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Meetbaar Beter Advisory Board; Daeter, Edgar J.; Timmermans, Marijke Jc; Hirsch, Alexander; Lipsic, Eric; Houterman, Saskia; van Veghel, Dennis; van der Nat, Paul B.

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Defining and Measuring a Standard Set of Patient-Relevant Outcomes in Coronary Artery Disease

Edgar J. Daeter, MD^{a,b,*}, Marijke J.C. Timmermans, PhD^a, Alexander Hirsch, MD, PhD^c, Eric Lipsic, MD, PhD^d, Saskia Houterman, PhD^{a,e}, Meetbaar Beter advisory board, Dennis van Veghel, MSc^a, and Paul B. van der Nat, PhD^{a,f}

Systematic outcome measurement enables to continuously improve treatment results and stimulates dissemination of best practices. For patients with coronary artery disease, no examples yet exist of standard sets of patient-relevant outcome measures that have already been fully implemented at a large scale in clinical care. The aim of this paper is twofold: (1) to share the standard set of outcome measures as developed by Meetbaar Beter, and (2) to show how the standard set is presented and published to support improvement of cardiac care. A step-wise approach was followed by an expert panel to construct a standard set of outcome measures. This resulted in a comprehensive set of relevant outcome measures, comprising 4 generic and 11 treatment-specific outcomes. Both short-term and long-term outcomes measures up to 5 years of follow-up were included. Relevant initial conditions were selected to enable case-mix adjustment. The standard set has been implemented in 21 hospitals across the Netherlands. The results and experiences have been used to fine-tune the set in 4 reporting cycles in 2012 to 2016, using an annual maintenance cycle. Currently about 83,000 percutaneous coronary interventions and 30,000 coronary artery bypass graftings are included in the dataset, covering the majority of all percutaneous coronary interventions and coronary artery bypass graftings in the Netherlands. In conclusion, Meetbaar Beter has defined and implemented a comprehensive set of patient-relevant outcome measures for coronary artery disease, and the variation of the results among the centers indicates that there are sufficient opportunities to further improve cardiac care in the Netherlands. © 2018 Elsevier Inc. All rights reserved. (Am J Cardiol 2018;121:1477–1488)

Cardiovascular diseases are the most important cause of death in almost all countries of the European Union, of which coronary artery disease (CAD) affects most people.^{1–3} In the face of increasing treatment costs and uncertain outcome gains,⁴ value-based decisions about how and where to treat patients with CAD are needed. Value-Based Healthcare has been proposed to improve quality of care. In this framework, value is defined as a patient's outcome divided by the

costs to achieve the outcome.⁵ Key to measuring value is defining condition-specific outcomes that matter to patients. Systematic outcome measurement enables to continuously improve treatment results and share best practices. To be able to compare outcomes over time and between hospitals, standard sets of well-defined outcomes that provide a complete overview of quality of care for a specific medical condition are needed. In 2012, Dutch physicians started Meetbaar Beter

¹Department of Cardiology, Onze Lieve Vrouwe Gasthuis, Amsterdam, The Netherlands; ²Department of Cardiology, VieCuri Medical Center, Venlo, The Netherlands; ³Department of Cardiology, Haga Hospital, Den Haag, The Netherlands; ⁴Department of Cardiothoracic Surgery, Academic Medical Center, Amsterdam, The Netherlands; ⁵Department of Cardiology, Tergooi Hospital, Hilversum, The Netherlands; ⁶Department of Cardiology, Isala Hospital, Zwolle, The Netherlands; ⁷Department of Cardiology, Jeroen Bosch Hospital, 's-Hertogenbosch, The Netherlands; ⁸Department of Cardiology, Maasstad Hospital, Rotterdam, The Netherlands; ⁹Department of Cardiology, Erasmus Medical Center, Rotterdam, The Netherlands; ¹⁰Department of Cardiothoracic Anesthesiology, Medical Center, Leeuwarden, The Netherlands; ¹¹Department of Cardiology, University Medical Center, Utrecht, The Netherlands; ¹²Department of Cardiology, Elisabeth-TweeSteden Hospital, Tilburg, The Netherlands; ¹³Department of Cardiothoracic Surgery, Radboud University Medical Center, Nijmegen, The Netherlands; ¹⁴Department of Cardiology, Medisch Spectrum Twente, Enschede, The Netherlands; ¹⁵Department of Cardiology, St. Antonius Hospital, Nieuwegein, The Netherlands; ¹⁶Department of Cardiothoracic Surgery, Catharina Hospital Eindhoven, Eindhoven, The Netherlands; ¹⁷Department of Cardiology, Noordwest Hospital, Alkmaar, The Netherlands; ¹⁸Department of

Cardiology, Maastricht University Medical Center, Maastricht, The Netherlands; ¹⁹Department of Cardiology, Amphia Hospital, Breda, The Netherlands; ²⁰Department of Cardiothoracic Surgery, University Medical Center Groningen, Groningen, The Netherlands; and ²¹Department of Cardiology, ZorgSaam Hospital, Terneuzen, The Netherlands. ^aMeetbaar Beter Foundation, Eindhoven, The Netherlands; ^bDepartment of Cardiothoracic Surgery, St. Antonius Hospital, Nieuwegein, The Netherlands; ^cDepartment of Cardiology, Thoraxcenter, Erasmus Medical Center, Rotterdam, The Netherlands; ^dDepartment of Cardiology, University Medical Center Groningen, University of Groningen, Groningen, The Netherlands; ^eDepartment of Education and Research, Catharina Hospital Eindhoven, Eindhoven, The Netherlands; and ^fValue-Based Healthcare Department, St. Antonius Hospital, Nieuwegein, The Netherlands. Manuscript received November 21, 2017; revised manuscript received and accepted February 26, 2018.

See page 1488 for disclosure information.

Meetbaar Beter merged within the Netherlands Heart Registry (NHR) in September 2017.

*Corresponding author: Tel: (31) 088-3201170; fax: (31) 883201196.

E-mail address: edgar.daeter@nederlandsehartregistratie.nl (E.J. Daeter).

(English: Measurably Better) to select, define, and evaluate treatment outcomes in heart care.⁶ Meetbaar Beter is a physician-driven and patient-focused initiative that aims to improve quality of cardiovascular care in the Netherlands by creating transparency on patient-relevant outcomes. Meetbaar Beter has defined standard sets of outcome measures and initial conditions for several heart conditions, which currently are being used in 21 hospitals to improve cardiac care. The aims of this paper are to share the standard set of outcome measures for CAD and to show how it is yearly presented and published to support quality improvement.

Methods

A fixed step-wise approach was followed to construct a standard set of patient-relevant outcome measures for CAD. The aim was to select a limited number of up to 10 outcome measures per treatment option, including both disease-generic measures and treatment-specific measures, leading to a practical standard set that can be fully implemented in any hospital and not impacting the administrative burden too much. The treatment options are: (1) coronary artery bypass grafting (CABG), patients where the intention is to perform an isolated CABG are included from the moment that a skin incision is made; (2) percutaneous coronary intervention (PCI), patients where the intention is to perform an isolated PCI by the placement of an angioplasty guidewire, balloon, or other device (e.g., stent, atherectomy, brachytherapy, or thrombectomy); and (3) conservative treatment (CT), patients with CAD for which the local heart team (team of different cardiovascular specialists, including interventional cardiologists and cardiac surgeons) decided to opt for a CT due to the high risk of mortality or complications when performing an intervention.

To select outcome measures, an outcomes team of 4 physicians was composed, comprising both cardiologists and thorax surgeons with expertise in the field of CAD. Next, a modified Delphi procedure was conducted,⁶ in which the ideas and tools of Value-Based Healthcare were integrated.^{5,7} First, a long list of potentially relevant outcome measures related to the treatment of CAD was constructed. This was done by describing in detail each of the steps of Michael Porters' Care Delivery Value Chain⁸ (i.e., monitoring/preventing, diagnosing, preparing, intervening, recovering/rehabbing, and monitoring/managing) and identifying outcomes of each of those steps. In addition, potential outcomes were extracted from relevant documents such as national guidelines, scientific publications, clinical trials, and international best practices. This led to the identification of in total 94 outcome measures for CABG, 105 for PCI, and 83 for CT. Second, these outcomes were ranked by all team members on the following criteria: (1) patient relevance, defined as the impact on patient quality of life (QoL); (2) medical relevance, defined as the level of impact health professionals can have on the outcome; and (3) patient volume, defined as the number of patients affected by the (negative) outcome. In [Supplementary Figure 1](#), as an example, the scores of the top 30 outcome measures for PCI are presented. Third, the top 30 outcome measures were ranked on the feasibility of data collection and the quality of the outcome definition. The rankings were performed by each team member

separately. Differences in prioritization between team members were discussed in detail until consensus was reached. The results were clustered in accordance with the 3 tiers of the outcome hierarchy: (1) health status achieved or retained, (2) process of recovery, and (3) sustainability of health.⁵ To provide a complete overview of quality of care, it was a requirement that each tier was represented in the final set of outcome measures.

Baseline data are essential to make meaningful comparisons between patients. A selection was made of 10 to 15 risk factors or initial conditions related to the patient at the moment of diagnosis with highest impact on the patient outcomes. This was done by constructing a long list of initial conditions from literature and outcomes team discussions. The first selection resulted in 115 initial conditions. The final selection of initial conditions resulted from a prioritization based on impact on outcomes, feasibility, and patient volume.

The systematic approach used for the set development and the final standard set of medical outcomes and initial conditions were validated by an international academic advisory council ([Supplementary Table 1](#)). This council consists of 3 separate parts: (1) a methodology council, with 5 experts in Value-Based Healthcare, change management, and quality improvement; (2) a medical council, with 19 medical experts, of which 6 provided feedbacks on the standard set of CAD; and (3) a data management and statistics council, with 3 internationally renowned experts. Also a sounding board validated the final set, representing national health-insurance companies, patient organizations, and government organizations.

A standard set of outcome measures needs to be validated in practice. Insights from data collection and use for quality improvement lead to refinements in the selection and definition of the outcome measures and initial conditions. Also, for example, improvement in outcomes over years and developments in treatment protocols and operation techniques can impact the standard set. Therefore, annual maintenance cycles are organized with the medical experts of the outcomes team. During these cycles, both the selected outcome measures and the initial conditions are systematically evaluated. Based on results and feedbacks from all participating centers and new scientific evidence, specific outcome measures and/or initial conditions could be added to the standard set. Measures can also be removed, for example, in case an initial condition turned out to have no predictive value for the outcome measures. In addition, definitions of the included measures are further improved when necessary. The maintenance cycles led in the first year to 34 refinements in definitions and minor changes in the composition of the outcome measure set and the initial conditions. In the cycle of 2016 only 1 change was implemented, showing that the standard set has become stable and ready for publication.

The standard set for CAD was implemented in 2013. To date, 21 hospitals across the Netherlands are participating. Each participating hospital annually collects data on the outcome measures and initial conditions from patient records and submits data of the 5 most recent years. Data regarding events that occurred in other hospitals than the hospital where the patient was initially included in the cohort were collected by means of active follow-up. Patient-reported

outcome measures were collected by 2 questionnaires which were sent within a maximum of 2 months before the intervention and 10 to 14 months afterward. All initial outcomes were collected before treatment initiation.

To ensure validity and consistency of the data, Meetbaar Beter provides a detailed data manual.⁹ Clear criteria were defined to guarantee data quality: (1) data were collected according to the definitions as described in the data manual, (2) the percentage of random missing values was maximum of 10% per measure, (3) the electronic database of the regional municipal administration registration (Gemeentelijke Basis Administratie) was used for obtaining mortality data, and (4) a clear demonstration that the data collection regarding the outcomes considering out-of-hospital data was carried out for the complete patient cohort. Subsequently, the validity of data was centrally controlled within Meetbaar Beter by means of checks on incorrect values, logical checks of specific entries with respect to other data of the same patient, and the presence of extreme outliers. In addition, medical and nursing experts of Meetbaar Beter conduct annual audits at each of the participating centers to check the integrity and completeness of the data. During the audit, a selection of the data that was submitted to Meetbaar Beter is compared with the information in the medical records.

Before submission to Meetbaar Beter, the medical specialist who is responsible for the quality of the data needs to sign for the accuracy and completeness of the data. When the data checks by Meetbaar Beter are completed successfully, data are assumed to be appropriate for statistical analyses. Center-specific results will be published independent of the outcomes without possibilities for withdrawal. Hospital names are specified in all published results, allowing hospitals to contact each other based on published results.

Descriptive statistics with means (with SDs) or counts (with proportions) were used to present uncorrected center-specific and national performances. In case of a sufficient number of events, segmented uncorrected percentages of the prevalence for each selected outcome measure were calculated. This indicates the dependence of the outcome measure relative to the most important selected initial conditions.

To be able to compare center-specific performances, multivariable logistic regression analyses were performed with risk-adjustment for the selected initial conditions. First, power calculations were conducted to calculate whether the power was sufficient to show reliable differences between centers. In case of sufficient power, the number of expected cases for dichotomous outcome measures was calculated per center by means of multivariable logistic regression analyses, using the outcome measure as dependent variable and the selected initial conditions as independent variables. For each center, the calculated number of expected cases was plotted against the percentage of the standardized number of cases in a funnel plot. The percentage of the standardized number of cases was calculated by dividing the number of observed cases by the number of expected cases multiplied by 100. In addition, a mean ratio for all centers together was calculated with corresponding 95% confidence intervals, to be able to assess which centers deviate significantly from the national mean. A c-statistic was calculated to indicate the discriminatory power of the predictive model. The c-statistic takes on values between

0.5 (classification no better than a coin flip) and 1.0 (perfect classification).¹⁰

For outcomes regarding time that pass before the event occurs, multivariable Cox proportional hazard analysis was performed, with risk-adjustment for the selected initial conditions. The results are presented in risk-adjusted Kaplan-Meier curves.

Several exclusion criteria were specified for analyses to ensure the validity of the outcomes. If a center had more than 10% missing values for an initial condition, the condition was excluded from the regression analyses for that center. In case a center had more than 1 missing initial condition, the whole center was excluded from the analysis. An initial condition was totally excluded from the regression analyses if 25% or more of the centers were not able to provide data for this particular condition. Patients with 2 or more missing initial conditions were excluded, as well as patients who died before complete follow-up and for which the event did not occur (competing risk). All analyses were performed per treatment option as well as for the total group of patients with CAD, regardless of the specific treatment (i.e., consolidated CAD). For both the funnel plots and the Kaplan-Meier curves, missing data were imputed through multiple imputations.¹¹ Analyses were performed using IBM SPSS Statistics for Windows, version 23.0, (IBM Corp, Armonk, New York). The level of statistical significance was set at $\alpha = 0.05$.

Results

The stepwise procedure of outcome measure development resulted in a set of 4 generic outcome measures covering all patients with CAD. In addition, 6 outcome measures that were specific for CABG, 3 measures that were specific for PCI, and 2 measures that were specific for CT were included in the standard set. Table 1 listed the final set of outcome measures and initial conditions. The outcome measures are clustered in accordance with the levels of the outcome hierarchy. The definitions of the outcome measures are presented in Supplementary Table 2. Table 1 also indicates how many hospitals collected data for each treatment. Two (high volume) hospitals collected data for all medical treatments, resulting in 25,259 patients in the consolidated CAD group. Per treatment option, the means and proportions (%) for all outcome measures and initial conditions are presented in Table 1 when appropriate, indicating that data collection is feasible.

Survival is measured at several time points. For all treatment options, survival is assessed at 1 year after inclusion. In addition, long-term survival is measured up to 5 years of follow-up. Thirty-day mortality is selected as outcome measure for patients treated with a PCI, whereas mortality of patients treated with CABG is measured at 120 days. For the CABG group, mortality is measured at 120 days because previous research of Siregar et al¹² showed that 60 to 120 days after surgery, the survival curves of patients who underwent CABG stabilized after an initial steep decline. At 120 days postsurgery, all cardiac surgery-related mortalities were covered. For PCI, mortality is measured at 30 days as risk of death seems to move from cardiac to noncardiac after a period of 30 days after PCI.¹³ For all selected time periods,

Table 1

The standard set of outcome measures and initial conditions for coronary artery disease per treatment option for the cohort 2011–2015

		OM	Group	Consolidated CAD • 2 hospitals • 25259 patients	CABG • 13 hospitals • 30240 patients	PCI • 19 hospitals • 91697 patients	CT • 3 hospitals • 112 patients
National mean (SD) or proportion (years 2011 till 2015)							
Tier 1	Survival	Long-term survival (≤ 5 years)	All	*	*	*	*
		1-year mortality	All	971/20453 (5%)	765/24142 (3%)	3814/69260 (6%)	4/95 (4%)
		120-day mortality	CABG	n/a	606/30093 (2%)	n/a	n/a
		30-day mortality	PCI	n/a	n/a	2463/91318 (3%)	n/a
	Degree of health/recovery	Quality of life $\dagger$ mean (SD)	All				
		Physical health <i>baseline</i>		$\dagger$	54 (21)	$\dagger$	$\dagger$
		1 year			68 (20)		
		Mental health <i>baseline</i>			60 (20)		
		1 year			67 (18)		
		Chest pain (≤ 1 year)	CT	n/a	n/a	n/a	$\ddagger$
Tier 2	Time to recovery and return to normal activities						
	Disutility of the care or treatment process	Surgical reexploration (≤ 30 days)	CABG	n/a	1172/26763 (4%)	n/a	n/a
		Cerebrovascular accident (CVA) (≤ 72 hours)	CABG	n/a	199/29129 (1%)	n/a	n/a
		Deep sternal wound infection (≤ 30 days)	CABG	n/a	245/28312 (1%)	n/a	n/a
		Urgent CABG (≤ 24 hours)	PCI	n/a	n/a	235/89776 (0.3%)	n/a
Tier 3	Sustainability of health/recovery and nature of recurrences	Myocardial infarction (≤ 30 days)	All	180/21632 (1%)	303/19877 (2%)	444/52458 (1%)	6/111 (5%)
		Occurrence of target vessel revascularization (TVR) (≤ 1 year)	PCI	n/a	n/a	2586/37427 (7%)	n/a
		Free of myocardial infarction	CABG	*	*	*	*
		Free of coronary artery reintervention	CABG	*	*	*	*
		Free of Major Adverse Cardiac Event (MACE)	CT	*	*	*	*
	Long-term consequences of therapy						
	Demographic characteristics	Initial condition	Group	National mean (SD) or proportion (years 2011 till 2015)			
		Age mean (SD)	All	65 (11)	66 (10)	65 (12)	69 (10)
		Gender	All				
		male		18842/25259 (75%)	24061/30240 (80%)	65821/91694 (72%)	77/112 (69%)
		female		6417/25259 (25%)	6179/30240 (20%)	25873/91694 (28%)	35/112 (31%)

(continued)

Table 1
(continued)

OM		Group	Consolidated CAD • 2 hospitals • 25259 patients	CABG • 13 hospitals • 30240 patients	PCI • 19 hospitals • 91697 patients	CT • 3 hospitals • 112 patients
National mean (SD) or proportion (years 2011 till 2015)						
Medical condition	Left ventricular ejection fraction	All				
	EF>50%		6831/7755 (88%)	20534/27615 (74%)	‡	70/109 (64%)
	EF 30–50%		550/7755 (7%)	5852/27615 (21%)		30/109 (28%)
	EF <30%		374/7755 (5%)	1229/27615 (5)		9/109 (8%)
	Diabetes mellitus	All	5145/24944 (21%)	7643/30224 (25%)	18331/89584 (21%)	40/110 (36%)
	Multivessel disease	All	15335/25197 (61%)	22914/24311 (94%)	44647/91080 (49%)	62/99 (63%)
	Renal insufficiency	All	4828/24004 (20%)	6059/30217 (20%)	14083/67273 (21%)	36/112 (32%)
	Logistic EuroSCORE I mean (SD)	CABG	n/a	4.9 (7.0)	n/a	n/a
	Logistic EuroSCORE II mean (SD)	CABG	n/a	2.3 (3.9)	n/a	n/a
	Chronic lung disease	CABG	n/a	§	n/a	n/a
	Cardiogenic shock	PCI	n/a	n/a	2505/ 89371 (3%)	n/a
	Chronic total occlusion	PCI	n/a	n/a	5104/91092 (6%)	n/a
	Resuscitation	PCI	n/a	n/a	3774/90571 (4%)	n/a
	Urgency of the procedure¶	All				
	Urgent		6958/25256 (28%)	1711/30161 (6%)	24436/74920 (33%)	0/112 (0%)
	Elective		18298/25256 (73%)	28450/30161 (94%)	50484/74920 (67%)	112/112 (100%)
	Indication PCI	PCI				
	Elective		n/a	n/a	28886/80835 (36%)	
	NSTEMI & Instable angina				25761/80835 (32%)	
	STEMI				26188/80835 (32%)	
Medical history	Previous heart surgery	CABG	n/a	651/30190 (2%)	n/a	n/a
	Previous CABG	PCI	n/a	n/a	9386/90889 (10%)	n/a
	Previous myocardial infarction	PCI, CT	n/a	n/a	19111/87194 (22%)	52/111 (47%)
	Previous CABG or PCI	CT	n/a	n/a	n/a	76/112 (68%)

Note: The standard set presented in this table can differ slightly from the set presented in Supplemental Table 3, as the results in this table cover the period 2011–2015, while Table S3 reflects the most recent version of the standard set (year 2017).

CABG = coronary artery bypass grafting; CAD = coronary artery disease; CT = conservative treatment; n/a = not applicable for the concerning treatment option; PCI = percutaneous coronary intervention; OM = outcome measure.

* Because these outcome measures represent survival rates over time (up to 5 years of follow-up), no event rate can be presented.

† Measured at baseline and between 10 till 14 months after treatment by the SF-36 or SF-12. This outcome measure has not yet been implemented for treatment with PCI and for conservative treatment.

‡ Because too much centers had >10% missing values on this measure, valid percentages cannot be presented.

§ As chronic lung disease is recently added to the standard set, no measures can be presented yet.

¶ For analysis of the consolidated CAD, all patients with a conservative treatment are assumed to be elective. Level of urgency for the patients treated with a PCI is based on the initial condition ‘indication of PCI’.

Figure 1. The incidence of deep sternal wound infection after coronary artery bypass grafting, segmented to diabetes. The incidence rates for 2 hospitals are not presented in the figure because of incomplete data. AMC = Academic Medical Centre Amsterdam; Amphia = Amphia Hospital; Antonius = St. Antonius Hospital; Catharina = Catharina Hospital; Erasmus = Erasmus MC; Haga = Haga Hospital; Isala = Isala Hospital; MCL = Medical Centre Leeuwarden; MST = Medical Spectrum Twente; MUMC = Maastricht University Medical Centre; OLVG = Onze Lieve Vrouwe Gasthuis; Radboud = Radboud University Medical Centre; UMCG = University Medical Centre Groningen; UMCU = University Medical Centre Utrecht.

the outcomes team decided to assess all-cause mortality using central death registers. Disease-specific mortality was not selected as it was considered to be less meaningful to patients than all-cause mortality. Besides, the validity of the data may be limited if cause of death is not clinically assigned.

On the level of degree of health/recovery, QoL is assessed by the Short-Form 36 (SF-36) questionnaire. The SF-36 is a widely used generic measure in QoL, developed and validated in the Medical Outcomes Study to assess important QoL domains relevant to patients with a wide range of medical conditions.¹⁴ The SF-36 consists of 8 QoL domains that comprise 2 summary measures: the physical component and the mental component. The SF-36 has already proven to be valid for measuring QoL among coronary patients.^{15,16} To address the considerable burden placed on respondents to fill out the questionnaire, some hospitals choose to use the SF-12, which is a shorter form of the SF-36. Both measures have been found to be highly correlated.¹⁷ The SF questionnaire is assessed at baseline and between 10 and 14 months after treatment.

Three high-impact outcome measures in the tier 'process of recovery' concern only the CABG patients: cerebrovascular accident within 72 hours, surgical exploration within 30 days, and deep sternal wound infection within 30 days after surgery. For patients who undergo a PCI, urgent CABG within 24 hours was included. Some outcomes such as 'in-hospital cardiac arrest', 'cardiac tamponade,' and 'intubation-related damage' do have high impact on patients but were not included because of their relatively low incidence.

'Myocardial infarction' (MI) was included as generic outcome measure for patients with CAD. For all treatment

options, MI is assessed at 30 days after start of the treatment. Both for the CABG group and the CT group, MI is measured up to 5 years of follow-up as well. Free of coronary artery reintervention was selected specific for CABG, whereas occurrence of target vessel revascularization within 1 year was selected for PCI. Free of major adverse cardiac event, in which MI, reintervention (CABG or PCI), and mortality are included, is measured for the CT group.

The outcomes teams identified the baseline case-mix variables considered to be essential for risk adjustment to enable meaningful comparisons between hospitals. Initial conditions common to all CAD patients were defined as well as treatment-dependent initial conditions. In addition to the total score on the European System for Cardiac Operation Risk Evaluation (EuroSCORE) I and II,^{18,19} several specific risk factors were selected that have a main impact on 1 or several outcomes. All selected initial conditions are presented in Table 1. The corresponding definitions are described in Supplementary Table 2.

Figures 1 to 6 show a selection of results to indicate how the standard set is presented and published. The types of graphs are selected to optimally facilitate benchmarking and outcomes-based quality improvement within the centers. The selection is made such that every tier in Porters hierarchy is represented. All other tables and figures are available online.⁶ The names of the centers are explicitly included for transparency and to stimulate and allow sharing and learning between individual centers.

Outcomes are published both unadjusted and risk-adjusted (in case of sufficient power), as both types of presentations have proven to be a useful starting point for quality improve-

Figure 2. Funnel plot for 30-day mortality after percutaneous coronary intervention in STEMI patients.

ETZ = Elisabeth-TweeSteden Hospital; JBZ = Jeroen Bosch Hospital; Maasstad = Maasstad Hospital; Noordwest = Noordwest Hospital group; Tergooi = Tergooi Hospital.

ment in practice. Three different levels can be distinguished. (1) The uncorrected percentages of the incidence for each selected outcome measure. An example for urgent CABG after PCI is presented in Table 2. As incidence rates are relatively low, no additional analyses were performed for this measure. (2) The uncorrected percentages of the incidence for each selected outcome, segmented for preselected initial conditions. An example is presented in Figure 1. This graph shows the impact of the initial condition diabetes on the outcome measure deep sternal wound infection within 30 days after CABG. Further analysis has to point out whether such variation is caused by differences in case-mix or by differences in the care process. (3) In case of sufficient power, risk-adjusted results are presented. Most outcomes are presented in funnel plots, in which per center the observed event rate is plotted against the predicted event rate. Examples are presented in Figures 2 and 3, which represent the outcomes for respectively 30-day mortality after PCI for ST-elevation myocardial infarction patients, and MI within 30 days after PCI. Survival rates over time are presented in risk-adjusted Kaplan-Meier curves. For example, Figures 4 and 5 present risk-adjusted curves for mortality after CABG and coronary reintervention after CABG. Center-specific risk-adjusted survival rates are compared with the center with the highest survival rate, showing the potential for further improvement of the quality of care. In addition, critical time points during

the follow-up period of 5 years can be noticed. Figure 6 presents the QoL for CABG across 3 hospitals. Both the physical component and the mental component have improved 1 year after the intervention. Next to the average QoL at baseline and 1 year (10 to 14 months) after the intervention, we also show the proportions of patients who had an increased QoL after the intervention, who had an equal QoL after the intervention, and who had a decrease of QoL.

Discussion

Meetbaar Beter has defined a standard set of patient-relevant outcome measures for CAD. The set has been fine-tuned using a yearly maintenance cycle for 3 consecutive years. Now the set has become stable and is considered to be suitable for scientific publication. It is the first set of patient-relevant outcome measures for CAD that has been published, fully implemented at a large scale, and is being used as a basis for quality improvements in routine clinical care. In 2016, about 83,000 PCIs and 30,000 CABGs were included in the dataset, covering the majority of all PCIs and CABGs in the Netherlands. The variation of the results among the centers indicates that there is potential to further improve cardiac care in the Netherlands. Several hospitals have already been successful in conducting improvement projects for patients with CAD, based on the presented figures.^{6,20} However,

Figure 3. Funnel plot for myocardial infarction after percutaneous coronary intervention. A total of 6 hospitals are not presented in the funnel plot because of incomplete data.

presented data have to be interpreted cautiously. The c-statistics, describing the discriminatory power of the predictive models which underlie the funnel plots, varied from 0.59 (poor discriminatory power) to 0.89 (good discriminatory power).²¹ Possible reasons for the relatively low predictive accuracy of some of the regression models are: (1) relevant initial conditions are missing in the standard set, (2) the reliability of the data is uncertain, as more soft end points like MI and target vessel revascularization are difficult to assess objectively than hard end points like mortality, or (3) differences in care delivery processes influence the outcome. The annual maintenance cycle in combination with the data quality checks are used to continuously improve the dataset and thus reduce the chances that a relatively low predictive value is caused by scenarios 1 or 2. In case of the third scenario, differences between centers are caused by quality differences in the underlying care processes, which can indicate potential for improvement. This can include patients' adherence to therapy and lifestyle. Although the c-statistics is clearly important, we believe that funnel plots with a relatively low discriminatory power are also valuable to present. In general, more variations have been found for the short-term end points than for the long-term end points. A reason might be that short-term results are more dependent on the initial care provided around the cardiac intervention, whereas long-term results might reflect other processes as well.¹²

A strength of the standard set is that it has been validated in clinical practice. The results and feedbacks from the

participating centers led to fine-tuning of definitions and changes in the composition of the standard set. Last year, no new outcome measures were added. However, it is important to recognize that the set is a work in progress and should not limit the inclusion of additional variables to optimize the prediction models. Another strength is that the standard set includes both treatment-specific outcome measures and generic outcome measures covering all patients with CAD. We selected treatment-specific measures because the outcomes of care and the care delivery process differ in the treatment options. In addition, generic outcome measures are used to create insight in the quality of treatment decisions. The interpretation of the generic outcome measures will require further research. Lastly, a strength of this standard set is that Meetbaar Beter provided detailed definitions of the outcome measures and initial conditions. This is important to assure valid data collection to allow comparison between time points and hospitals.

The standard set has been developed in 2012 and has been published about 5 years later. In the meantime, the International Consortium for Health Outcomes measurement (ICHOM) has proposed a standard set of outcome measure as well.^{22,23} Although the sets do largely overlap, some differences can be highlighted. The main difference is that the set of ICHOM includes a larger number of outcome measures. For instance, acute renal failure, prolonged ventilation, and patient reported outcomes such as angina, dyspnea, and depression are not included in our standard set. Although these

Figure 4. Survival curve for coronary artery bypass grafting.

measures are clearly important, we aimed to restrict our set to limit administrative burden on patients and involved professionals from the participating centers and to increase the feasibility to use the standard set in practice. Another difference is that the Meetbaar Beter standard set has been validated by its implementation and use in clinical practice. Currently the first steps are taken to cooperate with ICHOM to create internationally comparable data on patient-centered outcomes. The current presented outcomes can be seen as first proof of principle of the ICHOM set in practice.

Avoidance of high-risk patients is an important topic when using outcome measures to assess center-specific performance.²⁴ To minimize this type of risk avoidance, Meetbaar Beter analyses disease generic outcomes next to the treatment-specific outcome measures for CAD. In the disease generic analyses, all patients with CAD are included, includ-

ing high-risk patients who received a CT. Also not submitting high-risk patients for registries is an example of risk-avoidance. Therefore, participation to Meetbaar Beter is voluntary, but completeness of the submitted data is mandatory. This type of risk avoidance was not detected during the audits organized by Meetbaar Beter. Finally, Meetbaar Beter invests in an open culture with high levels of trust between physicians, in which potential limitations and misinterpretations of the data are openly discussed.

A challenge is the improvement of the implementation of the standard set for CT. Patients are included in the CT group in case the multidisciplinary heart team decides to give the patient a CT due to the high risk of mortality or complications when an intervention would be performed. A limitation is that, even though according to the guidelines all patients that are eligible for an intervention for CAD should be

Figure 5. Freedom of coronary reintervention after coronary artery bypass grafting. A total of 7 hospitals are not presented in the figure because of incomplete data.

discussed in a heart team,²⁵ in practice this is most likely not happening for all patients. The local policies can have major impact on the number of included patients in the CT group and thus on the completeness of the data. Currently, a project is started to evaluate the proposed methods for data collection for the CT group. Another challenge is the implementation of the QoL questionnaires. The number of patients who returned both questionnaires was low, as response rates varied from 26% to 42%. In addition, no systematic approach has yet been developed to interpret variations in QoL in terms of quality of the care delivery process.

In conclusion, Meetbaar Beter defined a comprehensive set of patient-relevant outcome measures for CAD. The implementation of the set has proven to be feasible. The variation of the results among the centers indicates that there are sufficient opportunities to further improve cardiac care in the Netherlands. Further research is mandatory to investigate whether this initiative indeed leads to an increased quality of care for patients with CAD. The standard set in combination with the detailed definitions and measurements of the indicators can function as benchmark data for heart centers from other countries.

Figure 6. Quality of life of patients after coronary artery bypass grafting.

Table 2

Uncorrected incidence of urgent coronary artery bypass grafting after percutaneous coronary intervention per hospital

	AMC	Amphia	Antonius	Catharina	Erasmus	Haga	Isala	MCL	MST	MUMC
Included years	2012–2015	2012–2015	2011–2015	2011–2015	2011–2015	2012–2015	2011–2015	2011–2015	2011–2015	2013
Number of patients	5190	5386	7207	11225	7343	4833	8430	5868	6936	1257
Urgent CABG (%)	0.2%	0.3%	0.3%	0.4%	0.2%	0.3%	0.4%	0.3%	0.2%	0.4%

	OLVG	Radboud	UMCG	UMCU	ETZ	JBZ	Maasstad	Noordwest	Tergooi
Included years	2011–2015	2013–2015	2012–2015	2012–2015	2013–2014	2015	2015	2013–2015	2014–2015
Number of patients	8579	2390	5369	3071	1387	957	1374	3427	1468
Urgent CABG (%)	0.1%	0.1%	0.5%	0.1%	0.0%	0.0%	*	0.0%	0.1%

CABG = coronary artery bypass grafting; AMC = Academic Medical Centre Amsterdam; Amphia = Amphia Hospital; Antonius = St. Antonius Hospital; Catharina = Catharina Hospital; Erasmus = Erasmus MC; Haga = Haga Hospital; MCL = Medical Centre Leeuwarden; MST = Medical Spectrum Twente; MUMC = Maastricht University Medical Centre; Radboud = Radboud University Medical Centre; UMCG = University Medical Centre Groningen; UMCU = University Medical Centre Utrecht; ETZ = Elisabeth-TweeSteden Hospital; JBZ = Jeroen Bosch Hospital; Maasstad = Maasstad Hospital; Noordwest = Noordwest Hospital group.

* As this hospital had more than 10% missing data for the outcome measure urgent CABG, the incidence rate is not reported.

Collaborators Group: Meetbaar Beter Advisory Board

- G Amoroso, Department of Cardiology, Onze Lieve Vrouwe Gasthuis, Amsterdam, the Netherlands
- S Aydin, Department of Cardiology, VieCuri Medical Center, Venlo, the Netherlands
- M Bax, Department of Cardiology, Haga Hospital, Den Haag, the Netherlands
- WJ van Boven, Department of Cardiothoracic Surgery, Academic Medical Center, Amsterdam, the Netherlands
- SL Brinckman, Department of Cardiology, Tergooi Hospital, Hilversum, the Netherlands
- JHE Dambrink, Department of Cardiology, Isala Hospital, Zwolle, the Netherlands
- S de la Fuente, Department of Cardiology, Jeroen Bosch Hospital, 's-Hertogenbosch, the Netherlands
- M van der Ent, Department of Cardiology, Maasstad Hospital, Rotterdam, the Netherlands
- TW Galema, Department of Cardiology, Erasmus Medical Center, Rotterdam, the Netherlands
- J Haenen, Department of Cardiothoracic Anesthesiology, Medical Center Leeuwarden, the Netherlands
- AO Kraaijeveld, Department of Cardiology, University Medical Center Utrecht, the Netherlands

- M Magro, Department of Cardiology, Elisabeth-TweeSteden Hospital, Tilburg, the Netherlands
- L Noyez, Department of Cardiothoracic Surgery, Radboud University Medical Center Nijmegen, the Netherlands
- JM van Opstal, Department of Cardiology, Medisch Spectrum Twente, Enschede, the Netherlands
- BJWM Rensing, Department of Cardiology, St. Antonius Hospital, Nieuwegein, the Netherlands
- AHM van Straten, Department of Cardiothoracic Surgery, Catharina Hospital Eindhoven, Eindhoven, the Netherlands
- VAWM Umans, Department of Cardiology, Noordwest Hospital, Alkmaar, the Netherlands
- K Vernooij, Department of Cardiology, Maastricht University Medical Center, Maastricht, the Netherlands
- J Vos, Department of Cardiology, Amphia Hospital, Breda, the Netherlands
- TW Waterbolk, Department of Cardiothoracic Surgery, University Medical Center Groningen, Groningen, the Netherlands
- P. Rademaker, Department of Cardiology, ZorgSaam Hospital, Terneuzen, the Netherlands

Disclosures

The authors have no conflicts of interest to disclose.

Supplementary data

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1. Beller GA, Zaret BL. Contributions of nuclear cardiology to diagnosis and prognosis of patients with coronary artery disease. *Circulation* 2000;101:1465–1478.
2. Wilkins E, Wilson L, Wickramasinghe K, Bhatnagar P, Leal J, Luengo-Fernandez R, Burns R, Rayner M, Townsend N. European Cardiovascular Disease Statistics 2017. European Heart Network, Brussels, 2017:192.
3. GBD 2013 Mortality and Causes of Death Collaborators. Global, regional, and national age-sex specific all-cause and cause-specific mortality for 240 causes of death, 1990–2013: a systematic analysis for the Global Burden of Disease Study 2013. *Lancet* 2015;385:117–171.
4. Heidenreich PA, Trogon JG, Khavjou OA, Butler J, Dracup K, Ezekowitz MD, Finkelstein EA, Hong Y, Johnston SC, Khera A, Lloyd-Jones DM, Nelson SA, Nichol G, Orenstein D, Wilson PW, Woo YJ American Heart Association Advocacy Coordinating Committee; Stroke Council; Council on Cardiovascular Radiology and Intervention; Council on Clinical Cardiology; Council on Epidemiology and Prevention; Council on Arteriosclerosis; Thrombosis and Vascular Biology; Council on Cardiopulmonary; Critical Care; Perioperative and Resuscitation; Council on Cardiovascular Nursing; Council on the Kidney in Cardiovascular Disease; Council on Cardiovascular Surgery and Anesthesia, and Interdisciplinary Council on Quality of Care and Outcomes Research. Forecasting the future of cardiovascular disease in the United States: a policy statement from the American Heart Association. *Circulation* 2011;123:933–944.
5. Porter ME. What is value in health care? *N Engl J Med* 2010;363:2477–2481.
6. Meetbaar Beter. Meetbaar Beter Boek. 2016 [Measurably Better Book 2016]. Available at: <http://www.meetbaarbeter.com/english/>. Accessed on August 18, 2017.
7. Campbell SM, Braspenning J, Hutchinson A, Marshall MN. Research methods used in developing and applying quality indicators in primary care. *BMJ* 2003;326:816–819.
8. Porter ME. Value-based health care delivery. *Ann Surg* 2008;248:503–509.
9. Meetbaar Beter. Handboek dataverzameling 2017 [Data collection manual 2017]. Available at: <http://www.meetbaarbeter.com/documents/handboek-dataverzameling/>. Accessed on August 18, 2017.
10. Hanley JA, McNeil BJ. The meaning and use of the area under a receiver operating characteristic (ROC) curve. *Radiology* 1982;143:29–36.
11. Sterne JA, White IR, Carlin JB, Spratt M, Royston P, Kenward MG, Wood AM, Carpenter JR. Multiple imputation for missing data in epidemiological and clinical research: potential and pitfalls. *BMJ* 2009;338:b2393.
12. Siregar S, Groenwold RH, de Mol BA, Speekenbrink RG, Versteegh MI, Brandon Bravo Bruinsma GJ, Bots ML, van der Graaf Y, van Herwerden LA. Evaluation of cardiac surgery mortality rates: 30-day mortality or longer follow-up? *Eur J Cardiothorac Surg* 2013;44:875–883.
13. Pedersen F, Butrymovich V, Kelbæk H, Wachtell K, Helqvist S, Kastrup J, Holmvang L, Clemmensen P, Engstrøm T, Grande P, Saunamäki K, Jørgensen E. Short- and long-term cause of death in patients treated with primary PCI for STEMI. *J Am Coll Cardiol* 2014;64:2101–2108.
14. Ware JE, Kosinski M, Dewey JE. How to Score Version Two of the SF-36® Health Survey. Lincoln (RI): QualityMetric Incorporated; 2000:238.
15. Failde I, Ramos I. Validity and reliability of the SF-36 Health Survey Questionnaire in patients with coronary artery disease. *J Clin Epidemiol* 2000;53:359–365.
16. Lindsay GM, Hanlon P, Smith LN, Wheatley DJ. Assessment of changes in general health status using the short-form 36 questionnaire 1 year following coronary artery bypass grafting. *Eur J Cardiothorac Surg* 2000;18:557–564.
17. Failde I, Medina P, Ramirez C, Arana R. Assessing health-related quality of life among coronary patients: SF-36 vs SF-12. *Public Health* 2009;123:615–617.
18. Nashef SA, Roques F, Michel P, Gauducheau E, Lemeshow S, Salamon R. European system for cardiac operative risk evaluation (EuroSCORE). *Eur J Cardiothorac Surg* 1999;16:9–13.
19. Nashef SA, Roques F, Sharples LD, Nilsson J, Smith C, Goldstone AR, Lockowandt U. EuroSCORE II. *Eur J Cardiothorac Surg* 2012;41:734–744.
20. van der Nat PB, van Veghel D, Daeter E, Crijns HJ, Koolen J, Houterman S, Soliman MA, de Mol BA, Meetbaar Beter Study Group. Insights on value-based healthcare implementation from Dutch heart care. *Int J Healthc Manag* 2017;doi:10.1080/20479700.2017.1397307. [Epub ahead of print].
21. Austin PC, Steyerberg EW. Interpreting the concordance statistic of a logistic regression model: relation to the variance and odds ratio of a continuous explanatory variable. *BMC Med Res Methodol* 2012;12:82.
22. International Consortium for Health Outcomes Measurement. The ICHOM Standard Set for Coronary Artery Disease. Available at: <http://www.ichom.org/medical-conditions/coronary-artery-disease/>. Accessed on August 18, 2017.
23. McNamara RL, Spatz ES, Kelley TA, Stowell CJ, Beltrame J, Heidenreich P, Tresserras R, Jernberg T, Chua T, Morgan L, Panigrahi B, Rosas Ruiz A, Rumsfeld JS, Sadwin L, Schoeberl M, Shahian D, Weston C, Yeh R, Lewin J. Standardized outcome measurement for patients with coronary artery disease: consensus from the International Consortium for Health Outcomes Measurement (ICHOM). *J Am Heart Assoc* 2015;4.
24. Resnic FS, Welt FG. The public health hazards of risk avoidance associated with public reporting of risk-adjusted outcomes in coronary intervention. *J Am Coll Cardiol* 2009;53:825–830.
25. Bol Raap G, Drijver YN, Noyez L, Van Putte BP, Versteegh MIM, Vonk A. Richtlijn beslismomenten pre-, per- en postoperatieve traject van de hartchirurgische patiënt. *Nederlandse Vereniging voor Thoraxchirurgie* 2017;17.