type of equipment used, and personnel composition.

The cost to run alternative models of CR have also been described[12,43]. As reported by Whittaker et al. a 6-week telehealth-enabled home-based CR program costs $1633AUD (2013; PPP$1112)[12]. A systematic review by Taylor et al. found home-based CR to be equally effective as centre-based CR in improving clinical and health-related quality of life outcomes, while having similar costs[43]. Carlson et al. demonstrated that a modified CR program with reduced ECG monitoring is less costly (PPP$2060 vs. PPP$3187) and as effective in improving

physiological outcomes in patients[44]. A study by Kraal et al. showed home-based CR was PPP$3400 less expensive compared to hospital-based CR and had higher patient satisfaction[45].

Low-cost models of CR can include telehealth, home-based and community-based programs, and can have comparable or better efficacy to traditional programs. Telehealth has been shown to be less costly and produce similar clinical outcomes in patients compared to supervised CR[12,46,47]. Moreover, it improves access to care and CR completion rates. The Fit@home study showed a home-based model was more cost-effective compared to supervised CR, while producing similar results in physical fitness and health-related quality of life[45]. In addition, a community-based model of CR had similar effects on medication and risk factors compared to a supervised, hospital-based program, although costs were not examined[48]. Southard et al. showed a 6-month internet-facilitated home-based CR program was less costly compared to usual care in patients with CVD[49]. Moreover, a heart disease self-management program (similar to CR) in women with cardiac disease resulted in lower costs and reduced health care utilization compared to usual care[50].

The available literature on CR personnel costs specifically is displayed in Table 1. Given the multi-component nature of CR, and hence the multiple disciplines required to deliver it comprehensively, personnel costs are quite high. There is wide variation in the staffing complement of CR programs as well as staff-to-patient ratios during exercise for safety[41,51,52], and hence correspondingly overall costs to programs would vary. The value of the personnel with respect to achieving beneficial patient outcomes is not reflected, but strategies to mitigate these costs are considered below.

The available literature on the cost of delivering each of the core CR components is displayed in Table 2. For some medications and smoking cessation, data was available for cost of

secondary prevention but outside of CR settings. Very little is known about costs to promote maintenance of physical activity post-program.

The overall cost of delivering supervised CR was expressed on a per patient (for a complete program), or per session basis in the literature. Table 3 summarizes the available data on the cost to deliver traditional CR by country, sorted by country income classification. As can be shown, these costs are considerably less expensive than the cost of acute cardiac procedures[31]. In HICs, the cost to deliver a supervised CR session ranged from PPP$12 in Finland to PPP$310 in Italy.

Available data on CR delivery costs in low- and middle-income countries (LMICs) is also shown in Table 3. As shown, there is only information on delivery in MICs in South America. Interestingly, delivery costs are higher in private versus public healthcare, except in Paraguay. Unfortunately, whether these costs can be attributed to differences in CR care quality in these settings is not known, but the lower cost is likely due to higher volume (personal communication, Claudia Anchique Santos, December 18, 2016). The review by Oldridge et al. juxtaposed these overall CR costs in relation to healthcare expenditure per capita[53]. It was concluded that CR as delivered traditionally was not affordable in the LIC setting, but was in MICs.

Finally, one must consider costs to patients to attend CR. Patients attending supervised programs have to incur expenses related to transportation (including parking), as well as time costs. These have been characterized in a few studies[12,13,54], and can be considerable. These likely also vary widely by country / region given, the broad variation in CR session frequency and program duration[51,55]. Lost productivity to attend supervised sessions must also be

considered. Recent research has shown that delivery of unsupervised CR costs considerably less for patients[12]; equivalent benefits are achieved in these settings[46,47,56].

DISSERTATION OBJECTIVES

Study #1-CVD Outpatient Costs, Including CR.

The objectives of this study were to: (1) describe cardiac healthcare utilization (including CR) and associated patient time and out-of-pocket costs (OOP) over 2 years following a CVD diagnosis or event; (2) understand the drivers of time and OOP costs incurred by outpatients living with CVD, namely sociodemographic (e.g., age, sex, work status, educational level, marital status, ethnocultural background, area of residence), and clinical (e.g., smoking, disease severity, and functional capacity); and (3) describe patient's time and OOP costs related to CR participation.

Study #2 -Global Comparison of Costs to Deliver CR.

The objectives of this study were to characterize: (1) funding source, and (1b) the proportion of the program cost as well as (1c) direct cost, to patients where they pay for CR; and (2) the estimated cost to CR programs to provide service to 1 patient, (2b) which elements of the program were perceived as most expensive, and (2c) whether cost varies by funding source. The association of: (3i) a program's patient capacity per year, (ii) the number and nature of healthcare professionals on the CR team, (iii) the number of patients served per exercise session (including staff-to-patient ratio), (iv) the number and nature of core components the program delivers; (v) the dose of CR (i.e., sessions per week x duration in weeks x duration of exercise sessions in minutes); (vi) the equipment/resources the program has (e.g., exercise equipment, supplies for cardiovascular risk assessment) including whether patients are monitored during exercise using telemetry, and (vii) whether the program offers alternative CR models (i.e., home or community-

based) to both funding source and cost to treat 1 patient were explored to understand factors that impact CR delivery costs. Finally, (4) the degree to which financial and other resources serve as barriers to CR delivery were described. Each were compared by country income classification (i.e., high vs LMICs; http://data.worldbank.org/country), and described in all countries of the world where CR is offered.

Study #3- Costs to Promote Exercise Maintenance in CR Graduates

The objective of the last study was to determine the costs to promote exercise maintenance post-CR in a randomized controlled trial of CR graduates. In particular, the objective was to assess costs for implementing an exercise facilitator intervention for 52 weeks.

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STUDY 1

CERTIFICATE OF AUTHENTIFICATION

Re: Healthcare Utilization and Associated Time and Out-of-Pocket Expenditures for Cardiovascular Disease Patients in a Publicly-Funded Healthcare System

I hereby confirm that the author of this manuscript, Mahshid Moghei, was responsible for overseeing the development of this paper, including quantitative analysis and write-up. Co-authors Krahn and Chessex are co-investigators on the larger study who provided input on measures and minor editorial feedback just prior to submission. Co-author Ali was a master's student learning about academic manuscript preparation.

Signature: _____ Date: Mar 20, 2019

Signature: _____ Date: Mar 20, 2019

Healthcare Utilization and Associated Time and Out-of-Pocket Expenditures for Cardiovascular Disease Patients in a Publicly-Funded Healthcare System

Abstract

Background: The objectives of this study were to describe: (1) healthcare utilization and associated patient time and out-of-pocket costs (OOP) over 2 years following a cardiac diagnosis, (2) the sociodemographic and clinical drivers of these costs, and (3) patient costs related to cardiac rehabilitation (CR) participation.

Methods: Secondary analysis was conducted on an observational, prospective CR program evaluation cohort in Ontario which has a publicly-funded healthcare system. A convenience sample of patients from one of 3 CR programs was approached at their first visit, and consenting participants completed a survey. Participants were emailed surveys again 6 months, 1 and 2 years later; these assessed their cardiac care and medications, and the time and OOP costs associated with care visits. Patient time was valued based on average wages in Ontario.

Results: Of 411 consenting patients, 240 (58.3%) completed CR, and 192 (46.7%) were retained at 2 years. Patients most often had visits to their general practitioner, electrocardiograms, and treatment for angina. The total cost to patients over 2 years was $73.70±275.84 for time and $377.01±321.72 for OOP costs ($525.93±467.08 overall). With adjustment, there was a trend towards higher OOP costs for females (p=.09), and less educated (p=.07) patients. Participants spent considerable money relatively OOP on CR visits alone ($384.78±269.67), with time costs at $379.07±1035.49 ($939.43±1333.29 overall; 1.6% share of 1 year's income).

Conclusions: In conclusion, time and OOP costs are modest for cardiac patients, except for CR. Alternative delivery models are needed, in particular for low-income patients.

INTRODUCTION

Cardiovascular disease (CVD) is among the leading burdens of disease and disability globally.[1] Due to advances in acute treatment, there are many patients living chronically with CVD. They are at risk for recurrent events, and require long-term follow-up and management. This includes regular visits with specialists, testing of their cardiovascular risk factors and function, taking on average 3-4 classes of medications, and participating in cardiac rehabilitation (CR).

The costs of CVD to the healthcare system have previously been characterized,[2,3,4] and are substantial. CVD is the costliest of any health condition. However, there has been little consideration of the costs (not only out-of-pocket [OOP] costs, but also time-related costs) to patients to attend visits for tests and treatments, including CR, as well as for medications.[5] These have been characterized in cancer patients, who also require ongoing monitoring and management.[6] In a publicly-funded healthcare system or one with a good system of private healthcare insurance, costs to patients would certainly be lower than in systems without such coverage. In Canada for example, healthcare services are generally covered, but there is limited coverage of medications for those <65 years old (except in Quebec which has a publicly-funded medication coverage plan, or the Ontario Trillium Drug Program for those who are eligible when costs are > 4% of income, for example). These patients must pay OOP if they do not have a benefit plan through an employer or purchased privately.

CR is a chronic disease management program that successfully prolongs quality and quantity of life,[7] and clinical practice guidelines recommend CVD patients participate.[8,9] Most patients attend supervised programs located in academic centers;[10] on average patients attend 2-3 times per week for 5 months.[11] While CR services are reimbursed in some jurisdictions in

Canada, there can also be significant costs borne by patients associated with transportation and parking at hospitals. These have been infrequently considered[12] (and only characterized once in Canada approximately 25 years ago);[13] costs for CR sessions when not reimbursed by government or private insurance companies are also scantly reported.[5] In addition, most programs offer sessions during business hours,[14] and therefore participants must miss paid work to attend.

The objectives of this study were to: (1a) describe healthcare utilization and associated patient time and out-of-pocket costs (OOP) over 2 years following a CVD diagnosis or event; (2) understand the drivers of time and OOP costs incurred by outpatients living with CVD, namely sociodemographic (e.g., age, sex, work status, educational level, marital status, ethnocultural background, area of residence), and clinical (e.g., smoking, disease severity, and functional capacity); and (3) describe patient's time and OOP costs related to CR participation.

METHODS

Design and Procedure

We conducted this prospective, observational study as part of a CR program evaluation. Approval was received from the research ethics review boards at the institutions of each participating CR site. Patients referred to CR at one of 4 centers following a qualifying hospitalization or diagnosis were approached to participate at their initial visit between July 2010 and February 2014. Based on median times from hospital discharge to CR initiation in the region,[15] baseline assessment would have occurred approximately 1.5 months post event/procedure. Consenting participants were asked to complete surveys at CR intake and discharge (or the expected time of graduation for those who did not complete), as well as 1 and 2

years from CR initiation (online or paper). Clinical data were extracted from participants' medical charts for their CR intake and discharge assessments (where available).

Setting and Participants

This study was undertaken in Canada, which has a publicly-funded healthcare system. Therefore, all CVD tests and acute treatments are covered by provincial health insurance plans. There is a pharmacare program for Canadians above the age of 65. Most patients under the age of 65 years must pay OOP for medications, unless they have a very low income or very high medication costs in proportion to their annual income, have a health benefit plan through an employer or purchase a benefit plan privately.

The cohort consisted of participants from 3 CR sites and one satellite program in the Greater Toronto Area of Ontario, Canada. The attributes of each site are described elsewhere.[16] In brief, one program was located within the city and the others in the suburbs of Toronto. The programs were 4-6 months in duration, offering 1-2 sessions / week. Three programs offered CR at no cost to participants (one program charged a nominal fee for educational materials). In the remaining program, patients were required to pay a monthly fee of $55CDN to participate, which was reimbursable through private healthcare insurance for patients with such coverage (i.e., through work or purchased privately). This fee was added to OOP costs for participants attending this program (i.e., $55 x 6 months).

This convenience sample consisted of all consenting participants attending an initial visit at 1 of the CR programs. Participants were generally systematically referred to the CR programs following hospitalization for cardiac conditions or procedures, such as: acute coronary syndrome, chronic stable angina, or stable heart failure, as well as percutaneous coronary or

valvular intervention, coronary artery bypass graft (CABG) ± valve surgery, cardiac transplantation, or mild non-disabling stroke.[17] The inclusion criterion was that participants were deemed eligible to complete CR following the intake assessment (i.e. no co-morbidities identified or indications from the exercise stress test that would preclude CR participation). Participants who were not proficient in the English language were excluded from the study.

Measures

Sociodemographic characteristics such as participants' ethnocultural background (adapted from Statistics Canada categorizations), marital status, highest educational attainment and work status (also assessed in the 2nd survey), were assessed via self-report in the initial survey. Participants from the CR program in the city were considered "urban" for their area of residence, with those attending the other programs considered "suburban". Age, sex, as well as clinical data were extracted from CR referral forms, as well as CR intake and discharge assessments, where available. The following variables were collected: CR referral indications, and cardiac risk factors (e.g., blood pressure, lipids, blood glucose, and anthropometrics; smoking was assessed via self-report). Functional capacity was obtained from the graded exercise stress test at intake (i.e., peak Metabolic Equivalents of Task [METs]), and the Duke Activity Status Index[18] was administered in the discharge survey.

Patient Costs Related to Cardiac Healthcare Utilization

CVD-related healthcare utilization was assessed via self-report at each assessment point following intake. Participants were asked to report the number of times they visited a primary and specialist care provider, as well as emergency department visits and hospital admissions. They were also asked to indicate whether they had experienced any in a list of CVD-related tests, events or procedures. Completion of CR was ascertained from CR charts where available

(defined as engagement to a sufficient degree in the program to warrant formal post-program re-assessment and completion of said re-assessment);[19] otherwise dropout of CR was confirmed via self-report in the discharge survey. Healthcare system costs were not considered.

Patient OOP and time costs were assessed via self-report in each follow-up survey. Items were based on those developed for cancer survivors,[6] and adapted for cardiac patients. Participants were asked to report OOP costs (e.g., transportation, parking, food) as well as time (e.g., "in the last 12 months, how much time was associated with these health care visits, including travel and waiting?") for the above healthcare visits, tests and treatments, including costs for any accompanying persons. Whether participants lost time from paid work, and required assistance with unpaid work were also assessed in the CR discharge survey specifically. Participants were asked to report costs since the last assessment point (i.e., the discharge / 6-month survey assessed costs since CR intake; the 1 year survey assessed costs since the 6 month survey and the 2 year survey assessed costs for the full year).

Patient cost for medication was assessed in the 1 year and 2-year follow-up surveys. Participants were asked to list all of their cardiac-related prescribed and herbal/alternative medications, whether secured over (e.g., acetylsalicylic acid) or under-the-counter. Participants were asked to list them from the pill bottles to ensure accurate responses. They were then asked to self-report OOP costs for these medications during the previous 12 months. Finally, OOP costs associated with CR (e.g., transportation to and from each session, parking, shoes) and time associated with CR participation (i.e., travel to and from sessions) were assessed in the discharge survey only, based on Oldridge et al.[13]

Patient time was valued as per the average hourly wages in August 2016 in Ontario, namely $28.76/hour for those above the age of 55 (http://www.statcan.gc.ca/tables-

tableaux/sum-som/l01/cst01/labr69g-eng.htm; based on 50 weeks of work / year @ 40 hours / week this would be $57,520/year [value also used to calculate share of income]). This was computed relative to work status: the hourly wage was multiplied by the patient time among those working full-time, multiplied by half the hourly wage among those working part-time, and no time cost was computed for those reporting any other work status (e.g., retired, on disability). Total patient time cost was calculated for each follow-up time point, and summed for a grand total time cost across the 2 years from CR initiation. Total OOP costs, namely costs for healthcare visits and medications, were similarly summed at each assessment point, and then across all assessment points for a grand total. This was only computed in participants who completed surveys at all 3 assessment points. Finally, OOP and time costs were also averaged, to ascertain total patient cost. Unit cost for medical tests and procedures were obtained from the Patient Cost Estimator tool developed by the Canadian Institute for Health Information https://www.cihi.ca/en/patient-cost-estimator and the Schedule of Benefits, Ministry of Health and Long Term Care. Total costs were calculated by multiplying the unit costs by the frequency of visits across all time points.

Statistical Analysis

IBM SPSS software version 24 (IBM, Armonk, NY) was used for statistical analysis. A significance cut-off value of $p < .05$ was applied throughout. Descriptive statistics were used to describe the sociodemographic and clinical characteristics of the sample, as well as healthcare system and patient costs at each assessment point.

To test the second objective, the associations between sociodemographic as well as clinical characteristics with total patient time and OOP costs were tested using t-tests and Pearson's correlation, as appropriate. A general linear model was computed to test the

association of any significant characteristics, with adjustment for characteristics which differed by retention status. To test the final objective, patient time and OOP costs related to CR use specifically were described; this was followed by a comparison of these costs in CR completers versus dropouts.

RESULTS

Respondents Characteristics

Figure 1 displays the flow of participants through the study. Table 1 displays participant sociodemographic and clinical characteristics pre-CR. As shown, there were some differences in the characteristics of participants retained at 2 years versus those lost-to-follow-up. With regard to sociodemographic characteristics, retained participants were more likely to self-report "North American" ethnocultural background compared to those lost to follow-up. No other differences were observed.

Patient healthcare use and associated time and out-of-pocket costs

Cardiac-related healthcare visits (i.e., costs to the healthcare system) participants reported at CR discharge, as well as at 1 and 2-year follow-up are shown in Table 3. Costs to the healthcare system were primarily related to visits to general practitioners, electrocardiograms and blood tests, as well as treatment of angina and other cardiac events (these were most commonly atrial fibrillation).

Time and OOP patient costs (in Canadian dollars) related to this healthcare utilization is also shown in Table 3 by assessment point. As displayed, approximately 10% of patients required an accompanying person to aid them in attending their healthcare appointments. Patient costs in the first year were on average $410.08±391.68. Including OOP medication costs (see below), the average grand total cost to patients living with CVD for 2 years in a publicly-funded

healthcare system was $525.93±467.08 This represents 0.91% share of income spent by patients for non-CR cardiac care.

Total costs for diagnostic interventions and medical procedures are reported in Table 3. As shown, total costs for healthcare visits and CVD procedures ranged from $44.41 to $209,697.

In the CR discharge survey, 18 (16.8%) participants (who were not retired) reported difficulty working at their paid job because of their CVD. They reported having difficulty working 13.93±16.43 days, and that their work capacity was reduced by 65.00±26.29% during this time. With regard to unpaid work (e.g., household chores), 46 (20.0%) participants reporting requiring assistance since their event/procedure (regardless of work status). They required 79.40±157.89 hours of assistance, and the cost for this was $856.43±2089.90 (median=340.00).

Cardiac medication use, by class, in this cohort is reported elsewhere.[16] Participants reported taking an average of 5.40±2.34 medications at 1 year and 5.01±2.32 at 2-year follow-up. Mean OOP medication costs are shown in Table 3 by assessment point; the total OOP medication cost to patients over the 2 years following their event procedure was $271.86±324.77. Participants under the age of 65 (i.e., less likely to have some form of coverage) at study initiation reported spending $287.67±354.69 OOP on medication at 1 year, and $29.50±34.34 at 2 years. Figure 2a displays the breakdown of costs, including medications, in those working full-time for illustrative purposes.

The association between participant sociodemographic and clinical characteristics and patient costs are shown Table 2. As expected, time costs were significantly higher for younger participants (i.e., time costs were only considered in participants who were working). OOP costs were significantly higher among female, unmarried, less educated patients than their male, married, more educated counterparts respectively; there was also a trend towards higher OOP

costs in obese patients. As shown, no other differences were observed. A full model was tested, with adjustment for ethnocultural background as there was retention bias for this characteristic, of the association of age to time costs. The overall model was significant (F=3.75, p=.02), with age (F=5.11, p=.02) surviving this adjustment. A second full model was also tested, with again adjustment for ethnocultural background, of the association of sex, marital status, education and obesity to OOP costs. The overall model was significant (F=4.13, p<.01), with only a trend for sex (F=2.99, p=.09) and education (F=3.35, p=.07).

Patient Costs Related to CR

As shown in Figure 1, less than two-thirds of participants completed the CR discharge assessment and were considered to have completed CR; 60 (25.4%) of these participants were working full or part-time. Participants were on average prescribed 41.50±13.27 CR sessions by the program, and completed 25.80±16.66 sessions.

They reported spending a mean of 44.82±51.81 hours (including travel) to participate in these sessions. The total patient cost to attend CR was $939.43±1333.29 (1.63% share of 1 year's income; Given $25,163/year is considered a low-income in Canada [https://www150.statcan.gc.ca/t1/tbl1/en/tv.action?pid=1110024101], the total patient cost would be 3.7% share of 1 year's low income): $384.78±2269.67 OOP and $379.07±1035.49 on time associated with CR visits. Figure 2b displays the breakdown of costs, including CR, in those who are retired for illustrative purposes.

DISCUSSION

In this first characterization of CVD patient costs in a publicly-funded healthcare system, results show that these are quite modest. OOP costs were somewhat higher than those reported by cancer survivors.[6] The costs can be attributed to visits to general practitioners, for tests such

as electrocardiograms and bloodwork, and treatment for angina and atrial fibrillation, as well as medications. Workforce participation was not highly hindered by 6 months post-event/procedure. There were some potential drivers of patient costs however, suggesting women and less educated patients may have higher costs. Finally, the cost of CR participation to patients was shown to be double that for all other cardiac care over the 2 years.

That medication costs were lower over time could be explained by participants achieving the age of 65 and hence their medication costs may be covered by government or work benefits, or medication cessation due to excessive OOP costs. Optimal medical therapy is key to secondary prevention, and hence more investigation of the impact of OOP costs for medication on cardiac patient use and adherence is warranted.[20,21,22]

Cardiac patients who were younger reported significantly higher costs, with a trend towards higher costs in women and less educated patients as well. The higher time costs in younger patients was a function of missing work to attend appointments. While reasons were not ascertained in this study, one could surmise that costs were higher for women as they often suffer from a higher burden of comorbidities than men.[23] Reasons for higher OOP costs for less educated patients are likely socio-economic, as patients of lower socioeconomic means often have more severe disease, comorbidities and poorer outcomes. As less educated patients likely earn less money, it could also be the case that they were more likely to recall expenses related to their cardiac care, and to perceive them as greater, than their more educated, higher-income earning counterparts.

Participation in CR costs patients almost $1000CAD. Time costs in the HF-ACTION (Heart Failure: A Controlled Trial Investigating Outcomes of Exercise Training), a trial of exercise rehabilitation in heart failure patients were $1045USD (2008) for an average of 33

sessions requiring 53 hours.[12] This is considerably higher than the findings reported herein (~$400), likely because no time cost was assigned to non-working patients. In the only Canadian study ever characterizing costs for CR participation to our knowledge,[13] patients paid $99 (1987) OOP for travel and other expenses (not including time) to attend 16 sessions over 8 weeks. Considering inflation (purchasing power parity of $178 in 2017 Canadian dollars) and the greater number of sessions in which patients participated in the current study, this is considerably lower than the costs reported in the current cohort. Nevertheless, it is no wonder patients of low socioeconomic status are under-represented in CR programs,[24,25] and that utilization rates overall are suboptimal.[26,27,28]

Strategies to mitigate these costs to patients include a national pharmacare program (i.e., no out-of-pocket costs for medications), tele-healthcare,[29] and home-based CR.[30] Providing care to patients in their home contexts remotely may reduce costs to the healthcare system[31] (although this is not the case for home-based CR which is equivalent in cost to delivering traditional supervised CR),[32] and would discernibly reduce costs to patients as well.[31] Reviews demonstrate equivalent outcome improvement with home[32] and telehealth-based[33,34] versus traditional supervised CR. At present, there is not broad availability of care via these means.

Caution is warranted in interpreting these results. First, given cost data was collected through self-report at fixed assessment points, inaccurate recall and recall failure may have biased results. In particular, there may have been more error associated with patient estimation of costs over the full second year of the study follow-up period. Second, time costs were computed using average provincial wages rather than actual income, as this information was not collected. On a related note, third, coverage for medications was not directly assessed. Assumptions were made based on age, so further research is needed to better understand cardiac patient OOP for

medications. Fourth, multiple comparisons were performed with regards to costs and time, increasing the chance of type 1 error. Fifth, there was some selection and retention bias in the sample, and there was much loss to follow-up. Sixth, generalizability is limited in several additional ways. Results are likely not very generalizable to other funding systems. In particular, patient costs for CR will vary widely by Canadian province given reimbursement policies differ, and as does prescribed CR dose.[35,36] Moreover, results may not be generalizable outside major urban centers in Canada, as costs such as parking are likely higher in more densely-populated areas for example. Finally, generalizability is further limited to patients who access CR. While CR is the standard of care for this population, only approximately 30% of patients access it.[37] Moreover, patients who attend CR are shown to be different than those who do not.[38]

CONCLUSION

Time and OOP costs were generally modest for cardiac patients over the course of their chronic disease, and would generally not represent a barrier to care. This excludes CR however, which cost almost double all their other cardiac care over 2 years combined. The heavy costs explain the low rates of CR use, particularly in those of low socioeconomic means. Alternative delivery approaches which reduce these costs must be delivered more broadly, so more patients access and complete these life-saving programs.

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Figure 1. Participant Flow Diagram

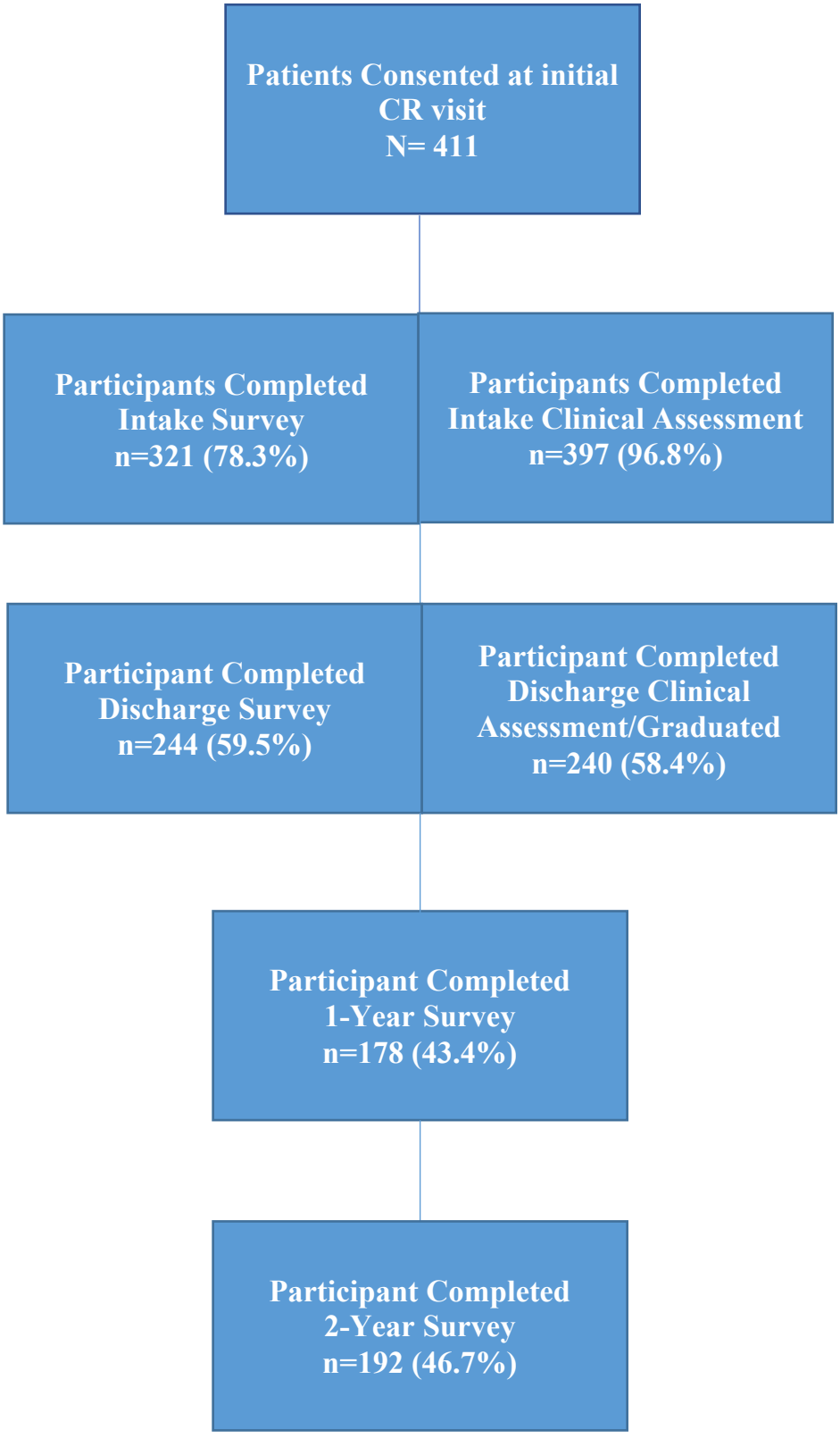
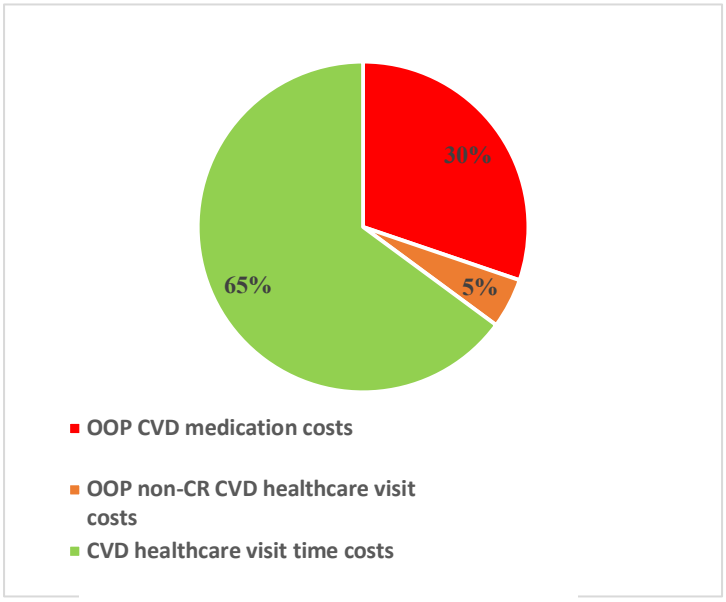
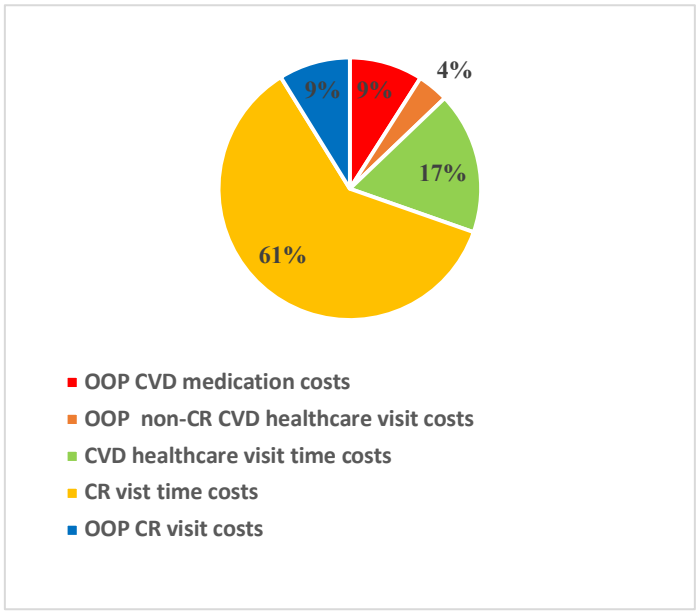


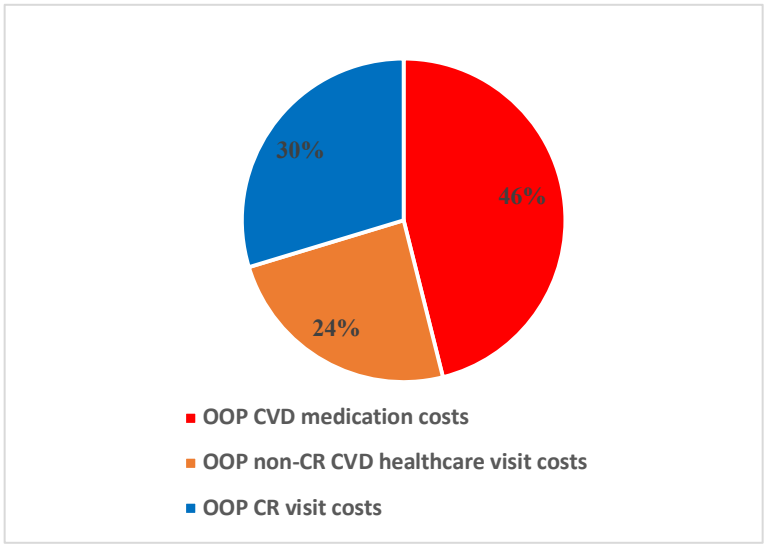
Figure 2. Patient CVD-related costs by work status and cardiac rehabilitation participation from CR intake over 2 years



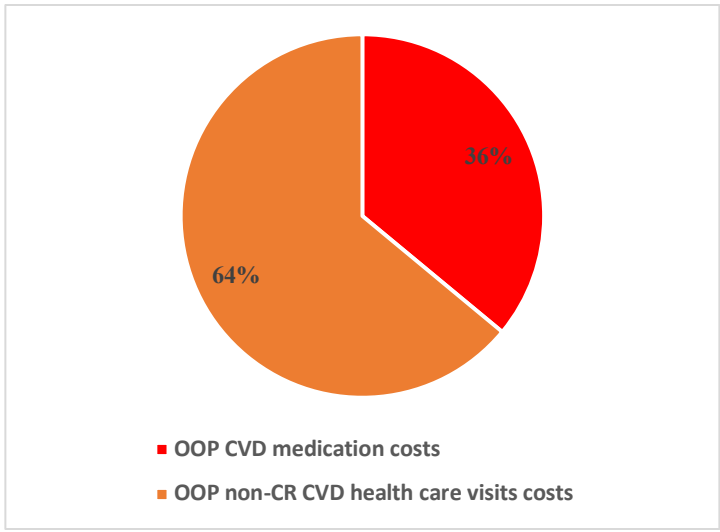
A) Full-Time, did not attend cardiac rehabilitation



B) Full-Time, attended cardiac rehabilitation



C) Retired participants who participated in cardiac rehabilitation



D) Retired participants who did not participate in cardiac rehabilitation

OOP=out-of-pocket; CR=cardiac rehabilitation; CVD=cardiovascular disease

Table 1. Sociodemographic and Clinical Characteristics of Participants at Cardiac Rehabilitation intake by 2-year Survey Completion

Characteristics	Retained at 2 years (n= 192, 46.7%)	Lost to follow-up (n=219, 53.3%)	Total (N= 411)
Sociodemographic			
Age† (mean years ± SD)	65.17 ± 9.32	63.82 ± 11.30	64.47 ± 10.42
Sex† (% Male)	138 (71.9)	148 (68.5)	286 (70.1)
Ethnocultural background (% North American)	74 (46.5)	52 (33.1)	126 (39.9)*
Marital Status (% married)	100 (77.5)	91 (71.7)	191 (74.6)
Education (% < college/university)	74 (48.7)	69 (52.3)	143 (50.4)
Work Status (% retired)	74 (47.7)	48 (52.7)	122 (51.5)
Clinical			
Previous cardiac diagnosis (% yes)	7 (41.2)	12 (41.4)	19 (41.3)
Peak METs§ (mean ± SD)	7.26 ± 2.93	7.08 ± 2.95	7.17 ± 2.94
CR Referral Indication†			
PCI	72 (39.3)	81 (40.3)	153 (39.8)
CABG	56 (30.8)	53 (26.4)	109 (28.5)
Other	141 (73.4)	150 (68.5)	291 (70.8)
Risk Factors†			
Dyslipidemia	86 (80.4)	86 (74.8)	172 (77.5)
Hypertension	96 (81.4)	104 (81.3)	200 (81.3)
Obesity	69 (39.9)	85 (44.7)	154 (42.4)
Diabetes	31 (18.8)	46 (24.3)	77 (21.8)
Current Smoker	10 (5.4)	0 (0.0)	10 (5.4)

SD, standard deviation; CABG, Coronary artery bypass grafting; PCI, Percutaneous Coronary Intervention; MET, Metabolic Equivalent of Task.

†source is medical chart (hospital or cardiac rehabilitation program)

§from pre-CR graded exercise stress test.

*p<.05

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Table 2. Participant sociodemographic and pre-CR clinical characteristics, with associated time and out-of-pocket healthcare costs (N=411)

Characteristics	N (%) or mean ± SD	Total Patient Time Cost○ ($73.70±275.84)	Total Out-of-Pocket Cost○ ($377.01±321.72)
Sociodemographic			
Age† (% <65 years)	207 (51.2)	147.18±398.27**	423.19±380.13
(≥65 years)		28.02±142.36	337.30±258.85
Sex† (% Male)	287 (70.2)	76.89±302.36	314.41±239.97
(Female)		67.62±218.77	522.34±429.95**
Self-reported Ethnocultural Background (% North American)	126 (39.9)	81.89±243.32	364.66±335.01
(Other)		36.88±131.15	405.34±343.72
Marital Status (% married)	236 (74.7)	56.43±178.03	337.47±292.06
(Other)		52.03±207.87	557.09±438.98*
Education (% completed < college / university)	160 (50.6)	42.13±178.98	504.43±413.62**
(≥ college / university)		70.91±194.51	283.17±215.30
Work Status (% Full-Time / Part-Time)	83 (35.2)	491.36±557.42	317.98±354.50
(Other)		-	412.80±301.40
Area of residence (% urban)	128 (31.1)	44.30±133.10	319.89±252.09
(Suburban)		83.21±308.01	398.02±343.07
Clinical			
Peak METs†§‖ (mean ± SD at intake)	7.17±2.93	0.08	-0.03
Functional capacity‡‖ (mean ± SD at discharge)	25.10±10.28	0.07	-0.03
CR Referral Indication†			
PCI (% yes)	153 (39.8)	43.79±123.92	409.76±342.56
(no)		91.40±337.70	330.56±297.06

CABG (% yes)	109 (28.5)	99.52±270.61	322.10±260.74
(no)		63.42±284.82	370.12±320.63
Other (% yes)	211 (80.5)	48.84±133.55	362.73±324.92
(no)		143.35±590.03	527.54±274.17
Risk Factors†			
Dyslipidemia (% yes)	293 (82.5)	60.33±272.29	359.35±310.75
(no)		84.74±253.65	433.22±377.53
Hypertension (% yes)	290 (76.9)	73.27±294.72	388.17±337.10
(no)		80.34±244.44	329.66±255.80
Obesity (% yes)	154 (42.4)	86.60±381.49	461.26±355.84††
(no)		72.61±215.20	325.91±296.75
Diabetes (% yes)	77 (21.8)	126.19±499.13	394.84±210.21
(no)		67.31±206.63	384.55±345.98
Smoker (% yes)	11 (4.5)□	81.23±161.23	234.11±170.96
(no)		73.74±281.64	380.16±324.07

Note: Due to missing data, percentages for each characteristic were computed using a denominator value specific to the sample size with complete data for that variable.

Costs are reported in Canadian dollars.

for test of association between characteristic and cost, using t-test or Pearson correlation as appropriate, **p<.01; *p<.05; ††trend p<.10.

SD, standard deviation; CABG, Coronary artery bypass grafting; PCI, Percutaneous Coronary Intervention; MET, Metabolic Equivalent of Task.

- Participants who were not working were considered to have no time costs.

†source is medical chart (hospital or cardiac rehabilitation program). ǂsource is medical chart and/or self-report.

§from pre-cardiac rehabilitation graded exercise stress test. ‡from Duke Activity Status Index.

‖Pearson's r reported in this row for correlation with costs. ○Sum of CR discharge, 1 and 2 year costs.

□inferential test not calculated due to small cell sizes.

Table 3. Healthcare Utilization, Patient Time and Out-of-Pocket Costs by Time from CVD Diagnosis/Event

Indicator	CR Intake to Discharge / 6 Months Later§ N=240	CR Discharge / 6 Months Later to 1 year N=178	1 year post-CR Intake to 2 years N=192	Unit cost ($)	Total cost ($)
Healthcare Visits‖					
General Practitioner Visits (mean ± SD)	2.13±2.38	3.21±3.40	2.64±2.09	77.20 (assessment) 31 (subsequent visits)	293.58
CVD Specialist visits (mean ± SD)	1.23±1.40	1.46±1.71	1.37±1.09	157.00 (consultation) 31 (subsequent visits)	251.86
Emergency Department (mean ± SD)	0.15±0.53	0.29±0.91	0.17±0.55	97.60	59.53
Hospital Admissions (mean ± SD)	0.08±0.39	0.13±0.53	0.06±0.24	79.90	21.57
CVD Events and Procedures□ (n, %)					
Myocardial Infarction	5 (2.9)	4 (1.5)	3 (2.5)	6,820	81,840
Angina	22 (12.0)	13 (13.4)	19 (14.6)	3,671	198,234
Percutaneous Coronary Intervention	6 (3.5)	4 (4.2)	3 (2.5)	8,946	116,298
Bypass Surgery	2 (1.2)	1 (1.0)	1 (0.8)	31,625	126,500
Valve surgery	0 (0.0)	3 (3.1)	0 (0.0)	24,884	74,652
Heart Failure	2 (1.2)	2 (2.1)	0 (0.0)	11,436	45,744
Heart Transplant	0 (0.0)	0 (0.0)	0 (0.0)	130,298	130,298
Left Ventricular Assist Device	0 (0.0)	0 (0.0)	1 (0.8)	209,697	209,697

Rhythm Device	2 (1.2)	3 (3.1)	1 (0.8)	11,628	69,768
Ablation	0 (0.0)	2 (2.1)	1 (0.8)	3,074	9,222
Stroke	3 (1.7)	1 (1.0)	3 (2.5)	5,447	38,129
Peripheral Vascular Disease	0 (0.0)	1 (1.1)	2 (1.7)	6,264	18,792
Other	21 (11.7)	9 (9.0)	13 (10.5)	-	-
Cardiac Tests ‖ (n, %)					
X-Ray	43 (9.3)	50 (10.8)	60 (40.7)	32.65	4,995.45
Electrocardiogram	95 (46.1)	121 (74.2)	118 (69.8)	11.05	3,690.70
Blood Test	167 (76.6)	148 (89.2)	153 (87.4)	7.68	3,594.24
Urine Test	68 (34.5)	98 (70.0)	106 (68.8)	4.30	1,169.60
CT Scan	19 (10.4)	34 (29.1)	31 (23.7)	147.50	12,390
Echocardiogram	50 (25.8)	87 (60.8)	83 (54.2)	208.80	45,936
Stress Test	82 (40.6)	92 (59.7)	82 (53.9)	106.15	27,174.40
Other	21 (11.6)	18 (16.2)	25 (19.7)	-	-
Time & Out-of-Pocket Costs					
Cost for healthcare visits* (mean ± SD)	$98.94±163.21	$79.03±88.32	$52.93±47.98	-	-
Accompanying person (% yes)	39 (9.5)	41 (10.0)	57 (12.3)	-	-
Accompanying person's age (mean ± SD)	62.51±8.80	65.06±12.86	63.66±11.83	-	-
Accompanying person's sex (% female)	26 (52.0)	35 (49.3)	47 (62.7)	-	-
Time† (mean ± SD hours)	11.18±26.10	9.56±11.06	8.17±9.54	-	-
Medications	-	$240.09±299.48[a]	$25.95±30.47	-	-
Total time cost‡	$72.37±306.14	$75.04±191.03	$72.70±168.52	-	-
Total out-of-pocket cost	$47.78±121.15	$272.40±275.58	$58.57±49.34	-	-

Average total patient cost	$123.74±341.43	$381.42±355.37	$157.11±205.10	-	-

Note: Due to missing data, percentages for each characteristic were computed using a denominator value specific to the sample size with complete data for that variable.

Costs are reported in Canadian dollars.

CVD, Cardiovascular Disease; SD, Standard deviation; CT, Computed tomography.

*transportation, parking, food, lodging; including accompanying person where applicable.

†for healthcare visits, including travel and waiting. ‡ household chores, caregiving, running errands.

ǂ Total hours spent on health care visits were multiplied by the average hourly wages in 2016 in Ontario ($28.76/hour for those above the age of 55) working full-time. The hourly rate was halved for those working part-time. No time costs were considered for non-working patients.

§Assessment point 6 months post-initial CR visit.

[a]Respondents were asked to report their medication costs in the previous 12 months, whereas all other values in this column were for the 6 months since the previous assessment, as per column header.

‖Unit costs were obtained from the Schedule of Benefits, Ministry of Health and Long-Term Care, 2015.

□Unit costs were obtained from the Patient Cost Estimator tool developed by the Canadian Institute for Health Information https://www.cihi.ca/en/patient-cost-estimator

STUDY 2

CERTIFICATE OF AUTHENTIFICATION

Re: Funding Sources and Costs to Deliver Cardiac Rehabilitation around the Globe: Drivers and Barriers

I hereby confirm that the first author of this manuscript, Mahshid Moghei, was responsible for quantitative analysis, the write-up of the manuscript, and drafting revisions for journal reviewers. Co-authors Turk-Adawi, Supervia and Lopez-Jimenez were collaborators from the global survey of cardiac rehabilitation programs, who were involved in study development and data collection, and provided minor editorial feedback just prior to submission. Co-author Schraa provided input from an economic perspective on the draft. Co-author Pesah was a master's student in the lab who performed early data cleaning.

Signature: _____ Date: March 20, 2019

Signature: _____ Date: March 20, 2019

Funding Sources and Costs to Deliver Cardiac Rehabilitation around the Globe: Drivers and Barriers

ABSTRACT

Background:

Cardiac rehabilitation (CR) reach is minimal globally, primarily due to financial factors. This study characterized CR funding sources, cost to patients to participate, cost to programs to serve patients, and the drivers of these costs.

Methods:

In this cross-sectional study, an online survey was administered to CR programs globally. Cardiac associations and local champions facilitated program identification. Costs in each country were reported using purchasing power parity (PPP). Results were compared by World Bank country income classification using generalized linear mixed models.

Results:

111/203 (54.68%) countries in the world offer CR, of which data were collected in 93 (83.78% country response rate; N=1082 surveys, 32.0% program response rate). CR was most-often publicly funded (more in high-income countries [HICs]; $p<.001$), but in 60.20% of countries patients paid some or all of the cost. Funding source impacted capacity ($p=.004$), number of patients per exercise session ($p<.001$), personnel ($p=.037$), and functional capacity testing ($p=.039$). The median cost to serve 1 patient was $945.91PPP globally. In low and middle-income countries (LMICs), exercise equipment and stress testing were perceived as the most expensive delivery elements, with front-line personnel costs perceived as costlier in HICs ($p=.003$). Modifiable factors associated with higher costs included CR team composition

(p=.001), stress testing (p=.002) and telemetry monitoring in HICs (p=.01), and not offering alternative models in LMICs (p=.02).

Conclusions:

Too many patients are paying out-of-pocket for CR, and more public funding is needed. Lower-cost delivery approaches are imperative, and include walk tests, task-shifting, and intensity monitoring via perceived exertion.

INTRODUCTION

Cardiovascular diseases (CVD) are among the leading burdens of disease and disability globally[1]. In addition to health impacts, CVD also poses a major economic burden on patients, society, and healthcare systems. On a global level, it is predicted that by 2030, the total cost of CVD will rise to a staggering $1,044 billion US dollars (USD) (from $863 billion USD in 2010)[75]. Evidence suggests that CVD pushes approximately 10% of affected families into poverty in low and middle-income countries (LMICs) where the epidemic of CVD is at its worst[20].

Cardiac rehabilitation (CR) is a chronic disease management program that successfully prolongs quality and quantity of life[7], and hence clinical practice guidelines recommend CVD patients participate[8,76]. The cost-effectiveness of CR is well-established across many contexts and perspectives[77–80]. CR participation is associated with return to work and healthcare avoidance. CR costs much less than percutaneous coronary intervention, yet equivalent outcomes are often achieved, supporting affordability[31].

Unfortunately, CR is grossly under-used[31]. While there are multiple factors at play[32], arguably the primary reason is financial. Most programs are under-resourced to deliver comprehensive evidence-based services. Indeed, surveys of CR programs in Australia and New Zealand[33], China[81], Japan[35], Scotland[82], Spain[37], Latin America and the Caribbean[38–40], the Arab Region as well as Canada[83] substantiate this.

CR Coverage

A major issue affecting financial viability of CR is whether services are reimbursed or "covered" by government or private insurers, among other sources. There is wide variation around the world in reimbursement sources however, and in many countries patients must pay

out-of-pocket (OOP). Recently, the International Council of Cardiovascular Prevention and Rehabilitation (ICCPR) surveyed CR leaders around the globe regarding reimbursement sources (respondents were asked to check all that apply); 61% reported the government, 55% reported patients pay OOP, and 52% reported insurance companies[19]. Clearly too many patients pay OOP for CR, and thus a better understanding of these costs is needed, given the likely impacts on utilization[84]. Indeed, the cost to patients to participate in CR has been scantly characterized[12–14].

Delivery Costs

Moreover, while financial resources are the major cause of under-utilization, little is known about the costs to deliver (quality) CR around the world. Most patients attend supervised programs located in clinical centres[10]; on average patients exercise on site 2-3 times per week for 5 months[11]. Most programs are staffed by a multi-disciplinary team, to ensure competent delivery of all core components for secondary prevention[85]. Hence, delivering the traditional model of CR carries with it costs associated with personnel, exercise equipment and other supplies, space and other operating costs[12,13,42].

In only 14 (12.6%) of the 111 countries known to offer CR globally[86] are the costs to run a program per patient known, at a median of $884 USD (2016 PPP) in high-income countries (HICs)[87]. Where assessed, delivery costs were generally higher in private versus public healthcare systems. Moreover, CR is delivered at much lower cost in LMICs than in HICs, and what evidence is available suggests equivalent benefits are achieved[68]. Other than these, factors affecting delivery costs have never been examined to our knowledge.

Therefore, the objectives of this study were to characterize: (1) funding source, and (1b) the proportion of the program cost as well as (1c) direct cost, to patients where they pay for CR;

and (2) the estimated cost to CR programs to provide service to 1 patient, (2b) which aspects of program delivery are perceived as most expensive, and (2c) whether cost varies by funding source in countries around the globe that deliver CR. The association of: (3i) a program's patient capacity per year, (ii) the number and nature of healthcare professionals on the CR team, (iii) the number of patients served per exercise session (including staff-to-patient ratio), (iv) the number and nature of core components the program delivers; (v) the dose of CR (i.e., duration of program in weeks x the frequency of sessions per week); (vi) the equipment/resources the program has (e.g., exercise equipment, supplies for cardiovascular risk assessment) including whether patients are monitored during exercise using telemetry, and (vii) whether the program offers alternative CR models (i.e., home or community-based) to both funding source (1) and cost to treat 1 patient (2) will also be explored, to understand factors that impact CR delivery costs. Finally, (4) the degree to which financial and other resources serve as barriers to CR delivery will be described. Each will be compared by country income classification (i.e., HICs vs LMICs), and described in all countries of the world where CR is offered.

METHODS

Design & Procedure

This research was observational and cross-sectional in design; detailed methods are reported elsewhere[86]. In brief, countries where CR services were available were identified first through previous reviews[31,84]. In countries where CR services were not suspected to be available, the internet was searched and major CR and cardiology societies were contacted to identify any programs or verify lack thereof.

For each country identified to offer CR, first available CR or cardiac societies leadership was contacted, and if there was no society available or response, "champions" were identified.

Identified leaders were sent an e-mail requesting their collaboration to administer the survey to each program in their country.

The most responsible clinician at each program was emailed with the request to complete the survey. Informed consent was secured through an online form. The survey was administered through REDCap, with data collection occurring from June 2016 to July 2017. Contacts were sent 2 e-mail reminders, at 2 week intervals.

Sample

The sample consisted of all CR programs identified in the world, that offer services to patients following an acute cardiac event or hospitalization (i.e., Phase II). This includes residential programs[88]. The inclusion criteria were CR programs that offered: (1) initial assessment, (2) structured exercise, and (3) at least one other strategy to control CV risk factors.

Measures

Development of the survey is described in detail elsewhere[83]. In short, items were based on previous national/regional CR programs surveys (e.g.,[10,39,89]). Most items had forced-choice response options, and skip-logic was used to obtain more detail where applicable. The survey is available elsewhere[86].

Respondents were asked to state their country. These were also categorized as high vs LMIC based on the World Bank classifications (http://data.worldbank.org/country).

Cost-related items used herein included: who pays for CR (i.e., public sources such as government, private sources such as insurance companies or patients [and the amount they pay], or other sources), the cost to the CR program to serve one patient if they complete the program , perceived expense of various CR program elements, and resource-related barriers to CR delivery (the latter 2 were rated on a 5-point Likert-type scale). The drivers of costs were also assessed,

including: annual patient capacity, types of personnel on the CR team, staff-to-patient ratio during exercise sessions, and telemetry monitoring of patients, core components delivered, dose and alternative model delivery (i.e., home and community-based).

Costs were reported using purchasing power parity (PPP), which is a widely used metric to compare different countries' currencies with USD. PPP is an economic theory that compares different countries' currencies using a "basket of goods" approach. According to this concept, two currencies are in equilibrium when a basket of goods is priced the same in both countries, taking into account the exchange rates (Organization for Economic Co-operation and Development, Manual on Purchasing Power Parities). PPPs (2016) for each country were computed using a cost conversion tool developed by the Cochrane Economic group (http://eppi.ioe.ac.uk/costconversion/default.aspx).

Data analysis

SPSS version 24 was used for analysis[90]. All initiated surveys were included. The number of responses for each question varied due to missing data (e.g., respondent did not answer a question due to lack of willingness or potential inapplicability, use of skip logic); for descriptive analyses, percentages were computed with the denominator being the number of responses for a specific item.

Descriptive statistics were applied for all closed-ended items in the survey (i.e., objective 1). All open-ended responses were coded / categorized. Associations were first tested on a univariate basis, using chi-square, t-tests, analysis of variance or correlations as appropriate.

Costs and funding sources were then compared by World Bank country income classification, using generalized linear mixed models to take into consideration the multi-level nature of the data, to handle missing data and different distributions of the dependent variables.

Given variation in healthcare systems around the globe, country-level comparisons were not undertaken inferentially.

RESULTS

As reported elsewhere,[86] there were 111/203 (54.68%) countries in the world with CR, of which data were collected in 93 (83.78%). The number of responses (mean=9.74±17.26/ country), and response rate (32.07% overall) by country are also reported there. The total sample size was N=1082 surveys.

Cardiac Rehabilitation Funding Sources

CR funding source is shown by country in Figure 1. Overall, in 46 (49.46%) countries CR was most often paid by public sources (i.e., government, hospital), in 22 (23.66%) countries CR was paid by private sources (i.e., patients or private healthcare insurance), and in 25 (26.88%) countries CR was paid by a combination of these sources. Some respondents also listed other sources, which included research (n=8 programs), fundraising/charity foundations (n=4), and veteran services (n=3).

CR was significantly more often paid by public (n=489, 66.40%) sources in HICs than in LMICs (n=103, 31.70%, $p<0.001$). Accordingly, CR was less often paid by private (n=87, 11.80%) and hybrid (n=161, 21.80%) sources in HICs than in LMICs (n=115, 35.30%; $p<0.001$; and n=107, 33.10%; $p<0.001$ respectively).

For the countries where patients paid some or all of the program cost (n=56, 60.20%), the mean proportion of the program cost and the amount they paid are shown in Table 1. Patients in Kenya and the Philippines paid all of the cost in most programs; patients pay all the cost in some programs in Greece, Pakistan, Peru and New Zealand. The cost to the patient was the highest in the following countries (PPP2016): Greece, Spain and Mexico (as well as Tunisia, but with only

1 response caution is warranted). The proportion of the program that patients paid (p=0.19) nor the direct cost to patients (where they pay) for CR (p=0.79) were not significantly different in HICs than in LMICs.

Table 2 shows aspects of CR programs that are associated with funding source. As shown, program capacity (greater with hybrid sources), healthcare providers on team (greater with public than private funding), individual consult with physicians (greater with private funding), cardiopulmonary stress testing (greater with private funding), and patients per exercise session (greater with public and hybrid than private funding) varied significantly by funding source. When testing each of the 10 core components individually, tobacco cessation (p<0.001), return-to-work counselling (p=0.02), and patient education (p<.01) were significantly more-commonly offered with public funding. While funding source was not associated with delivery of CR in any alternative setting, programs with public funding more often offered community-based CR specifically than privately-funded ones (p=.03). No other associations were observed. Finally, Table 2 also shows that program capacity (higher where patients paid), the number of healthcare providers on the CR team (lower), and number of core components delivered (lower where patients paid) were also significantly different based on whether patients paid for at least some of program costs or not.

Costs to Deliver CR

The estimated cost to deliver a full CR program to one patient is shown in Table 1. This did not differ significantly in LMICs versus HICs. Costs were highest in the following HICs: Bermuda, Austria, United States; costs were lowest in Chile, Uruguay and Singapore. Costs were highest in the following LMICs: Republic of Northern Macedonia, Dominican Republic, and Venezuela; costs were lowest in Cuba, Pakistan and Indonesia.

The elements of CR that contribute to these costs are shown in Table 4. As shown, in HICs, front-line personnel and exercise stress testing were perceived as most expensive and in LMICs, exercise equipment and exercise stress testing were perceived as most expensive. Front-line personnel was considered significantly more expensive in HICs than LMICs ($p<0.01$); no other differences were observed.

Drivers of costs in HICs and LMICs are shown in Table 3. In HICs, program delivery costs significantly varied by funding source (i.e., higher with public and hybrid than private, and no patient finding versus any), were significantly higher with greater program capacity (and volume; data not shown), more providers on the healthcare team, higher where there was a physician on the CR team and patients had an individual consult with said physician, patients undergo cardiopulmonary stress tests, more core components are delivered, and patients are monitored with telemetry during exercise. In LMICs, higher program delivery costs were similarly associated with greater program capacity and with a greater number of providers on the healthcare team (trend for physicians specifically), but also with fewer patients per exercise session, and were significantly lower where programs offered alternative CR models (e.g., unsupervised). There was only a trend for funding source.

Degree to Which Financial Resources Are Barriers to Cardiac Rehabilitation Delivery

Finally, the perceived degree to which financial factors impede greater CR provision is reported by country[91] and by country income classification elsewhere[92]. When compared by funding sources, human resources, space and equipment were greater delivery constraints with public funding compared to private funding (Figure 2).

Nature of CR Services in Canada

Program responders were asked to report who pays for their services, and could check all applicable sources (n =27,37.0% reported >1 source). Figure 3 displays the most common funders of CR by province/territory. Nationally, 41 (56.2%) reported hospital/clinical centre funding (with significant provincial variation, P= 0.02), 32 (43.8%) programs reported government funding, 23 (31.5%) reported the patient pays (and when they do they pay for on average 33.4% ±35.7% of the program, or CAD$253.10 ±235.24), 6 (8.2%) reported private health insurance, and 9 (12.3%) reported other funding sources (these included fund raising, a University and the Young Men's Christian Association (YMCA); all n =1, 1.4%). In 4 (5.5%) programs, the sole source of funding was the patient. The funding source in Canada was not different than other HICs (P=0.43).

It is important to highlight that in Canada, the proportion of CR program costs incurred by patients is 33.23% ± 38.66. The direct cost to patient is $275.29 ± $194.68 and cost to deliver CR to 1 patient is $938.29 ± $563.81.

DISCUSSION

CR funding and costs have been characterized globally for the first time herein. Of the countries with CR in the world (just over half), CR was funded from public sources solely in half, and this was more common in HICs (consistent with the fact that there is more public funding of health systems in HICs than LMICs[93]). Funding source impacted delivery costs, program capacity, patients per session, number and nature of healthcare providers on the team, and types of functional testing used. Moreover, some key CR components that would likely result in greater return-on-investment and downstream cost-savings (e.g., return-to-work and tobacco cessation counselling) were significantly more-commonly offered with public funding. CR resource availability, investment and care quality should not be impacted by funding source.

In almost 2/3rds of the countries with CR, patients are paying for some or all of their CR programs OOP (on average 50% of the program cost or over $600USDPPP2016). This would lead to greater under-utilization. Given more patients in LMICs pay OOP than HICs, yet there is no significant difference in the proportion of the program costs paid or the amount in LMICs vs HICs (which likely reflects the fact that healthcare is more expensive in HICs[93]), this represents an especially heavy burden on patients in LMICs where economic well-being is significantly lower.

The estimated cost to deliver CR to 1 patient, which should indeed be considered a gross estimate at this stage, was consistent in high LMICs (~$1500 2016PPP). Whether this represents a sufficient investment for effective CR remains to be established. These costs varied in relation to CR personnel composition, including physicians who are generally more expensive. Cardiopulmonary stress testing and telemetry monitoring increased costs in HICs and alternative models reduced them in LMICs. The main costs associated with CR delivery were for exercise equipment, human resources and exercise stress testing, with most of these factors impeding CR delivery to a much greater degree in programs with some public funding. In LMICs, higher volume of patients per exercise session was associated with cost efficiencies.

The $1500PPP cost to deliver CR is considerably lower than percutaneous intervention[94,95], which is sometimes performed without benefit when compared to optimal medical therapy. Moreover CR results in less healthcare utilization and more return-to-work, which further economically benefits society, adding further value to the low delivery cost. The only other available data on overall program costs[87] stem from the HICs of Canada ($884 2016USDPPP)[13] and Australia ($1312 2016USDPPP)[12]. In the former, while human resource and equipment costs were high, space figured more prominently, as it did in the

Australian study (although they considered some unit costs not assessed herein such as "administration" and "technology" which should be considered in future research). The available literature on CR personnel costs specifically is reviewed elsewhere[87]. Given the multi-component nature of CR, and hence the multiple disciplines required to deliver it comprehensively, personnel costs are understandably quite high. There is wide variation in the staffing complement of CR programs, as well as program policies around staff-to-patient ratios during exercise for safety[45,46,83]; correspondingly overall costs to programs would vary. In LMICs, exercise equipment is considered the most expensive aspect of program delivery. As per the International Council of Cardiovascular Prevention and Rehabilitation (ICCPR) consensus statement on CR delivery in low-resource setting, low-cost alternatives for exercise equipment are put forward[96,97], which should be seriously considered based on these findings.

In many LMICs (55.32% of those with CR), the cost of CR delivery is higher than the mean health expenditure per capita (although we concede this is a crude comparison, but it does reflect affordability and relative investment). This would be an even higher percentage if we considered revascularization, yet we would not argue it should not be delivered, and therefore we need to consider how CR can be delivered in a safe, high-quality manner while containing costs. In addition to the suggestions to keep costs down in ICCPR's consensus statement[96,97] and our previous review[87], based on the findings herein, strategies to reduce costs that should be tested include task-shifting to less expensive personnel (e.g., community healthcare workers), using physicians for consultation purposes as needed only, using a cheaper functional test than a cardiopulmonary stress test such as a 6 minute walk or shuttle walk test[98], exercising more patients per session, delivering exercise through non-equipment-based modalities, and not monitoring patients with telemetry during exercise unless they are established as high-risk. But

more research is needed as we do not know how these factors may impact program quality or safety.

Limitations

Caution is necessary when interpreting the findings, particularly due to limits on generalizability. Firstly, response rates to online surveys are notoriously low. While generalizability to countries with CR can be considered high, extrapolation within some countries should be undertaken with caution due to low program response rates. Second, it may not have been possible to identify programs, especially in LMICs where they may not have a website or have published any research, and in countries where no society or champion was identified. Therefore, extra caution should be taken when generalizing results from these countries.

The final limitation relates to measurement. Costs were self-reported and in most cases likely estimated, such that there is likely much measurement error. Moreover, there are no international accounting standards for program-level costing. Therefore, it was not considered appropriate to compare costs across countries (moreover given the variation in disease burden and severity, the likely variation in CR dropout rates, etc. by country). The cost items in the survey were not sufficiently detailed to capture what types of costs respondents included in their estimates (e.g., capital, overhead, how human resource costs are partitioned on a per patient basis). Additionally, costs were likely considered differently depending on the health system in a given country (e.g., budgeted values, charges or billing data, or actual total or marginal costs). However the $1500PPP cost is consistent with delivery costs in Canada and the United Kingdom for example, and hence the data appear reasonable. Future research is needed to better characterize unit costs of CR delivery globally. On a related note, mean healthcare expenditure

values used to put the costs in context were not available post-2014, yet data were collected in 2016.

CONCLUSION

Where available, CR is most often funded by public sources, but in 60% of programs, patients pay all or part of the cost OOP (on average half of the program cost or over $600PPP). The $1500 cost to treat one patient was driven primarily by personnel, exercise equipment and exercise stress testing costs, and varied by funding source in HICs. Funding source was also related to program capacity, patients per session, number of personnel (including physicians), and the type of functional capacity test used. Public (including hybrid) funding for CR had distinct advantages. Task-shifting, use of functional walk tests, exercising more patients per session, not monitoring with telemetry and offering CR in unsupervised settings can reduce costs; safety of such approaches warrant testing on a large-scale.

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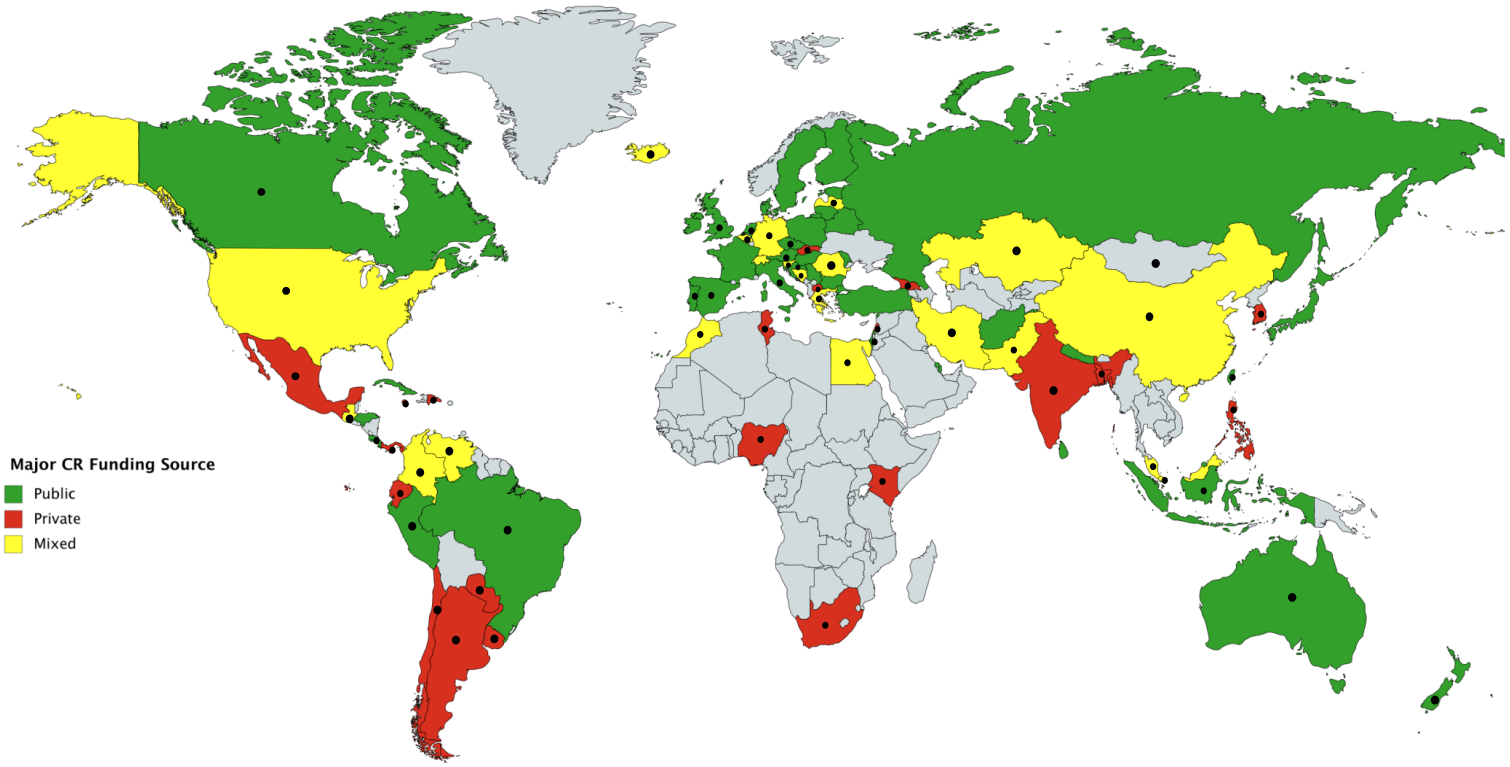
Figure 1. Most Common Cardiac Rehabilitation Funding Source by Country, Including Patients.

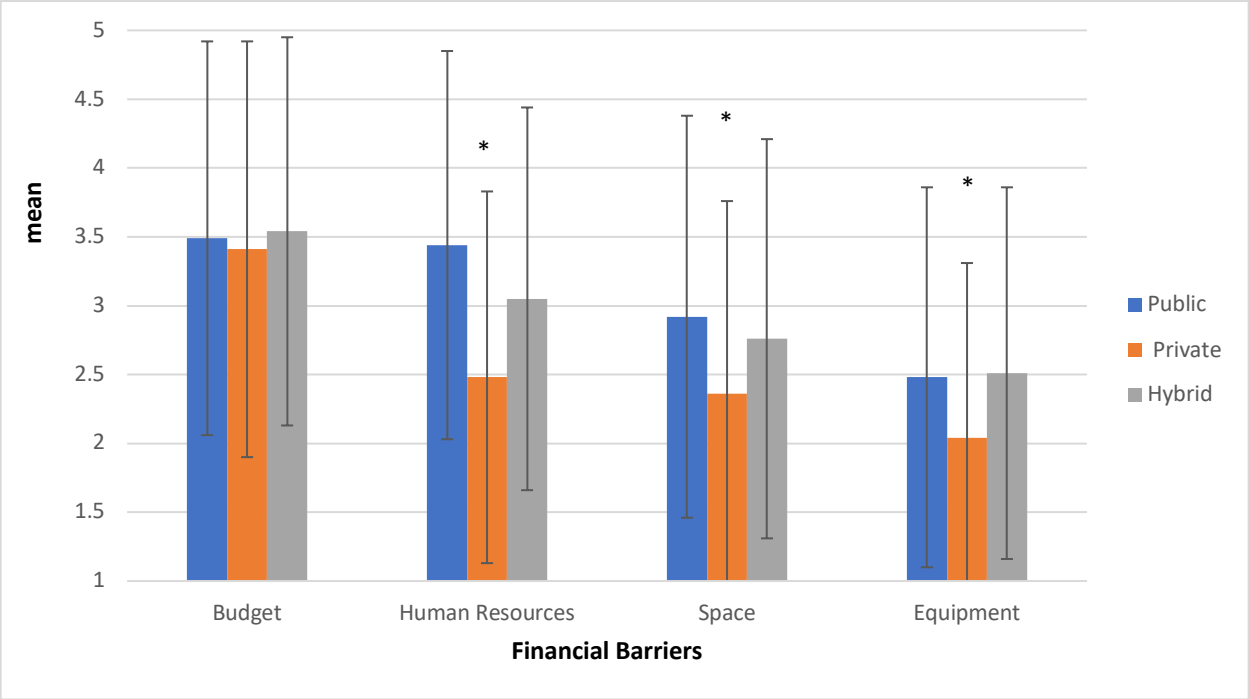


- Patients pay some or all of costs

Country has no CR

CR, Cardiac Rehabilitation

Figure 2. Degree to which financial resources serve as barriers to cardiac rehabilitation delivery by funding source†



*p<.001.
Rating scale from 1="not an issue" to 5 "major issue".
†shown by country income classification elsewhere[92].

Figure 3. Most common cardiac rehabilitation funding source by province/territory

Table 1. Patients Paying for CR, as well as Cost to Deliver CR Juxtaposed by Mean Healthcare Expenditure Per Capita, by Country with CR and Country Income Classification, N=1082

Income Classification Country	n	Proportion of Program Cost Patient Pays (Mean ± SD %)	Direct Cost to Patient (2016 PPP†) Mean ± SD	Cost to Deliver CR to 1 Patient (2016 PPP†)§ Mean ± SD	Healthcare Expenditure per Capita in 2014 PPP[99] (CR proportion)
High-Income					
Australia	85	37.33 ± 54.42	$144.88 ± $280.41	$1023.99 ± $602.76	$6031.11 (16.98%)
Austria	5	_	_	$5668.26 ± $421.90	$5580.49 (101.57%)
Bahrain	1	0	NA	_	$1242.84
Barbados	1	0	NA	_	$1146.04
Belgium	9	9.70 ± 6.83	$317.77 ± $231.50	$1951.81 ± $945.05	$4839.83 (40.33%)
Bermuda	1	_	_	$7,073.00	n/a
Canada	55	33.23 ± 38.66	$275.29 ± $194.68	$938.29 ± $563.81	$5291.74 (18.58%)
Chile	1	50.00	$100.00	$100.00	$1137.35 (8.79%)
Croatia	3	17.00 ± 0.00	$73.44 ± 0.00	$346.40 ± $158.28	$1050.33 (32.98%)
Czech Republic	6	50.00 ± 0.00	$185.82	$3493.38	$1378.52 (253.42%)

Curaçao	1	_	_	$586.00	_
Denmark	1	0	NA	$1960.53	$6463.24 (30.33%)
Estonia	2	0	NA	$938.63 ± $0.00	$1248.28 (75.19%)
Finland	11	0	NA	$984.66 ± $894.82	$4612.29 (21.34%)
France	16	0	NA	$4598.05 ± $2066.49	$4958.99 (92.72%)
Germany	34	12.82 ± 25.97	$734.14 ± $700.61	$2427.81 ± $977.11	$5410.63 (44.87%)
Greece	4	100.00 ± 0.00	$3114.75 ± $231.84	$1967.21 ± $1614.57	$1743.04 (112.85%)
Hungary	20	0	NA	$1467.41 ± $183.66	$1036.62 (141.56%)
Iceland	4	56.00 ± 26.51	$309.45 ± $152.01	$2369.77 ± $3754.25	$4661.62 (50.84%)
Ireland	6	0	NA	$716.33 ± $0.00	$4239.15 (16.90%)
Israel	6	15.00 ± 21.21	100.00	$1450.00 ± $1100.00	$2919.29 (49.67%)
Italy	68	47.20 ± 39.64	$1675.00 ± $2238.71	$4375.73 ± $2111.61	$3257.75 (134.32%)
Japan	9	0	NA	$396.00 ± $434.46	$3702.95 (10.69%)
Latvia	1	13.00	$262.10	$2096.77	$920.70 (227.74%)
Lithuania	9	0	NA	$1400.29 ± $467.15	$1063.42 (131.68%)
Netherlands	29	15.00	_	$1662.51 ± $1297.79	$5693.86 (29.20%)

New Zealand	27	100.00 ± 0.00	$491.19 ± $129.35	$557.81 ± $740.05	$4896.35 (11.39%)
Northern Ireland	10	0	NA	$859.60	n/a
Poland	20	0	NA	$1507.98 ± $810.68	$910.28 (165.66%)
Portugal	20	53.20 ± 44.17	$694.99 ± $1277.56	$789.93 ± $610.14	$2096.82 (37.67%)
Qatar	1	0	NA	_	$2106.35
Russian Federation	3	0	NA	_	$892.85
Scotland	23	60.00	_	$778.65 ± $502.25	$3934.82 (19.79%)
Singapore	7	45.00 ± 37.75	$263.87 ± $247.23	$226.37 ± $93.86	$2752.32 (8.22%)
Slovak Republic	1	95.00	$374.22	$374.22	$1454.81 (25.72%)
Slovenia	2	75.00	$383.97	$1277.13 ± $1263.11	$2160.75 (59.11%)
South Korea	12	98.18 ± 6.03	$681.03 ± $445.72	$820.20 ± $429.63	$2060.25 (39.81%)
Spain	47	_	$2470.06 ± $740.98	1679.14 ± $1466.69	$2658.27 (63.17%)
Sweden	1	0	NA	_	$6807.72
Switzerland	4	_	_	$1601.83 ± $1189.05	$9673.52 (16.56%)
Taiwan	22	9.83 ± 1.36	$151.53 ± $45.11	$894.14 ± $775.41	n/a
United Kingdom	57	66.5 ± 47.37	$157.59	$731.54 ± $220.07	$3934.82 (18.59%)

United States	65	15.78 ± 8.45	$1272.00 ± $2291.59	$5016.60 ± $2723.11	$9402.54 (53.35%)
Uruguay	5	75.00 ± 28.87	$722.56 ± $1035.39	$148.16 ± $97.73	$1442.27 (10.27%)
Wales	15	_	$35.82	$1002.87	_
HIC Mean ± SD		*40.67 ± 38.87*	*$675.49 ± $1178.54*	*$1865.48 ± $1857.57*	*$3420.37 ± $2315.79*
HIC Median (Q25-Q75)		*20.00 (10.00-86.25)*	*$244.86 (142.40-595.66)*	*$1267.10 (580.63-2427.04)*	*$2835.81 (1345.96-4912.01)*
Low and Middle-Income					
Afghanistan	1	0	NA	_	$56.57
Algeria	1	_	_	_	$361.73
Argentina	3	75.00 ± 35.35	$47.50 ± $10.61	$1200.00	$605.19 (198.28%)
Bangladesh	1	20.00	$336.38	$336.38	$30.83 (1091.08%)
Belarus	1	0	NA	_	$450.21
Bosnia and Herzegovina	1	20.00	$175.95	$879.77	$463.64 (189.75%)
Brazil	29	77.5 ± 36.15	$1262.22 ± $453.69	$844.57	$947.43 (89.14%)
Brunei Darussalam	2	0	NA	_	$957.60

Bulgaria	1	0	NA	_	$661.85
China	81	40.82 ± 30.00	$618.37 ± $672.60	$706.75 ± $734.16	$419.73 (168.38%)
Colombia	47	14.33 ± 7.68	$132.92 ± $141.53	$833.96 ± $597.59	$569.18 (146.52%)
Costa Rica	6	_	$867.38 ± $802.39	$300.00	$970.00 (30.93%)
Cuba	8	0	NA	$45.28	$816.62 (5.54%)
Dominican Republic	1	15.00	_	$3549.61	$268.99 (1319.60%)
Ecuador	2	_	$450.00	$900.00 ± $848.53	$579.19 (155.39%)
Egypt	2	20.00	$150.00	_	$177.77
Georgia	11	83.75 ± 29.61	$749.86 ± $540.81	$729.53 ± $284.76	$302.60 (241.09%)
Guatemala	2	10.00	$89.57	_	$232.62
Honduras	1	_	_	$300.00	$212.31 (141.30%)
India	18	90.78 ± 23.87	$357.61 ± $195.55	$1027.12 ± $2030.27	$74.99 (1369.68%)
Indonesia	9	21.67 ± 25.66	$541.20 ± $327.06	$276.05 ± $14.21	$99.41 (277.69%)
Iran	14	29.82 ± 18.08	$249.16 ± $343.18	$1906.88 ± $2947.68	$350.74 (543.67%)
Jamaica	1	_	_	_	$266.19
Kazakhstan	1	_	_	_	$538.78

Kenya	1	100.00	$1598.30	$1598.30	$77.69 (2057.28%)
Lebanon	1	80.00	$1000.00	$1000.00	$568.71 (175.84%)
Republic of Northern Macedonia	1	_	_	$6116.21	$353.92 (1728.13%)
Malaysia	4	25.00 ± 22.91	$255.63 ± $72.30	$749.83 ± $379.53	$455.82 (164.50%)
Malta	1	0	NA	_	$2470.59
Mauritius	1	_	_	_	$482.45
Mexico	9	84.17 ± 29.39	$2400.41 ± $1919.58	$1808.92 ± $1955.39	$677.19 (267.12%)
Moldova	1	0	NA	$944.80	$228.85 (412.85%)
Morocco	1	_	_	_	$190.05
Mongolia	1	_	_	_	$195.33
Nepal	1	0	NA	_	$39.87
Nigeria	1	90.00	_	_	$117.52
Pakistan	2	100.00	$171.35	$171.35	$36.15 (473.99%)
Panama	1	_	$108.00	_	$958.98
Paraguay	3	50.00	$325.00 ± $247.49	$400.00	$464.09 (86.19%)
Peru	7	100.00	$1584.28	$883.39 ± $991.20	$358.58 (246.36%)

Philippines	10	100.00 ± 0.00	$764.27 ± $297.64	$485.60 ± $198.47	$135.20 (359.17%)
Romania	2	_	_	$532.94	$556.81 (95.71%)
Serbia	2	0	NA	$868.71 ± $354.25	$632.92 (137.25%)
South Africa	14	53.00 ± 41.91	$1251.08 ± $1063.39	$1716.99 ± $1474.63	$570.21 (301.11%)
Sri Lanka	1	0	NA	_	$127.33
Tunisia	1	66.00	$2853.07	$2139.80	$305.30 (700.88%)
Turkey	9	0	NA	$1549.36 ± $576.87	$567.63 (272.95%)
Venezuela	8	85.00 ± 23.80	$391.50 ± $256.95	$2972.29 ± $1978.09	$873.38 (340.32%)
LMIC Mean ± SD		*49.60 ± 38.30*	*$597.25 ± $783.03*	*$1038.26 ± $1202.81*	*$455.39 ± $401.28*
LMIC Median (Q25-Q75)		*35.00 (11.50-100.00)*	*$338.28 (100.60-814.21)*	*718.23 (337.33-1232.43)*	*$390.73 (194.01-572.45)*
Global Mean± SD		46.13 ± 38.70	$626.07 ± $946.33	$1527.84 ± $1671.11	$1803.11 ± $2166.96
Global Median (Q25-Q75)		30.00 (11.50-100.00)	$295.42 (119.64-711.045)	$945.91 (438.89-1940.42)	$901.57 (357.41-2517.51)

CR, cardiac rehabilitation; SD, standard deviation; USD, United States Dollars; Q25-Q75, 1st- 3rd quartile
§this item assessed total program costs (i.e., not itemized) and hence was likely estimated grossly by respondents. Therefore there is likely considerable measurement error which should be taken into consideration when interpreting the values.
†PPP, Purchasing Power Parity (http://eppi.ioe.ac.uk/costconversion/default.aspx)
- Response about CR cost was not provided by any respondent in the country

NA – not applicable as patients do not pay for any part of CR in this country
n/a not available

Table 2. Impact of Cardiac Rehabilitation Funding Source

n (%) or mean ± standard deviation	**Public Only**	**Private Only (insurance or patient)**	**Hybrid**	**All**	**Any Patient Funding**
Program capacity (patients / year)	522.46 ± 887.86 ‖	534.46 ± 923.20 †	926.98 ± 1661.00 ‖ †	627.32 ± 1151.93 **	768.41 ± 1473.59 *
Median (Q25-Q75)§	273.00 (120.00-510.00)	200.00 (100.00-580.00)	400.00 (200.00-900.00)	300.00 (120.00-600.00)	300.00 (128.00-700.00)
Number healthcare providers on team	5.97 ± 2.72 †	5.25±2.54 †	6.15 ± 3.10	5.88 ± 2.81 *	5.61 ± 2.82 **
Physician on team (% yes)	210 (40.50%)	80 (46.20%)	124 (52.80%)	414 (44.70%)	174 (49.00%)
Staff-to-patient ratio	1:5.15 ± 9.45	1:3.52 ± 3.19	1:5.07 ± 7.31	1:4.81 ± 8.04	1:4.29 ± 6.11
Median (Q25-Q75)	1:4.00 (3.00-5.25)	1:3.00 (2.00-4.62)	1:4.00 (2.83-5.00)	1:4.00 (2.50-5.00)	1:3.60 (2.00-5.00)
Patient receives individual consult with physician (% yes)	271 (60.0%) †	130 (81.80%) † ‖	151 (70.20%) ‖	552 (66.80%) **	246 (75.70%)
Program uses cardiopulmonary stress tests (VO_2)	352 (68.20%)	138 (77.50%) †	162 (68.10%) †	652 (70.00%) *	266 (74.30%)

Number risk factors assessed (/12)	8.48 ± 3.59	8.35 ± 3.69	8.79 ± 3.52	8.54 ± 3.59	8.87 ± 3.29
Core components delivered (/10)	7.24 ± 2.98	6.93 ± 2.92	7.33 ± 2.83	7.21 ± 2.93	7.27 ± 2.64 **
Patients monitored during exercise with telemetry (% yes)	244 (48.70%)	97 (57.10%)	170 (73.00%)	511 (56.50%)	236 (67.00%)
Patients per exercise session	9.95 ± 5.75 †††	6.10 ± 5.41 ††† ‖‖	9.28 ± 5.31 ‖‖	9.04 ± 5.76 ***	7.80 ± 5.59
Median (Q25-Q75)	9.00 (6.00-12.00)	5.00 (2.00-8.00)	8.00 (5.00-12.00)	8.00 (5.00-12.00)	6.00 (4.00-10.00)
CR dose (hours)	33.09 ± 48.70	42.11 ± 55.07	41.05 ± 60.11	37.03 ± 53.27	40.77 ± 53.71
Median (Q25-Q75)	18.00 (10.37-36.00)	28.00 (18.00-45.00)	30.00 (18.33-41.95)	24.00 (12.00-36.00)	30.00 (18.00-45.00)
Program offers alternative models (% yes)	194 (38.60%)	38 (22.10%)	51 (21.80%)	283 (31.20%)	81 (22.80%)

§median and 1st- 3rd quartile (Q25-Q75) shown where variation high (i.e., standard deviations greater than means).
Compared by funding source using Generalized Linear Mixed model adjusting for country – one model for each row.
* p<.05; ** p<.01; *** p<.001 for Generalized Mixed Models testing for overall model significance
†‖ 1 symbol p<.05; 2 symbols p<.01; 3 symbols p<.001 for pairwise comparisons

Table 3. Drivers of Program Delivery Costs, by Country Income Classification

Driver n (%) or mean ± standard deviation (median)	**High-Income** **(n=749)**	**p†**	**Low or Middle-Income** **(n=333)**	**p†**
Funding source ($2016PPP‖)		0.003		0.07
Public	$1981.20 ± 1962.69 ($1306.73)		$1262.69 ± 1275.21 ($1012.04)	
Private (incl. patients)	$1051.22 ± 963.02 ($582.66)		$1200.29 ± 1291.33 ($828.13)	
Hybrid	$2084.86 ± 1898.54 ($1513.24)		$780.38 ± 1036.84 ($517.65)	
Patients (full or partial)	184 (24.90%)	<0.001	211 (65.30%)	0.35
Yes	$1399.21 ± 1554.68 ($797.87)		$998.77 ± 1207.05 ($641.64)	

No	$2054.81 ± 1939.76 ($1408.45)		$1176.54 ± 1199.78 ($998.29)	
Program capacity (patients / year)	537.48 ± 809.79 (300.00)	0.005	806.56 ± 1623.82 (300.00)	<0.001
Number healthcare providers on team§	5.91 ± 2.78 (5.50)	0.001	5.81 ± 2.85 (5.50)	0.002
Physician on team (% yes)	227 (36.30%)	0.006	188 (61.20%)	0.06
Yes	$2486.99 ± 1914.59 ($1960.53)		$1168.82 ± 1403.41 ($731.48)	
No	$1158.00 ± 1403.94 ($716.33)		$798.66 ± 678.37 ($568.64)	
Staff-to-patient ratio	1:5.45 ± 9.58 (1:4.00)	0.19	1:3.51 ± 2.69 (1:3.00)	0.52
Patient receives individual consult with physician (% yes)	303 (54.30%)	0.001	253 (93.00%)	0.85
Yes	$2158.57 ± 1905.31 ($1668.08)		$980.50 ± 1095.68 ($702.22)	
No	$1190.50±1602.96		$822.38 ± 786.76	

	($716.33)		($474.55)	
Program has cardiopulmonary stress tests (VO_2) (% yes)	403 (63.50%)	0.002	253 (83.80%)	0.33
Yes	$1942.74 ± 1774.64 ($1440.64)		$1098.10 ± 1288.65 ($836.35)	
No	$1281.36 ± 1806.42 ($716.33)		$810.01 ± 773.99 ($585.19)	
Core components delivered (/10)	8.23 ± 1.59 (8.50)	0.01	7.68 ± 1.75 (8.00)	0.87
Patients monitored during exercise with telemetry (% yes)	341 (56.10%)	0.01	172 (57.00%)	0.26
Yes	$2199.64 ± 2050.47 ($1445.78)		$943.72 ± 1040.08 ($701.94)	
No	$1147.22 ± 1043.09 ($828.50)		$1126.70 ± 1384.41 ($718.23)	
Number patients per exercise session	9.68 ± 5.55 (8.50)	0.71	7.77 ± 6.08 (6.00)	<0.001
CR dose (hours)	35.93 ± 57.44	0.87	39.65 ± 43.51	0.68

	(22.50)		(30.00)	
Program offers alternative models (% yes)	219 (36.00%)	0.38	66 (21.50%)	0.02
Yes	$1588.30 ± 1867.82 ($800.00)		$684.68 ± 605.38 ($431.41)	
No	$1956.69 ± 1790.90 ($1516.44)		$1122.69 ± 1305.00 ($731.48)	

‖ PPP, Purchasing Power Parity (http://eppi.ioe.ac.uk/costconversion/default.aspx)
§part-time staff counted as .5.
†association with cost to deliver CR to 1 patient, using generalized linear mixed model adjusting for country.

Table 4. Perceived expense of elements to deliver cardiac rehabilitation

Mean ± Standard Deviation‖	**High-Income (n=747)**	**Low or Middle-Income (n=335)**	**All (N=1082)§**
Front-line personnel	3.51 ± 1.25	2.83 ± 1.10	3.29 ± 1.24**
Exercise equipment	3.13 ± 1.21	3.49 ± 1.24	3.25 ± 1.23
Exercise stress testing	3.21 ± 1.33	3.27 ± 1.17	3.23 ± 1.28
Equipment/supplies for CVD risk assessment	2.84 ± 1.12	3.10 ± 1.20	2.93 ± 1.15
Space	2.76 ± 1.32	2.85 ± 1.28	2.79 ± 1.30
Patient education material	2.29 ± 0.89	2.36 ± 0.97	2.31 ± 0.92
Blood pressure assessment device	2.27 ± 0.82	2.16 ± 0.93	2.23 ± 0.86
Blood collection and lipid testing	2.42 ± 1.00	2.63 ± 1.03	2.50 ± 1.02†
Resistance training equipment	2.44 ± 0.91	2.56 ± 0.98	2.48 ± 0.93

CVD, Cardiovascular disease

‖scores range from 1="free" to 5="very expensive"

***p<.01.

†trend, p=.08

§ Compared by country income classification using generalized linear mixed model adjusting for country – one model for each row.

Table 5. Cardiac rehabilitation funding source by province/territory

Province	CR Funding Source n (%)				
	Government	Hospital	Patient	Insurance	Other
Alberta	1 (100%)	--	--	--	--
British Columbia	1 (14.3%)	4 (57.1%)	5 (71.4%)	--	3 (42.9%)
Manitoba	1 (100%)	--	1 (100%)	--	--
New Brunswick	1 (50%)	2 (100%)	--	--	--
Newfoundland & Labrador	1 (50%)	--	--	--	1 (50%)
Nova Scotia	--	1 (100%)	--	--	--
Ontario	10 (38.5%)	20 (76.9%)	6 (23.1%)	5 (19.2%)	2 (7.7%)
PEI	1 (100%)	--	--	--	--
Quebec	4 (66.7%)	3 (50%)	1 (16.7%)	--	--
Saskatchewan	6 (35.3%)	8 (47.1%)	6 (35.3%)	1 (5.9%)	2 (11.8%)
North -- No CR	--	--	--	--	--
Canada	25 (45.5%)	33 (60%)	17 (30.9%)	5 (9.1%)	6 (10.9%)

STUDY 3

Promoting Exercise Maintenance Post-CR

Exercise maintenance post-CR remains a challenge. Numerous studies have reported that CR graduates are failing to maintain adequate levels of physical activity (PA) (150 minutes of moderate/vigorous physical activity weekly)[1–3] despite education and counselling in CR[4],[5]. Willmer et al.[6] compared how PA at one and five years post-CR varied in patients that had engaged in an exercise maintenance program versus those that had not. Regardless of their membership in an exercise maintenance program, both groups engaged in fewer minutes of PA (maintenance program at 1 and 5 years [140 and 120 minutes per week respectively], no maintenance program at 1 and 5 years [138 and 105 minutes per week respectively]), and less frequently met the recommended 30 minutes of PA per day.

Given PA declines, interventions to increase PA levels post-CR have been tested. To date, there have been 10 published RCTs of interventions to improve exercise maintenance post-CR[7–15]; 8 of these RCTs have shown beneficial results[7–9], [12–15]. Interventions that improved PA levels or helped maintain CR induced benefits (e.g., improvements in cardiometabolic fitness), incorporated a mix of self-regulatory skills training on exercise planning;[13] exercise consultation;[8] an exercise diary and quarterly group meetings;[7] a home walking program and daily activity log [10]; written action and coping plans[14,15]; and self-monitoring of vital measurements, and pedometer-measured PA with personal feedback.[9] Only one study was undertaken in Canada; it did not improve exercise maintenance 52 weeks post-CR.[11]

There are substantial limitations to the literature assessing interventions for exercise maintenance. One of the most critical limitations is the lack of an economic evaluation; previous studies[7,10,13,16] that have assessed interventions for maintenance of PA levels did not consider incorporating community resources for exercise to facilitate sustainability and affordability.

One strategy to promote exercise maintenance post-CR is the use of an exercise facilitator intervention via telephone. Our randomized controlled trial of post-CR participants[17], ecologically optimizing exercise maintenance in men and women post-cardiac rehabilitation (ECO-PCR), assessed costs for implementing an exercise facilitator intervention for 52 weeks. Participant characteristics of the sample is shown in Table 1. The intervention employed a single face-to-face introduction between the participant and facilitator, small group counseling teleconferences, personal telephone contacts, and community exercise program demonstrations (where desired). The facilitator helped participants develop plans for adhering to their exercise. Small group counseling teleconferences were held 3, 13, 26, 39 and 50 weeks after randomization. At each session, participants reviewed their activity diaries, identified barriers to exercise maintenance experienced and brainstormed solutions as a group.
The facilitator contacted participants individually by telephone 20, 34 and 45 weeks after CR program completion. During each telephone call, the facilitator reviewed the participant's activity diary and assessed their confidence and motivation with respect to exercise maintenance.

Data was collected on resources used to deliver the intervention, including training time for facilitators; phone equipment and long distance charges for teleconference counseling, workbooks and pedometers. Costs were derived by multiplying the quantities of resources used by their appropriate unit costs. The total cost for teleconference counselling was $2645.64,

parking pass for patients cost $5,500 and the pedometers cost $974. Phone equipment was included in the overhead clinical costs; therefore, it was not a cost to the study.

Facilitator training took 15 hours. Intervention delivery required 5.6 facilitator hours per participant. Out of the 9 facilitator sessions offered to each patient, on average 7.50±2.23 calls were attended (4.02±1.41 /5 group calls and 2.66±0.79 /3 personal calls). The overall intervention cost, as shown in Table 1, was $29,320.18 Canadian dollars (CAD); this averaged to $129.73 CAD per patient.

Of note in the ECO-PCR intervention, we did try to exploit existing community exercise facilities but few to no participants took advantage of this (n=49, 16.10% engaged in physical activity at a facility recommended by the rehab program; n=37, 12.10% went to a "heartwise exercise program"; n=9, 3.00% attended an Alumni/ maintenance program; n=134, 44.10% engaged in community physical activity in other places), therefore this is not an avenue to pursue for our population.

The intervention was only effective at promoting PA maintenance in women adherent to it, therefore, a full analysis of whether the intervention is cost-effective is not warranted. Among women adherent to the intervention, the group in whom the intervention was proven effective, PA intentions at 26 weeks were significantly greater in the intervention arm (p=.04), with no other differences. There were some differences in socio-ecological elements associated with MVPA by arm. There were also some differences by sex, with MVPA more often associated with exercise benefits/barriers in men, versus with working and the physical environment in women. However, in future, it should be considered whether effective post-CR exercise interventions are associated with less downstream healthcare utilization and hence could be cost-saving.

Although previous interventions did not consider costs, it is expected that one-to-one exercise consultations with a trained professional are costly. Therefore, other low-cost strategies to promote exercise maintenance post-CR must be considered. Of the effective interventions previously tried, the CHANGE intervention[12] might be particularly low-cost. The intervention consisted of five small group sessions of counselling and behaviour modification based on several cognitive-behavioural theoretical frameworks. An experienced cardiac nurse delivered three 1.5-hour sessions once a week during the last three weeks of CR and two sessions at 1- and 2-months post CR. The costs of delivering the intervention were approximately $30 per participant (nurse salary and teaching materials).

Other ideas not yet tried in CR graduates include the use of a lifestyle-focused text messaging service, smartphone applications and incentive-based rewards. Text messaging has been shown to result in improvements in lifestyle and risk factor modification in CVD patients[18]. Moreover, a recent study showed that providing very small but immediate rewards for daily step goal achievement, as part of a multi-component intervention, increased daily step counts on a population scale[19]. Participants earned incentives in the form of loyalty points (worth Can $0.04) every day they reached their personalized daily step goal (ie, baseline mean+1000 steps=first daily step goal level). Participants could earn up to Can $5.00 during the 12-week evaluation period. Although this study was not in CVD patients, it could be tested post-CR.

Unfortunately, there have not been any studies on the cost-effectiveness of interventions to promote exercise post-CR. Also, the duration of effects and whether or not these interventions result in less downstream healthcare utilization remain to be determined.

CONCLUSIONS

CVD patients incur modest time and OOP costs over the course of their disease. The high OOP costs of CR are particularly a challenge in those with low socioeconomic status. Many patients are paying OOP for CR services, therefore, alternative approaches of CR delivery are needed to reduce costs in addition to more public funding. Strategies to reduce CR delivery costs include the use of walk tests, task-shifting, and intensity monitoring via perceived exertion. Long-term maintenance of exercise behaviour remains a challenge in CVD patients. Maintaining and enhancing physical activity levels is imperative for patients to protect their cardiovascular health following CR. Further research is needed to determine the effectiveness of exercise maintenance interventions more importantly their cost. Once established, low-cost interventions that result in improvements in exercise behaviour maintenance in CVD patients must be incorporated into CR practice guidelines and disseminated to programs.

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Table 1: Background Characteristics of the ECO-PCR Sample

	Female Participants		Male Participants	
	Intervention (n=68)	Usual Care (n=67)	Intervention (n=158)	Usual Care (n=156)
Background and demographics				
Age, mean (SD), y	65.3 (10.3)	66.1 (10.5)	63.0 (9.8)	63.2 (9.4)
White, n (%)	55 (80.9)	56 (83.5)	124 (78.4)	118 (75.6)
Married or cohabiting, n (%)	33 (48.5)	34 (50.7)	114 (72.1)	115 (73.7)
Employed full-time, n (%)	14 (20.5)	10 (14.9)	46 (29.1)	47 (30.1)
Current smoker, n (%)	1 (1.5)	1 (1.5)	2 (1.2)	3 (2.0)
Body mass index, mean (SD), kg/m^2	27.0 (5.1)	28.9 (5.7)	29.0 (4.8)	28.3 (4.8)
Medical History				
Hypertension, n (%)	36 (52.9)	47 (70.1)	94 (59.5)	83 (53.2)
Dyslipidemia, n (%)	33 (48.5)	48 (71.6)	99 (63.9)	99 (63.5)
Diabetes mellitus, n (%)	13 (19.1)	14 (20.8)	28 (17.7)	29 (18.5)
Prior cardiac history, n (%)	7 (10.3)	5 (7.5)	15 (9.5)	24 (15.4)
PVD, n (%)	2 (2.9)	2 (3.0)	4 (2.5)	1 (0.6)
Heart failure, n (%)	0 (0.0)	1 (1.5)	1 (0.6)	2 (1.3)
Chronic kidney disease, n (%)	1 (1.5)	0 (0.0)	4 (2.5)	4 (2.6)
LVEF, %	57.5 (9.0)	59.8 (7.3)	51.8 (11.7)	54.3 (11.2)
Indication for CR				
CABG, n (%)	12 (17.6)	17 (25.4)	48 (30.4)	39 (25.0)
PCI, n (%)	43 (63.2)	38 (56.7)	102 (64.6)	100 (64.1)
MI, n (%)	36 (52.9)	30 (45.5)	78 (49.7)	71 (45.8)
Angina, n (%)	6 (9.1)	10 (15.6)	10 (6.8)	13 (9.0)
Medications				
ACE inhibitor, n (%)	33 (48.5)	33 (49.3)	92 (58.2)	83 (53.2)
Angiotensin receptor blocker, n (%)	14 (20.6)	18 (26.9)	13 (8.3)	15 (9.6)
Beta-blocker, n (%)	49 (72.1)	54 (80.6)	121 (76.6)	121 (77.6)
Calcium channel blocker, n (%)	13 (19.1)	11 (16.4)	19 (12.0)	24 (15.4)
Diuretic, n (%)	7 (10.3)	10 (14.9)	17 (10.8)	9 (5.8)
Diabetes medication, n (%)	6 (8.8)	11 (16.4)	28 (17.7)	21 (13.4)
Nitrates, n (%)	24 (35.2)	32 (47.8)	63 (40.1)	55 (35.3)
Aspirin, n (%)	60 (88.2)	60 (89.6)	149 (94.3)	149 (95.5)
Other anti-platelet medication, n (%)	29 (42.6)	25 (37.3)	65 (41.1)	60 (38.5)
Psychotropic medication, n (%)	14 (20.6)	16 (23.9)	15 (9.6)	15 (9.6)
Statin, n (%)	60 (88.2)	61 (91.0)	151 (95.6)	145 (92.9)

SD, standard deviation; PVD, pheripheral vascular disease; LVEF, left ventricular ejection fraction; CABG, coronary artery bypass grafting; PCI, percutaneous coronary intervention; MI, myocardial infarction

Table 2

Micro-costing from healthcare perspective for the intervention group

Item	**Unit Price**	**Total Cost**
Training Exercise Facilitator (Includes training and patient call times)	$25.41	$22,329.04
Teleconference Calls	$220.47	$2645.64
Pedometer Costs	$13.00	$1755.00
Workbook Costs	$23.55	$2590.50

Note: amounts shown in Canadian dollars.

Appendices

Appendix A

Study 1 Informed Consent Form

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

STUDY NAME: **Cardiovascular Rehabilitation—Chronic Disease Management Program Evaluation and Cost-Effectiveness Analysis**

INVESTIGATORS:

Sherry L. Grace, PhD (Principal Investigator)	**York University and University Health Network**
Caroline Chessex, MD (Co-Principal Investigator)	**University Health Network**
Doug S. Lee, MD (Co-Investigator)	**Institute for Clinical Evaluative Sciences and University Health Network**
Harindra Wijeysundera, MD (Co-Investigator)	**Sunnybrook Health Sciences Centre and University of Toronto**
Mansoor Husain, MD (Co-Investigator)	**University Health Network**

You are being asked to take part in a research study. Please read this explanation about the study and its risks and benefits before you decide if you would like to take part. You should take as much time as you need to make your decision. You should ask the study doctor or study staff to explain anything that you do not understand and make sure that all of your questions have been answered before signing this consent form. Before you make your decision, feel free to talk about this study with anyone you wish. Participation in this study is voluntary.

Background and Purpose

You have already agreed to participate in the University Health Network Cardiovascular Rehabilitation and Prevention Program. In this research study, we would like to better understand how quality of life in our participants with atrial fibrillation changes following participation in CR.

Study Design and Procedures

As a patient who has had atrial fibrillation, you will be asked to complete 2 surveys online: one at the beginning of the cardiovascular rehab program, and one at the end. The survey includes questions about your symptoms, how you participate in activities, and any concerns about your treatment. The survey takes about 5 minutes to complete.

Finally, we would also like your permission to link your survey responses with the information gathered as part of the cardiac rehab program for the Canadian Cardiac Rehab Registry. This would not require any paperwork on your behalf.

Voluntary Participation

Your completion of both surveys is voluntary. If you consent to participate in this study, your survey responses would be used for research purposes.

You may decide not to be in this study, or to be in the study now, and then change your mind later. You may leave the study at any time without affecting your current or future care.

Potential Benefits and Risks

You may not receive any direct benefit from being in this study. Information learned from this study may help other people with your condition in the future.

There are no additional risks to you if you take part in this study. Being in this study may make you feel uncomfortable. You may refuse to answer questions if there is any discomfort.

As a general reminder, email may not always be a secure method of communication. For this study, email is being used for general communication purposes only, and will not be used to collect/provide personal health information. If you take part in this study, please be reminded that personal information will be collected in a de-identified manner through the online survey.

Confidentiality

If you agree to join this study, the study doctor and his/her study team will look at your personal health information and collect only the information they need for the study. Personal health information is any information that could be used to identify you and includes your:

- name,
- email address,
- address,
- OHIP number, new or existing medical records, that includes types, dates and results of medical tests or procedures.

A list linking your study number with your name will be kept by the study doctor in a secure place, separate from your study file.

The information that is collected for the study will be kept in a locked and secure area by the study doctor for 10 years. Only the study team or the people or groups listed below will be allowed to look at your records.

Representatives of the University Health Network Research Ethics Board may look at the study records and at your personal health information to check that the information collected for the study is correct and to make sure the study followed proper laws and guidelines.

We are collaborating with some other programs in the country. Therefore, parts of the information you provide in your survey may be securely and anonymously shared with the research investigators from this larger study.

Please note that any information that you provide for this study in the online survey, even though de-identified, when transferred to the U.S, is subject to U.S. laws, and in particular, to the U.S. Patriot Act. The US Patriot Act allows authorities access to the records of study participants in the event of auditing by authorities.

All information collected during this study, including your personal health information, will be kept confidential and will not be shared with anyone outside the study unless required by law. You will not be named in any reports, publications, or presentations that may come from this study.

If you decide to leave the study, the information about you that was collected before you left the study will still be used. No new information will be collected without your permission.

Costs

You will not have to pay for any of the procedures involved with this study. You will not be reimbursed for completing the survey.

Conflict of Interest

Researchers have an interest in completing this study. Their interests should not influence your decision to participate in this study.

Questions About the Study

Feel free to speak to one of our staff members if you have any questions or concerns.

If you have any questions about your rights as a research participant or have concerns about this study, call the Chair of the University Health Network Research Ethics Board (UHN REB) or the Research Ethics office number at 416-581-7849. The REB is a group of people who oversee the ethical conduct of research studies. The UHN REB is not part of the study team. Everything that you discuss will be kept confidential.

CONSENT

☐ ***This study has been explained to me and any questions I had have been answered. I know that I may leave the study at any time. I agree to take part in this study.***

Date: _____

Appendix B

Study 1 Patient Survey

Cardiovascular Rehabilitation—Chronic Disease Management Program Evaluation

12 Month Follow-up Survey

Instructions for completing the survey questions appear at the beginning of each section.

Please return your completed survey in the paid-postage return envelope.

Mackenzie Health

SOUTHLAKE REGIONAL HEALTH CENTRE

UHN Toronto General Toronto Western Princess Margaret Toronto Rehab

COURAGE LIVES HERE

SECTION H: USING MEDICAL CARE

We would like to know about the health professionals you saw during **the last 12 months BECAUSE OF YOUR CARDIOVASCULAR HEALTH.** It will be easier to answer if you refer to a calendar or appointment list on which you record your appointments. If you did not keep a record, try to remember if any appointments were on or near special days, such as your birthday, or the day of a social event. Please answer the questions below by entering the number of times in the past 12 months that you have:

		Number of times
1.	Seen your family doctor	_____
2.	Seen a heart specialist	_____
3.	Gone to the Emergency Department	_____
4.	Been admitted to the hospital	_____

5. Have you experienced any of the following heart problems or procedures **in the last 12 months**? (Please check ☑ all that apply):

- ❑ Heart Attack
- ❑ Angina
- ❑ Angioplasty (stent)
- ❑ Bypass Surgery
- ❑ Valve Surgery
- ❑ Heart Failure
- ❑ Heart transplant
- ❑ Pacemaker or implantable cardioverter defibrillator
- ❑ Stroke
- ❑ Peripheral Vascular Disease
- ❑ Ablation
- ❑ Left ventricular assist device
- ❑ Other, please specify: _____
- ❑ None of the above

6. Have you experienced any of the following diagnostic tests **in the last 12 months**? (Please check ☑ all that apply):

- ❑ X-Ray
- ❑ Electrocardiogram (ECG)
- ❑ Blood test
- ❑ Urine test
- ❑ CT Scan
- ❑ Echocardiogram
- ❑ Stress Test
- ❑ Other, please specify: _____

- ❑ None of the above

7. How much **<u>of your own money</u>**, in total, did you pay for these health care visits (eg., transportation, parking, food, lodging), including the money paid by anyone who accompanied you?
   - ❑ None **OR** enter amount: $_____

8. How much time was associated with these health care visits (include travel, waiting, etc.)?

   _____hours in total

9. In the last **12 months,** who <u>USUALLY</u> accompanied you on these health care visits? Check (√) all that apply**.**
   - ❑ Nobody; I usually went by myself
   - ❑ Partner
   - ❑ Son, daughter, or grandchild
   - ❑ Sister, brother, friend, or neighbour
   - ❑ Volunteer
   - ❑ Paid homemaker or caregiver
   - ❑ Other, please specify_____

   9b. This person's age is: _____years.

   9c. This person is: ☐ Male OR ☐ Female

SECTION K: YOUR MEDICATIONS

Please record **all medications**, prescribed by a health professional or bought over-the-counter, that you used **DURING THE LAST 8 MONTHS FOR CARDIOVASCULAR HEALTH.** Include medications taken for heart disease and its problems (e.g., pain), or problems caused by treatment (e.g. loss of sexual function).

Write the dose used each time (e.g. two 5 mg pills=10 mg) and the number of times used each day. If you used it less often than once per day (e.g., an injection once every 4 weeks), please write this in the space after "Times taken/used per day". If you used more than 6 medications, please write them on the back page.
We suggest that you put the medications you have at home in front of you while you answer these questions. Remember to include herbal medicine, skin creams, drops, needles, etc., as well as pills.

- ❑ I used **NO** medications during the last 12 months.

1. Medication: _____

   Dose (each time taken/used) :_____ Times taken/used per day:_____

2. Medication: _____

   Dose (each time taken/used) :_____ Times taken/used per day:_____

3. Medication: _____

   Dose (each time taken/used) :_____ Times taken/used per day:_____

4. Medication: _____

   Dose (each time taken/used) :_____ Times taken/used per day:_____

5. Medication: _____

   Dose (each time taken/used) :_____ Times taken/used per day:_____

6. Medication: _____

   Dose (each time taken/used) :_____ Times taken/used per day:_____

7. Medication: _____

   Dose (each time taken/used) :_____ Times taken/used per day:_____

8. How much **<u>of your own money</u>** did you spend in the last **<u>12</u>** months, with **<u>no reimbursement</u>**, for **<u>all</u>** of your medications?

$ _____

Appendix C

CR Global Survey Informed Consent Form

International Council of Cardiovascular Prevention and Rehabilitation (ICCPR)

GLOBAL CARDIAC REHABILITATION PROGRAM SURVEY

Consent form

You are being asked to participate in a research study to understand the availability and characteristics of cardiac rehabilitation programs globally. You are being asked to participate because you are the most responsible clinician or administrator of a cardiac rehabilitation program.

What You Will Be Asked to Do in the Research:
If you agree to participate, you will be asked to respond to an online survey that takes about 20 minutes to complete.
Data will be collected primarily via online survey. Phone or paper administration may be possible in some instances if you do not have internet access and are willing to provide your information in this manner.

Confidentiality:
All information you supply during the research will be held in confidence, and your name will not appear in any report or publication of the research.

Your data will be safely stored. Each completed survey will only be identifiable by a unique research identification number. Electronic survey responses will be stored on a secure database. It will not be stored on any portable media. Only the research team will have access to the collected information. The Principal Investigators will destroy the data 15 years after the completion of the project: the electronic database will be deleted from the system. Confidentiality will be provided to the fullest extent possible by law.

Benefits of the Research and Benefits to You:
This research is designed to understand the availability of cardiac rehab, particularly in low- and middle-income countries where there is a growing burden of cardiovascular disease. We hope to use the findings to inform policy in international and national fora, on the status of and gaps in cardiac rehabilitation.

If you are interested, we will provide you with comparative information about the characteristics of other cardiac rehabilitation programs in your country or region. This information may be of use to you in advocating for CR services in your region.

You will not receive payment for your participation.

Risks and Discomforts:
We do not foresee any risks or discomfort from your participation in the research. You may refuse to answer any question(s) that you do not wish to answer.

Voluntary Participation:
Your participation in the study is voluntary and you may choose to stop participating at any time. Your decision not to volunteer will not influence the nature of the ongoing relationship you may have with the researchers, or study staff, or the nature of your relationship with York University of the Mayo Clinic either now, or in the future. You have the right to withdraw your consent or discontinue participation at any time without penalty.

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 Dr. Sherry Grace

This research has been reviewed and approved 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, 5th Floor, York Research Tower, York University. In addition, if you have any concerns, complaints, or general questions about research or your rights as a participant, please contact the Mayo Institutional Review Board (IRB) to speak to someone independent of the research team at 507-266-4000 or toll free at 866-273-4681.

Legal Rights and Consent:

I consent to participate in "*Global Cardiac Rehabilitation Survey: Availability and Characteristics of Programs*" conducted by Drs. Sherry Grace & Francisco Lopez. I have understood the nature of this project and wish to participate. I am not waiving any of my legal rights by completing this form. My checkmark below indicates my consent.

- ❑ I consent

Today's date: _____ (dd/mmm/yyyy)

Appendix D

Global CR Program Survey

CARDIAC REHABILITATION PROGRAM QUESTIONNAIRE

1. What is your Title/Position at the cardiac rehabilitation program? (check ✓one):
   - ☐ Director
   - ☐ Coordinator / Manager / Supervisor
   - ☐ Clinician, specify: _____
   - ☐ Other, specify: _____

SECTION A: GENERAL INFORMATION

2. In what country is your cardiac rehabilitation program? _____

3. City / Region: _____(optional)

4. Your cardiac rehabilitation program is located in an:

   - ☐ Urban area (e.g.larger cities, towns)
   - ☐ Suburban (a residential district located on the outskirts of a city)
   - ☐ Rural area or countryside (a geographic area that is located outside towns and cities).

5. In what year was your cardiac rehabilitation program initiated? _____ (year)

6. Who pays for cardiac rehabilitation ? (Check all that apply)
   - ☐ Social security / government
   - ☐ Hospital or clinical center where the cardiac rehab service is based
   - ☐ Patient (answer 6b & c)
   - ☐ Private health insurance
   - ☐ Other (specify): _____

6b. What is average percent of the total program cost that patients pay, if they complete the program?

_____ % **OR** □ I don't know

6c. What is the direct cost to patients to participate, if they complete the program?

_____ _____ **OR** □ I don't know
Amount currency

7. Is your cardiac rehabilitation program located within a hospital (check ✓one)?
   - ☐ Yes – it is in a referral centre/ quarternary / tertiary facility and / or academic centre
   - ☐ Yes – it is in a community hospital
   - ☐ Yes - it is in a rehabilitation hospital/ residential facility
     If checked: Is your CR program a spa/residential program? □ Yes □ No
   - ☐ Yes – other (please specify: _____)
   - ☐ No **(skip to question 10)**

8. **If Q7 was marked yes**, does the hospital have an inpatient cardiology service? Check one box:
   - ☐ Yes, and these patients are referred to our cardiac rehabilitation program regularly
   - ☐ Yes, and these patients are sometimes referred to our cardiac rehabilitation program
   - ☐ Yes, and these patients are rarely referred to our cardiac rehabilitation program
   - ☐ No

9. **If Q7 and Q8 were marked** yes, do they offer? (check all that apply)
   - ☐ Revascularization via percutaneous coronary intervention (PCI)
   - ☐ Coronary artery bypass graft surgery (CABG)
   - ☐ Percutaneous valve implantation
   - ☐ Implantable heart devices (pacemakers or defibrillators)
   - ☐ Cardiac transplant
   - ☐ None

10. In what department is the cardiac rehabilitation program situated administratively?
    - ☐ Cardiology department
    - ☐ Physical Medicine and Rehabilitation department
    - ☐ Internal Medicine department
    - ☐ Primary / general practice
    - ☐ It is in a community facility
    - ☐ None – it is stand-alone
    - ☐ Other (specify) :_____

11. For patients referred following a cardiac hospitalization, on average how many weeks after discharge does a patient start your program? (i.e., initial assessment appointment)

    _____ **weeks**

12. How many unique cardiac rehabilitation patients do you <u>provide service</u> to each year in your program?

    _____ **patients per year**

13. How many patients do you have <u>capacity</u> to serve each year, in terms of staff and space?
    _____ **patients per year**

14. What is the cost to your program to serve one (1) patient, if they complete the program?

_____ _____ **OR** □ I don't know
Amount currency

15. Who can refer a patient to your program? Check all that apply
- ☐ Patients can self-refer
- ☐ Physicians
- ☐ Allied healthcare providers and / or nurses
- ☐ Community health care workers
- ☐ Other, please specify: _____

16. Are there any other Cardiac Rehabilitation programs in your area? Check one box
- ☐ Yes, within approximately a 20 km radius
- ☐ Yes, but more than 20 km away
- ☐ None
- ☐ I don't know

17. Please rate the degree to which each of the following are barriers to greater patient participation in your cardiac rehab program, from "this is definitely not an issue" to "this is a major issue": Check one per row.

	This is definitely not an issue 1	This is not an issue 2	Neutral 3	This is a minor issue 4	This is a major issue 5
Lack of patient referral	○	○	○	○	○
Lack of equipment (specify:_____)	○	○	○	○	○
Lack of space	○	○	○	○	○
Lack of human resources	○	○	○	○	○
Lack of financial resources/ budget	○	○	○	○	○
Other (specify:_____)	○	○	○	○	○

SECTION B: DETAILS ABOUT YOUR CARDIAC REHABILITATION PROGRAM

18. Who has overall responsibility for cardiac rehabilitation at your program? Please check one box:
    - ☐ Cardiologist
    - ☐ Physician specialist in internal medicine
    - ☐ Physical medicine and rehabilitation (physiatrist)
    - ☐ Physician, other specialty (please specify: _____)
    - ☐ Nurse
    - ☐ Exercise physiologist
    - ☐ Physiotherapist
    - ☐ Other (specify)_____

19. How expensive are the following aspects of delivering your cardiac rehab program? (check one box per row)

	Free	Only a minor cost	Costs a bit	costs quite a bit	Very expensive	Not applicable as we do not have this
a. Front-line personnel						
b. Space						
c. Exercise equipment						
d. Equipment / supplies for cardiovascular risk assessment (not including exercise stress tests)						
e. Exercise stress testing on a treadmill or cycle ergometer						
f. Patient education materials						
g. Blood pressure assessment device						
h. Blood collection and lipid testing						
i. Free weights etc. for resistance training						

20. Which of the following components of cardiac rehabilitation are provided in your program? If they are provided, are they provided in all the models you deliver? (i.e., supervised and home-based programs)?

Please check one box per row. If you only offer one model of rehabilitation and you offer the listed component, please check "yes, in all models".

	Yes In all models	**Yes For some models**	**No**
Initial assessment			
Individual consultation with a physician			
Individual consultation with a nurse			
Exercise stress test			
Other functional capacity test (please specify: _____)			
Assessment of strength (e.g., handgrip)			
Assessment for comorbities / issues that could impact exercise (e.g., cognition, vision, musculoskeletal / mobility issues, frailty, and / or balance / falls risk)			
Exercise prescription			
Physical activity counseling			
Supervised exercise training			
Heart rate measurement training for patients			
Resistance training			
Management of cardiovascular risk factors			
Prescription and/or titration of secondary prevention medications			
Nutrition counseling			
Depression screening			
Psychological counseling			
Smoking cessation sessions/classes			
Vocational counseling / support for return-to-work			
Stress management / Relaxation techniques			
Alternative forms of exercise, such as yoga, dance, or tai chi (please specify: _____)			
Women-only classes			
End of program re-assessment			
Electronic patient charting			
Communication of patient assessment results with their primary care provider			
Follow-up after oupatient program			
Other (please specify): _____			

21. How many education sessions are provided to each patient in your program? _____ (enter zero if none)

22. How many minutes on average is each education session? _____ minutes (enter zero if none)

23. In your program, do you assess the following risk factors? Please check one box per row.

	Yes	**No**
Time spent being sedentary		
Tobacco use		
Harmful use of alcohol		
Blood pressure		
Body mass Index		
Waist circumference		
Hip circumference		
Body composition		
Total Cholesterol		
Cholesterol fractions (HDL-c, LDL-c)		
Triglycerides		
HbA1c for diabetic patients		
Blood glucose for non-diabetic patients		
Sleep apnea		
Depression / Anxiety		
Physical inactivity		
Poor diet		
Other (please specify:_____)		

24. Which types of personnel are part of your cardiovascular rehabilitation (CR) team? If they are part of your team, do they work in Cardiac Rehabilitation only, or do they have other department obligations? (Check one box in each row):

a. Cardiologist Yes- only CR ( ) Yes- partial ( ) No ( )

b. Physiatrist (Physical medicine and rehabilitation) Yes- only CR ( )Yes- partial ( ) No ( )
c. Sports Medicine Physician Yes- only CR ( ) Yes- partial ( ) No ( )
d. Other Physician (specify:_____)Yes- only CR ( ) Yes- partial ( ) No ( )
e. Physiotherapist Yes- only CR ( ) Yes- partial ( ) No ( )
f. Nurse Yes- only CR ( ) Yes- partial ( ) No ( )
g. Nurse practitioner Yes- only CR ( ) Yes- partial ( ) No ( )
h. Psychiatrist Yes- only CR ( ) Yes- partial ( ) No ( )
i. Psychologist Yes- only CR ( ) Yes- partial ( ) No ( )
j. Social worker Yes- only CR ( ) Yes- partial ( ) No ( )
k. Dietitian Yes- only CR ( ) Yes- partial ( ) No ( )
l. Kinesiologist Yes- only CR ( ) Yes- partial ( ) No ( )
m. Pharmacist Yes- only CR ( ) Yes- partial ( ) No ( )
n. Exercise specialist Yes- only CR ( ) Yes- partial ( ) No ( )
o. Community Health worker Yes- only CR ( ) Yes- partial ( ) No ( )
p. Administrative assistant/ Secretary Yes- only CR ( ) Yes- partial ( ) No ( )
q. Other (specify): _____ Yes- only CR ( ) Yes- partial ( ) No ( )

25. Do all your clinical staff supervising patients during exercise sessions have cardiopulmonary resuscitation (CPR) training / certification?

☐ Yes
☐ No (skip to question 26)

25b. If yes, are they required to renew their CPR training regularly?

☐ Yes
☐ No

25c. If yes, is the CPR certification advanced or basic? (circle one per row)

Physicians:	Advanced	Basic
Nurses:	Advanced	Basic
Other:	Advanced	Basic

26. Does your program have each of the following ítems, and if yes, is its' use dedicated to your program or shared with another group (circle one option in each row)?

Bicycle ergometer	Dedicated	Shared	Not available
Treadmill ergometer	Dedicated	Shared	Not available
Arm cycloergomenter	Dedicated	Shared	Not available
Doppler Echocardiography	Dedicated	Shared	Not available
Stress test (no O_2)	Dedicated	Shared	Not available
Stress test with O2	Dedicated	Shared	Not available
Telemetry	Dedicated	Shared	Not available
Group education room	Dedicated	Shared	Not available
Gym space	Dedicated	Shared	Not available
Individual assessment/ Counselling room	Dedicated	Shared	Not available
Patient change room	Dedicated	Shared	Not available
Administrative office	Dedicated	Shared	Not available
Electronic patient charts	Dedicated	Shared	Not available
Resistance training equipment	Dedicated	Shared	Not available
Body composition analyzer	Dedicated	Shared	Not available
Staff meeting room	Dedicated	Shared	Not available
Staff office space	Dedicated	Shared	Not available
Other (specify):	Dedicated	Shared	Not available

27. Does your site offer a supervised Cardiac Rehabilitation program?

☐ Yes
☐ No (skip to section D)

SECTION C: CARDIAC REHABILITATION – Supervised Program

28. Which of the following cardiac diagnoses or indications do you accept for your supervised program? (Check all that apply)
    - ☐ Post Myocardial Infarction / acute coronary syndrome
    - ☐ Stable coronary artery disease, without a recent event or procedure
    - ☐ Post percutaneous coronary intervention (PCI)
    - ☐ Post coronary artery bypass graft surgery (CABG)
    - ☐ Heart failure
    - ☐ Patients who have had valve surgery/repair or transcatheter aortic valve implantation (TAVI)
    - ☐ Heart transplant
    - ☐ Patients with ventricular assist devices
    - ☐ Arrhythmias (hemodynamically-stable)
    - ☐ Patients with implanted devices for rhythm control (i.e., ICD / CRT, pacemaker)
    - ☐ Congenital heart disease
    - ☐ Cardiomyopathy
    - ☐ Rheumatic heart disease
    - ☐ Patients at high-risk of cardiovascular disease (primary prevention)
    - ☐ Non-cardiac chronic diseases
    - ☐ Other (specify): _____

29. Which of the following non-cardiac diagnoses or indications do you accept for your on-site program? (Check all that apply)
    - ☐ Stroke
    - ☐ Intermittent claudication / peripheral vascular disease
    - ☐ Cancer
    - ☐ Diabetes
    - ☐ Chronic lung disease
    - ☐ None
    - ☐ Other (specify): _____

30. Which of the following patient levels of cardiac risk do you accept for your supervised program? (Check all that apply)
    - ☐ Low
    - ☐ Moderate
    - ☐ High
    - ☐ Not applicable because we do not risk stratify at our program

31. Do patients have an individual consult with a physician during the program?
    - ☐ Yes, please specify # times in a full program: _____
    - ☐ No

32. What is the standard duration of the on-site cardiac rehabilitation program that you provide to patients?

_____ weeks

33. On average, for how many sessions do patients come on-site each week?

_____ sessions per week OR _____ sessions / day (residential programs)

34. On average, how many patients are in each exercise session?

_____ patients / session

35. On average, how long is each exercise session (including warm up, aerobic exercise, strength training and/ or cold down)?

_____ minutes / session

36. What is the maximum number of patients that your program allows in the same exercise session?

_____ patients / session

37. What is the staff to patient ratio during supervised exercise at your program? _____:_____ patients

38. Which healthcare professionals are usually present during exercise sessions? (Check one box in each row)

a.	Cardiologist	Yes ( ) No ( )
b.	Physiatrist (Physical Medicine and Rehabilitation)	Yes ( ) No ( )
c.	Sports Medicine Physician	Yes ( ) No ( )
d.	Other Physician (specify:_____)	Yes ( ) No ( )
e.	Physiotherapist	Yes ( ) No ( )
f.	Nurse	Yes ( ) No ( )
g.	Nurse practitioner	Yes ( ) No ( )
h.	Psychiatrist	Yes ( ) No ( )
i.	Psychologist	Yes ( ) No ( )
j.	Social worker	Yes ( ) No ( )
k.	Dietitian	Yes ( ) No ( )
l.	Kinesiologist	Yes ( ) No ( )
m.	Pharmacist	Yes ( ) No ( )
n.	Exercise specialist	Yes ( ) No ( )
o.	Community health worker	Yes ( ) No ( )
p.	Other (specify): _____	

39. Does the supervised program offer telemetry or another method of monitoring patients' clinical status while exercising? (check all that apply)
    - ☐ Yes, telemetry
    - ☐ Yes, other method of monitoring; please specify:
        - ☐ Borg scale (perceived exertion)
        - ☐ Heart rate
        - ☐ Other: _____
    - ☐ None

Appendix E

ECO-PCR Informed Consent Form

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title:	**Ecologically Optimizing Exercise Maintenance in Men and Women Following Cardiac Rehabilitation: A Randomized Controlled Trial of Efficacy with Economics**
Principal Investigators:	**Dr. Robert Reid, PhD MBA (Ottawa)** **Sherry L. Grace, PhD (Toronto)**
Sponsor	**Heart and Stroke Foundation of Ontario**

Introduction

You are being asked to take part in a research study. Please read this explanation about the study and its risks and benefits before you decide if you would like to take part. You should take as much time as you need to make your decision. You should ask the study doctor or study staff to explain anything that you do not understand and make sure that all of your questions have been answered before signing this consent form. Before you make your decision, feel free to talk about this study with anyone you wish. Participation in this study is voluntary.

Background and Purpose

Physical activity is an important contributor to fitness for patients with heart disease. Canadian guidelines recommend 30-60 minutes of moderate to vigorous physical activity most, preferably, all days of the week.

Participation in an outpatient cardiac rehabilitation program is the usual first step toward developing an exercising lifestyle after a heart problem is diagnosed. About 70-85% of people report achieving recommended guidelines for physical activity during the time they are participating in cardiac rehab. Unfortunately, these levels of physical activity are often not maintained after participation in the program ends.

You have been asked to take part in this research study because you have graduated from a supervised cardiac rehabilitation program at the University Health Network (Toronto Western Hospital or Toronto Rehabilitation Institute).

We have developed a new intervention to promote the continuation of exercise following cardiac rehab. It incorporates an exercise "facilitator" to transition patients from structured, supervised exercise to home walking or approved community-based exercise programs (also known as Heart Wise Exercise Programs).

This research study will examine whether the facilitator intervention is related to more exercise maintenance over the year following cardiac rehab, which elements of the process affected your exercise, your clinical profile, and the cost of in the intervention, including whether patients are less likely to use the healthcare system.

About 604 people from Ottawa and Toronto will be in the study. About 169 people will come from the University Health Network (Toronto Western Hospital and the Toronto Rehabilitation Institute cardiac rehab programs).

Study Design

This study is a one and a half year study that that will compare an intervention group (exercise facilitator) with a control group (usual care). Whether you assigned to the intervention or the control group will be decided randomly (by chance) like flipping a coin or rolling dice. The number of people getting study intervention will be 302 and the number of people in the control group will be 302.

Study Procedures

Questionnaires

You will be asked to complete four (4) survey questionnaires: one at the beginning of the study, one at 26 weeks (6 months), one at 52 weeks (1 year) and one at 78 week (1.5 years). The questionnaires will ask you about your demographics (age, gender, education), lifestyle (exercise behaviours, cardiac risk factors, medications), as well as questions about your health and emotional well-being. Completion of the questionnaires will require approximately 45 minutes of your time.

Intervention Group

Participants in the intervention group will receive five small group counselling teleconferences, be invited to multiple community exercise program demonstrations, and three personal telephone calls from a trained exercise facilitator over a 50-week (almost 1 year) intervention period.

- Small group teleconferences will take place in study weeks: 3, 13, 26, 39 and 50. These sessions are 20 minutes long.
- Personal (individual phone calls) will take place in study weeks: 20, 34 and 45. These

sessions are 15 minutes long.
- A random sub-sample of these calls would be audio-taped with your permission so we can audit the consistency of the session content the facilitator is providing.
- The above activities will actively explore and review your exercise behaviours and barriers.

Usual Care Group

The usual care group will receive the usual exercise advice provided to patients exiting cardiac rehabilitation at the study centers. Patients in both programs are provided with an updated exercise prescription and a home-based walking program prior to program completion and exercise maintenance strategies are reviewed with program exercise staff. There is no further patient contact after program completion at either program.

Follow up

Participants in both groups will have their follow-up continue through to 78 weeks (1.5 years later).

- Results from your exit assessments will be collected from your cardiac rehab charts.
- Measures will be taken at 26 weeks (6 months), 52 weeks (1 year) and 78 weeks (1.5 years) after randomization.
    - You will be asked to come on site for these assessments, and complete a survey measuring your thoughts and feelings about exercise. It will take approximately 45 minutes to complete.
    - In order to measure your health, we would also like to test your blood pressure and measure your waist.
    - You will be asked wear an accelerometer device to measure your physical activity for 9 days. You will be provided with a pre-paid addressed envelope to return the accelerometer.
- All patients will be asked to do a physician-supervised, symptom-limited cardiopulmonary test at the 1-year assessment. Cardiac rehab graduates from the Toronto Rehabilitation Institute program are asked to do this as a standard part of the program, so if this information is available we would simply want to get the results.

As part of the study, we will review your medical records to obtain information about your diagnosis and your medical history, including the nature of your cardiac problem, heart history and medications. We will also collect the information obtained as part of your rehab program, which includes test results, blood pressure and waist measurements, cholesterol levels, as well as your participation level and dates of attendance.

Economic Measures

Finally, we would also like permission to link your information gathered from this program with a provincial database to determine your health care use and health outcomes over time. This would not require any paperwork on your behalf.

<u>Reminders</u>

While you are in this study you should continue with everything your family doctor or cardiac specialist has recommended. You will still receive your usual care from your family doctor and cardiac specialist. You do not have to stop or change anything.

Potential Risks and Benefits

It is very unlikely that participation in this research study will result in any side effects. The Cardiopulmonary stress test will require you to walk (starting at a low level with the speed and grade slowly increasing throughout the test) on a treadmill with electrodes on your chest in order to see how the heart works during exercise. It will help us measure your heart minimal and maximal exercise capacity. This test is based on your own efforts and you can stop at any time throughout the procedure. There will be a full medical staff supervising the stress test.

You will be revealing personal information about yourself; however this information will remain private.

Benefits to Being in the Study

You may receive direct benefit from being in this study by receiving further support to maintain exercise. Your participation will also help us improve the care of future cardiac patients following cardiac rehab participation.

Voluntary Participation

Your participation in this study is voluntary. You may decide not to be in this study, or to be in the study now, and then change your mind later. You may leave the study at any time without affecting your care. You may refuse to answer any question you do not want to answer.

We will give you new information that is learned during the study that might affect your decision to stay in the study.

Confidentiality

If you agree to join this study, the study doctor and his/her study team will look at your personal health information and collect only the information they need for the study. Personal health information is any information that could be used to identify you and includes your:

- name
- address
- email address
- OHIP number
- new or existing medical records (including types, dates and results of medical tests or procedures)

The information that is collected for the study will be kept in a locked and secure area by the

study doctor for 10 years. Only the study team or the people or groups listed below will be allowed to look at your records. Your participation in this study also may be recorded in your medical record at this hospital.

The following people may come to the hospital to look at the study records and at your personal health information to check that the information collected for the study is correct and to make sure the study followed proper laws and guidelines:

- Representatives of the study organizing committee.
- University Health Network Research Ethics Board.

All information collected during this study, including your personal health information, will be kept confidential and will not be shared with anyone outside the study unless required by law. Any information about you that is sent out of the hospital will have a code and will not show your name or address, or any information that directly identifies you. You will not be named in any reports, publications, or presentations that may come from this study.

If you decide to leave the study, the information about you that was collected before you left the study will still be used. No new information will be collected without your permission.

In Case You Are Harmed in the Study

If you become ill, injured or harmed as a result of taking part in this study, you will receive care. The reasonable costs of such care will be covered for any injury, illness or harm that is directly a result of being in this study. In no way does signing this consent form waive your legal rights nor does it relieve the investigators, sponsors or involved institutions from their legal and professional responsibilities. You do not give up any of your legal rights by signing this consent form.

Expenses Associated with Participating in the Study

You will not have to pay for any of the procedures (i.e. stress test) involved with this study. You will be reimbursed for your parking costs for your 4 on-site visits to complete study assessments (initial, 26, 52 and 78 weeks). You will not be paid for participation in this study.

Questions About the Study

If you have any questions, concerns or would like to speak to the study team for any reason, please call: Sherry Grace, PhD at 416-603-5800 x. 3495# or the Study Coordinator at 416-736-2100 x20575.

If you have any questions about your rights as a research participant or have concerns about this study, call the Chair of the University Health Network Research Ethics Board (REB) at 416-581-7849 or please call the Toronto Rehab Research Ethics Board Office at (416) 597-3422

x 3081.The REB is a group of people who oversee the ethical conduct of research studies. These people are not part of the study team. Everything that you discuss will be kept confidential.

Consent

This study has been explained to me and any questions I had have been answered. I know that I may leave the study at any time. I agree to take part in this study.

Print Study Participant's Name	Signature	Date

(You will be given a signed copy of this consent form)

My signature means that I have explained the study to the participant named above. I have answered all questions.

Print Name of Person Obtaining Consent	Signature	Date

Appendix F

ECO-PCR Intervention

Intro Session w/ Facilitator ***(face to face)***	• Oriented to program • Exercise Journal • Pedometer • Online tools/apps   
5 Group & 3 Personal telephone calls	• Exercise Plan • Barriers • Successes • Strategies • Motivation 
HWE Demonstrations ***(optional)***	• Pt picks convenient location • Intro to HWE • Review of programs offered • Exercise plan • Equipment demos