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Standardized Outcome Measurement for Patients With Coronary Artery Disease: Consensus From the International Consortium for Health Outcomes Measurement (ICHOM)

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Background—Coronary artery disease (CAD) outcomes consistently improve when they are routinely measured and provided back to physicians and hospitals. However, few centers around the world systematically track outcomes, and no global standards exist. Furthermore, patient-centered outcomes and longitudinal outcomes are under-represented in current assessments.

Methods and Results—The nonprofit International Consortium for Health Outcomes Measurement (ICHOM) convened an international Working Group to define a consensus standard set of outcome measures and risk factors for tracking, comparing, and improving the outcomes of CAD care. Members were drawn from 4 continents and 6 countries. Using a modified Delphi method, the ICHOM Working Group defined who should be tracked, what should be measured, and when such measurements should be performed. The ICHOM CAD consensus measures were designed to be relevant for all patients diagnosed with CAD, including those with acute myocardial infarction, angina, and asymptomatic CAD. Thirteen specific outcomes were chosen, including acute complications occurring within 30 days of acute myocardial infarction, coronary artery bypass grafting surgery, or percutaneous coronary intervention; and longitudinal outcomes for up to 5 years for patient-reported health status (Seattle Angina Questionnaire [SAQ-7], elements of Rose Dyspnea Score, and Patient Health Questionnaire [PHQ-2]), cardiovascular hospital admissions, cardiovascular procedures, renal failure, and mortality. Baseline demographic, cardiovascular disease, and comorbidity information is included to improve the interpretability of comparisons.

Conclusions—ICHOM recommends that this set of outcomes and other patient information be measured for all patients with CAD. (*J Am Heart Assoc.* 2015;4:e001767 doi: 10.1161/JAHA.115.001767)

Key Words: coronary artery disease • outcomes • patient-centered

ardiovascular disease represents the single greatest global disease burden, both in mortality and morbidity. Recent alarming increases in incidence noted in low-income and middle-income countries raise concern for future generations. However, increasing cardiovascular disease burden is not inevitable. High-income nations have invested heavily in addressing this problem. Mortality from cardiovascular dis-

ease, especially coronary artery disease (CAD), has dramatically decreased in the past few decades.^{3,4} While public health initiatives aimed at primary prevention have certainly led to some of these gains, advances in treatment for patients with CAD have accounted for a significant portion.^{5,6}

Despite overall improvement in high-income countries, significant variation in outcomes for patients with CAD still

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exists. Significant differences in 30-day mortality following acute myocardial infarction (AMI) have been found between the United Kingdom and Sweden. Even among elderly patients admitted for AMI within the United States, a greater than twofold difference in 30-day risk standardized mortality was found, depending on which hospital provided the care. These findings suggest an opportunity to identify the best management practices that lead to optimal outcomes and then to implement them across broad populations, lessening the global burden of cardiovascular disease.

Cardiovascular registries have been operating worldwide for several decades in large part to accomplish these goals, 9,10 and impressive gains in quality of care and outcomes have been made. 11-13 However, the full potential impact of cardiovascular registries is currently constrained by the lack of 2 key factors: international standard definitions and longer-term patientcentered outcomes. With the notable exception of collaborations in the United State between the American College of Cardiology and the Society of Thoracic Surgeons registries, most cardiovascular registries have developed in isolation, and they rarely cross national borders. This approach has led to registries tracking different outcomes and/or using different definitions for equivalent outcomes. This lack of standard outcomes and definitions has limited the validity of international comparisons across providers of different health systems. Educational and quality improvement activities have remained primarily local or regional, and the wider variation in care and outcomes globally has remained unaddressed. In addition, cardiovascular registries have focused primarily on improving quality of care by reporting process measures and short-term outcomes, most commonly tracking in-hospital or 30-day mortality and complications. Longer-term outcomes (for example, after 1 and 5 years), and patient-centered outcomes (for example, angina burden, functional status, and healthrelated quality of life), more closely reflect the ultimate benefit of care but are rarely tracked in real-world settings. Hence, the true value of individual interventions and of whole systems of health care is never fully understood.

To align outcome measurement efforts globally and to promote more comprehensive measurement of outcomes, the nonprofit International Consortium for Health Outcomes Measurement (ICHOM)¹⁴ formed a CAD working group. ICHOM was founded in 2012 by Harvard Business School, The Boston Consulting Group, and The Karolinska Institutet and has so far completed 11 other standard sets of outcomes. It is funded through support from the founders and from a wide range of international sponsoring partners. In accordance with the goals of ICHOM, the CAD Working Group aimed to define a parsimonious, consensus, standard set of outcomes that are meaningful to patients with CAD and are able to be tracked for an appropriate length of time across diverse health systems.

Methods

Objectives

The primary goal of this initiative was to identify a parsimonious, consensus, set of outcomes with standard definitions for patients with CAD that could be tracked by health systems and clinical registries around the world. In particular, this standard set would encompass a range of outcomes relating to mortality, morbidity, and patient health status (ie, symptoms, functional status, and health-related quality of life). The use of a standard set of outcome measurements would not preclude any system or registry collecting and reporting additional measures as desired. A secondary goal was to identify a standard set of variables to be systematically collected to enable case-mix adjustment, which would support comparison of CAD outcomes among providers and health systems with different case mixes of patients.

Composition of Working Group

ICHOM brought together an internationally recognized group of clinician and nonclinician leaders in the field of CAD with expertise in (1) clinical trials and registries, (2) public and private health system management, (3) patient-centered outcomes research, (4) outcomes measurement, (5) quality improvement, and (6) patient advocacy. There were a total of 17 members from 4 continents and 6 countries. ICHOM also formed a project team, which consisted of a project leader (C.J.S., then T.A.K.), who coordinated the process and a research fellow (E.S.S.), a cardiologist who provided subject-specific expertise.

Process

A modified Delphi technique was used to develop consensus around all major decision areas, including the scope of the population to be covered, the minimum outcome set, and the risk factors required for case-mix adjustment. Consistent with this method, a combination of teleconferences and surveys was used to forge consensus. Between December 2012 and November 2013, the Working Group participated in 11 conference calls, 10 of which were followed by surveys on key decision points. Prior to each teleconference, the ICHOM project team developed an agenda, listed key proposals, and summarized relevant evidence from the literature. The Working Group reviewed these documents in advance and discussed them during each teleconference.

The Working Group selected outcomes based on 4 criteria: (1) the *frequency* of the outcome; (2) its *impact* on the patient; (3) the potential to *modify* the outcome; and (4) the *feasibility* of "capturing" the outcome in clinical practice. Additional

criteria for patient-reported outcome measures (PROMs) included (1) the domain coverage; (2) the psychometric properties; (3) the feasibility to implement; and (4) the clinical interpretability. Next, time points for data collection were selected for each outcome. Risk-adjustment variables were selected based on 3 criteria: (1) the relevance (strength of the causal linkage between the risk factor and the outcome), (2) the risk factor independence, and (3) feasibility of measurement.

Following each call, the ICHOM team circulated detailed minutes and an electronic survey on each key decision point. Decisions were finalized when more than two thirds of the Working Group members concurred. In cases where consensus was not achieved, further discussion ensued during subsequent teleconferences, which was followed by a second survey. The final standard set was approved unanimously by all members of the Working Group.

Results

Cohort Definition

As defined by the CAD Working Group, the target population is all patients with CAD, including patients presenting with any

of the following qualifying diagnoses, test findings, or interventions: angina, acute coronary syndrome, AMI, CAD noted on angiography or other coronary imaging modalities (eg, computed tomography; magnetic resonance imaging), stress testing suggestive of CAD, percutaneous coronary intervention (PCI), or coronary artery bypass grafting (CABG). Informing the Working Group's approach to cohort selection was the recognition that the same set of longitudinal outcomes (eg, survival, symptoms, and quality of life) was relevant to all patients with CAD, regardless of disease state or treatment received, while additional treatment and eventspecific outcomes could be described for patients experiencing AMI or undergoing PCI or CABG. In addition, the Working Group decided that the outcomes should be assessed at particular times after initial diagnosis and from each major event (AMI, PCI, and CABG).

Outcomes

The CAD Working Group decided to focus on both short-term (hospitalization, 30 days posthospitalization) and long-term (1 year and 5 years from first enrollment) outcomes (Figure). To inform its work, the Working Group reviewed the outcome

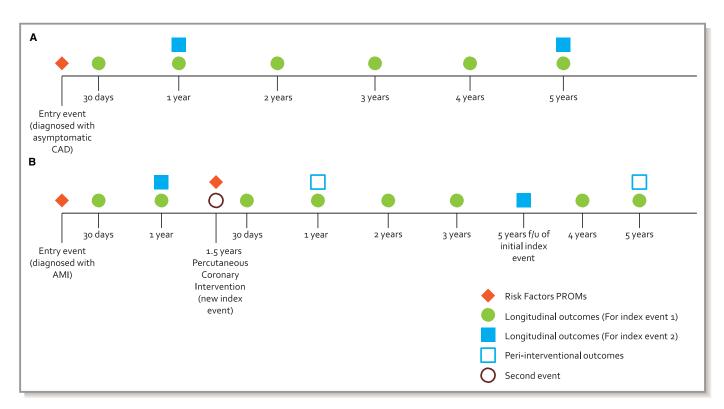


Figure. A, Example timeline for a patient diagnosed with asymptomatic CAD without any subsequent events. B, Example timeline for a patient initially diagnosed at time of an AMI and who subsequently undergoes a PCI one and a half years later. A new revascularization procedure or a new diagnosis of AMI constitutes a new index event, and tracking of PROMs should reset from this point, tracking again at 30 days, and then annually for 5 years. Given that longitudinal outcomes are obtained from administrative data, they are collected for both the entry event (eg, AMI) and the new event (eg, PCI). AMI indicates acute myocardial infarction; CAD, coronary artery disease; PCI, percutaneous coronary intervention; PROMs, patient-reported outcome measures.

domains, relevant definitions, and methods of ascertainment used in 13 established registries (Table 1). However, as these registries mainly report outcomes occurring during index hospitalizations and do not include patient-reported outcomes, the CAD Working Group proposed additional timelines for outcome measurement as well as collection of a set of PROMs.

Survival

The Working Group unanimously agreed to assess survival at 30 days postdischarge, and at 1 and 5 years following cohort entry. While longer follow-up is clearly important to patients, it may be less feasible for health systems to capture. Nonetheless, for the 3 selected time periods, the CAD Working Group decided to assess all-cause mortality using death registers. Limitations of such death registries were discussed, including the expense and time lag involved in obtaining these data. Additionally, in some countries, access to death registers is limited; in such circumstances, ICHOM will advocate that governments make these data more available. Disease-specific mortality was not selected as it is less meaningful to patients than all-cause mortality; additionally, the validity of the data may be limited if cause of death is not clinically adjudicated.

Longitudinal Outcomes

The CAD Working Group focused on longitudinal outcomes of CAD that are frequent, that are associated with a high morbidity (affecting patients' quality of life and functional

status), and that are costly. It elected to measure outcomes at 1 and 5 years from cohort entry. Patients who experience a cardiovascular event (eg, AMI) or undergo a cardiac procedure (PCI or CABG) during the follow-up period will not be censored; rather, they will continue to be followed for the entire 5-year period from the time they entered the cohort. However, they will also be included in a second cohort with an additional 5 years of follow-up from the new index event or procedure. The CAD Working Group elected to include the following outcomes, representing CAD progression and common, high-impact health outcomes related to cardiovascular disease: all-cause mortality (from death registers); AMI, revascularization procedures (PCI or CABG); new hospitalizations for acute coronary syndrome, heart failure, hemorrhagic and/or ischemic stroke; and advanced renal failure (detected as a new requirement for dialysis). It was decided not to include peripheral artery disease as an outcome as there is substantial international variation in detection of peripheral artery disease, depending on the intensity of diagnostic practices and therapeutic capacities.

The CAD Working Group decided to restrict longitudinal outcomes to those that could be captured via administrative data, as most current registries and electronic health record databases are not designed to capture events occurring outside of the acute care episode. It was recognized that for many countries without a single-payer healthcare system or an all-payer claims database, long-term outcomes can be difficult to ascertain. Therefore, linking of clinical data with administrative data was felt to be the most feasible and least resource-intense approach to collecting long-term outcomes.

Table 1. Registries Reviewed to Inform Outcome and Risk Factor Domains and Definitions

Country	Registry Name	Reference
Australia	Coronary Angiogram Database of South Australia (CADOSA)	15
Singapore	Singapore Myocardial Infarct Registry	16
Spain (Catalonia)	Codi Infarct Registry	17
Sweden	Swedeheart: Heart Surgery Registry	18
Sweden	Swedeheart: Swedish Coronary Angiography and Angioplasty Registry (SCAAR)	18
Sweden	Swedeheart: Swedish Register of Cardiac Intensive Care (RIKS-HIA)	18
Sweden	Swedeheart: Swedish Secondary Prevention Registry (SEPHIA)	18
United Kingdom	Myocardial Ischemia National Audit Project (MINAP)	19
United Kingdom	British Cardiovascular Intervention Society National PCI Audit	20
United Kingdom	Society for Cardiothoracic National Adult Cardiac Surgery Audit	21
United States	NCDR ACTION Registry—GWTG	22,23
United States	NCDR CathPCI Registry	22,23
United States	Society of Thoracic Surgeons National Database: Adult Cardiac	24

GWTG indicates Get With The Guidelines; NCDR, National Cardiovascular Data Registry.

Patient-Reported Health Status

PROMs are increasingly recognized as providing valuable information about health-related quality of life and are guiding more informed discussions about care management. A review of existing PROMs used in describing cardiovascular disease revealed 3 main instruments, specifically, the Seattle Angina Questionnaire²⁵ (SAQ-7), Rose Dyspnea Score,²⁶ Patient Health Questionnaire²⁷ (PHQ-2), Quality of Life Index²⁸ (QLI) Cardiac Version IV, and Quality of Life after Myocardial Infarction (QLMI-2/MacNew).²⁹ These instruments measure cardiac-related symptoms (eg, shortness of breath, chest pain), functional status, and quality of life. The Working Group considered the above measurement tools based on the following qualities: domain coverage (symptom burden, functional status, and quality of life), psychometric properties (validity, sensitivity, and quality of life), feasibility to implement (length of questionnaire, language availability, and cost to implement), and clinical interpretability (knowledge of how to interpret scores in a clinically meaningful way). The SAQ-7, which is short, widely translated into many languages, and has a high degree of clinically interpretability most closely aligned with these qualities and was recommended in the standard set. The Working Group desired additional questions to assess patients' level of dyspnea and depressive symptoms. The PHQ-2, a widely used 2-item questionnaire assessing signs of depression, and 2 items from the Rose Dyspnea Score were included to cover these domains. The Working Group also desired but did not reach a consensus on including time to return to normal activities, return to work, sexual function, or medication side effects within the Standard Set, primarily due to a lack of standardized assessments. The set will evolve over time, and we anticipate these factors may be included in the future.

Complications

In addition to survival, longitudinal outcomes, and patientreported health status, the Working Group voted to measure complications following PCI and CABG procedures that can have a significant impact on patients' quality of life and health outcomes, and that can enable comparison of providers' and institutions' technical quality of care. Based on registries from the Society for Thoracic Surgeons and the National Cardiovascular Data Registry, the Working Group selected several periprocedural outcomes for inclusion in the standard set. These outcomes include stroke, renal failure, and length of stay (for patients undergoing PCI and CABG); prolonged ventilation, sternal wound infections, and reoperations (for patients undergoing CABG only); and coronary dissection/perforation, emergent CABG, and vascular complications (for patients undergoing PCI only) (Table 2). The Working Group excluded conditions that were considered to be particularly rare, variably detected depending on intensity of care, and difficult to diagnose, (eg, periprocedural MI [variable detection; unclear if clinically meaningful], cardiac tamponade [rare]; restenosis rate [variable detection]; pneumonia among patients undergoing CABG [often not distinguishable from atelectasis]; and deep venous thrombosis among patients with CABG [rare]).

Case-Mix Adjustment

The Working Group was tasked with defining a minimum set of risk factors that would qualify as candidate variables for casemix adjustment of both clinical and patient-reported outcomes. Risk factors common to all CAD patients were defined as well as add-on variables for patients with AMI, PCI, and CABG (Table 3). The intent was to highlight factors that every health system should be collecting using a standard definition to enable comparisons across health systems. Informing the selection of risk factors was a review of existing risk models commonly used to assess severity of illness and prognosis (eg, the GRACE model³⁰; TIMI risk score³¹) as well as assessing the impact that a specific risk factor has on the outcomes in our set, based on the literature and expertise of the Working Group. Of note, socioeconomic status and psychosocial factors were not included due to the difficulty of standardizing these variables in the international setting and the lack of consensus regarding adjusting for these variables in risk models. The set of covariates is not intended to be exhaustive but will serve as a basis of developing international risk models for adjusting outcome performance across institutions.

Data Collection

A very important long-term goal of this effort is to produce data that can be easily compared between providers, centers, and countries. To achieve this, we recommend processes to reduce variability including the use of similar data sources, recognizing that the specific details of data collection will necessarily differ by center. As outlined in Tables 2 and 3, the potential sources include administrative data and death registries, patient-reported sources, and clinical abstraction or physician-reported sources, and we recommend that the source of data as well as the response rate (if patient reported) be tracked for every measure. A data collection manual that further describes each measure, its definition, inclusion and exclusion criteria, and potential data sources is available on the ICHOM web site (http://www.ichom.org/project/coronary-artery-disease/).

Discussion

The ICHOM CAD Working Group identified a consensus standard set of outcomes for the spectrum of patients with a

Table 2. Summary of Standard Set of Outcomes for Patients With Coronary Artery Disease

Category (Cohorts)	Measure	Details	Timing	Data Source	
Longitudinal	All-cause mortality	Date of death	Tracked for 5 years after index		
outcomes (All)	Admissions (for AMI, hemorrhagic stroke, ischemic stroke or heart failure)	Date of each admission & discharge	event—reported at 1 and 5 years		
	Procedural interventions	Date of PCI and/or CABG			
	Acute renal failure	New requirement for dialysis			
Patient- reported health status (All)	Angina, dyspnea, depression, functional status, health-related quality of life	SAQ-7, PHQ-2, Rose Dyspnea	30 days+then annually to 5 years after index event	Patient reported	
Acute complications	Mortality post procedure	Date of death	Within index hospitalization+within	Clinical or administrative	
of treatment (PCI & CABG)	Place of death	Options: Home; acute care hospital or rehab; nursing home or hospice	30 days of procedure		
	Stroke and stroke type	Ischemic; hemorrhagic; unknown			
	Acute renal failure	New requirement for dialysis			
	Total length of stay	Date at arrival and discharge	Within index hospitalization		
	Post-procedure length of stay	Date of intervention and discharge			
Major surgery complications (CABG only)	Prolonged ventilation	Mechanical ventilation >24 h post-surgery	Within index hospitalization	Clinical	
	Deep sternal wound infection	Requires operative intervention, positive culture & antibiotics	Within index hospitalization+within 30 days of procedure		
	Reoperation required	Return to operating theatre (for other than wound)			
Interventional	Significant dissection	Type C to F dissections	Within index hospitalization	Clinical	
cardiology complications (PCI only)	Perforation	Angiographic or clinical evidence of perforation			
	Emergent CABG for failed PCI	Emergency cardiothoracic surgery			
	Vascular complications requiring intervention	At percutaneous entry site	Within index hospitalization+within 30 days of procedure		
	Bleeding event within 72 h	Within 72 h of PCI	Within index hospitalization+within 72 h of procedure		

The full list of definitions is available on the website (http://www.ichom.org/project/coronary-artery-disease/). AMI indicates acute myocardial infarction; CABG, coronary artery bypass grafting; PCI, percutaneous coronary intervention; PHO-2, Patient Health Questionnaire; SAQ-7, Seattle Angina Questionnaire.

diagnosis of CAD in order to provide a foundation for making appropriate comparisons among countries and health systems in efforts to improve quality. The set incorporates frequently unreported outcomes that are important to patients, such as symptom burden and quality of life, as well as traditional outcomes such as mortality and periprocedural complications. The Working Group recommended not only short-term in-hospital outcomes but longer-term (1- and 5-year) outcomes. As appropriate comparison of outcomes requires robust risk adjustment, this set also includes baseline patient demographic and clinical information. To our knowledge, this is the first coordinated, multinational

effort to recommend a standard set of outcomes that all health systems should aspire to collect.

Defining value in health care and sharing data across health systems will require standard definitions of outcomes and patient characteristics. Well-designed and implemented standardized registries have attempted to fill this void and have provided the foundation for quality improvement in CAD in many countries. However, there have been few international comparisons outside of selected populations within clinical trials. Recent investigations into treatment patterns and outcomes have shed some light but are limited to select countries with well-developed registries. Even

Table 3. Summary of Standard Set of Risk Factors for Patients With Coronary Artery Disease

services (eg, outpatient clinic or emergency department) Sex Sex at birth Documented Height Documented Previous AMI Documented in history Hypertension Stroke Diabetes Documented in history Insulin dependence Peripheral arterial disease Documented in history Chronic lung disease Documented in history Dialysis dependent Documented in history Documented in history Liver cirrhosis Documented in history The peripheral arterial disease Documented in history Doc	Timing for Collection	Measure	Details	Data Source	
or emergency department) Height	First contact with hospital services (eg, outpatient clinic or emergency department)	Age	Date of birth		
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Previous CABG/PCI Including date of procedure		Number of diseased vessels			
· ·		Previous CABG/PCI	Including date of procedure		

The full list of definitions is available in a Reference Guide on the International Consortium for Health Outcomes Measurement web site (http://www.ichom.org/project/coronary-artery-disease/). AMI indicates acute myocardial infarction; CABG, coronary artery bypass grafting; ED, emergency department; FFR, fractional flow reserve; NSTEMI, non-ST-segment elevation myocardial infarction; PCI, percutaneous coronary intervention; STEMI, ST-segment elevation myocardial infarction.

within these comparisons, subtle but potentially important differences exist in definitions for patient clinical characteristics and outcomes. Key data elements and definitions for measuring outcomes among patients with CAD have been put forth from the European Union³⁴ and the American Heart Association/American College of Cardiology.³⁵ The current effort supports the principles of these initiatives, taking into consideration the different health systems and different data-collecting capabilities across the globe. In this way, valid

comparisons will be feasible across a wider practice variation than found within a single country in the hope of improving quality of care for a broader population. In addition, international registry-based randomized clinical trials will become more feasible.

Notably, the current set emphasizes outcomes that are most important to patients, including PROMs. The "patient voice" has often been neglected in clinical registries and quality improvement efforts, ^{36,37} but awareness of its importance is

increasing.³⁸ The American Heart Association recently released a scientific statement advocating for patient-reported health status as a measure of cardiovascular health.³⁹ Understanding that collecting PROMs will place an increased burden of collection in most current practice settings, the working group recommends a parsimonious group of well-validated PROMs to efficiently cover the 3 main components of patient health status—symptom burden, functional status, and health-related quality of life—by using elements of the SAQ-7,²⁵ Rose Dyspnea Score,²⁶ and PHQ-2.²⁷

Current outcome assessments frequently are confined to shorter-term, often in-hospital, outcomes. When collected, longer-term outcomes are usually limited to mortality or a narrow list of events, such as myocardial infarctions, interventions, or surgical procedures. While important and relatively easy to obtain, these outcomes do not represent the full time horizon of health experience important to patients. Significant differences have been found evaluating hospital performance depending on the use of in-hospital mortality or 30-day mortality. Longer-term outcomes, including assessments at 1 and 5 years after events or treatment, would provide a clearer picture and a more appropriate basis for comparing different strategies and health systems. However, the implementation of these longer-term outcomes will present challenges that will need to be periodically assessed.

A unique strength of this effort was the diversity of the CAD Working Group members, which included a patient representative as well as physician leaders from around the world, including middle-income countries. All shared in common significant expertise in outcomes measurement, quality improvement, and policy. The Working Group members' unique, global perspectives were critical to informing the minimum standard outcomes set. While teleconferences were oriented around current literature and practices, the members shared their own country or health system's current efforts and challenges to implementing outcomes measures. Having designed this set, the CAD Working Group has elected a steering committee to oversee its continual iteration to reflect changes in data collection capacity, to clarify outcome and patient characteristic definitions as needed, and to respond to any improvements in outcome assessment. In particular, outcomes such as return to daily activities, productivity, and medication or device safety signals were not included in this set. Although acknowledged as important, these outcomes were not included in the initial minimum standard set due to the need for further investigation into how best to standardize assessment.

We recognize that implementation of a globally standardized set of indicators will not be easy. Key implementation barriers to overcome include (1) infrastructure cost to collect patient-reported outcomes, (2) linkages with longitudinal administrative data sources, (3) streamlining

clinician data collection within electronic health records, and (4) aligning existing registries and data-collection efforts to map to the global ICHOM standard. The nearterm goal will be to partner with pioneering provider institutions, including selected members of this Working Group, to implement all or part of the set and to use this as a proof of concept towards broader adoption in registries as well as endorsement by payers and governments. In this way, we can move in a step-by-step fashion towards our ultimate goal—internationally comparable data on patient-centered outcomes.

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Disclosures

Rumsfeld is the Chief Science Officer for the National Cardiovascular Data Registry (NCDR), USA. Kelley and Stowell are employed and paid by ICHOM, USA. Jernberg is the chairman of Swedeheart, National Coronary Artery Disease registry, Sweden. Shahian is chairman of the Society of Thoracic Surgeons Quality Measurement Task Force, USA. Weston is the Clinical Director of the Myocardial Ischaemia National Audit Project (MINAP), UK.

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