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## Special Article

# Cardiac Rehabilitation Delivery Model for Low-Resource Settings: An International Council of Cardiovascular Prevention and Rehabilitation Consensus Statement



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ABSTRACT

Keywords: Cardiac rehabilitation Delivery models Middle-income countries Cardiovascular disease (CVD) is a global epidemic, which is largely preventable. Cardiac rehabilitation (CR) is demonstrated to be efficacious and cost-effective for secondary prevention in high-income countries. Given its affordability, CR should be more broadly implemented in middle-income countries as well. Hence, the International Council of Cardiovascular Prevention

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Community health Primary care and Rehabilitation (ICCPR) convened a writing panel to recommend strategies to deliver all core CR components in low-resource settings, namely: (1) initial assessment, (2) lifestyle risk factor management (i.e., diet, tobacco, mental health), (3) medical risk factor management (lipids, blood pressure), (4) education for self-management; (5) return to work; and (6) outcome evaluation. Approaches to delivering these components in alternative, arguably lower-cost settings, such as the home, community and primary care, are provided. Recommendations on delivering each of these components where the most-responsible CR provider is a non-physician, such as an allied healthcare professional or community health care worker, are also provided.

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## Abbreviations and Acronyms

AHA = American Heart Association

**BMI** = Body mass index

BP = Blood pressure

CADE-Q = Coronary Artery
Disease Education Questionnaire

CHD = Coronary heart disease

CR = Cardiac rehabilitation

CVD = Cardiovascular disease

**DM** = Diabetes mellitus

ECG = Electrocardiogram

HDL-C = High-density lipoprotein
 cholesterol

**HF** = Heart failure

**HICs** = High-income countries

HTN = Hypertension

ICCPR = International Council of Cardiovascular Prevention and Rehabilitation

LDL-C = Low-density lipoprotein cholesterol

LICs = Low-income countries

**LMICs** = Low-income and middle-income countries

**MI** = Myocardial infarction:

MICs = Middle-income countries

PA = Physical activity

**PSS** = Psychosocial stress

PURE = Prospective Urban Rural Epidemiology study

**QoL** = Quality of life

SMS = Short message service

**TGs** = Triglycerides

WC = Waist circumference

WHO = World Health Organization

Cardiovascular disease (CVD) is global epidemic, but is at its worst in the developing world. Cardiac rehabilitation (CR) is an established model of care proven to reduce mortality and morbidity in patients with this disease. 1-3 While professional CR societies in high-income countries have published guidelines and recommendations on how to best deliver CR in the developed world,4-8 there is scant guidance on how to practically and affordably deliver these programs in lowerresource settings such as middle-income coun-(MICs).9 resource settings were defined according to the World Bank classification of low-income middle-income countries (LMICs) based on gross national income.<sup>10</sup>

Given the last international-scale guidance on CR delivery in low-resource settings was almost 25 years ago from the World Health Organization, 11 the International Council of Cardiovascular Prevention and Rehabilitation (ICCPR; www.globalcardiacrehab.com) endeavored to system-

atically develop practical, evidence-based recommendations on how to deliver each of the core components of CR, namely (1) initial assessment, (2) lifestyle risk factor management (i.e., physical activity (PA), diet, tobacco, and mental health), (3) medical risk factor management [e.g., lipid control, blood pressure (BP) control], (4) education for self-management; (5) return to work, and (6) outcome assessment.

The writing panel was comprised of CR practitioners and researchers from the MIC setting as possible, with expertise representing all the core components of CR. The methods for developing clinical practice recommendations, and the recommendations themselves, are published in a companion statement. <sup>12</sup> These were based on evidence from MICs where available, which was not often the case. We hope this consensus statement will incite more research in this area.

Adaptation of service provision by type of most-responsible healthcare provider is outlined subsequent to the model (Box 1). This is followed by recommendations and examples on how this model of CR can be delivered in more-accessible, less expensive settings, namely the community, home and primary care settings.

## Low-resource CR model

## Core components of CR

The core components of CR have been established by the major CR associations from high-income countries (HICs), namely the American, <sup>4</sup> Australian, <sup>5</sup> British, <sup>6</sup> Canadian, <sup>7</sup> and European associations. <sup>13</sup> These core components have also been agreed upon in the ICCPR Charter, which has also been endorsed by CR associations in LMICs. <sup>14</sup>Herein each of the following common core components has been adapted for the MIC setting: 1) initial assessment, 2) lifestyle risk factor management (i.e., diet, tobacco, and mental health), 3) medical risk factor management (e.g., lipid control, BP control), 4) education for self-management; 5) return to work and 6) outcome evaluation. Strategies to implement the PA recommendations are found in the companion article. <sup>12</sup>

## Initial assessment

The CR program should commence with a comprehensive assessment. It is recommended that the style of the assessment be consistent with motivational interviewing. <sup>15</sup> Specifically, the assessment should be client-centered and goal-oriented. Each of the following elements should be considered in the intake

assessment: physical activity, diet, tobacco consumption, overweight/obesity, coronary heart disease (CHD) knowledge, depression, return to work, lipids, BP, medications and diabetes mellitus (DM).

Physical activity. It is strongly recommended that every patient, independent of the type of CR program in which she/he will engage, should have a pre-exercise assessment. The basic assessment should cover both past and current levels of PA (types and volume of all activities), physical examination, and aerobic exercise capacity. This assessment should ascertain if the patient has any of the recognized contraindications to exercise, determine the risk of a medical event during exercise, the best-suited exercise program for the patient, and inform development of an individualized exercise program and daily PA plan. In some instances, an exercise test of functional capacity may not be possible, for example if the patient is frail or has orthopedic limitations. However, even in low-resource settings an exercise evaluation is imperative (e.g., use of field-based tests of walking or step-up protocols).

A resting BP and digital pulse palpation or electrocardiogram (ECG) should be performed where possible to exclude tachycardia or bradycardia, and screen for other cardiac arrhythmias or adverse BP recordings that might contraindicate exercise. Due to the high prevalence of comorbidities, particularly musculoskeletal disorders in the population with chronic disease, exercise assessment should also include a musculoskeletal screen of all major joints.

Where possible, a test of functional capacity could be performed with every patient. It is preferable that each patient participating in CR undertakes a multi-stage exercise stress test. If a treadmill test is not possible, a cycle ergometer can be used (also useful if patients have musculoskeletal limitations that necessitate non-weight bearing exercise). If neither a cycle ergometer nor treadmill is available, <sup>16</sup> the 6-min walk test or a step test can be conducted. <sup>17</sup> Basic professional tools to conduct this pre-exercise assessment include: a sphygmomanometer, stethoscope, ECG machine/monitor (or at least an accurate exercise heart rate monitoring device where unavailable), beacons or markers for a 6-min walk test, and a stopwatch.

Recognized contraindications to exercise training include: unstable angina or acute myocardial infarction (MI), uncontrolled hypertension (HTN) (e.g., >180/110 mmHg, or >100 bpm), symptomatic orthostatic hypotension <20 mmHg, significant aortic stenosis, uncontrolled atrial or ventricular arrhythmias, sinus tachycardia >120 beats per minute, uncompensated heart failure (HF), third degree atrioventricular block, active endo/pericarditis or myocarditis, recent embolism, acute thrombophlebitis, acute systemic illness or fever, uncontrolled DM (glucose concentrations >16 mmol/l), severe orthopedic conditions that would prohibit exercise, and other metabolic conditions including acute thyroiditis, hypokalemia, and hyperkalemia. If testing for any of these is not available, clinical signs and symptoms of these entities should be determined. <sup>18</sup>

Diet. Assessment of dietary intake is complex. <sup>19</sup> Due to the number of variables associated with dietary intake (i.e., culture, translation validity, food availability) no one questionnaire

will be valid worldwide. Moreover, all dietary assessments in clinical practice are limited by the ability of the patient to recall intake accurately.

Food diaries with dietary analysis are often cited as the gold standard way of assessing dietary intake, but this is labor-intensive for both the patient and professional.<sup>20</sup> More objective measures (biomarkers, urine analysis, glucose monitoring) would not be practical in a MIC clinical setting. Food frequency questionnaires and checklists are more commonly used to reduce cost and time. One potential food frequency questionnaire stems from the Prospective Urban Rural Epidemiology (PURE) study.<sup>21,22</sup> More generic measures that can capture changes in dietary patterns and be interview-led by a trained professional would be most feasible in MICs. Any questionnaire should be validated prior to use.

There is a lack of studies that collect detailed information on dietary patterns in CR. CR programs could consider one of the following questionnaires, all of which have been used to score diet and relate it to CHD risk:

- The WHO STEPwise approach to chronic disease risk factor surveillance (STEPS) core diet items assessing fruit and vegetable consumption, and the expanded items related to fat consumption and eating foods not prepared at home.<sup>23</sup>
- The alternative healthy eating index.<sup>24</sup> It accounts for type of fat, forms of carbohydrate and sources of protein elements which are highlighted in American Heart Association (AHA) guidelines.<sup>25</sup> It has been shown to be related to lower rates of chronic disease in both men and women.

The assessment should preferably include family members in the same household, especially the person who most often purchases food and beverages as well as prepares meals to ensure that it is as accurate as possible.

Tobacco use. Every individual should be asked if they currently use tobacco in any form. In some cultures, healthcare providers hesitate to ask women questions relating to tobacco consumption. However, this must be done since there is a high degree of smokeless tobacco consumption among women in MICs. If there is no current consumption of tobacco, assess for past consumption, if any. The WHO STEPS incorporates a core module to assess tobacco use, with an expanded section assessing quit attempts, use of smokeless tobacco and exposure to second-hand smoke. 23

Among smokers, duration of smoking and degree of dependence should additionally be assessed. While motivational factors drive quit attempts, it is primarily cigarette dependence (such as daily consumption and time to first cigarette of the day) that predicts successful quitting. <sup>28,29</sup> The Fagerstrom Test for Nicotine Dependence and Heavy Smoking Index are the most standardized and validated tools used for the purpose of assessing nicotine dependence, and should be incorporated into all CR programs. <sup>30,31</sup>

Overweight/obesity. Overweight/obesity should be assessed via two measures: body mass index (BMI) and waist circumference. Using the formula weight/(height × height), BMI is obtained,

#### Box 1

## Algorithm for CR Delivery Based on Availability of Healthcare Personnel.

There is a paucity of trained healthcare personnel to deliver CR in low-resources settings, particularly with expertise across all core components. It is recommended that MICs establishing or augmenting CR services establish a competent body to provide requisite training on all aspects of CR, to non-physicians as well as general practitioners. We recommend that academic institutions offering advanced cardiac services appoint clinical educators tasked with training CR providers at non-academic and developing CR centers, and that policies are enacted so that local laws and health care practice allow non-physicians to deliver CR. In future versions of this statement, we hope to establish training standards for CR professionals delivering care in low-resource settings.

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SCENARIO ONE
Informally-trained community health worker
ASSESSMENT
☐ Verbally assess family and personal history of heart attack, angina, stroke, transient ischemic attack and diabetes
□ Verbally assess physical activity history, including occupational or transportation activity. Also query for any musculoskeletal pain with exercise.
□ Verbally assess functional capacity and any contraindications to exercise (patients should not be prescribed exercise in the presence of contraindications as outlined in the assessment section); identify activities patient perceives as light to moderate-intensity (not breathing too hard)
□ Verbally assess consumption of foods high in saturated and trans fat, salt and sugar and alcohol (e.g., probe intake of processed, street and restaurant foods), as well as fruit and vegetable intake. Preferably use items from WHO STEPs if available in local language.
□ Verbally assess self-reported tobacco consumption.
□ Take weight (in kilograms) using weighing scale, waist circumference (in centimeters) using measuring tape, and height (in meters) using wall-mounted measuring tape. Calculate body mass index (BMI) using the formula weight/(height in m) <sup>2</sup>
☐ Verbally assess occupation type, employment status, and desired occupational status ☐ Verbally assess whether they have been told by a healthcare provider that they have raised BP or cholesterol. If yes to
either, ask whether they are taking any treatments
☐ Use WHO-Five Well-Being Index for depression screening, if diagnostic and treatment services are available
$\square$ Take BP reading using validated, automated, BP measuring instrument.
$\square$ Assess for raised blood glucose or diabetes, using urine test strips or glucometer, if available
□ Document in a paper-and-pencil chart, stored confidentially
LIFESTYLE MANAGEMENT
☐ Regular lifestyle physical activity should be recommended to all patients.
In addition, for low-risk patients, light to moderate-intensity exercise should be prescribed on at least 3, but preferably most days of the week. Intensity to be monitored via subjective assessment of rating of exertion and symptoms.  Non-equipment based exercises like walking would be the most feasible option. Location of exercise:
community setting or the patient's home.
For patients at medium and high-risk of an acute adverse event during exercise or with contraindications,
only supervised physical activity is recommended (scenario 2 or 3).
□ Overall dietary recommendations should be aligned to a cardio-protective dietary pattern with large intake of plant-
based foods (vegetables, fruits, pulses, legumes, whole grains, nuts, seeds), allow unsaturated fat intake, low intake of
saturated and trans fat (less processed and refined food), encourage intake of fish and poultry instead of red meat, if
culturally-acceptable, locally available and affordable
☐ If tobacco user, provide detailed quit advice using ask, advise, assess, assist and arrange (5As) protocol and information
about quitting support options.
☐ If face-to-face contact is not feasible for follow-up at community level due to resource constraints or distance, consider alternate methods of delivery of tobacco cessation, physical activity and dietary advice messages by using mobile
technology like SMS and pre-recorded voice messages  ☐ If BMI> 25 (kg/m²) or waist circumference exceeds WHO/IDF thresholds for abdominal obesity (based on region-specific
cut-offs), advise patient on risks of obesity and recommend target BMI/waist circumference
☐ Educate patients (and their family if possible) based on their information needs (e.g., risk factors, medications and side
effects, monitoring cardiac symptoms, and dealing with cardiac emergencies), and promote health behavior change
☐ Stress management: in addition to physical activity, offer deep breathing, progressive muscle relaxation, guided imagery, yoga, and/or meditation
☐ If urine test positive for glucose, refer to formally-trained healthcare worker/physician if available
If fasting blood sugar >100 mg/dl, offer dietary advice and physical activity counseling for impaired fasting glucose.  If fasting blood sugar >126 mg/dl, on two or more occasions, refer to formally-trained healthcare worker/physician if available

MEDICAL MANAGEMENT	
$\Box$ If patient is taking acetylsalicylic acid (ASA), reinforce continued use. If not, prescribe ASA, if available and patient do	oes
not have a contraindication (i.e., gastrointestinal disorder or bleeding, blood disorders)	
$\Box$ For patients without regular access to a formally-trained healthcare provider to support comprehensive seconds	
prevention, assess risk factors at regular intervals through follow-up visits (e.g., monthly contact) for 6 months to ensu	ure
effective monitoring of health status, and timely referral to formally-trained healthcare provider where warranted.	
□ Consider assessing compliance to medication, as applicable. If patient is non-adherent, enquire regarding reasons for t	
and reiterate importance of adherence; If patients have a valid clinical reason for non-adherence (e.g., muscle ache	es),
inform treating physician accordingly. If patient is adherent, provide encouragement and positive feedback.  □ Document treatment plan and provide a copy to primary care provider, where available	
EQUIPMENT NEEDED:	
BP measuring device and Stethoscope	
Measuring tape (loose, as well as wall-mounted)	
Weigh scale	
Urine test strips	
Glucometer, with strips, batteries	
Stopwatch	
Beacons or markers for 6-minute walk test	
Home-made weights for resistance training	
Paper and pencil; secure and confidential filing	
COPNIA DIO TRIVO	
SCENARIO TWO Trained healthcare worker	
Same as scenario one, but additionally:	
ASSESSMENT	
☐ Six-minute walk test to assess safety for exercise training, to develop exercise prescription, and consider return to wo	ork.
Observe for chest pain, and appropriate heart rate response with exertion.	
$\Box$ If patient aims to return to work, review region-specific requirements and/or vocational restrictions for return to work	ork
following a coronary event. This may include considerations in completion of disability forms.	
Undertake occupational assessment to ascertain safety to return to same vocation, or whether to recommend alternat	tive
employment (provide contacts for employment agencies).	
☐ If lab facility available and if affordable, send blood sample for lipid profile	
LIFESTYLE MANAGEMENT	
☐ Patient at moderate risk for adverse event during activity can be supervised during physical activity in this setting ☐ Dietary advice should be individualized to a patient's risk factor profile, including weight management for obesity.	
☐ If tobacco user, provide option of Nicotine Replacement Therapy where available	
MEDICAL MANAGEMENT	
☐ If depressed, initiate cognitive behavioral therapy where trained providers available	
☐ Discuss how patients are tolerating cardiac medications and any side-effects.	
ADDITIONAL EQUIPMENT RECOMMENDED:	
Resistance bands	
Hand weights	
Gym and yoga mats	
Pedometers	
Sphygmomanometer (regularly calibrated manual device to back up automated device)	
Watch to measure heart rate	
Automated external defibrillator	
SCENARIO THREE	
Trained physician (or licensed independent practitioners that can clinically supervise and prescribe CR)	
Same as scenario two, but add:	
ASSESSMENT	
$\Box$ Digital palpation of pulse and reading of baseline ECG to rule out any arrhythmia. Pulse oximeter reading for assessment	ent
of level of oxygen saturation.	
$\Box$ Exercise stress test (treadmill or cycle with ECG) to develop individualized exercise prescription and to assess readiness	
safety of return to work (as applicable). Advise patient on exercise prescription and recommended time for return to wo	ork.
☐ Send blood sample for fasting blood sugar (if diabetic) and lipid profile.	
☐ Other tests, such as renal (for diuretics) and liver (for statins) profiles should be done as required on a per-case basis	3.

LIFESTYLE MANAGEMENT	
$\label{thm:consider} \square \ \text{If tobacco user, consider pharmacotherapy such as Varenicline or bupropion.} \ (Varenicline \ may \ be \ unaffordable \ in \ LMIC \ settings)$	
MEDICAL MANAGEMENT	
$\square$ If depression unremitted, prescribe generic selective serotonin reuptake inhibitor.	
$\Box$ For BP above 140 mm Hg systolic or 90 mm Hg diastolic, treat with an ACE inhibitor. Diuretics may be added if BP requires additional lowering.	
$\square$ Initiate (or reinforce if already prescribed) low-dose statins for all patients, unless contraindicated.	
$\square$ In the presence of hypertension and dyslipidemia, prescribing the polypill may be warranted to promote adherence, if available	
$\square$ If patient has heart failure: educate patient on self-management strategies to avoid acute decompensation	
$\Box$ For type 1 diabetes, treat with insulin. For type 2 diabetes: if overweight, advise weight reduction and if needed	
metformin. For type 2 diabetes with normal weight, start with sulphonylurea.	
□ For blood sugar above 126 mg/dl, test urine for albumin. If no albuminuria, start with low-dose diuretics. If albuminuria	
present, then start with low-dose diuretics and ACE inhibitor.	
Regular follow-up.	
$\square$ Refer to credible, public, government-owned health facility if affordability of medication is an issue.	
ADDITIONAL EQUIPMENT:	
Pulse oximeter to assess PO <sub>2</sub> saturation and pulse rate	
Exercise equipment (e.g. treadmill and/or stationary bicycle)	
Electrocardiogram machine	
Tertiary care centre with cardiopulmonary assessment capability	
Access to laboratory with blood and urine analysis capability	

where height is measured in meters and weight is measured in kilograms. For BMI, values 25 to 29.9 kg/m² and above denote an overweight state and values 30 kg/m² and above denote obesity,  $^{32}$  however these thresholds do vary by region and ethnicity. In Asians for instance, the WHO has suggested BMI thresholds of 23 to 27.5 kg/m² and  $\geq$ 27.5 kg/m² to denote increased risk and high risk for CHD, respectively.  $^{33}$  BMI status should be communicated to all patients.

Waist circumference (WC) is measured in accordance with the WHO recommendations at the midpoint between the lower margin of the least palpable rib and the top of the iliac crest, using a stretch-resistant measuring tape. <sup>34</sup> This should be done in the standing position with feet together and arms at the side in a relaxed stance at end-expiration. Excess clothing should be removed prior to application of the measuring tape. The average of 2 measurements should be calculated and used as the final value. Cut-offs for central obesity measured by WC also vary by region and ethnicity. <sup>35</sup> Region-specific limits for WC should also be made known to all patients (see Table 6 of Alberti et al. 2006). <sup>35</sup> Again, height, weight and WC are incorporated in WHO STEPs. <sup>23</sup>

CVD knowledge. CR providers should have a comprehensive understanding of their patients' health literacy and health information needs to inform development and implementation of educational programs. 36-40 The assessment of these needs supports tailoring the information delivered in CR. The Information Needs in CR scale, 41 is a useful tool, assessing the heart (i.e., physiology, symptoms and their management, conditions), nutrition, exercise/PA, medication, work/social roles, psychosocial stress (PSS), emergency/safety, diagnosis and treatments, as well as risk factors.

Mental health. Several clinical practice guidelines for CVD care and CR recommend that all patients with CHD be screened for depression. <sup>7,42,43</sup> It is also recommended that patients are screened for PSS. Whether screening is of benefit in the context

of CR is unknown.<sup>44</sup> No studies have addressed the potential harms of screening, such as false-positive results, the cost and inconvenience of additional follow-up assessments, the adverse effects or costs associated with treating incorrectly-diagnosed patients, and inappropriate labeling. Thus, herein it is cautiously and initially recommended that CR programs screen patients, unless the program has no access to healthcare professionals to undertake formal diagnostic interviews or to evidence-based treatments.<sup>43</sup>

The WHO-Five Well-Being Index can be used,<sup>45</sup> and is available in many languages.<sup>46</sup> Alternatively, the AHA guidelines recommend screening with the two-item Patient Health Questionnaire (PHQ-2).<sup>43</sup> Patients who screen positive should be administered the PHQ-9. Stress can be assessed with the 2-item tool developed for the INTERHEART study.<sup>47</sup>

Return to work. Following a CHD event, CR providers should elicit desired occupational status from patients. Patients needing to return to paid work should be asked to describe the degree of force exerted on their job to facilitate risk assessment (i.e., whether their occupation is sedentary, or involves light to very heavy work). Again, the WHO STEPS measure includes core questions on work-related PA that could be used for this purpose.<sup>23</sup>

Timing of return to work should be discussed, taking into consideration the family's economic situation, the degree of force used on the job, and whether the nature of work could be modified. Information on type of CHD and acute treatment received should be obtained to guide decision-making. Resumption of other unpaid roles should also be considered, including the degree of force required for these activities. Similarly, resumption timing and modification options should be discussed for safety.

Lipids. Undertaking a blood draw for lipid assessment depends on the availability of equipment for venipuncture as well as laboratory support for processing of blood samples. Where available, components of the lipid profile that should be obtained are: total cholesterol, triglycerides (TGs) and high-density lipoprotein cholesterol (HDL-C). Low-density lipoprotein cholesterol (LDL-C) is calculated using the Friedewald equation: LDL-C = Total Cholesterol – HDL-C – TGs  $\times$  0.20 (if units mg/dL and 0.45 if units mmol/L).  $^{48}$  The Friedewald equation is known to underestimate LDL-C levels when TGs levels are elevated.  $^{49}$  Nonetheless, direct measurements of LDL-C have been found to correlate well with LDL-C estimated by the Friedewald equation.  $^{50}$  Fasting is not essential as non-fasting levels have been shown to correlate well with CHD risk.  $^{51}$  Total cholesterol assessment is included in core module of WHO STEPs, with TGs and HDL-C included in the expanded module.  $^{23}$ 

Regular assessment of lipid levels enables monitoring of therapeutic targets following commencement of lipid-lowering therapy, where available. This is crucial for individuals with established CHD as they are at high risk for future adverse CVD events and should receive lipid-lowering therapy regardless of baseline LDL-C levels.

Blood pressure. BP assessment should include both the seated (for usual therapeutic and diagnostic decision-making) and standing positions (for postural hypotension). BP assessment should utilize an automated device (semi-automated or fully-automated or a device designed to assess BP without an observer present) that has passed international standards for accuracy and that uses an upper-arm cuff. 52,53 In general, devices designed for self-measurement are not robust enough for clinical use. The website http://www.dableducational.org/can be used to select BP devices that have passed international accuracy standards. People with high readings (i.e., greater than or equal to 140/90 mmHg) at two or more visits and those on treatment for HTN with BP readings less than 140/90 mmHg are considered to have HTN. 54

Cardio-protective medication use. Medications may not be available and affordable in the MIC setting. Where available, patient use of, adherence to, tolerance of, and contraindication for cardio-protective therapies should be assessed and documented at the intake assessment. These may include anti-platelets, angiotensin-converting enzyme inhibitors (as well as angiotensin receptor blockers), beta-blockers, statins and other anti-HTN medications.

Diabetes mellitus. Patients should be asked whether they have a history of DM. There are several core items in the WHO STEPs to ascertain history, and if positive, forms of treatment. Fasting blood glucose should be assessed where available.<sup>23</sup>

At the completion of the comprehensive formal assessment, documentation should be made of the findings. The client and the CR provider should discuss a plan of treatment accordingly. The CR program should then include the following elements, as applicable to each patient:

### Lifestyle risk factor management

Strategies to implement the physical activity core component recommendations are found in the companion version of this consensus statement. 12

Diet. Unhealthy eating patterns are a significant contributor to CHD mortality, and influence many risk factors associated with CHD.<sup>55,56</sup> The consumption of foods high in saturated and industrially-produced trans-fat, salt, sugar and alcohol contributes to a high percentage of deaths from non-communicable diseases.<sup>57</sup>

Dietary patterns in MICs have dramatically changed over the last two decades due to globalization, the free movement of goods, services, technology, food processing, distribution and marketing. This has resulted in a more 'Westernized' diet. 19,58 An example of this is the increase in consumption of animal products and sugar-sweetened beverages observed in China, resulting in increased caloric intake, the glycemic load of diets and obesity levels. 59-61 Some eastern MIC dietary patterns have also changed from a high plant and grain-based diet to a diet higher in meat, dairy and eggs. 62 The PURE study showed that a healthy diet was followed by just under half the population of patients with CHD or a stroke in all the countries included (high through low), while the figure was less than one-quarter of the population in low-income countries.<sup>63</sup> In wealthier countries, red meats and fried foods were morecommonly consumed, whereas in poorer countries, foods such as fruits and vegetables may be cost-prohibitive. 63

Diet therapy is an integral part of the secondary prevention and treatment of CHD. While there are examples of nutritional interventions (group and individual) in CHD patients in the literature, these are mainly from HICs. <sup>64,65</sup> Evidence in MICs is very limited.

#### Dietary recommendations

Due to the large difference between MICs, approaches to improving the quality of diet will differ. Possible challenges may include variation in cooking methods, cultural and religious influences, tastes, availability, and affordability of foods.

The Mediterranean is an example of a dietary pattern has been shown to reduce CHD mortality and morbidity. <sup>66</sup> The components of this diet work together to improve CHD risk factor control. It is comprised of a wide variety and large intake of plant-based foods; fruit, vegetables, legumes, pulses, whole grains, nuts and seeds. It is also relatively high in fat intake; but mostly unsaturated fats (MUFA and PUFA) and low in saturated fat and trans-fatty acids. Poultry and fish are eaten rather than red meat, and there is a low intake of processed and refined foods. <sup>67</sup>

Helping people change their dietary habits will involve changing their lifestyle behaviors, which can be extremely difficult due to barriers to both implementation and maintenance. Unsurprisingly, patients do not respond uniformly to dietary interventions, so identification of underlying factors that may affect their readiness or motivation to change is necessary. Interventions in MICs should be sufficiently adapted to the cultural context and involve community members – both in the intervention design and in implementation – for the intervention to work. <sup>68</sup>

## Type of healthcare provider delivering dietary intervention

Dietitians use their training in promotion of behavioral change as well as their nutritional knowledge to help patients improve their diet. Access to dietitians varies considerably within and across different countries.<sup>9</sup> Consequently, it is important to identify alternative methods to deliver dietary messages. For example, many CR interventions in HICs provide group dietary education sessions led by a dietitian, but there are some studies that have shown that interventions delivered by other specifically trained health professionals also can promote improved dietary habits.<sup>64</sup> For example, community leader-led diet interventions have been shown to be successful in other disease populations.<sup>69</sup>

#### Tobacco

MICs are at the mid-stage of the tobacco epidemic, and have not yet witnessed the full brunt of the premature mortality due to smoking and smokeless tobacco use. 70,71 Hence, there is limited amount of research on tobacco cessation interventions for delivery at the individual-level conducted in MICs. 72 Guidelines formulation for tobacco cessation support for CR in MICs thus needs to build on the existing evidence of efficacy for smoking cessation interventions from HICs, supplemented by the limited but valuable research from MICs. This entails assessing the generalizability of findings from HICs about the efficacy of the existing smoking cessation interventions by placing them within MIC settings and considering the contextual issues of affordability, availability, accessibility, cultural acceptability and feasible delivery mechanisms. Further, for MIC countries in Asia like India and Bangladesh, where smokeless tobacco users outnumber smokers, efficacious and appropriate interventions for smokeless tobacco cessation are critical. 26,27

The evidence for the major interventions available to promote and aid tobacco cessation that can be delivered in the CR setting is reviewed in Table 1. By far the largest body of evidence is on cessation of smoking rather than smokeless tobacco. The interventions consist of psychological and pharmacological approaches, with the former being more feasible in lower-resource settings.

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Table 1 – Efficacy	ot smokin	g cessanon	interventions.

Intervention (Reference)	Efficacy
Advice from physician <sup>73</sup>	OR 1.66 (95% CIs 1.4 to 1.9)
Brief advice (< 20 min & up to 1 follow up)	OR 1.84 (95% CI 1.6 to 2.1)
Intensive intervention (>20 min and	
multiple follow-ups or other additions)	
Individual face-to-face counseling <sup>74</sup>	OR 1.6 (95% CI 1.3 to 1.8)
Telephone counseling <sup>75</sup>	OR 1.3–1.4 (95% CI 1.2 to 1.5)
Nursing interventions <sup>76</sup>	OR 1.5 (95% CI 1.3 to 1.7)
Tailored self-help interventions <sup>77</sup>	OR 1.2 (95% CI 1.0 to 1.4)
Group behavioral support <sup>78</sup>	OR 2.0 (95% CI 1.6 to 2.5)
Training health professionals <sup>79</sup>	OR-1.7 (95% CI 1.5 to 2.0)
Mobile phones <sup>80</sup>	OR 1.8 (95% CI 1.6 to 2.0)
Nicotine replacement therapy (NRT) <sup>81</sup>	OR 1.6 (95% CI 1.5 to 1.7)
NRT gum	OR 1.5 (95% CI 1.4 to 1.6)
NRT patch	OR 1.6 (95% CI 1.4 to 1.9)
Nicotine lozenge/tablets	OR 1.9 (95% CI 1.4 to 2.7)
Bupropion <sup>82</sup>	OR 1.56 (95% CI 1.10 to 2.21)
Varenicline <sup>82</sup>	OR 2.96 (95% CI 2.12 to 4.12)
Low-dose varenicline <sup>79</sup>	OR 3.98 (95% CI 2.01 to 7.87)
Cytisine <sup>83</sup>	OR 1.82 (95% CI 1.66 to 2.0)
Behavioral support plus	OR 1.60 (95% CI 1.26 to 2.03)
pharmacotherapy <sup>84</sup>	

Behavioral support involves one or more sessions of advice and discussion aimed at increasing the success of quit attempts. It can be delivered one-to-one, in pairs or in groups. It usually involves multiple sessions lasting between 15 min to an hour each delivered by trained personnel (non-physician). The WHO recommends using five steps, also called the five 'A's, as a protocol for counseling on smoking cessation. 85 These are: Asking about tobacco use at every visit; Advising those who consume tobacco to quit in a clear, strong and personalized manner; Assessing their readiness to quit; Assisting in their quit attempt and Arranging for appropriate follow-up and reinforcement.

The feeling of reward experienced by smokers and the inability to stop in spite of wanting to quit are due to the nicotine present in cigarette smoke which is an addictive substance. It has now been proven that nicotine from cigarette smoke gets rapidly absorbed into the bloodstream and binds with alpha 4 beta 2 receptor acetylcholine-nicotinic receptors in the ventral tegmental area of the brain.  $^{86}$  Nicotine replacement therapy aims to make it easier to stop smoking by providing nicotine to reduce the craving and withdrawal symptoms and to occupy nicotinic receptors, such that if a lapse occurs the cigarette is less rewarding. Multiple delivery options are available, namely gum, transdermal patches, inhalers, lozenges, sublingual tablets, as well as nasal and mouth spray. Nicotine replacement therapy is a pharmacological intervention, but in most countries it is available over-the-counter. However, in some countries prescription is required for the higher-dose products.

# Pharmacological interventions: where physicians and medications, are both available and affordable

## **Bupropion**

Bupropion is an atypical antidepressant approved to be prescribed to aid smoking cessation by reducing nicotine cravings and withdrawal symptoms. It has been shown to double the chances of remaining abstinent for a year. 82,87,88 It requires prescription by a physician and is not very expensive. It is available in several MICs.

#### Varenicline

Varenicline is a recently-approved agent for tobacco cessation. <sup>89</sup> It is a nicotinic partial agonist that targets the alpha 4 beta 2 receptor. It reduces craving and nicotine withdrawal symptoms and reduces the rewarding effects of smoking. It is much more effective than Bupropion. It requires a physician's prescription and is quite expensive, and therefore may not be a feasible recommendation to patients.

## Cytisine

Cytisine is a partial agonist targeting the alpha 4 beta 2 nicotinic receptor, and is the drug on which varenicline was modeled. 83,90 It is obtained from laburnum seeds and has been prescribed for smoking cessation in eastern European

countries like Poland and Russia for many years. It is not licensed in most countries, but would be affordable for MICs if licensed.

#### Smokeless tobacco cessation interventions

Evidence on the effectiveness of methods of smokeless tobacco cessation is still an area of emerging research, but some guidelines have been formulated. 91 Authors of the only Cochrane review on smokeless tobacco cessation in 2011 concluded that while there is evidence of clinically-significant benefit of behavioral interventions (11 out of 14 trials reported benefit, including seven which reported statistically significant benefit), bupropion (OR [odds ratio] = 0.9; CIs [confidence intervals] 0.5-1.6) and nicotine replacement therapy (OR = 1.14; CIs 0.9-1.4) have not shown significant benefit for smokeless tobacco users. 92 A single trial of varenicline published since the review has shown benefit (OR = 1.6; CIs 1.1-2.4). On the other hand, a recently-published trial in 2013 conducted in India of the effect of varenicline on smokeless tobacco use did not find a significant benefit.<sup>89</sup> In summary, the limited evidence currently available on efficacy of interventions for stopping smokeless tobacco has not shown clear evidence for efficacy of medications, but there is evidence for behavioral support.84,92

## Overweight/obesity

In patients with established CHD, the prevalence of overweight and obesity far exceeds that in the general population. <sup>93</sup> Large international epidemiological studies including those in MICs reveal up to 78% of CHD patients are overweight and up to 53% are obese. <sup>56,94</sup> Overweight and obesity are associated with various adverse CVD outcomes, including increased risk of angina, <sup>95</sup> CVD death and MI. <sup>56,96</sup> In MICs, the population attributable risk for abdominal obesity ranges from 29.3% to 48.5%, with increases in BMI accounting for up to 9% of deaths from CHD. <sup>97</sup>

The implementation of public awareness programs in MICs to highlight the significant burden of overweight and obesity has been highlighted as one of the most cost-effective approaches for primary and secondary prevention. Furthermore, the WHO and World Obesity Federation have emphasized the promotion of healthy diet and PA as a crucial strategy in tackling the global epidemic of overweight and obesity. Indeed, weight loss via increased PA and dietary modification is the mainstay of managing obesity. Penefits of weight loss are dose-dependent, and sustained weight loss of 5%–10% of baseline weight within 6 months has been shown to improve CVD risk factor control. (See recommendations 1 and 2 for PA and healthy diet, respectively, in the companion article).

Pharmacotherapy for treatment of obesity is not recommended in MICs due to limited options, difficulty sustaining weight loss and lack of cost-effectiveness. <sup>100</sup> Similarly, bariatric surgery as a therapeutic option is not considered herein due to lack of infrastructure for tertiary surgical units in MICs.

#### Mental health

Depression, anxiety, stress from work, relationships and finances, social isolation, as well as anger and hostility among cardiac patients may complicate or hamper recovery. Due to the lack of formally-trained psychotherapists in most low-resource settings, a practical method to address PSS in CR is through mental health education and PSS management (i.e., relaxation techniques, coping strategies). Patients also often report that the social support they receive from peers and providers in the CR setting facilitates coping with their heart condition and promotes their psychosocial well-being.

Depression is considered an emerging risk factor for CHD. 102 Slowed thinking, decreased pleasure, decreased purposeful PA, guilt and hopelessness as well as disordered eating and sleeping may be seen in the depressive syndrome. 103 In HICs, it is reported that about 20% of CVD patients have major depression, 104 with many more reporting elevated depressive symptoms. Depression is a leading cause of disability in MICs, 105 and given the burden of CHD in these countries, it is expected that the rate of comorbidity would be even higher.

Comorbid depression is related to greater mortality and morbidity when compared to patients with CHD alone. <sup>106</sup> It is predicted that the CVD event rate in CHD patients with severe depression is double over one year. Moreover, depression is associated with increased drop-out from CR. <sup>107</sup> Given this high burden and negative impact of depression on patient's quality of life (QoL), CR guidelines from HICs recommend screening and treatment for depression. Effective treatment options for depression include cognitive behavioral therapy and anti-depressant medications. In HICs, selective serotonin reuptake inhibitors are shown to be safe in CVD patients, and to result in moderate reductions in depressive symptoms. <sup>108</sup>

There has been a trend towards harm with PSS intervention provided to women with CHD by non-psychologically trained personnel. 109 Moreover, there is a paucity of research on the treatment of comorbid depression in MICs. Therefore it is recommended at this time that formal treatment not be initiated where trained providers are not available. This is because PA as part of CR is shown to reduce depressive symptoms to a similar magnitude as psychotherapy and anti-depressants. 110

## Medical risk factor management

## Lipid control

Based on international large-scale studies incorporating patients from MICs, the prevalence of elevated total cholesterol levels (widely accepted as >200 mg/dL or 5.2 mmol/L) in those with established CHD ranges from 40% to as high as 77%. <sup>19</sup> Cholesterol is a major culprit in CVD risk and outcomes in MICs. Raised cholesterol accounted for more than 70% of additional CHD deaths over time, <sup>111,112</sup> and abnormal lipids carry a population attributable risk of almost 50%. <sup>56</sup>

Management strategies for cholesterol lowering include lifestyle modifications, namely dietary changes and PA (See recommendations 1 and 2 for PA and healthy diet, respectively, in the companion article), 12 as well as pharmacotherapy. Of the variety of available lipid-lowering drugs, treatment of elevated cholesterol with statins remains the cornerstone of secondary prevention of CHD. Robust evidence extrapolated from HICs has demonstrated that LDL-C reduction corresponds to lowering of CHD risk regardless of baseline LDL-C levels. 113 Several international guidelines, including those recently-published by the International Atherosclerosis Society, have recommended lowering of LDL-C to less than 70 mg/dL (or 1.8 mmol/L) as an optimal therapeutic target for patients with established CHD as part of secondary prevention. 114,115 All patients with CHD should be prescribed statin therapy for LDL-C lowering regardless of baseline lipid levels unless contraindicated, regardless of baseline lipid levels, even when resources and affordability do not permit cholesterol measurement. Choice of statin will depend on cost-effectiveness studies performed for individual countries/regions.

However, studies investigating statin use in MICs reveal dismal prescription and compliance rates, ranging from 1.4 to 29.8%. <sup>19,116</sup> Lower socioeconomic status is associated with worse compliance. The CR team should promote medication adherence. <sup>117</sup> The polypill presents a potential solution for improving compliance rates, <sup>118</sup> where access is not an issue.

The program physician, designated healthcare professional, or primary care provider should be consulted when cardio-protective medication adjustment is needed, to ensure that patients achieve the recommended targets for BP and lipids (and blood glucose, as applicable).

#### Blood pressure control

Increased BP is a leading risk for death and disability globally. 119 Hypertension is present in the majority of people with CHD, and is causal in about half of CHD and HF cases, where increased BP has a particularly ominous course. 120

Lifestyle changes and medications are effective in reducing high BP (Information on exercise and diet is provided in the companion article). With regard to the latter, anti-HTN drug therapy (see Recommendations 9 and 10 in the companion article) can substantially lower the risk of recurrent CVD events; sequential addition of anti-HTN medications to achieve BP targets (i.e., <140/90 mmHg) is recommended in people with HTN who also have CHD and HF. 121

## Cardio-protective medications

Medications like aspirin, ACE-inhibitors and beta-blockers have been demonstrated to reduce CVD events and mortality in patients with CHD, regardless of the presence of HTN or other specific risk factors. Cardio-protective medications recommendations, where available and affordable, are shown in the companion article (See recommendations 10). Finally, management of diabetes within the CR context was considered beyond the scope of the current recommendations. Readers are referred elsewhere.

# Education to promote self-management for heart-health behavior changes

As outlined above, for persons with CHD, behavior changes (i.e., PA, improved diet, medication adherence and smoking cessation) are highly effective in reducing risk. These behavior changes required are multi-factorial, necessitating patient understanding and long-term adherence to optimize health outcomes. 7,123 Indeed, meta-analyses have demonstrated the importance of patient education for improving self-management behaviors 124 and health-related QoL, and potentially reducing healthcare costs and recurrence of acute CVD events. 125

A recent systematic review has demonstrated the benefits of educational interventions in CHD, through increasing patients' knowledge and behavior change. 123 Of the 42 included studies, one was undertaken in the MIC Turkey. 126 Results of this small quasi-experimental study with nurse-delivered education demonstrated improvements in risk factors (i.e., BP, lipids, BMI, smoking), as well as diet and exercise, but not medication adherence.

## Developing and delivering patient education in CR

CR education materials and content should be consistent with patient's level of health literacy and cultural beliefs. Health literacy may be lower in MIC settings where there is less exposure to health information and healthcare providers. Testing the health literacy of patients enables healthcare providers to: (1) match the readability level of materials to the reading skills of patients, (2) know whether supplemental teaching is needed, and (3) know when it is necessary to introduce different types of educational materials (e.g., audiovisuals, demonstrations). <sup>127</sup> CR programs should offer instruction at a level which is understandable to patients. <sup>127</sup>

It is suggested that the educational intervention be delivered with a basis in behavior change theory. Theories such as the Health Action Process Approach model, <sup>128</sup> social cognitive theory, <sup>129</sup> and adult learning principles are particularly applicable for CR education. <sup>130</sup> An example of social cognitive theory use is the self-management model, which has been shown to be effective in CVD patients. <sup>131</sup> In this model CR participants learn to monitor their health behavior and the circumstances under which it occurs, including identifying proximal goals to motivate themselves and to enlist social supports to sustain their efforts. <sup>132</sup>

CR sessions are delivered over several weeks or months permitting repeated patient contact with healthcare providers, enabling fulsome education regarding the numerous lifestyle changes and treatments shown to reduce risk over time. Among the content areas on which cardiac patients should be educated are: the heart (i.e., physiology, diagnoses), nutrition, exercise/PA, medication, work/vocational/social role resumption, PSS, safety in relation to cardiac symptoms and emergencies, tests and treatments, and risk factors. Information provided should match patients information needs, and be delivered in a format which is congruent with patient preferences (e.g., written materials, group and individual education sessions, multimedia).

### Return to work

In MICs, return to paid roles following a CHD event bears significant individual and societal importance for economic reasons. Occupational assessment is recommended for patients wanting to resume employment where available, with particular emphasis on physically-demanding occupations and jobs involving public safety (e.g., vocational driving). Risks related to the nature of the patient's job in relation to their health status should be weighed. Exercise testing is warranted in selected patients to assess functional capacity, myocardial ischemia and/or electrical instability. Patients who are able to carry out >7 metabolic equivalents of work without angina, with left ventricular ejection fraction of >40% by echocardiography (where available), and with no electrocardiographic changes suggestive of ischemia or electrical instability on exercise stress testing (where available) can be considered low-risk individuals. These patients may return to work as early as 2 weeks after the treated CHD event. 134 Identification of these individuals at low-risk of adverse CVD events facilitates cost-effective early return to work. 135 These general criteria can be adapted and modified to existing guidelines for return to work. 136

Psychosocial (e.g., mood, job satisfaction, motivation) rather than clinical (e.g., cardiorespiratory fitness) factors have been found to play an important role in individual's return to paid work in HICs.<sup>137</sup> Whether these factors are central in MICs is not known. Because acute mental and physical stressors can induce myocardial ischemia, both the physical and psychological demands of the patient's work should be considered. Efforts should be made to identify these issues, and promote work modifications for the patient, including negotiation of gradual return to work, where feasible. For patients who cannot safely return to their jobs, CR providers could provide them with the contact information for employment agencies.

Patients who return to work, particularly those who return within 2 weeks of their CHD event, should nevertheless receive comprehensive CR. Alternative delivery models should be applied, such as home-based CR (see Section home-based CR below).

#### Outcome assessment tools

Re-assessment, as well as audit and evaluation, is considered a core component of CR. The goal is to test whether patients are meeting treatment targets at program completion and have made significant changes through their participation. Where possible, an electronic database should be used to support ease of evaluation. To rule out potential biases, also where feasible, programs should attempt to assess all consecutive patients pre and post-program. Where patients' drop out, they should be called back for re-assessment where possible.

Given that many recommendations for CR delivery herein are based on evidence stemming from high-income countries or consensus, the writing panel particularly encourages evaluation wherever these recommendations are applied. Indeed the ICCPR plans to undertake field and feasibility tests of this model in future, using the assessment tools outlined below to inform future iterations of this consensus statement. Where formal

evaluation (not simply quality auditing) is undertaken for research purposes, protocols should be approved by a local institutional research ethics board, and all patients should provide written, informed consent. If feasible, incorporation of a control or comparison group, and randomization of participants to the consensus model versus a comparison group should be built into the evaluation design. It is hoped that in future all recommendations will be evidence-based.

#### Functional capacity

A half to 1 MET increase in functional capacity from pre to post-program is an important marker of CR outcome, particularly because an increase of this magnitude is associated with significantly lower morbidity and mortality. <sup>139</sup> As outlined above, the gold standard assessment is an exercise stress test, where available. The six-minute walk test can also be used to measure progress with respect to changes in functional capacity as the program continues.

## Lifestyle risk factors

## Physical activity

A low-cost, exercise adherence and monitoring tool is a pedometer. <sup>140</sup> While walking for 1.6 km equates to 2000 steps on average, and walking for 30 min a day would on average register 3000 to 4000 steps, patients should aim to gradually increase step counts (at intensities which are asymptomatic) to reach 5400 to 7000 or more steps per day. <sup>140</sup> Walking 6500 steps/day is considered consistent with the clinical guideline recommendations to accrue 150 min of physical activity per week. If a pedometer is not available, the WHO STEPs includes core items assessing recreational activity and active forms of transportation, <sup>23</sup> or patients can be asked to record their activity in a log.

#### Nutrition

It is essential that patients' dietary habits are re-assessed at the end of the program. The same tool should be administered at each assessment point, so that change in dietary patterns can be measured. See the recommended tools in the initial assessment Section Diet, which are sensitive to change.

#### Tobacco abstention

At each CR visit, tobacco consumption must be assessed in current and former smokers. One of the drawbacks of self-reported assessment is the possibility of socially-desirable reporting. There are several objective methods which can be used to assess tobacco consumption. These include assessment of carbon monoxide in exhaled air by a portable monitor. This gives immediate results and verifies whether the person has smoked in the past 24 h. Carbon monoxide is one of the constituents of cigarette or Bidi smoke, and the level should be below 10 ppm.

## Overweight/obesity

Re-assessment of BMI and WC is indicated in all patients at program completion. Patients should be informed of changes observed, and whether they have met thresholds outlined in the initial assessment Section Overweight/obesity.

## Education/knowledge

The Coronary Artery Disease Education Questionnaire (CADE-Q) assesses patients' knowledge about CHD, and was validated in CR patients in the MIC Brazil. 141 The CADE-Q failed to assess all core components of CR, such as nutrition and psychosocial risk. Therefore, the CADE-Q II was developed and psychometrically-validated. 142 It has been demonstrated to be sensitive to change from pre to post-CR and as such should be administered at both points, but has not yet been validated in LMICs.

#### Depression

To assess change in depressive symptoms from pre to post-program it is recommended that again the WHO-Five Well-Being Index, <sup>143</sup> or the PHQ-9<sup>43</sup> be administered in accordance with AHA guidance. <sup>43</sup> Preferably the same scale should be administered at both assessment points. The PHQ-2 is a screener only, and would not be sufficient to detect changes in depressive symptoms, so programs may wish to consider administering the PHQ-9 pre-program as well.

#### Return to work

Post-CR, patients should be asked whether their occupational status (as assessed via WHO STEPS; see the initial assessment Section Return to work) is consistent with their desired status. Time in days from CHD event to return to work should be recorded. Where applicable, patients should be asked whether their CHD symptoms were well-managed upon return to work, and to rate their satisfaction with their support in return to work by the CR program.

## Medical risk factors

## Lipids

Resource availability permitting, all patients with established CHD should have assessment of lipid levels pre and post-program. Moreover, upon initiating pharmacotherapy, reassessment of lipid levels should be performed every 6 to 8 weeks when dose adjustment is necessary, and every 4 to 6 months once treatment targets have been achieved. Outcome assessment can be performed by monitoring medication adherence (see iii below) and proportion of patients achieving target values of LDL-C. The WHO STEPS Instrument contains two questions (H14 and H19) that specifically assess if individuals are taking oral therapy for raised cholesterol, and if statins are consumed. 23

## Blood pressure

BP values should be measured as outlined in the assessment section, and the degree of change from pre to post-program considered. In general, values should be less than 140/90 mmHg at program exit.<sup>121</sup> Programs should aim for hypertension control to be achieved in the majority of patients (>70%) and for a minimum 20% improvement in control if the initial control rates are less than 50%. <sup>144</sup>

#### Cardiac medication adherence

Patient use of, adherence to, tolerance of, and contraindication for cardio-protective therapies should be re-assessed and documented at the discharge assessment. Adherence to medications could be assessed with the 8-item Morisky Medication Adherence Scale, or pill counts/prescription refills. $^{145}$ 

## Program utilization

Rates of referral and enrolment should be captured, and potentially wait times. Patients' adherence to the program and completion should be described, and reasons for dropout, be they clinical or otherwise, recorded. Other indicators of the structure, process and outcomes of CR, including data definitions have been developed in high-income settings. <sup>146,147</sup>

Finally, where possible, ascertainment of long-term healthcare utilization, as well as morbidity and mortality would be ideal.

# Adaptation of the CR model by type of most-responsible healthcare provider

Herein a comprehensive model for CR delivery in low-resource settings has been initially proposed. Similar to the "Secondary Prevention for All in Need" model previously forwarded, <sup>148</sup> the model is conceived as menu-based and flexible to be applicable in a variety of lower-income contexts and regions of the globe. Depending on the health system structure of each country, and the availability of trained healthcare providers, general practitioners or family physicians, nurses or other allied healthcare providers as well as community health workers can be engaged to deliver CR. <sup>149</sup> Box 1 displays approaches to risk factor assessment as well as lifestyle and medical management where the most highly-trained profession represented in a CR program is: (1) a community healthcare worker, or (2) an allied healthcare provider or nurse.

## Adaptation of CR for LMICS

There is now ample evidence that CR is equivalently-effective in high-income countries whether it is delivered in a formal facility or through a home-based model. 150,151 Clearly, delivery of CR without requirement for a facility and the associated costs would be much more feasible in low-resource settings. The section below considers key ways CR could be adapted to be more feasibly delivered in low-resource settings, through community, the home, the internet/mobile technology and within primary care. Box 2 provides a case example of CR delivery in a low-resource setting.

## Community-based CR

Most notably for LMICs, community-based CR has emerged as an alternative modality to traditional hospital-based CR.<sup>152</sup> For the purpose of this consensus statement, community-based CR refers to delivery of all the core components of traditional CR, but where patients engage in their prescribed exercise in a non-medical setting, such as a community center for example. A recent systematic review showed that community-based programs in high-income countries are as effective as hospital-based programs in lowering CHD risk factors and re-hospitalization as well as improving physical function.<sup>152</sup> A more recent study

# Box 2 Case Example: Cardiac Rehabilitation in Iran.

The first Cardiac Rehabilitation (CR) program in Iran was established in 1996 at the Isfahan Cardiovascular Research Centre, after which several other programs were established. To optimize their program, the CR staff have attended short-term courses in other countries to learn about best practices and alternative delivery models.

Their CR program consists of 20 sessions delivered over approximately 2 months. Their program is comprehensive, including risk factor assessment and control, structured exercise, patient education (including for patients' families and members of the community at high risk of cardiovascular disease) and psychosocial counseling. They also offer a home-based program.

The last 10 sessions are free if patients consent to use their information for research purposes. Their lab data, exercise test results, and echocardiographic findings are documented and then used for research purposes. After completion of the CR program, patients are followed up every three months by telephone to ascertain mortality, as well as re-hospitalization and its causes, including revascularization procedures.

The main barrier to patient participation was financial. The leadership lobbied the Ministry of Health and private insurance companies to achieve CR reimbursement. Based on evidence of the benefits of, and provision of CR in high-income countries, including economic, in 2000 the Ministry sent a directive to hospitals with cardiac services to offer CR and insurance companies now reimburse. As a result, an increase in CR participation has been observed.

This CR center also offers professional development courses for healthcare providers to promote establishment of more CR programs in Iran and neighboring countries. These cover the goals of CR, the roles of members of the multi-disciplinary CR team, management of patients with different risk factors and referral indications, and protocols for the management of cardiac emergencies.

demonstrated that a community-based CR program had similar effects as a hospital-based program on health-related QoL, PSS, exercise frequency, and smoking rates. <sup>153</sup>

The WHO promotes delivery of rehabilitative services including CR for chronic disease management in the community, especially in low-resource-settings. <sup>11</sup> This may enable affordable and sustainable CR services by making use of a community's available resources such as buildings and human resources. Community-based CR in LMICs could be delivered by trained healthcare personnel or community health workers (see algorithm in Box 1).

For example, a successful community-based project supported by the WHO was undertaken in Indonesia between 2003 and 2006, which aimed to reduce chronic disease risk factors. Non-communicable disease risk factor services were integrated in a public health center that provided basic health services, including anthropometry measurement, BP measurement, promotion of a healthy diet, exercise, and smoking cessation.<sup>154</sup>

Moreover, in Indonesia, while there is a lack of hospital-based CR programs, there are more than 2500 Healthy Heart Clubs around the country. These clubs are affiliated with the Indonesian Heart Foundation, and provide community-based exercise programs for healthy persons and patients with CVD. 155 Unfortunately however, there is no single published article on the components, staff, or effectiveness of these community-based clubs. As another example, in India, availability of structured, supervised CR programs is similarly limited; however, there are several community-based, free-standing centers which are not affiliated with hospitals that offer secondary prevention services for CVD patients. 156

A more comprehensive community-based CR model is delivered in Singapore. 157 The Singapore Heart Foundation Heart Wellness Centers offers a wide range of services, equipment and multidisciplinary healthcare expertise for primary and secondary prevention of CHD. Physiotherapists assess heart patients during the initial session to evaluate their physical abilities, medical limitations and health conditions. Patients are then prescribed individualized exercise programs, and they attend scheduled sessions. A variety of exercise equipment is available including treadmills, stationary bicycles, arm cycles, rowers, steppers, cross-trainers, and resistance training machines or dumbbells. Other services provided are nutritional counseling, smoking cessation counseling, health education sessions, and social support from other heart patients in the program. The program is run by physiotherapists, nutritionists, and smoking cessation counselors. The health talks are delivered twice a month by multidisciplinary healthcare professionals including cardiologists and cardiothoracic surgeons. 158 Recently, the effectiveness of this community-based CR program was evaluated. The results showed reduction in CHD risk factors (i.e., body fat and lipids), as well as improvement in exercise tolerance with patients' able to walk a significantly longer distance after 12 months than their baseline. A randomized controlled trial to evaluate the model is currently underway, to include 1000 patients over five years. 158

## Home-based CR

Home-based CR delivery can range from simple (i.e., paper-based educational material) to technologically-advanced (i.e., internetbased). Home-based CR has been successfully implemented in LMICs. 159,160 For example, in India, the Dream Program is a comprehensive, unsupervised CR program. 159 At hospital discharge, patients attended a briefing session and were given educational materials regarding the CR components including exercise, diet, and stress management for home practice. To track the progress of patients, they were asked to complete, on a daily basis, a self-evaluation chart consisting of all the components of CR. In addition, frequent follow-up (every 15th day) was offered through visits to the hospital-based CR unit. Upon re-assessment at the end of the 3 month program, this program was shown to be effective in reducing CVD risk factors including resting rate pressure, fasting blood sugar, total cholesterol, TGs and anthropometric indices as well as improving functional capacity. 159

Another study of home-based CR was reported in Brazil. 161 The model was comprised of 3 months of unsupervised exercise classes with bi-weekly telephone monitoring by a physician. Before starting the program, patients attended two supervised classes in a gymnasium led by a physiotherapist and received education on exercise and CHD risk factors. The home-based PA included stretching exercises and walking for 30 min, three times per week on non-consecutive days. A prepost evaluation of this program demonstrated improvement in aerobic capacity and QoL, despite its low cost, and with an adherence rate of 100%. <sup>161</sup>

In China, a 6-week home-based CR program was delivered through a program manual provided to patients before hospital discharge. <sup>162</sup> Patients had a 1-h session where each section was introduced, and relaxation skills (i.e., tai chi) were demonstrated. The manual contained 3 sections: (1) 6 weekly topics on health education such as anatomy and physiology of the heart, signs and symptoms of MI, stress management, a home exercise plan, and relaxation; (2) answers to commonly-asked questions about medication, cardiac procedures, and anxiety and depression after MI; and (3) information on risk factors. <sup>162</sup> Compared to a usual CR group, the home-based participants had significantly higher scores on QoL and significantly lower anxiety.

Other home-based CR program models delivered in high-income countries are somewhat hybrid. 163,164 This approach would be particularly promising in LMICs, particularly incorporating mobile devices, 165 as programs could make use of publically-available resources.

### Mobile technology

With 5 billion mobile phone users around the world, there is an increasing trend to use mobile technology in healthcare delivery. 166 According to the International Telecommunication Union, the mobile penetration rate is 90.2% in LMICs, which is 78% of the global subscriptions. 167 Clearly, mobile delivery represents an accessible approach for CR. Moreover, CR delivery via a mobile has the potential to overcome resource challenges in LMICs, such as cost, infrastructure, and human resource constraints. 163

Mobile delivery methods in LMICs include voice calls, text messaging, and voicemail messages sent to the user's voicemail inbox with short message service (SMS) notification. SMS messages can be personalized and motivate behavioral change. Other delivery methods observed in high-income countries include smartphone applications with electrocardiogram and heart rate monitoring. The mobile applications applied in the CR setting include step-counting, visual feedback, text message reminders, educational videos, web portals, and diaries for recording weight, BP, and PA. 163

Mobile technology has been used successfully in low-resource settings for non-CR health care delivery, such as the integrated community case management model for infectious diseases delivered by community health workers in African countries, including in remote areas. <sup>166</sup> In those settings, mobile has been used for education and raising awareness regarding required behavior changes, as well as for monitoring patients' health condition and promoting adherence to medication regimens. <sup>166</sup> Although no evaluation of the impact of these interventions on health outcomes in LMICs is available currently, a randomized controlled trial in sub-Saharan Africa showed

that text messaging via mobile phones resulted in increased medication adherence.  $^{168}$ 

Because mobile technology is a recent and growing health delivery modality, there is need for research to establish its effectiveness (even in high-income countries). A recent review provides initial evidence for the feasibility and acceptability of using mobile technology for CR. <sup>163</sup> For example, some studies showed that mobile-based delivery of CR is effective in improving self-efficacy, physical activity, exercise capacity, and general, physical, and mental health scores in patients with CHD. <sup>163,169</sup> More recently, the first randomized controlled trial on smartphone, a mobile with advanced features including applications, use for CR delivery revealed compelling results of significant improvement in CR utilization as well as improving functional capacity and psychological health outcomes as hospital-based program. <sup>164</sup>

Although there are no published data from LMICs on CR delivery via mobile, a randomized controlled trial is underway in Jordan (a middle-income country). <sup>165</sup> The aim of the study is to examine effect of a 6-month behavioral change intervention delivered via mobile on PA. The intervention consists of individualized consultation calls and motivational reminder text messages delivered once a week for 3 months, then bi-weekly for another 3 months. <sup>165</sup> Though results have not yet been published, the principal investigator indicates results are promising (E. AlSaleh, March12, 2014: personal contact).

## Integration of CR within the primary health care system

In high-resource settings, CR is most-commonly delivered in the hospital setting with program oversight by a specialist physician. Given that specialty care is less available than primary care in LMICs, if broad reach to the many patients with CHD is to be achieved, CR may better be developed in the primary care setting. Indeed, the WHO has the goal to ensure universal access to primary health care. As the integration of preventive and management services for HTN and DM and some other non-communicable disease in the primary healthcare setting has been successful, <sup>170,171</sup> the same approach may be warranted to achieve broader implementation of CR in LMICs.

## Conclusion

These are the first recommendations by a global body in almost 25 years on how CR can be delivered practically in the MIC setting. While each core component is addressed separately herein, it is conceived that the lifestyle and behavior elements weave consistently across all the recommendations, and should be applied in a patient-centered manner.

There are large variations in the levels of healthcare resources available in low-resource settings; the recommendations should be implemented as possible. Moreover, there is a paucity of trained healthcare personnel to deliver CR in low-resources settings, particularly with expertise across all these core components. It is recommended that MICs establishing or augmenting CR services establish a competent body to provide requisite training on all aspects of CR, to non-physicians as well as general practitioners. We recommend that academic

institutions offering advanced cardiac services appoint clinical educators tasked with training CR providers at non-academic and developing CR centers. In future updates of this statement, we hope to establish training standards for CR professionals delivering care in low-resource settings.

#### Statement of conflicts of interest

None of the authors have any conflicts of interests with regard to this publication.

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