



International Council of Cardiovascular Prevention and Rehabilitation (ICCP)

A GLOBAL, TECHNICAL REPORT ON ADVOCACY AND LOBBYING FOR OUTPATIENT CARDIAC REHABILITATION

2016

Endorsed by:

Babu AS, Lopez-Jimenez F, Wanrudeee I, Herdy A, Thomas R, Hoch J, Grace SL in conjunction with the International Council of Cardiovascular Prevention and Rehabilitation (ICCP).

A global, technical report on advocacy and lobbying for outpatient cardiac rehabilitation

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List of abbreviations

AACVPR	American Association of Cardiovascular and Pulmonary Rehabilitation
AHA	American Heart Association
CABG	Coronary artery bypass graft
CEA	Cost-effectiveness analyses
CR	Cardiac rehabilitation
CRRC	CR Research Centre
CVD	Cardiovascular disease
DALY	Disability-adjusted life years
EU	European Union
ICCP	International Council of Cardiovascular Prevention and Rehabilitation
LMIC	Low and middle-income countries
MOH	Ministry of Health
NHS	National Health Service
NICE	National Institute for Health Care Excellence
PCI	Percutaneous coronary intervention
QACPR	Qatar Association for Cardiovascular Prevention and Rehabilitation
QALY	Quality-adjusted life years
UK	United Kingdom
WHF	World Heart Federation
WHO	World Health Organization

SECTION 1: INTRODUCTION

Cardiac rehabilitation (CR) is an outpatient chronic disease management program for the secondary prevention of cardiovascular disease (CVD). The World Health Organization (WHO) has defined CR as the “sum of activities required to influence favorably the underlying cause of the disease, as well as the best possible physical, mental and social conditions, so that they may by their own efforts, preserve or resume when lost, as normal a place as possible in the society. CR cannot be regarded as an isolated form of therapy, but must be integrated within the entire continuum of treatment”.¹ In 2007, the American Heart Association (AHA) first described the core components of CR.² They include baseline patient assessment, nutritional counseling, risk factor modification, psychosocial interventions, physical activity counseling and exercise training. These components are generally common across the major CR associations internationally.²⁻⁶

Unfortunately, CR services are grossly under-utilized around the globe.⁷ While the reasons are multi-factorial, arguably the chief reason is lack of service reimbursement. Accordingly, the International Council of Cardiovascular Prevention and Rehabilitation (ICCP; www.globalcardiacrehab.com; Figure 1) hence set out to develop a resource for CR professionals and associations to advocate for reimbursement of CR services. Herein, the case for the need for CR is first forwarded, in terms of the burden of CVD internationally. Second, the health and economic impact of CVD is described. Third, the benefits of CR are summarized, including cost-effectiveness. These elements provide the rationale to advocate for CR services.

Next, the availability and use of CR globally is described, to demonstrate how under-utilized CR is. This is juxtaposed against the paradoxically higher utilization of more costly acute cardiac therapies. This is followed by a summary of results of a survey undertaken regarding CR coverage by government and insurance companies in various regions of the globe. Then, the role of CR associations in advocating for CR reimbursement is outlined. Finally, suggestions for advocating for CR reimbursement are provided. This is followed by 4 “success stories” where CR reimbursement has been achieved. A toolkit accompanies this report.

SECTION 2: BURDEN AND IMPACT OF CARDIOVASCULAR DISEASE

CVD is the most prevalent non-communicable disease globally. In 2010, an estimated 111.7 million individuals—that is 1.62% of the total world’s population—had angina due to ischemic heart disease, as reported in the Global Burden of Disease Study.⁸ According to the World Economic Forum, also in 2010, 62.5 million new cases of CVD were reported, of which 24.2 million were attributed to ischemic heart disease.⁹ Moreover, the burden of CVD is growing, particularly in low and middle-income countries (LMICs). By 2030, it is expected there will be 84 million individuals diagnosed with CVD, of whom up to 32.3 million will have ischemic heart disease.⁴

CVD is the leading cause of death globally¹⁰, of which, more than 80% of these occur in LMICs.¹¹ By 2030, 23 million people per year are predicted to die from CVD.⁹ Patients with established CVD have a high risk of adverse cardiovascular events, such as fatal and non-fatal myocardial infarction.¹² Consequently, CVD is also the leading cause of disability,¹³ accounting for 10% of disability-adjusted life years (DALYs) lost worldwide, 10% of DALYs lost in LMICs, and 18% of DALYs lost in high-income countries.¹⁴ Worldwide, 47 million DALYs were lost in 1990 due to coronary heart disease, a figure that is expected to rise to 82 million DALYs by 2020.¹⁴ Readers are referred to the Global Atlas of CVD Prevention and Control for further details on this burden in their respective regions.¹⁰

ECONOMIC BURDEN OF CVD

In addition to the impact of CVD on clinical and individual outcomes, CVD is associated with significant economic burden in many countries around the globe. The follow summarizes

the economic impact of CVD in the European Union (EU), the Russian Federation, the United States (US), Canada and in LMICs.

In the EU, in addition to being a main source of morbidity and mortality, CVD was estimated to cost the EU €169 billion annually in 2003 dollars.¹⁵ CVD accounted for over 126 million hospital bed days in the EU (or 277 hospital bed days per 1000 population), and represented an annual healthcare cost of €230 per EU citizen. Additionally, CVD was estimated to cost the EU €29 billion in informal care costs and €10.8 billion in productivity costs. These estimates varied significantly between countries. In this analysis, EU included Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, The Netherlands, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, and the United Kingdom (UK). Specifically, in the Russian Federation, CVD was estimated to cost approximately €24 billion in 2009. Of the total costs, about 21% were due to health care, and the remaining were due to indirect costs.¹⁶

In the US, CVD also accounts for a large share of total spending.¹⁷ The average annual cost per person with heart disease that is attributable to heart disease is \$4,734 (2005 US dollars). Medicare has the highest average costs per person among the three payers (Medicare, Medicaid, and Private Insurance). In the absence of CVD, annual medical expenditures could be reduced by approximately 17% or \$149 billion. By 2030, 40.5% of the US population is projected to have some form of CVD and total direct costs of CVD are projected to reach more than \$800 billion in 2008 US dollars (from \$273 billion in 2010).¹⁸ The indirect costs due to productivity loss are estimated to increase to \$276 billion in 2030.

In Canada, CVD is one of the top five illnesses with the highest total costs, and was associated with an economic burden of approximately USD \$12 billion. Approximately half of the burden was associated with hospital care, and the rest was for drug and physician care. Focusing on only direct cost (e.g., costs associated with hospital inpatient care, outpatient physician visits, and medications), CVD has the highest total costs of any health condition.

In the LMIC setting, CVD is also considered a significant problem.^{19, 20} Using economic growth models, which assess the effect of chronic diseases on national income, the estimated losses because of coronary heart disease, stroke, and diabetes ranged from \$20-30 million in Ethiopia and Vietnam to almost \$1 billion in larger countries such as India and China. In the scenario with no support to reduce risk of chronic diseases, an estimated \$84 billion of national income (US dollars) will be lost to heart disease, stroke, and diabetes alone in 23 selected countries between 2006 and 2015. The 23 selected countries included China, India, Russia, Brazil, Indonesia, Mexico, Turkey, Pakistan, Thailand, Bangladesh, Ukraine, Egypt, Argentina, Burma, Iran, Poland, South Africa, Philippines, Colombia, Vietnam, Nigeria, Ethiopia, and Democratic Republic of the Congo.

ECONOMIC IMPACT OF CVD ON THE PRIVATE SECTOR AND INDIVIDUALS

CVD impacts both the public and private sectors economically. For example, the impact of CVD on productivity loss influences individuals, regardless of whether they work in the private or public sectors. Furthermore, the impact of CVD on health care cost is considerable;

however, the structure of the health care system in each country will determine whether the impact of CVD health care costs will be incurred by the private or public sector.

From an individual's perspective, CVD may pose as an economic burden. Care costs can be catastrophic where patients do not have healthcare coverage. As previously stated, CVD is the leading cause of disability, which could significantly influence individuals both clinically and economically. With disability, individuals may require extra support in daily activities. Individuals may require financial support if their productivity decreases because of CVD (i.e., inability to work).

SECTION 3: CARDIAC REHABILITATION AND ITS ASSOCIATED HEALTH OUTCOMES IN THE SECONDARY PREVENTION OF CARDIOVASCULAR DISEASES

Over the past three decades, considerable evidence on the benefits of CR for patients with CVD in high-income countries has mounted. Documented benefits of CR are based on findings of 8 meta-analyses of randomized clinical trials, where outcomes among CR participants are compared with participants exposed only to usual care.²¹⁻²⁶ These have shown participation in CR reduces mortality and morbidity, promotes a healthy lifestyle, favourably modifies risk factors, and improves quality of life.²⁷

MORTALITY AND MORBIDITY

These previous meta-analyses have demonstrated that CR significantly reduced all-cause mortality by 13%-26% and cardiac mortality by 20%-36% among patients with CVD.²⁷ Further, a recent overview of six CR meta-analyses showed that participation in CR reduces all-cause mortality by a mean of 19%, and cardiac mortality by a mean of 20%.²⁸ In a recent observational study of 601,099 American Medicare beneficiaries enrolled in CR, five-year all-cause mortality rates were reduced by 21%-34%.²⁹

With regard to fatal and/or non-fatal myocardial re-infarction, there was a significant decrease by 25%-47% with CR.²⁷ The recent overview of 6 meta-analyses showed that CR reduced re-infarction by a mean of 15%, and hospitalization by a mean of 31%.²⁸ An even more recent Cochrane overview of 6 CR Cochrane reviews concluded that compared to usual care alone, the addition of CR participation is related to significantly reduced hospital readmissions,

even in low-risk patients post-myocardial infarction, percutaneous intervention or with heart failure.³⁰

CR-ASSOCIATED OUTCOMES IN LMICS

With respect to information from LMICs, there are 3 RCTs^{31, 32, 33, 34} and 8 primary studies from LMICs on CR benefits published in the English-language.²⁷ These studies show that participation in CR is associated with significant reductions in triglycerides,^{31, 35, 36} total cholesterol,^{31, 35, 36} low-density lipoprotein,^{31, 36, 37} body mass index,³⁶⁻³⁸ as well as systolic^{31, 37} and diastolic blood pressure.³¹ CR is also associated with significant increases in high-density lipoprotein.^{36, 37} Additionally, some studies revealed significant improvements in health-related quality of life, self-efficacy,³⁸⁻⁴¹ self-regulation³⁸ and functional capacity.^{36, 37, 41}

Based on these benefits, CR is recommended in clinical practice guidelines for cardiac patients by learned medical societies around the globe. This includes American, European and World Health Organization¹ guidelines and statements.^{1, 42, 43} For example with regard to the former country specifically, referral is advocated for the following cardiac patients as a Class I, Level A or B recommendation: myocardial infarction (ST-elevation non-ST elevation),⁴⁴ chronic stable angina / ischemic heart disease,⁴⁵ heart failure,⁴⁶ following percutaneous coronary intervention,⁴⁷ coronary artery bypass graft surgery.⁴⁸

SECTION 3: CARDIAC REHABILITATION AND COST BENEFITS

The basic principles of cost-effectiveness analyses (CEA) are described in Appendix A. Numerous studies have assessed the cost-effectiveness of CR. For the purpose of this document, the following information refers to CEA comparing CR versus no CR, and will not include comparisons between different types of CR or different settings.

CR has consistently shown to be either cost-saving or to be cost-effective regardless of the country where it was performed, the perspective used, the costs included, and the year when it was performed. European studies have demonstrated that CR may be a cost-saving intervention.⁴⁹ A CEA using pooled data from randomized clinical trials and cohorts demonstrated that CR would cost \$4,950 per year of life saved.⁵⁰ Systematic reviews of all the available evidence show savings of \$12,000/CR patient over five years, to \$9,200 per QALY.⁵¹ To put this in perspective, Table 1 shows cost-effectiveness values for common treatments and procedures for the secondary prevention of CVD.

Table 1. Cost-effectiveness estimations for different interventions in patients with coronary artery disease.

Author (year)	Intervention	Patient population	Estimated savings
Ades et al. (1997) ⁵⁰	CR versus with other post-MI treatment interventions	Post MI or revascularization	CR was found to result in savings of 2,130 \$/YLS in 1980, which was projected to be 4,950 \$/YLS for 1995
Cleland et al. (1997) ⁵²	CABG + Medical therapy + aspirin versus CABG + medical therapy + aspirin + statin versus medical+aspirin+statin versus medical + aspirin	Chronic stable angina	\$36,709, \$55,156 and \$23,730 per QALY for each comparison over 5 years
Johannesson et al. (1997) ⁵³	Statins (i.e., Simvastatin) versus no statins	Angina or MI	Simvastatin use resulted in \$3,800 to \$27,400 cost per year of life gained
Chan et al. (2007) ⁵⁴	High intensity versus low intensity statin	Acute coronary syndrome, Chronic coronary disease	From \$20,000 to \$35,000 if cost difference of statins is between \$2 and \$3.50 From \$70,000 to \$125,000 if cost difference of statins is between \$2 and \$3.50
Dendale et al. (2008) ⁵⁵	CR versus no CR	Post PCI	Reduction in total health care costs with CR (€4,862/patient versus €5,498 Euro/patient)
Weinbraub et al. (2008) ⁵⁶	PCI and medical therapy versus Medical therapy alone	Stable angina	\$168,000 to \$300,000 per QALY gained with PCI
Wilson et al (2012) ⁵⁷	Smoking cessation with varenicline plus counseling versus counseling only	CVD	Savings ranging from €5151 - €6120 per QALY gained
Smith et al. (2013) ⁵⁸	Implantable cardiac defibrillator versus no defibrillator	Primary prevention of sudden death in	€43,993 per QALY gained compared to no defibrillator

		patients with left ventricular ejection fraction <40% (ischemic and non-ischemic)	
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Because CR has been demonstrated to decrease total mortality, cardiovascular mortality, cardiovascular events, procedures, and re-hospitalizations, and has shown to improve quality of life, the denominator in the cost-effectiveness equation is generally as good, or better, than many other cardiovascular interventions. Those values are presumably stable across countries and geographic regions, as the benefit of CR is expected to be similar (as long as the CR program is of good quality and similar to the programs used in the primary studies). In contrary, the cost component of a CEA for CR will vary from country to country, because the cost of major components of CR can be significantly different across geographic regions. For example, major components of CR like the salary for nurses, physicians, and other healthcare providers are significantly higher in high-income countries when compared to LMICs. Likewise, costs related to use of physical space and other costs related to the overall expenses of CR can also be significantly higher in a high-income country. Therefore, as the measure of effectiveness is expected to be similar but costs are expected to be lower in LMIC, it is safe to assume that the estimates of cost-effectiveness for CR will probably be more favorable in LMIC. For example, if the overall cost of CR in a LMIC is only one-half of the total cost in a high-income country, the already favorable estimates for cost-effectiveness may actually become cost-saving. This suggests that not providing CR might actually be more expensive to payers and to

society than providing CR. This can occur because the lack of a medical intervention (i.e., CR) meant to prevent adverse events and procedures would lead to major expenses, making the lack of CR more expensive than offering CR itself.

SECTION 4: AVAILABILITY AND UTILIZATION OF CARDIAC REHABILITATION

CR is grossly under-used. The reasons are multi-factorial and include low availability of programs, low rates of physician referral, and most centrally to this report, low reimbursement for CR services. With regard to the former, CR is available in only 38.8% countries worldwide: 68.0% of high-income, 28.2% of middle-income and 8.3% of low-income countries.⁷

Where CR programs are available, it has been seen that most, if not all countries have insufficient capacity to treat indicated patients.⁷ The number of CR programs per inhabitant (referred to as CR density), is a crude estimate of the number of patients who might have access to CR in each country.⁵⁹ Based on national and regional surveys in high-income countries, CR density ranges from one program per 100,000 to one program per 300,000 inhabitants.⁶⁰⁻⁶² In middle-income countries, CR density ranges from 0.9 to 6.4 million inhabitants per program.⁶⁰

REFERRAL AND UTILIZATION PATTERNS

In many countries, referral is required for patients to access CR. In high-income countries, low or no physician referral to CR is a key barrier to patients enrolling in a program. In their review, Turk-Adawi et al. reported a range of referral rates from 25-81% in population-based studies,⁶³ however targets have been set at 85%.⁶⁴

In LMICs, referral rates are even lower. For example, in a survey undertaken in Iran, cardiologists reported that <15% of patients are referred.⁶⁵ In a review on CR in Brazil, low CR referral was reported as a barrier to enrolment.⁶⁶ In several middle-income countries of Europe,

CR 'advice' in the EUROASPIRE III survey was reported to range from 7.3% in Turkey to 57.0% in Hungary.⁶⁷

Accordingly, participation in CR is also low. Less than half of eligible patients participate in CR programs in the majority of HICs.^{29, 67, 68} The EUROASPIRE III Survey showed that only 36.5% of the 8,845 patients eligible for CR from 22 European countries (19 of which were high-income) attended the program.⁶⁷ The participation rates were as low as <1% in Greece and Spain and as high as 86.4% in Lithuania (although there may be an error in this estimate). Notably, participation rates >50% were reported in only six (19.4%) of the 31 countries with available data. Findings from the European CR Inventory Survey revealed that CR enrolment rates >50% were seen in only 3 (10.7%) countries while rates <30% were reported in 15 (53.6%) of the 28 countries.⁶⁹ In the United States, the largest study ever on CR utilization among 601,099 Medicare beneficiaries eligible for CR demonstrated that only 12.2% of this cohort participated.²⁹ This contrasts sharply with the target CR participation rate of 70%.⁶⁴

CR in middle-income countries is also under-utilized. The international STABILITY study that included 15 middle-income countries revealed participation rates were <30% in 10 (66.6%) of the 15 included countries.⁷⁰ This rate is likely an over-estimation because CR participation was self-reported. Other available data on CR participation were reviewed by Turk-Adawi et al.,²⁷ and revealed rates range from 3%-89%.

DISCREPANCY BETWEEN AVAILABILITY OF ACUTE VS CHRONIC CVD THERAPIES

The WHO states that CR should be an integral component of the long-term, comprehensive care of cardiac patients.¹ However, in high-income countries, governments allocate more resources to acute CVD treatment than less expensive, long-term disease management strategies, such as CR.^{71, 72} For example, in a national survey, only 6.5% of 1,059 surveyed hospitals in Japan were approved for reimbursement of CR services by the health insurance system. Contrarily, 61.8% and 58.8% of hospitals in Japan implement coronary angiography and percutaneous coronary intervention (PCI), respectively, following myocardial infarction.⁷¹

While acute revascularization strategies such as coronary artery bypass graft (CABG) surgery and PCI confer benefit for patients, CR is similarly considered a Class IA indication in clinical practice guidelines (i.e., the treatment is useful and effective).^{47, 48, 73} CABG surgery reduces mortality by 39% (OR 0.61, 95% CI 0.48–0.77) at 5-year follow-up⁷⁴ and PCI by 20% (OR 0.80, 95% CI 0.64–0.99) at an average of 4-year follow-up.⁷⁵ In a review of 34 trials, CR had comparable mortality reductions to the invasive procedures of 26%, over 3 months to 5-year follow-up (OR 0.74, 95% CI 0.58–0.95).²⁶ Moreover, in a study conducted in the US, out of the 10 known effective treatments for myocardial infarction and their degree of implementation, CR ranked second, after revascularization, as the treatment which would prevent or postpone the greatest number of deaths.⁷⁶ In the same study, CR provision was estimated to prevent or postpone the greatest number of deaths in patients with unstable angina and heart failure compared with other treatments.⁷⁶

Healthcare systems in middle-income countries are starting to reimburse expensive revascularization procedures. Although such procedures are appropriate given the epidemic of CVD, resources are still very limited and where possible alternatives might be more suitable than revascularization in these countries. As in high-income countries, the cost of CR provision in LMICs is likely to be much less than that of acute revascularization, although no specific data are currently available. In patients at low-risk of a cardiovascular event (for example, those with a Thrombolysis In Myocardial Infarction risk score of 1 or 2),⁷⁷ revascularization at the time of acute care admission is unlikely to change clinical outcome and, therefore, is not only costly but futile. Mortality reductions can be achieved with non-invasive medical therapy and CR in low-risk patients.⁷⁸ If revascularization was discontinued in low-risk individuals, and the associated financial costs diverted to CR, resources for such programs would greatly increase. CR should, therefore, be developed in combination with the building of operating theatres and cardiac catheterization facilities. However, a survey of centres offering cardiac catheterization in 13 countries in Latin America revealed that only 56% had CR programs.⁷²

SECTION 5: THE STATUS OF CARDIAC REHABILITATION REIMBURSEMENT

Little is known about reimbursement for CR services around the globe.⁵⁹ In a similar approach to recent research,^{59, 79} we surveyed ICCPR members regarding the nature of coverage for CR services by government and healthcare insurance companies. Thirty-one responses were received, of which 18 (58%) were from high-income, 10 (32%) upper middle-income, and 3 (9.86%) were from lower middle-income countries. Two (6%) respondents had no CR available in their country and hence did not respond to further survey questions. Four (12.9%) respondents reported that CR is offered in their country, but the nature of the services provided are not consistent with guidelines from high-income countries.

When asked who reimburses CR in their country (respondents were asked to check all that apply), 19 (61.3%) reported the government, 17 (54.8%) reported patients pay out-of-pocket, 16 (51.6%) reported insurance companies, 12 (38.7%) reported that it is shared between the patient and another source, and 7 (22.6%) reported another source (e.g., public hospitals only, subsidized by Heart Foundation, insurance for some companies only).

GOVERNMENT REIMBURSEMENT

For those who reported government reimburses CR, respondents were asked what proportion of the adult population in their country is covered by government healthcare insurance. Responses ranged from 30-100%, with a mean of 74.7 ± 31.3 (standard deviation), with 11 (55.0%) of respondents basing their response on official government statistics. All reported that PCI was fully ($n=17$, 85.0%) or partially ($n=3$, 15.0%) reimbursed by government;

and similarly all respondents reported that CABG surgery was fully (n=16, 84.2%) or partially (n=4, 21.1%) reimbursed by government.

Reimbursed indications for CR were most often myocardial infarction (n=15, 100.0%), CABG surgery (n=15, 100.0%) and PCI (n=15, 100.0%), followed by heart failure (n=13, 86.7%), valve surgery / procedures (n=13, 86.7%), heart transplant (n=13, 86.7%), stable angina (n=11, 73.3%), rhythm devices (n=9, 60.0%), ventricular assist devices (n=4, 26.7%), and arrhythmias (n=6, 40.0%), with 'other' (n=4, 26.7%) including peripheral artery disease and congenital heart disease.

Aspects of CR which were reimbursed most often included supervised exercise (n=14, 93.3%), followed by dietary counselling (n=12, 80.0%), mental health / psychological support (n=12, 80.0%), smoking cessation (n=12, 80.0%), hypertension control (n=12, 80.0%), hyperlipidemia control (n=12, 80.0%), education (n=11, 73.3%), weight control (n=10, 66.7%), and return-to-work / occupational therapy (n=8, 53.3%). Respondents reported that 25.33±28.47 sessions were covered, and that 72.50±41.46% of the total CR program cost is covered by government (i.e., no deductible or out-of-pocket fee). Three (18.8%) respondents reported that the government limits the components of CR covered.

When asked whether the government specified the type of professional treating the cardiac patient to be eligible for funding, 9 (56.3%) responded yes, 5 (31.3%) no and 2 were uncertain. Where the type of provider was specified (respondents were asked to check all that apply), 17 (99.4%) responded it was a cardiologist, 17 (99.4%) responded a nurse, 17 (99.4%) responded a physiotherapist, 13 (72.2%) responded a dietitian, 10 (55.6%) responded a

psychologist, and 6 (33.3%) responded another physician or healthcare profession (e.g., physiatrist, exercise physiologist, occupational therapist, occupational therapist, pharmacist, and sports medicine or general physician).

INSURANCE COMPANY REIMBURSEMENT

For those who reported private healthcare insurance reimburses CR, respondents reported most (92%) insurance companies also reimburse both PCI and CABG surgery.

Respondents were asked to contact the 3 largest health insurance companies in their country (on the basis of premiums collected) to ascertain coverage levels. Of those identified, 7 (100%) of the first companies reimbursed CR, 3 (75%) of the second companies reimbursed, and 4 (80%) of the third companies reimbursed CR (with some respondents being uncertain). Some respondents commented that the insurance companies only covered physical activity and exercise training, and only for 2 months post-procedure. Some respondents also commented that the insurance companies did not cover all sessions, tele-rehabilitation, and another commented they do not cover nutrition counselling, risk factor management or psychosocial interventions.

Respondents reported that 22.2 ± 15.4 sessions were covered, and that $48.3 \pm 50.5\%$ of the total CR program cost is covered by private healthcare insurance (i.e., no deductible or out-of-pocket fee). Where the patient paid some money toward CR, the average cost was USD\$ 18 ± 7 /session or USD\$ 345 ± 38 /program.

Reimbursed indications for CR were most often myocardial infarction (100%), CABG surgery (100%) and PCI (100%), followed by heart failure (87%), valve surgery / procedure (87%), heart transplant (87%), stable angina (73%), rhythm devices (60%), ventricular assist devices (27%), and arrhythmias (40%).

When respondents were asked whether the insurance company would only reimburse CR if it was offered in a specific location, 3 (43%) reported it had to be offered in some form of a medical setting, 2 (29%) reported it had to be delivered in a hospital, 1 (14%) reported it had to be medically-supervised but no location was specified, and 1 (14%) reported that location was not a requirement related to reimbursement of CR services. Almost half (48.8%) of insurance companies specified the type of healthcare professional who delivered CR services as a requirement for reimbursement.

SECTION 6: MANDATE FOR CARDIAC REHABILITATION PROFESSIONAL ASSOCIATIONS TO ADVOCATE FOR REIMBURSEMENT

As CVD represents the main cost to all national health systems, various cardiology and other healthcare provider societies and independent groups have been formed with a mandate to prevent and control CVD. For many years, these groups of physicians, nurses, dietitians, psychologists and exercise specialists have isolated their efforts to their disciplines, countries or regions. In the last 10 years however, international groups have been created in order to collaborate and coordinate preventive actions, building integrated global plans. More recently, the World Heart Federation (WHF) has aligned to the World Health Organization's (WHO) plan of 25 by 25 (i.e., 25% decrease in CV mortality by the year 2025; see http://www.world-heart-federation.org/no_cache/what-we-do/global-advocacy/25-by-25/), citing the need for global galvanization of groups and coordination of efforts for maximal impact.

International groups such ICCPR and the European Association of Preventive Cardiology have been serving an important role integrating secondary prevention efforts across many countries from different areas of the globe (see Figure 1 for a display of the 29 ICCPR member associations). Through cooperation of these groups, common agreement on the way forward to promote CR has been achieved.⁶ This cooperation has culminated in CR guidelines adapted to low-resource settings and regions, and greater understanding of the availability and characteristics of CR programs in LMICs. CR associations should also use the tools identified herein to advocate for broader reimbursement of CR services, as well as greater CR availability and capacity.

Although important progress has been achieved and every year there are an increasing number of CR associations affiliated with ICCPR, many parts of the world such as Africa, the Middle East and South East Asia remain grossly under-developed in CR. These areas include many LMICs of high population densities, high CVD prevalence, but with unknown programs, groups and policies for CR. Advocacy for CR in these regions should not be neglected due to this dearth of leadership.

SECTION 7: ADVOCACY FOR CARDIAC REHABILITATION

While it would seem logical that important and effective medical services are quickly and equitably made available to all people in society, today's complex medical world is not quite that simple. The current medical environment, in fact, is filled with examples of significant gaps in the delivery of life-saving healthcare services to individuals who are in need of those services. These gaps occur for many reasons, and generally require considerable, organized, and sustained efforts to resolve. It is in the midst of these efforts to connect under-used healthcare services to under-served healthcare consumers, that the art and science of healthcare advocacy emerges.

Advocacy is “the act or process of supporting a cause or proposal” (ref: <http://www.merriam-webster.com/dictionary/advocacy>, accessed January 27, 2015). It involves the art of communication by an individual or group, often on behalf of others, with the purpose of supporting an idea or cause. Effective advocates influence public policy, laws and budgets by using facts, personal stories, their relationships, the media, and messaging to educate government officials, policy-makers and the general public about the importance and the potential impact of the idea or cause they are supporting. When applied in the healthcare setting, advocacy is carried out at various levels by a variety of people—patients, providers, healthcare advocacy groups, healthcare industry representatives, and others. Healthcare advocacy work is important because the voice of advocates can help shape and implement important and beneficial healthcare policies and practices.

Policy-makers face a challenging task of decision-making while being inundated with a large amount of data, opinions, and requests. They must maintain a delicate balance between what is best for individuals and what is best for society. Effective advocates assist policy-makers in these balancing efforts by helping to clarify and simplify the complexities of issues that surround a given idea or cause. Advocates generally speak with a unique degree of authenticity, as they bring personal stories and experiences with them that link them to the cause for which they advocate. Please see the accompanying kit for some CR-specific reimbursement advocacy resources and tools.

OPTIONS FOR COUNTRIES WITHOUT CARDIAC REHABILITATION COVERAGE, OR TO ENSURE CARDIAC REHABILITATION DELIVERY UNTIL COVERAGE IS ACHIEVED

In countries where advocacy work has not yet resulted in healthcare insurance coverage—either from governmental or private sources—for CR services, a variety of options exist to provide the financial support for CR services:

- a. **Low-cost models of CR** are an attractive approach, especially in LMICs. An example of such a program is the CR program offered by ASCARDIO in Barquisimeto, Venezuela. The ASCARDIO model of CR includes exercise sessions in an outdoor patio where dance classes are held, and where a surrounding walking trail is used by patients in the program.
- b. **Direct contracting with employers** is another option that is effective in certain communities around the world. CR programs can contract directly with companies—

large and small—to provide rehabilitative and preventive services to the company’s employees. An example of this practice has been demonstrated at the University of Wisconsin-Madison.

- c. **Self-pay** models also exist in which patients pay out-of-pocket for the expenses of the CR program. This model is more typical for “late” outpatient CR (“maintenance” or Phase III/IV CR), but could also be possible for early outpatient CR (Phase II) programs.
- d. **New models of care** represent an emerging option for feasible and affordable CR services. New mobile technologies allow CR professionals to provide center-based CR services more efficiently and home-based CR services more reliably and safely, as these technologies allow professionals to monitor, educate, coach, assess, and even examine CR patients.
- e. **Hybrid models of care:** Some CR programs have found ways to combine traditional CR with alternative CR delivery models. Examples in the United States include programs at Duke, Vanderbilt, and at Kallispell, where patients all along the continuum are together for long-term structured service, with individualized and seamless transition from insurance to self-pay option in the same setting.

SECTION 8: FOUR CARDIAC REHABILITATION ADVOCACY SUCCESS STORIES FROM AROUND THE WORLD

Though most literature and research in CR has resulted in detailed evidence-based recommendations, its implementation and use in other countries other than in North America and Europe are far from optimal. However, there have been individuals and groups working in various parts of the world to help promote and improve the quality of CR in their respective countries. The following section highlights these successes in CR from Iran and Qatar. In addition, we also highlight significant contributions from the UK and USA towards advocacy in CR.

IRAN

The first CR program in Iran was established in 1996 at the Isfahan Cardiovascular Research Centre (ICRC): after that, several CR programs were established in Iran. With a research mandate this unit was later developed into the CR Research Centre (CRRC) in 2010 as part of the Cardiovascular Research Institute (<http://crc.mui.ac.ir/ICRC/>). The CRRC's long-term goals are: (1) Improving existing knowledge about CR and secondary prevention of CVD; (2) Conducting clinical, epidemiologic and basic research in the secondary prevention and CR fields; (3) Delivering PhD training through research courses; and (4) Holding training courses for national and international groups to teach them how to establish CR programs as well as different CR models (5) Providing technical assistance to Non-Governmental Organizations like

the “Heart Friends society” to train cardiac patients and their families of the importance, attendance and adherence to CR programs.

One of the main patient-related barriers to participate in CR is financial in most countries in the world; Iranian patients faced the same problem. This led to more drop-outs or non-adherence, or patients failing to even enroll in CR. Therefore, several sessions with the insurance companies and the Ministry of Health (MOH) were held to advocate for CR. Its importance from an economic, developmental, and social perspectives were highlighted, in addition to the health benefits. We organized meetings as seminars/workshops or face-to-face discussions with health decision -makers from the MOH and the insurance companies. Moreover, we communicated and wrote to these companies, as well as the Under-Secretary of treatment related to the MOH, and other private or public hospitals and academic institutes or associations and explained to them the important role of CR and secondary prevention in return-to-work and improving patients’ quality of life. Furthermore, we sent them documentation from other countries where CR provision is national policy, and subsequently how patients are systematically referred to CR in these countries.

We persisted in our efforts until we reached an agreement in 2000. The MOH sent a circular to inform hospitals with cardiology or cardiovascular surgery departments that have CR programs that all components of CR will be covered by insurance companies. As a result CR attendance rates have gradually increased and CR programs whether public or private increased in other states in the country The ICRC and CRRC helped with organizing multiple short-term training courses for other state’s interested teams(more than 25 course until 2014)

and now undertaking national studies on CR with the support of the “National network for CVD research; www.ncrn.net.research.ac.ir” monitoring and evaluation to demonstrate the impact of this policy change for patient access, as well as patient health outcomes and auditing CR programs in the country

QATAR

CR services in Qatar are young and expanding. In 2000, two physiotherapists started providing services to patients with CVD who had been admitted to Hamad General Hospital in Doha. Soon the benefits of early physiotherapy in this patient group were appreciated, and budget for the recruitment of additional staff was approved. Nursing and occupational therapy also joined the “Cardiac Care Team” and education on CVD risk factors and home activities were included in the provided services. Educational materials were created and translated into several languages, including Hindi, Urdu, and Malayalam.

In 2009, and while the team included seven physiotherapists and three occupational therapists, a CR Planning Committee was formed in order to plan, develop, and implement a CR program in Hamad Medical Corporation, the principal public healthcare provider in Qatar. The committee’s work resulted in a proposal for the creation of a CR Program and coincided with the opening of the Heart Hospital, a hospital exclusively for patients with heart disease, in 2010. The proposal was approved by the founder of cardiology in Qatar and Director of Medical Education at that time, and a CR Department was founded in the Heart Hospital.

Staff recruitment followed and in 2011 the CR Department officially implemented phase 1 CR. The team expanded and new disciplines, such as dietetics, pharmacy, and speech therapy, were included. The phase 2 CR program was officially implemented in 2013, and provides CR services based on the Canadian,⁸⁰ American,⁸¹ and European⁴² guidelines for CR and secondary prevention.

One year later the working group of Qatar Association for Cardiovascular Prevention and Rehabilitation (QACPR) was created, as an official branch of the Gulf Heart Association-Qatar. Its primary goals include the development of the QACPR, the promotion of CR as an essential not optional service, the establishment of nationwide coverage of CR in Qatar, and the communication and collaboration with regional and international associations and healthcare providers.

Currently, the CR department is comprised of more than 30 staff members, and fosters an interdisciplinary approach to patient care. It is the sole provider of CR in the state of Qatar. In 2014, 85% of eligible patients were referred for CR; however, due to challenges in capacity and staffing, only 26% of the referred patients enrolled in a CR program. The department is continuously expanding in space and staff and it is expected to increase the absorption of eligible patients in the coming years. To this end, alternative program models, such as home-based and telephone-based CR programs are also being considered for implementation. At the same time, collaborations with external institutions, such as Qatar Diabetes Association, are being formed in order for CR phase 3 (community-based phase) to be initiated.

ENGLAND

In England, advocacy for CR has resulted in the creation of a National Commissioning Guide and Tool-kit

(http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/Browsable/DH_117504).

The package provides a tailored set of guidance, templates, tools and information to commission CR in a standardized fashion. The commissioning guide was mainly designed for Health Service commissioners in England, which are divided into 211 regional service commissioning groups, which serve a population of ~50 million people. The National Health Service (NHS) distributes money to these groups, which are then led by cooperatives of General Practitioners, who agree service contracts on behalf of their regional patient population.

The development of the CR commissioning guide was led by a dedicated service delivery support team (NHS Heart Improvement), from the Department of Health. The guide was written in collaboration with the national heart and cardiovascular health charity (The British Heart Foundation; <https://www.bhf.org.uk>) along with specialist representatives from the British Association for Cardiovascular Prevention and Rehabilitation (www.bacpr.com) and other stakeholder groups, including the national heart patients association (The Cardiovascular Care Partnership UK; http://www.bcs.com/pages/page_box_contents.asp?PageID=325). This first service commissioning guide for CR was produced in 2010, after years of evidence-based campaigning. It has been augmented by a more recent commissioning guide produced by England's National Institute for Health Care Excellence (NICE CMG40, 2013;

<http://www.nice.org.uk/guidance/cmg40>), along with complimentary guidance published in NICE's myocardial infarction secondary prevention guide (CG172, 2013; <http://www.nice.org.uk/guidance/cg172>). Success of the implementation of the commissioning pack has been evaluated both as a benefit to service commissioners and service providers (http://www.cardiacrehabilitation.org.uk/docs/NACR_NHS_Improvement_audit.pdf).

With years of campaigning, these guides to commissioning as well as the release of national standards for delivering CR (http://www.bacpr.com/resources/46C_BACPR_Standards_and_Core_Components_2012.pdf), in 2014 CR uptake reached almost 50% of eligible patients. This uptake of CR is 1.5 to 2.0 times greater than what is observed in other high-income countries (<http://www.cardiacrehabilitation.org.uk>).

UNITED STATES OF AMERICA

A sample of advocacy work by the American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR) includes the following:

- 1) Performance Measures for CR Referral:** Beginning in 2005, AACVPR partnered with the American College of Cardiology and the American Heart Association to develop and test performance measures (i.e., quality metrics) for CR referral. These measures were aimed at improving CR referral and participation through the process of quality improvement and accountability. The CR referral performance measures were endorsed by the National Quality Forum, an organization that is a governmental-private partnership that identifies

and endorses performance measures that may be potentially used by the Centers for Medicare and Medicaid Services (CMS) and other healthcare insurance carriers. The process of performance measurement development, testing, endorsement, and implementation is complex, long, and ever-changing. The impact of performance measures on CR utilization is still unclear, but one initial study suggests that they may have contributed to significant increases in CR referral in the United States from 2007, when the performance measures were officially endorsed and published, to 2011.⁸²

- 2) Heart Failure as a covered indication for CR:** AACVPR, in coordination with other partnering organizations, submitted scientific evidence supporting the benefit of CR participation for heart failure patients over a 10-year span. These efforts, along with a growing body of evidence in support of these efforts, led the U.S. government's health insurance provider (CMS) to provide coverage for heart failure beginning in 2014.
- 3) Expansion of covered diagnoses for CR coverage:** AACVPR submitted published, scientific evidence in 2001 to CMS, as they successfully petitioned CMS to expand coverage for CR to include additional diagnoses: heart valve repair/replacement, heart or heart/lung transplantation, and percutaneous coronary intervention. CMS granted this petition in 2006.
- 4) Demonstration projects** with governmental or private insurance companies seeking clinical and/or cost-savings outcomes of CR:
 - a. Government-sponsored demonstration projects are currently being carried out with CMS that are exploring the impact of bundled payment for the continuum of

cardiovascular care for patients with heart failure and other forms of cardiovascular disease. CR services are an important part of the expected care received for the bundled payment.

- b. In 2014, the government required that state health plans cover essential health benefits, defined as items and services in ten benefit categories. Two of those categories potentially related to CR are: (1) rehabilitative services and devices, and (2) preventive/wellness services and chronic disease management. The Maryland Essential Health Benefit Benchmark Plan is an example of a state that chose to include CR under required benefits.

5) Program Certification: Proliferation of CR programs nationally and internationally consequent to the development and promotion of voluntary program certification (quality improvement) and professional certification (individual practitioners) offered by the national professional organization AACVPR.

- a) On a national level, hospitals competing for business have an incentive to promote a local certified CR program with certified professionals over others in the region that are not certified or cannot claim similar staff qualifications.
- b) An international example is South Korea which has embraced the opportunity to belong to the AACVPR, to model CR services in South Korea after those in the U.S., and to offer professional certification as this relatively new field emerges in that country.

SECTION 9: CONCLUSIONS

Herein the need for CR has been demonstrated, and the financial benefits of CR provision have been forwarded. Given the evidence of the benefits of CR for patient health and vocational outcomes, greater provision of CR services through coverage will result in fewer recurrent cardiac events and associated hospitalizations, fewer revascularization procedures, as well as greater return-to-work and productivity. Given CR is cost-effective, greater provision of CR will be of significant economic benefit to government, the private sector and individuals.

It is imperative to advocate for reimbursement of CR services so that availability and affordability for patients will be greatly increased. An ancillary consequence will be that healthcare providers will be motivated to train and work in the field of CR, which will also enable greater implementation. It is incumbent upon CR associations to advocate for CR coverage, using the strategies forwarded herein.

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Figure 1: ICCPR Member Associations (as of March 2017)



Appendix A

Key Principles of Cost-Effectiveness Analyses^{49,50,51,83,84,}

The purpose of a cost-effectiveness analysis (CEA) is to compare different treatments or medical interventions from an economic standpoint, to identify medical interventions with the highest clinical benefit per dollar spent. Simply put, a CEA is calculated by dividing the incremental cost of an intervention by the incremental benefit, that is generally expressed as years of life saved or as quality-adjusted life years saved (QALY).⁸³

$$\text{Cost effectiveness} = \frac{\text{Cost (treatment a)} - \text{Cost (treatment b)}}{\text{QALYs saved (treatment a)} - \text{QALYs saved (treatment b)}}$$

The cost component of a CEA includes all the expenses generated by the intervention and incorporates direct and indirect costs. CEAs generally compare a new intervention versus standard of care, and the results are expressed as the incremental cost per unit of benefit. Thus, a CEA does not include absolute costs, and the results are not necessarily a reflection of the absolute benefit, but the cost and benefit compared to the next best intervention or standard of care.

Something is arbitrarily defined as cost-effective if CEAs show values that are similar or more favorable than interventions which are socially accepted as cost-effective. For example, the cost effectiveness of hemodialysis is widely used as the yardstick to define cost effectiveness, with a cost per year of life saved in the range of \$40,000.⁸⁴

The cost component of the CEA and the results are expressed in monetary values specific for a given year. Therefore, results from a CEA from 1995 would need to be adjusted to an actual value, as dollars from 1995 will not be the same to dollars spend in 2015. Given the uncertainty and variability of many values used in a CEA like cost of procedures, supplies, and salaries for example, an economic analysis generally includes a sensitivity analysis considering extreme values for the most important cost and benefit components inputted in the formula. The sensitivity analysis would give a range of cost-effectiveness under conditions of higher or lower costs or under different estimations of benefit.

Finally, CEA is performed from a specific perspective, depending who is affected by the expense of the intervention. The most commonly accepted perspective is societal; this takes into consideration the cost to society as a whole and not a specific payer or the patients themselves. Interestingly, most CEAs of CR have been performed from the payer's perspective.