

# Outcomes Evaluation in Cardiac Rehabilitation/Secondary Prevention Programs

## IMPROVING PATIENT CARE AND PROGRAM EFFECTIVENESS

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Writing Group

- The reported outcomes statement is an update to the previous recommendations for outcomes evaluation in cardiac rehabilitation/secondary prevention programs. The purposes of outcomes evaluation are reviewed, and practical information with examples is provided to help programs implement an outcomes-directed approach within routine patient care and program management functions.

### KEY WORDS

outcomes

cardiac rehabilitation

quality improvement

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Quantifying and improving the quality of healthcare are a priority for healthcare organizations. Although outcomes measurement for accountability often is mandated by external organizations, such as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and the Centers for Medicare/Medicaid Services (CMS), the primary function of such measurement is to serve as an internal force for evaluating, understanding, and improving the quality of patient care.<sup>1</sup>

In 1992, the American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR) established an Outcomes Committee in response to a need to document the benefits from rehabilitation efforts directed at patients with cardiovascular and pulmonary disease. The committee's primary purposes were to identify priority areas for outcomes evaluation and to provide suggestions for methods and measures. The AACVPR first published outcomes recommendations for cardiac and

pulmonary rehabilitation programs in 1995,<sup>2</sup> emphasizing the importance of a comprehensive approach to outcome measurements within routine clinical practice. Specific recommendations included the importance of identifying measures that reflect the results of care in three domains: the behavioral, clinical, and health domains. Program staff were advised to track outcomes consistently within their clinical practice, with the minimum expectation of including at least one behavioral, one clinical, and one health domain measure in their outcomes evaluation.

The purpose of the current statement is to update the previous recommendations for outcomes evaluation in cardiac rehabilitation/secondary prevention programs. This statement complements the most recently published Guidelines for Cardiac Rehabilitation (CR) and Secondary Prevention Programs,<sup>3</sup> and is in accordance with the AACVPR and American Heart Association collaborative paper on the Core Components of Cardiac Rehabilitation/Secondary Prevention.<sup>4</sup> A similar outcomes statement for pulmonary rehabilitation will be available after the publication of the Third Edition of the Guidelines for Pulmonary Rehabilitation.

The objectives of this document are to review the purposes of outcomes evaluation and to provide practical information that may help in the implementation of an outcomes-directed approach within routine patient care and program management functions. Sample forms are provided with recommendations for an outcomes-directed approach to care at two levels: (1) assessment of patients at program entry to help guide treatment plans and repetition of the measures at defined intervals (eg, at completion of 12 weeks of CR programming) to evaluate patient outcomes, and (2) evaluation of program effectiveness on the basis of aggregate patient and service-related outcomes data. The importance of connecting outcomes evaluation with quality improvement processes is reinforced throughout this document. A brief discussion of future directions for CR in outcomes evaluation concludes this report.

## BACKGROUND

Table 1 describes important activities that have occurred since the first AACVPR outcomes statement,<sup>2</sup> which influenced the development of the current recommendations. It is important to recognize that recommendations for outcomes evaluation must be dynamic to reflect new findings in outcomes research related to CR and secondary prevention. The current recommendations have been updated and coincide with revised evidence-based guidelines for the treatment of coronary artery disease and the associated risk factors.<sup>5-10</sup>

Other research<sup>11,12</sup> has provided information on the effectiveness of behavioral and psychosocial interven-

tions that is specific to CR settings, which can help guide treatment strategies. Psychosocial and health status measurement tools have been tested with CR patient populations,<sup>13,14</sup> and the information gained can help to refine decision making in the choice of the most appropriate tools for individual programs and their patient population.

Furthermore, as clinical programs continue to publish their own outcomes data,<sup>15,16</sup> these observations can help to identify issues that may be applicable for quality improvement initiatives. The dissemination of “real-world” CR experiences, including the reporting of program observational data and lessons learned from quality improvement projects, can help guide future and more effective approaches to CR/secondary prevention care. The combination of outcomes research and well-documented practical experiences in the CR setting can contribute to the advancement of outcomes

**Table 1 • HISTORICAL REVIEW OF AACVPR ACTIVITIES RELATED TO OUTCOMES EVALUATION**

1992	AACVPR Outcomes Committee established
1995	Outcomes Committee published statement on outcomes measurement <sup>2</sup>  Cardiac Rehabilitation Clinical Practice Guidelines (#17) published and recommended the inclusion of comprehensive services (exercise training, education, counseling and behavioral interventions) to achieve desired outcomes for eligible patients. <sup>37</sup>
1996	Outcomes Committee published the Outcomes Tools Resource Guide that compiled available outcomes measurements used in research and/or clinical settings. <sup>19</sup>
1998	AACVPR certification process was established and required evidence of outcomes evaluation within programs for national certification. AACVPR provided small grant to Affiliates for proposed projects related to outcomes evaluation.
1999	AACVPR published updated guidelines with the expanded title: Guidelines for Cardiac Rehabilitation and Secondary Prevention Programs (3rd edition). <sup>38</sup>
2000	AHA/AACVPR Scientific Statement published “Core Components of Cardiac Rehabilitation/Secondary Prevention Programs” that defined specific information regarding evaluation, intervention, and expected outcomes of the core components of care. <sup>4</sup>
2001	AHA/ACC published updated guidelines for secondary prevention in patients with atherosclerotic cardiovascular disease. <sup>5</sup>
2002	Outcomes Committee updated the Outcomes Tool Resource Guide and published on AACVPR Web site with additional resource information. <sup>19</sup>

AACVPR, American Association of Cardiovascular and Pulmonary Rehabilitation; AHA, American Heart Association; ACC, American College of Cardiology.

evaluation and, ultimately, to an improvement in patient outcomes and program effectiveness.

To accomplish this goal, the outcomes evaluation process must be meaningful to practitioners at the patient level and must add value to the overall effectiveness of the program.<sup>17</sup> Outcomes evaluation needs to be a proactive program expectation, and must not be driven primarily by reactive requirements from external forces such as program certification applications, administrative reports, or other mandated projects.<sup>18</sup> However, it is recognized that most programs have limited personnel and resources, particularly as they may relate to outcomes data management (eg, standardized data collection, completion of forms, computer data entry, data analyses, and report generation). The development of user-friendly forms and patient assessment protocols that serve dual purposes (medical record documentation and outcomes evaluation) continues to be a work-in-progress for most programs.

No single form, assessment protocol, or questionnaire (eg, tool, instrument) will fit the needs of all programs. Although programs offer similar services, there is wide variability among programs related to patient populations, service delivery methods, and available resources for outcomes evaluation. Therefore, this statement does not direct program staff to use a specific questionnaire, but rather provides a structural framework for outcomes measurement that will guide programs in the development of standardized assessment protocols that fit their specific needs. If this is accomplished, programs will be able to fulfill at least the minimum expectations of outcomes evaluation as described in the recently published clinical guidelines.<sup>3</sup>

A team effort with input from those providing direct patient care, the program medical director, and the program manager is needed in the development of a functional outcomes evaluation for a specific program. The ability to enter and manage data efficiently from the point of patient care to the generation of program summary reports is important for the integration of outcomes evaluations into routine patient care and program management processes. A computer and a database that meets the needs of the program are wise investments for accomplishing this goal. However, if databases are allowed to become unfocused or too large, data management becomes burdensome and detracts from the intended purpose of quality improvement.

## **CORE COMPONENTS OF CARE AND THE OUTCOME MATRIX**

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Cardiac rehabilitation/secondary prevention programs are advised to provide specific core components of care to optimize cardiovascular risk reduction, reduce dis-

ability, and promote healthy behaviors, including long-term adherence to these behaviors.<sup>3,4</sup> Information regarding evaluation, intervention, and expected outcomes in each of the core components is described in detail elsewhere.<sup>4</sup> Table 2 provides data from the core components that outlines a battery of outcome measures recommended for CR/secondary prevention programs. At the individual patient level, these measures are necessary for assessing the patient's baseline status and identifying priority secondary prevention needs. Reevaluation of the same measures at the end of the program documents progress toward the secondary prevention therapy goals.

Cardiac rehabilitation programs need to establish a standardized method of data collection and maintain effective communication with other healthcare providers who also provide care for the referred patient. Secondary prevention goals are not isolated to the CR setting, and collaboration with other healthcare providers is essential in the effort to identify the specific needs of the patient and guide him or her to goal achievement. For example, lipid assessment is standard care in secondary prevention,<sup>5</sup> but duplicate testing is unnecessary and not cost effective. A program-specific protocol defining acceptable periods and methods for documenting laboratory data from referring physicians or the acute care setting permits the capture of important information without needless additional testing. It also promotes a collaborative relationship with other care providers. The establishment of consistent data collection methods within the program is not only necessary at the patient level, but also imperative in the interpretation of aggregate patient data for evaluating program effectiveness.

The structural framework suggested for outcomes measurement is the Outcomes Matrix, as illustrated in Table 3. The Matrix was developed by the AACVPR Outcome Committee<sup>19</sup> to help link outcomes evaluation to the core components of care. The framework provides a menu of outcome measures within the behavioral, clinical, and health domains and is in accordance with the core components of CR/secondary prevention programs.<sup>4</sup> It also introduces the service domain, which includes other program measures described in more detail later.

## **Outcome Measures**

Although the factors to measure are well defined, the measures to use may not be as clear-cut. The program staff members need the flexibility to choose measures that are meaningful for their patient population, providing results that can be interpreted and used by the staff. Decisions about what measures to use are influenced by the level of resources available in individual programs and the practicality of implementing the

**Table 2 • SUMMARY OF PATIENT ASSESSMENT AND OUTCOMES EVALUATION IN CARDIAC REHABILITATION AND SECONDARY PREVENTION PROGRAMS**

Core Component	Assessment and Outcome Evaluation
Patient assessment	<p>Review medical history: diagnoses, interventional procedures, comorbidities, test results, symptoms, risk factors, and medications.</p> <p><b>Assess:</b> Vital signs, current clinical status, administer a battery of standardized measurement tools to assess status in each component of care.</p> <p><b>Goal:</b> Develop a goal-directed treatment plan with short- and long-term goals for cardiovascular risk reduction and improvement in health-related quality of life.</p>
Lipid management	<p><b>Assess:</b> Lipid profile; current treatment and compliance</p> <p><b>Goal:</b> LDL &lt; 100 mg/dL; secondary goals: HDL &gt;40 mg/dL, triglycerides &lt;150 mg/dL.</p>
Hypertension management	<p><b>Assess:</b> Resting blood pressure (BP), current treatment strategies, and patient's adherence.</p> <p><b>Goal:</b> BP &lt;130 mm Hg systolic and &lt;80 mm Hg diastolic</p>
Diabetes management	<p><b>Assess:</b> Diabetes present: HbA<sub>1c</sub> and fasting blood glucose (FBG); current treatment strategies and patient's adherence.</p> <p><b>Goal:</b> HbA<sub>1c</sub> &lt; 7.0; FBG 80 -110 mg/dL</p>
Weight management	<p><b>Assess:</b> Weight, height; calculate body mass index (BMI): determine risk (obese ≥30 kg/m<sup>2</sup>; overweight 25-29.9 kg/m<sup>2</sup>)</p> <p><b>Goal:</b> If weight risk identified: energy deficit of 500-1000 kcal/day with diet and exercise to reduce weight by at least 10% (1-2 lb/wk).</p>
Psychosocial management	<p><b>Assess:</b> Psychological distress (depression, anxiety, hostility, etc.); refer patients with clinically significant distress to appropriate mental health specialists for further evaluation and treatment.</p> <p>Goal: Reduction of psychological distress; enhance coping and stress management skills. Address issues affecting health-related quality of life.</p>
Exercise training	<p><b>Assess:</b> Functional capacity (maximal or submaximal); physiological responses to exercise.</p> <p><b>Goal:</b> Individualized exercise prescription defining frequency (times/week), intensity (THR, RPE, MET level), duration (minutes), and modality to achieve aerobic, muscular, flexibility, and energy expenditure goals.</p>
Physical activity counseling	<p><b>Assess:</b> Current (past 7 days) physical activity behavior—include leisure and usual activities (occupational, domestic, etc.). Specify: time (minutes/day) frequency (days/week) and intensity (eg, moderate or vigorous).</p> <p>Goal: 30 minutes a day on most (at least 5) days/wk for moderate (3-5 MET level); 20 minutes a day for 3-4 days/wk for vigorous (6+ MET level). Promote adherence.</p>
Nutritional counseling	<p><b>Assess:</b> Current dietary behavior: dietary content of fat, cholesterol, sodium, caloric intake; eating and drinking habits.</p> <p><b>Goal:</b> Individualized prescribed diet based on needs assessed. Promote diet adherence.</p>
Smoking cessation	<p><b>Assess:</b> Smoking status: current, recent (quit &lt; 6 months), former, never.</p> <p>If current or recent: stage of change, amount of tobacco/day (or other nicotine).</p> <p><b>Goal:</b> Abstinence from smoking and use of all tobacco products.</p>

Data from: AHA/AACVPR Scientific Statement: Core components of cardiac rehabilitation/secondary prevention programs: a statement for healthcare professionals. *Circulation* 2000;102:1069-1073; and *J Cardiopulm Rehabil* 2000;20:310-316.

selected measures within routine patient care and program functions.

Although improved health and health-related quality of life are the ultimate goals of care,<sup>20</sup> it is the accumulation of positive changes that leads to the more global measures of health. For example, when CR/secondary

prevention interventions are implemented, changes in behavioral domain measures may be observed before changes in clinical domain measures, and changes in clinical domain measures may be observed before changes in health domain measures. Although changes in outcomes are much more complex than the follow-

**Table 3 • CARDIAC REHABILITATION/SECONDARY PREVENTION OUTCOMES MATRIX: CONCEPTUAL FRAMEWORK FOR ASSESSING PATIENT AND PROGRAM OUTCOMES**

Core Components of Care	Health	Clinical	Behavioral	Service
Overall management	Health-related quality of life Morbidity Mortality	Risk factor profile Symptoms Hemodynamic regulation	Improved knowledge and application of self-care actions Appropriate response to symptoms, complications Return to work or desired level of activities Medication adherence Assessing needed resources Session attendance	<b>Patient satisfaction:</b> (eg, satisfaction with care received, progress toward goals)  <b>Financial and economic:</b> Patient: healthcare utilization (eg, clinic, office, emergency visits, hospitalizations, medication use, loss of work days) <b>Access and utilization of service</b> (eg, referral, enrollment and completion rates)
Exercise training Endurance/aerobic Strength and flexibility		Untoward events detected during supervised sessions  Functional capacity: maximal and/or submaximal capacity (eg, walk test) Resting and exercise response: heart rate, blood pressure, rate of perceived effort, rate of perceived breathing, oxygen saturation Measures of strength and flexibility Lipid levels	Physical activity stage of change Energy expenditure: minutes or calories spent in physical activity/week Adherence to exercise prescription	
Lipid management		Blood pressure	Adherence to diet, exercise, and medication Diet and exercise stage of change	
Hypertension		HgA1c; glucose levels	Adherence to diet, exercise, and medication Diet and exercise stage of change	
Diabetes management		Weight, BMI, waist, anthropometric measures	Diet and exercise stage of change Self-monitoring behaviors Adherence to diet and exercise	
Weight management		Depression, anxiety, hostility, distress, sexual function	Diet/physical activity diaries or logs Coping mechanisms Stress management and relaxation skills Social support network	
Psychosocial management			Smoking stage of change Number of smokes/day	
Smoking cessation				

Data from: AHA/AACVPR Scientific Statement: Core components of cardiac rehabilitation/secondary prevention programs: a statement for healthcare professionals. *Circulation* 2000;102:1069-1073; and *J Cardiopulm Rehabil* 2000;20:310-316.

ing simplified illustration suggests, it may help engender understanding concerning the expected sequence of change as a direct result of the care provided in CR (Figure 1).

Patient outcome measures need to include at least one outcome measure for each core component of care that can be integrated consistently into preprogram and follow-up patient assessments (Table 3). The battery of measures needs to include an assortment of patient outcome measures (for the behavioral, clinical, health domains) and a service domain measure that will provide sufficient data for evaluating the effectiveness of the program in delivering each component of care, as well as overall program effectiveness. These data will contribute important information for developing quality improvement initiatives. The following discussion describes some specific examples of measures for each domain.

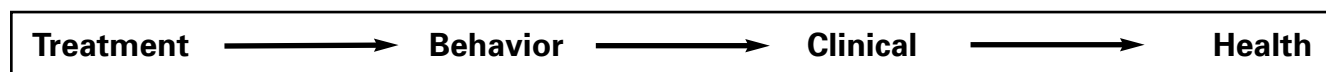
*Behavioral domain measures* reflect the patient's ability to make the recommended lifestyle changes that potentially lead to goal achievement in the clinical and health domains. These measures often are neglected or underused as important tools for guiding individual treatment plans and evaluating the effectiveness of the education and behavioral interventions. Behavioral domain measures are most commonly collected through administration of validated self-report questionnaires and by observation of patient behaviors during program participation. Suggested behavioral domain measures include physical activity (eg, minutes of physical activity or energy expenditure per week), diet habit scores, smoking (eg, current smoking status and number of cigarettes or amount of tobacco used per day), and demonstration of skills in stress management techniques. Other important behavioral domain measures include adherence to medications and other recommended secondary prevention strategies.

*Clinical domain measures* are necessary for assessing the patient's status at program entry to determine the priority strategies in the treatment plan. The measures are repeated at scheduled intervals (eg, at program exit) to evaluate the patient's progress and guide the development of long-term goals in the discharge plan. Clinical domain measures probably are the most familiar to program staff because they are routinely collected when patients are enrolled in CR. Ideally, medical record documentation should include at least one measure that provides an assessment of the patient in each core component of care: exercise training-functional capacity (maximal or submaximal), lipid management (lipid profile), hypertension management (blood pressure), diabetes management (patients with diabetes,

glycosated hemoglobin (H<sub>g</sub>A<sub>1</sub>C) or fasting blood glucose level), weight management (body mass index), and psychosocial management (eg, depression screen and other psychosocial measures). If a clinical domain measure representing a specific component of care for the majority of patients is not feasible, then a behavioral domain measure needs to represent that specific core component of care. For example, if a patient is prescribed a limited number of sessions or a brief period in CR, repetition of laboratory tests for assessing lipid management at completion of the supervised sessions may not be warranted or meaningful at that time. However, a dietary habit measure would provide some information about the patient's progress in making the desired changes known to improve lipid management.

*Health domain measures*, or global outcomes, include morbidity, mortality, health status, and health-related quality of life. Although morbidity and mortality are valid health domain measures, interpretation of the data at the program level usually is not meaningful or practical because of small sample sizes, the brief interval between measures, and other influences beyond the program's scope. Outcomes research has pointed to the importance of the patient's viewpoint on the goals of medical care, so "patient-centered outcomes" are increasingly viewed as the focus of medical interventions in which patient values shape the goals of medical care.<sup>21</sup> A measure of patient-perceived health status or health-related quality of life usually is the most feasible measure for inclusion in CR settings. There are generic and disease-specific measures of health status and health-related quality of life. Whereas generic measures provide general information about patients' perceived health-related quality of life, specific measures may be more responsive to treatment impact than generic measures.<sup>14</sup>

Finally, *service domain measures* represent an area of outcomes measurement that although often tracked by programs, does not typically fit within the behavioral, clinical, or health outcome domain measures. Service domain measures are those that the program staff can use to evaluate a number of indices regarding the effectiveness of the program's structure and methods for delivering services. Patient satisfaction is a specific example of a service-related measure that is becoming increasingly more important as a strategic measure in healthcare organizations.<sup>22</sup> Other measures in the service domain include utilization rates (referral, enrollment, and completion rates), costs of providing care, and satisfaction with the various interventions provided.



**Figure 1.** Response to treatment may be progressive where behavioral outcomes improve before clinical outcomes, and clinical outcomes improve before health outcomes.

In summary, a minimum expectation in outcome evaluation is selection of an outcome measures battery that can be administered to the majority of patients and includes a measure for each component of care (behavioral or clinical domain, ideally both), a measure of health status or health-related quality of life, and a measure in the service domain (patient satisfaction, utilization rates, cost data, and the like). The information gained in routinely reviewing the summarized reports should be used to answer the question, "How effective is our treatment overall and in each component of care?"

## **PATIENT ASSESSMENT**

Patient assessment usually is the most familiar step in outcome evaluation because it is a part of routine clinical care. However, the documentation of patient assessment may not reflect an outcomes-directed approach. Ideally, as each individual patient is enrolled for therapy, standardized baseline assessments are performed, documented, and used to guide the development of individualized goals and a treatment plan. The treatment plan needs to reflect the patient's unique status relative to the established treatment goals with a specific plan of action to help guide the patient in achieving these short- and long-term health goals. An ideal patient assessment protocol involves collecting and entering the patient data into a database during the initial intake process. This not only reduces staff time by eliminating duplicate documentation (writing data on the form and then reentering data into the database), but also provides an opportunity for immediate generation of a patient report. This patient report can be used for patient and physician feedback to facilitate goal setting and treatment plans, and for medical record documentation. At follow-up assessment, the patient is reevaluated with the measures used at baseline to determine the progress that was made toward the goals. The patient's outcomes evaluation is used to help guide discharge plans for achieving long-term secondary prevention and health goals. A sample patient assessment and evaluation report that reflects an outcomes-directed approach is illustrated in Figure 2.

Implementation of treatment plans that target individualized patient goals is a minimal expectation in the CR/Secondary Prevention Guidelines.<sup>3</sup> Even if no computer or database is available within a program, paper-and-pen documentation of the patient assessment is necessary to reflect a comprehensive and outcome-directed approach to care as part of the medical record. This patient-level process, the essence of outcomes evaluation, needs to be integrated and documented within routine clinical practice.

## **PROGRAM EFFECTIVENESS**

Evaluating program effectiveness in improving patient outcomes is an important program function. It provides information that helps programs evaluate how effective the treatment activities were for a group of patients (aggregate patient data) in reaching goals for secondary prevention and health. Quality improvement initiatives can be developed to address the specific issues of concern. Program effectiveness can be evaluated through an internal review of outcomes data by examining the changes observed between pre- and posttreatment and by comparing the outcomes with a predetermined goal. Program effectiveness also can be evaluated by comparing the outcomes of program with the aggregate outcomes of other programs. This often is referred to as "benchmarking" (external comparison). Because the purpose of the current document is to provide a practical approach to outcome evaluation for individual programs, the emphasis in this statement is directed at evaluating the effectiveness of a single program through internal review and comparison with therapy goals.

In an ideal setting, patients' preintervention and follow-up measures are entered into a computerized database to facilitate ongoing and effective data management, and to generate both patient and program summary reports. Program summary reports reflect a "snapshot" picture of the program's patient population and trends in outcomes achievement. Such information allows the manager and rehabilitation team to make data-driven decisions in prioritizing program activities and in identifying quality improvement initiatives specific to their program and patient population. Program summary reports are most helpful if they include descriptive information (demographic and clinical) about the enrolled patient population, followed by a summary of the changes (outcomes) achieved among patients who completed the program. A critical review of patient and program outcomes can help identify the program's unique strengths and weaknesses as well as issues for quality improvement.

A sample report of information that can be used for internal evaluation of program effectiveness is illustrated in Figure 3. This example is designed for internal critical review and may not be appropriate for external reporting, marketing, or other report purposes. Although numerous options exist for analyzing and displaying aggregate patient outcome data, it is important that the method chosen provide helpful and timely information to that specific program for quality improvement purposes. The sample form provides one option for describing and summarizing a program's patient population and outcomes. This example shows outcomes results by comparing the distribution of patients "at goal" before and at follow-up assessment within each core component of care. This program



Patient Population	Diagnoses Prevalence (%)	Risk Factor Prevalence (%)	Service
Mean age: _____	Stable angina _____	Dyslipidemia _____	Refer/enroll rate _____
Gender: Female (%) _____	MI _____	Hypertension _____	Enroll/complete rate _____
Race: non-white (%) _____	CABG _____	Diabetes _____	Drop-out reasons (%) _____
	Other _____	Physical inactivity _____	Medical _____
<b>Medication (% on Rx)</b>	<b>Risk Stratify</b>	Obesity _____	<b>Financial/Cost</b>
Lipid therapy _____	High _____	Smoking _____	Cost/pt/session _____
ASA _____	Intermediate _____		Other _____
Beta blockers _____	Low _____		
Others _____			

Patients Completing Program Outcomes: <i>Menu of potential measures:</i>	Goal	% at Goal		Patient Satisfaction
		Pre	Post	
<b>Behavioral</b>	<i>Behavioral goals are based on measures used.</i>			Mean scores
<input type="checkbox"/> Physical activity (minutes or kcal/week)				Exercise _____
<input type="checkbox"/> Diet score				Education _____
<input type="checkbox"/> Smoking cessation				Personal progress _____
<input type="checkbox"/> Medication adherence				Convenience _____
<input type="checkbox"/> Stress management practice				Staff _____
				Overall satisfaction _____
<b>Clinical</b>				<b>Treatment Activities</b>
<input type="checkbox"/> Lipid management	LDL < 100 mg/dL			% yes
<input type="checkbox"/> Hypertension management	SBP < 130 mmHg			Attended group classes _____
<input type="checkbox"/> Diabetes management	HgbA <sub>1c</sub> < 7			Individual consultation _____
<input type="checkbox"/> Weight management (BMI)	Normal < 25 kg/m <sup>2</sup>			Dietitian _____
<input type="checkbox"/> Psychosocial management	Overweight and obese			Psychosocial _____
<input type="checkbox"/> Exercise training	Weight loss ≥ 10%			Other _____
	<i>Goals are based on measures used.</i>			
	Functional capacity			<b>Program</b>
<b>Health</b>				Patient mean
<input type="checkbox"/> Health status or health-related quality of life	<i>Compare pre/post changes.</i>			Number of sessions: _____
				Duration (# of weeks): _____

This report is solely for quality improvement purposes through internal review of patient outcomes to evaluate program effectiveness. The information is thus confidential and it shall not be a public record or available for court subpoena

**Figure 3.** Sample form: cardiac rehabilitation rehabilitation group summary report. Data collected from patient records for quarterly and/or annual evaluation. MI, myocardial infarction; CABG, coronary artery bypass graft.

summary format can help provide answers when potential quality issues are explored within each of the following outcome domains:

- **Behavioral and clinical domains.** At discharge, is the proportion of patients at goal higher than at entry in all the components of care? Does the program appear to be effective in contributing to the overall risk reduction observed in this group of patients? If improvement is not observed in all patients, what program changes are needed for the specific subgroup of patients (eg, women,

elderly, or patients with a specific risk factor)? Is there a specific behavioral or clinical domain outcome that needs to be targeted for quality improvement actions? What are the current processes of care (assessment, education, counseling, and behavior interventions) that focus on this specific outcome? What can be done differently that may lead to improved outcomes?

- **Health domain.** Did patients perceive an overall improvement in health status or health-related quality of life at discharge as compared with scores at program entry? How do the scores com-

pare from baseline to program end or with those of a reference population at the time of discharge? Is there a positive trending, or do the results raise issues that need to be addressed?

- *Service domain.* Does the program's patient population have demographic characteristics similar to those of the geographic region or the primary referral source in acute care settings? Do the proportions reflect adequate access to the program for minority populations (women, nonwhite, and elderly)? Does the distribution of diagnoses reflect the proportion of diagnoses at discharge from the acute care setting? Are there opportunities to increase recruitment for underserved groups of patients? What is the distribution of patients within the risk stratification categories? Can this information help guide decisions in determining needs for staff training or resource allocation for the program? What is the program completion rate? Are there actions that can be implemented to address adherence issues? Do patients indicate a high level of satisfaction? If not, what can be done to improve patient satisfaction in a problematic area?

Despite the increased level of complexity involved in evaluating program effectiveness, all programs that consistently assess and document outcomes at the patient level are prepared to evaluate program effectiveness. The example provided in Figure 3 is a comprehensive summary report that includes multiple measures for each domain, which may not be feasible for some programs. However, programs must include at least a measure for each component of care (behavioral or clinical domain, ideally both), a measure of health status or health-related quality of life, and a measure in the service domain to help identify the program's strengths and weaknesses in delivering care. Although more complex analyses are necessary for interpreting the statistical significance of the observed changes, these usually are not necessary at the program level in the provision of practical information to the rehabilitation team. Programs that have the available resources and expertise to perform outcomes research using more complex statistical analyses are encouraged to disseminate their findings through professional publications.

## IMPROVING HEALTHCARE QUALITY

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Quantification of healthcare quality is a complex and challenging process that often leads to frustration among clinicians who strive to provide the best possible patient care within their available resources. An outcomes approach to patient care and program evaluation can be compared with geology. It goes beyond "rock-col-

lecting" or simply collecting data and generating reports. The numbers need to make sense from the patient and program perspective through data analyses and interpretation. Healthcare professionals must actively engage in the process to ensure that the data collected are relevant and valid. The results need to guide decision making in program activities and to help prioritize the selection of quality improvement plans. Ongoing evaluation is needed to determine whether the plans were effective, or whether different strategies are warranted.

Outcomes are influenced by factors other than the care provided to patients and include demographic and psychosocial characteristics, disease severity, clinical status, and the treatment setting.<sup>23</sup> Thus, risk adjustment is necessary to control the variability when patient outcomes are compared and interpreted among multiple programs. Without proper risk adjustment, the following question will always come up: "Are the differences in outcomes between programs attributable to quality of care or to the underlying differences in patient characteristics or provider settings?" Outcomes measurement serves a critical need in healthcare quality, but unless there is a method for discovering the reasons for observed differences in outcomes, the knowledge of results is useful only for judgment, not improvement.<sup>24</sup> Because of the complexity and sophistication of the analysis required for risk adjustment and because of the substantial possibility of misinterpretation, patient outcomes measurement and evaluation in clinical programs are considered most appropriate for internal quality improvement purposes.<sup>25</sup>

## FUTURE DIRECTIONS

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Healthcare providers must acquire the knowledge to participate in the assessment of healthcare quality that includes outcomes evaluation. However, the current healthcare environment also demands performance evaluation because quality improvement goals are aimed at eliminating inappropriate variation in the processes, which should lead to improved outcomes.<sup>26</sup> Performance measures are quantifiable measures applied to the steps or processes that lead to an outcome. These performance measures are discrete measures of activities used to define optimal care for which providers are held accountable. For example, an outcome goal in CR and secondary prevention is smoking cessation. The outcome measure is smoking status, number of cigarettes smoked, or both. The performance measure is the method of smoking cessation counseling that was provided. Performance measures are derived from, but are not, practice guidelines.<sup>25</sup> They are intended to provide healthcare providers with tools for measuring the quality of care that they provide by defining specific, measurable elements in their delivery of care.

Interest in performance measures to provide comparative data for external review of healthcare quality is increasing among consumers, regulatory agencies, healthcare organizations, and health professionals.<sup>27</sup> Examples of cardiology projects using performance measures include the National Registry of Myocardial Infarction- II (NRMI-II),<sup>28</sup> Medicare's Cooperative Cardiovascular Project,<sup>29</sup> the American College of Cardiology—National Cardiovascular Data Registry (ACC-NCDR),<sup>30</sup> and the American Heart Association (AHA)—Get With the Guidelines (GWTG).<sup>31</sup> More recently, evidence-based performance measures for practitioners in outpatient settings have been developed through the collaborative efforts of the AHA, the American College of Cardiology (ACC), and the American Medical Association (AMA)<sup>32</sup> for the diagnoses of stable coronary artery disease, heart failure, and hypertension. These performance measures will be pilot tested in physician offices over the next 2 years, and may continue to evolve as further evidence is gathered. Establishing evidence-based performance measures and outpatient tools specific to the outpatient CR setting that are modeled after the AHA/ACC outpatient performance measures may be a challenging yet progressive step for our professional organization.

## CONCLUSION

Outcomes evaluation permits assessment of effectiveness in providing patient care and the subsequent improvement in quality of care. This is a simple concept, but it involves complex processes that may challenge a program's resources to achieve the goal. The recently published Guidelines for CR and Secondary Prevention Programs define expectations in outcomes evaluation.<sup>3</sup> The intent of this report is to review the purposes of outcome evaluation and provide practical information and sample forms to help programs integrate an outcomes-directed approach within routine patient care and program functions.

Although it is imperative that individual programs take proactive steps to integrate outcomes evaluation processes within their routine functions, there is a critical need for direction and support from a national perspective to move outcomes efforts forward. Some lessons learned from innovative regional outcomes projects<sup>32-35</sup> have demonstrated the ability of multiple programs to collaborate and initiate standardized protocols, analyze data, and generate descriptive reports. However, leadership and consensus building are needed to help guide a unified national effort in outcomes evaluation that directly links activities and resources to quality improvement goals. From a national unified perspective, the greatest challenges in

quantifying quality include confusing terminology, non-standard definitions, measurement issues, changes in treatment recommendations, and limited resources.<sup>29</sup> With the current imperative to improve healthcare quality, each step taken to address these challenges in outcomes measurement and quality improvement represents advancement for our profession.

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