

Title: Are We Delivering Optimal Pulmonary Rehabilitation? The Importance of Quality Indicators in Evaluating Clinical Practice

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Author Byline: Pat G. Camp, Walden Cheung

Author Information:

P.G. Camp, PT, PhD, Department of Physical Therapy, Centre for Heart Lung Innovation, University of British Columbia, 166 – 1081 Burrard Street, Vancouver, BC, V6Z 1Y6 Canada.

Address all correspondence to Dr. Camp at: pat.camp@hli.ubc.ca.

W. Cheung, MSc, Department of Physical Therapy, University of British Columbia

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ABSTRACT

Pulmonary rehabilitation (PR) is a complex intervention that has been shown to improve exercise capacity and quality of life, reduce dyspnea, and decrease the risk of exacerbations and hospitalization. Although the evidence for PR is strong, the translation of this evidence into clinical practice remains a challenge, and important gaps in care exist. To date, most research in PR has focused on questions related to treatment efficacy. Less attention has been paid to confirming whether the strong evidence base of PR has been effectively translated to this complex clinical setting. Policy makers and other stakeholders in PR are calling for the establishment of core standards and quality indicators in PR to evaluate existing programs and improve patient care. However, what are quality indicators, and how are they used? This Perspective explores quality assurance in the context of PR and introduces the concepts and uses of quality indicators that can be used to evaluate and improve the quality of care.

“Quality is not an act, it is a habit.”

—Aristotle

Pulmonary rehabilitation (PR) is a key component of the management of patients with chronic obstructive pulmonary disease (COPD)¹ and other chronic lung diseases.² PR is a complex intervention comprised of individualized aerobic, resistance, and flexibility exercise; education for patients and families; and behavior modification to improve self-management skills and reduce the risk of worsening disease. PR is recommended for all patients with COPD with disabling symptoms and reduced quality of life.^{1,3}

The benefits of PR have been demonstrated in several high-quality randomized clinical trials and subsequent systematic reviews with meta-analyses.⁴ People with COPD who complete PR have reduced dyspnea during rest and exercise, and have improved quality of life, exercise tolerance, and muscle strength. These benefits are maintained for a period of 6-12 months after the program is completed.

Although PR is typically offered as a hospital-based, outpatient program,^{5,6} research has demonstrated the benefits in other settings, such as in the home,⁷ community,⁸ and via telehealth.⁹ As programs settings expand, the delivery of high-quality, evidence-based programs has become a focus of policymakers and PR leaders. In a 2015 policy paper¹⁰ issued by the American Thoracic Society, Rochester et al argued that the heterogeneity of PR program delivery within and between countries has the potential to adversely affect

program quality. Program heterogeneity was reported in several recent papers that surveyed PR programs in Canada,⁵ the United States,¹¹ and worldwide.⁶

Heterogeneity in complex programs such as PR does not necessarily negatively affect program quality if the program follows evidence-based recommendations. However, although several professional associations have produced statements and guidelines for PR,^{1,12,13} translating these recommendations into high-quality clinical programs is challenging, and not all necessary aspects of PR are reflected in published recommendations. The American Thoracic Society¹⁰ recommends that “...a core set of processes and outcomes should be established (by national respiratory societies) to enable national and international benchmarking in PR; this should include process and performance metrics to enable recommendations for international standards based on evidence and best practice.” In order to do this, there is a need for a common understanding of what quality PR is, and a common language that can be used to evaluate programs. In this Perspective article, we discuss PR as a complex intervention and ways in which unnecessary heterogeneity or variation in rehabilitation could contribute to poor quality care. We introduce a framework for understanding quality in rehabilitation, and describe how quality indicators are developed and used to assess infrastructure, process and outcomes of rehabilitation. Finally, we use examples from the literature and our clinical experience to illustrate how these indicators can support evidence-based pulmonary rehabilitation.

PR as a Complex Intervention

We know that people, and their health, are multifaceted. In the context of PR, program participants have a diagnosis of chronic lung disease, and most report dyspnea and reduced activity tolerance. Despite these common characteristics, there are often more differences between participants than similarities. For example, PR participants may have a diagnosis of COPD – but there are several phenotypes of COPD which express themselves functionally in different ways and change over the natural history of the disease.¹⁴ Participants in PR also may have additional comorbidities, such as heart disease, diabetes, or arthritis.¹⁵ They have different educational levels, different occupational histories, different socioeconomic backgrounds, and different goals for their rehabilitation. The manifestation of the disease and individual patient characteristics requires a complex health care intervention that is adaptable to patient needs.

PR is described as consisting of exercise, education and behavioral modification. However, this basic description does not take into account the multidimensional nature of the intervention.¹ For example, the exercise component is individualized for each participant to take into account their existing level of physical performance, their safety, their goals, the available resources, and the expertise of the program health care professionals. The education may follow a structured curriculum, but participants will use this information (or not) as it suits them. The success of the behavior modification element to PR (increase exercise and physical activity outside of the program; adopt different breathing patterns; manage exacerbations; quit smoking; employ stress management and energy conservation; use good inhaler technique) is influenced by personal, behavioral,

cultural and societal factors of the participant. In addition, programs will have different resources available, will be situated in different settings, in countries with different health care systems and payment mechanisms.⁶ Studies which have attempted to dissect the benefits of the individual components of PR have been problematic – while it has been relatively straightforward to conclude that exercise impacts physiologic measures,¹⁶ it has been more difficult to determine which program components can be attributed to changes in specific domains of quality of life, patient satisfaction, mental health, or health care utilization. PR is an example of a complex intervention that is: “...built up of a number of components...which may act both independently and inter-dependently.”¹⁷ As a whole these interventions improve patient health outcomes, but the specific components that lead to the improvement are difficult to describe. The United Kingdom Medical Research Council states that “*the greater the difficulty in defining precisely what, exactly, are the ‘active ingredients’ of an intervention and how they relate to each other, the greater the likelihood that you are dealing with a complex intervention.*”¹⁷

Due to the complexity of the intervention, there is *necessary variation in care* between patients participating in PR. It is not a “one-size-fits-all” approach – there is a careful individualization of the program components for each patient. However, the multifaceted nature of the patients and the necessary lack of standardization in the intervention itself could also result in variation *that may be unnecessary*. This may negatively influence patient safety and health outcomes.¹⁸ To reduce potential unnecessary variation, there have been a number guidelines published^{1,12,13} that recommend specific approaches to care.

Quality in the Context of Rehabilitation Care

Over the past several decades, PR research has focused on studies that demonstrate the efficacy and effectiveness of the intervention. As physical therapists we know rehabilitation has a strong, albeit emerging base of evidence. While efficacy studies have been crucial to establish the knowledge base of our discipline in general (and rehabilitation interventions in particular), these studies have not always translated into quality care at the bedside. To address the need to increase the use of research results in clinical practice, the field of “knowledge translation” (KT) was developed. KT involves taking evidence from the research setting and using a variety of strategies to implement evidence into clinical practice. But KT strategies alone are not enough to ensure quality of rehabilitative care. In complex rehabilitation environments, we propose that there are four components that need to be in place for patients to receive optimal benefits of care (Fig. 1). There must be: 1) Evidence supporting the intervention; 2) Health Care Professionals with the skills to deliver the program; 3) Infrastructure & Policy in place to support the program; and 4) Evaluative Processes in place to assess the program – and all of these components and sub-components must be of high quality.

In PR, there is high-quality evidence supporting the intervention.⁴ In fact, in 2015 the Cochrane Collaboration took the unusual step of deciding that there would be no further Cochrane systematic reviews to determine if pulmonary rehabilitation conferred benefits compared to placebo, as the evidence base was unequivocal.¹⁹ However, despite the strong base of evidence and specific guidelines recommending care, we know that

unnecessary variation in PR practice occurs. Garvey et al¹¹ noted that substantial variation occurred in PR programs in the United States, especially in the components related to exercise intensity, exercise progression, and outcome measures used. In 2005 Brooks et al²⁰ surveyed Canadian PR programs and reported substantial variation in the duration of programs, outcomes measures used, and post-discharge components such as follow-up or maintenance. More recently, the Canadian Thoracic Society (CTS) conducted a study of PR programs in Canada.⁵ They found that 59% of programs had completion rates of less than 80%; 20% of programs had no defibrillator or access to a code blue team; and less than 50% kept track of completion rate, wait list time or drop-out rates. A British Thoracic Society audit of COPD care²¹ found gaps in some aspects of PR care, including the lack of PR care for patients with recent exacerbations of COPD, and the limited use of muscle strength outcome measures despite almost all programs offering resistance training. Similarly, Spruit et al⁶ published an international survey of PR programs and reported a wide variation in length of programs; outcome measures used; and treatments provided.

What may lead to unnecessary variation in practice? While infrastructure issues such as inequitable funding or limited resources may play a role, there needs to be a close examination of the practice behavior of health care professionals. In PR specifically, the limited training of entry-level health care professionals and few opportunities for ongoing professional development may be contributing factors. There are numerous disciplines involved in PR but in general, few get formal training in PR principles.²² For instance, physiotherapists are well-trained in rehabilitation care but may not have received much exposure to pulmonary patients in their clinical rotations. Respiratory therapists have

extensive knowledge of respiratory disease and related education, but rarely have the principles of exercise testing and training in their curricula. Pulmonologists are required to receive training in the medical direction of PR but in practice, this may not occur. Even for those clinicians who do receive entry-level training in PR, there are few opportunities for ongoing, structured continuing professional development. Because of this, even when new knowledge is created, the dissemination and implementation of this knowledge (i.e., KT) may be limited. Without regular reinforcement of rehabilitation principles, demonstrated competence in practice, and an opportunity to develop new skills as the evidence-base grows, clinicians in PR could experience an ‘eroding’ or gradual movement away from optimal evidence-based practice. This gradual decrease in optimal practice is known as “therapist drift”²³ but is rarely acknowledged as a potential contributor to poor patient outcomes. When patients fail to improve after rehabilitation, they may be termed ‘non-responders’ with their lack of benefit attributed to patient-related factors such as adherence issues or disease severity – when in fact therapist drift and a lack of evidence-based practice may be a reason for lack of improvement.

How can we determine if PR practice is suboptimal, and target areas for improvement? The fourth component of rehabilitation care: “Evaluative processes to assess the program” is a necessary but overlooked element of quality PR. Qualitative assessment and improvement is a well-recognized research and policy area in health care but there has been less attention paid to it in rehabilitation compared to other aspects of health care, such as surgery, pharmaceutical management, and diagnostic services. There is also little data linking care gaps in PR with poor patient outcomes. A key component of

quality assessment and improvement is some agreement around *what* constitutes a quality program. To do this, quality indicators are needed.

Quality Indicators: A Common Language to Assess Quality of PR

Variation in PR may impact care, but it is difficult to measure variation and its impact if we don't have a standard language or agreement on what characteristics define a quality program. Quality indicators are part of that standard language and can provide a guide to improve the quality of an individual program as well as the overall practice of PR as part of a complete system of care.

There has been a great deal of emphasis on the importance of measuring the quality and safety of the health care system using quality indicators. But what are quality indicators? They: “*are explicit standards of care against which actual clinical practice is judged;...should be followed for all suitable patients with the exception of extraordinary circumstances...and define how to practically identify those patients for whom a specific action should be taken...*”²⁴ Quality indicators are different than performance indicators, in that they “*infer a judgment about the quality of care provided*”²⁵ whereas performance indicators monitor care in a population but may be measuring aspects of care other than quality, such as financial performance or efficiency. Although they have been defined in different ways (see Institute of Medicine, *Crossing the Quality Chasm: A New Health System for the Twenty-first Century*²⁶; also work by Mainz et al^{27,28}) in general, quality indicators describe the necessary attributes of the *structure, processes, and outcomes* of care that should be in place in order to improve patient health outcomes²⁹ (Fig. 2).

Structure Quality Indicators

Structure quality indicators are related to the static, technical, and/or tangible aspects of the intervention²⁸ and are in place prior to the patient receiving care. In rehabilitation, examples of structure quality indicators would include the physical setting, available equipment and resources (including educational resources), the number and experience of health care professionals involved, the presence of consistent funding, and/or the availability of safety equipment. The measurement of structural indicators in PR is relatively straightforward – it typically requires documenting if a program has the necessary equipment and resources to provide PR. However, deciding *what* structural elements constitute a quality program is more difficult, as there are few clinical trials that have investigated the benefits of certain structural elements over others. However, in the absence of head-to-head comparisons, it may be enough to demonstrate that a particular structural element results in positive patient outcomes. For example, a study by Wootton et al³⁰ examined the impact of an 8-10 week ground-based walking program on health status and exercise endurance and, although they did not compare ground-based walking with treadmill walking (the typical walking modality in PR) they reported clinically-important improvements in patient outcomes. Based on this type of evidence, a quality indicator related to aerobic exercise equipment could then be written to incorporate a variety of equipment modalities to use in the program.

Guidelines could also be used to inform structural quality indicators. In PR, the British Thoracic Society PR guidelines³¹ have several recommendations related to

structural elements that could be re-stated as quality indicators. For example, they suggest that supplemental oxygen be available; that housebound patients with severe dyspnea not be offered home-based rehabilitation; or that during exercise non-invasive ventilation, heliox, or neuromuscular stimulation not be routinely used. Based on these guideline recommendations, quality indicators regarding what structural elements are necessary could be created.

Process Quality Indicators

Process indicators are related to the 'how' of the intervention. In rehabilitation, process indicators state how the patient should "flow" through the system, and the background elements that must be in place to facilitate that flow. Some process indicators in PR have a strong evidence base; for example, there is evidence that programs of longer length (>8weeks) provide greater benefit than those of shorter length (<6 weeks)³²; that aerobic exercise intensity should be >60% of peak workload,³¹ or that smoking cessation treatments should be included.^{1,31} Other process indicators may not be developed based on research evidence but may be more indicative of the health care system in general; for example, there may be a tacit understanding that the average patient should wait no more than 2 months to be admitted to a program; or that specific educational components are beneficial despite the lack of evidence to support those statements.

Outcome Quality Indicators

Outcome quality indicators measure aspects of patient benefits and patient safety. Most of these measures are quantitative in nature and the details and expected outcomes

are typically derived from the research literature. Despite this, outcome quality indicators do not always name specific measures to be used. For example, in PR there are accepted and well-researched¹ outcome measures, such as the six minute walk distance and incremental shuttle walk distance for exercise, the MRC Dyspnea scale, and the St. George's Respiratory Questionnaire (SGRQ) and the Chronic Respiratory Disease Questionnaire for health status. However, outcomes measures developed for research trials are not always feasible for use in clinical programs, which make naming specific measures in indicator statements problematic. For example, the SGRQ is an accepted research measure of health status of individuals with COPD,³³ and a minimal clinically important difference has been calculated to assist with the interpretation of aggregated data of patient improvement in clinical trials.³⁴ However, there are challenges to its use in clinical practice, including the interpretation of the score for an individual patient. The developers of the measure state that the SGRQ has been translated into 77 languages³⁵ via the back-translation process. However, there are only a few published validation studies in languages other than English,^{35,36} raising concerns that the measure may not adequately reflect health status in all COPD populations. Similarly, validity and reliability studies of the six minute walk test recruited a relatively homogenous population of older, predominantly male, COPD patients from English-speaking countries.³⁷ Therefore, although outcome measurement is an important indicator of program quality, there may not be consensus as to which outcome measure to use, or which specific measure is valid and reliable in a diverse patient population."

Quality Indicators and Benchmarks

Quality indicators describe what a quality program looks like, but how do we know when quality has been achieved? A *benchmark* establishes the proportion of times the quality indicator is met in order to make a determination of the quality of the program overall. For example, the British Thoracic Society³⁸ has developed a PR quality indicator that states that *“People attending pulmonary rehabilitation have the outcome of treatment assessed using as a minimum, measures of exercise capacity, dyspnoea and health status.”* While it would be optimal for this to occur for 100% of the patients, the reality is that 100% is rarely achievable. Perhaps it is acceptable if outcome measurement occurs for 85% of the patients. The actual value of a benchmark is relatively arbitrary and depends on the context – there may be little tolerance for some aspects of quality related to patient safety (for example: a quality indicator states that there must be a functioning CODE BLUE or Automated External Defibrillator available at all times; Benchmark = 100%) but more tolerance for other aspects of patient care (for example, each patient completes a quality of life questionnaire at the beginning and end of the program; Benchmark: 85%). Benchmarks may be set at a regional, national or international level – therefore, benchmarks may reflect local administrative decisions, whereas the quality indicator is based on the evidence.

How Are Quality Indicators Developed?

An accepted approach to developing quality indicators is to use the Rand Appropriateness Method.³⁹ This method consists of a review of peer-reviewed literature and grey literature (technical reports and audits) to create a potential quality indicator list, which is then distributed to an expert panel of patients, health care professionals,

academics and managers for rating. The rating is then followed by a face-to-face meeting with the entire expert panel, during which the candidate indicators are discussed and selection by consensus is reached.

One of the challenges in developing quality indicators is determining how the actual QI statement and benchmarks are written. One format, developed by Mainz⁴⁰ and Campbell,²⁵ involves writing the QI as a rate-based statements with a numerator and a denominator. This format allows for conversion to percentages and comparisons to benchmark criteria, and therefore works well for healthcare services where certain benchmark criterion has been established. However there are many QIs that do not have established benchmarks, and in some cases benchmarking may not account for individual variability for participants in a healthcare service.⁴¹ This is especially challenging for healthcare services such as PR which requires tailoring of the service for its participants.^{1,10}

In general, there is a lack of consensus on how quality indicators should be written, making it difficult to compare work from different jurisdictions. For example, in 2002 Marshall and colleagues⁴² compared quality indicators for diabetes management developed in the United States and the United Kingdom to see if they could be transferred between the two countries. Many of the QIs were classified as “near equivalent,” meaning that there was common ground shared but there was enough of a difference that they could not be transferred effectively. This can be seen in the following example they provided: in the United States, one quality indicator stated that: *“Type 2 diabetics who have failed dietary treatment should receive oral hypoglycaemic treatment.”* In the United Kingdom, a similar quality indicator stated that *“If the HbA1c level of a diabetic patient is measured as >8%, the following options should be offered 6 months apart: change in dietary or drug management,*

explanation of the raised test, or written record that a higher level is acceptable.” Although the two indicators both stress the importance of controlling poor glycaemic levels, the United Kingdom indicator has enough clarity in its statement to be operationalized and measured in medical records. The US indicator is written more as a guideline statement; it is difficult to measure the statement when it does not define what “failed dietary treatment” is or how often they should specifically receive hypoglycaemic control.

In PR, differences also exist in how quality indicators are developed, and their subsequent content. Both the British Thoracic Society³⁸ and the Spanish Society of Pneumology and Thoracic Surgery⁴³ have published quality indicators for PR. The British Thoracic Society developed “quality standards” based on United Kingdom’s National Institute for Health and Care Excellence (NICE) Quality Standards Process Guide,³⁸ for the use of stakeholders in England (with adaptations by programs in Wales, Scotland and Northern Ireland). Quality standards for PR included a “quality statement” which describe best practice of a specific component of PR, and a “quality measure” which is used to assess the quality of care. The BTS PR quality standards were developed by a large committee (n = 18) of quality improvement and content experts and other stakeholders who used their expertise to prioritise areas, debate the evidence, consider the resource impact and feedback from other stakeholders, draft the standards and submit to the NICE Board for approval. This committee developed 10 quality standards: three regarding eligibility and referral, one that refers to duration of program and frequency of session, two regarding PR program components, one regarding an maintenance exercise plan, one regarding outcome measurement, and two regarding standard operating procedures. These standards then form the basis of a regular audit of programs⁴⁴ as well as the development of a national PR

surveillance and accreditation system (<https://www.brit-thoracic.org.uk/standards-of-care/quality-improvement/pulmonary-rehabilitation/>).

Similarly, the Spanish Society of Pneumology and Thoracic Surgery charged its Quality Healthcare Committee to prepare PR quality standards to support a national audit and surveillance program which will ensure equitable, quality PR in all geographical and jurisdictional areas of Spain. Their committee was comprised primarily of a small group (n = 6) of health care professionals with expertise in PR. This committee reviewed existing guidelines and original research to develop 35 indicators: eight referring to indications for PR; seven referring to patient evaluation; five referring to the components of the program; fourteen referring to specific details on how the exercise and education components should be delivered; and ten referring to how the program should be administered. Overall, the Spanish Society indicators are very specific (e.g. “The first evaluation should include chest xray, electrocardiogram, spirometry, six minute walk test, Borg Dyspnea Scale, nutritional evaluation, and evaluation of quality of life”). In contrast, the British Society quality standards are more generally worded (e.g. “pulmonary rehabilitation programmes include supervised, individually tailored and prescribed, progressive exercise training including both aerobic and resistance training”). The Spanish Society also developed a total quality healthcare scoring system whereby a score of <60% was indicative of “deficient” practice. Both societies developed their indicators without the use of a formal review and voting process, such as the RAND method, although the evidence supporting each standard was evaluated.

Although it may seem unnecessarily redundant to have individual respiratory societies develop their own PR indicators, a “one-size-fits-all” approach may not be

practical. It is important to incorporate local realities of health care delivery when developing indicators. This should not be interpreted as creating indicators that merely describe and affirm *existing* practice – quality indicators must be evidence-based where possible and provide direction to ultimately improve health care practices and patient outcomes. However, there are many aspects of PR for which the evidence is scant, or based on results primarily obtained from research laboratories. For example, although it is known that exercise intensity based on the results of a symptom-limited cardiopulmonary exercise test results in increased exercise capacity,⁴⁵ the lack of proper testing equipment in many locations, including Canada and the United States, precludes its use as an indicator related to evidence-based exercise prescription. A quality indicator that states the need for this equipment is not practical for many settings. In addition, the expansion of PR to home and telehealth settings in some areas will necessitate the development of indicators that identify the components of structure, process and outcome in those settings. Therefore, jurisdiction-specific indicators will likely continue to be developed in order to reflect the unique differences in health service delivery between countries or regions.

How Can Quality Indicators Be Used in Rehabilitation?

Much of the work to develop and use quality indicators has occurred in acute care hospital settings. Although less work has been done in the areas of rehabilitation, indicators have been developed for stroke rehabilitation⁴⁶; arthritis rehabilitation^{47,48}; cardiac rehabilitation⁴⁹ and pulmonary rehabilitation.^{38,43} In pulmonary rehabilitation, how might clinicians and managers use quality indicators in their programs? A quick assessment of the structural, process and outcome components of the program can give a

snapshot as to whether the program is functioning well, or if there are early signs of problems. A large-scale, regional audit with several programs participating would select more indicators, and may attempt to assess the impact of all programs on a regional outcome, such as reduced hospitalization or emergency room visit. Clinicians may select just one or two indicators to assess the quality of their care. In our clinical program, we regularly evaluate the impact of our program on patient outcomes such as exercise capacity, and investigate what are the factors that are related to non-completion of the program, or outcomes that were less than expected. This helps to prevent “therapist drift” and ensure that we are maintaining the quality standards of a complex, evidence-based rehabilitation program.

Conclusion

As a complex intervention, PR has many components which, optimally, work in harmony to confer the greatest benefit on the patient. When the quality of any of the components is lacking, the patient’s potential for benefit may not be realized. Quality indicators are statements that define the necessary structural, process, and outcome related factors that must in place in order to deliver the best possible care to the patient. In the pulmonary rehabilitation setting, the adoption and use of quality indicators may show us where our programs are lacking, and where we need to focus our efforts to support programs and staff to improve the quality of their care.

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Concept/idea/research design: P.G. Camp

Writing: P.G. Camp, W. Cheung

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FIGURE CAPTIONS

Figure 1. Components of quality pulmonary rehabilitation. CPD = continuing professional development; HCP = health care professional; KT = knowledge translation; PR = pulmonary rehabilitation.

Figure 2. Quality indicators in pulmonary rehabilitation (PR). There are 3 categories of quality indicators: structure, process, and outcome indicators. They articulate the conditions by which a patient can receive quality health care. Structure indicators describe the conditions of the program that must be in place prior to the patient accessing care. Process indicators describe the conditions by which the patient receives care, which, evidence shows, results in patient improvement. Outcome indicators describe what should be measured *after* the care is received, to better understand the impact of the care on the patient.