Are You Ready for Kaizen in Your Clinical Practice?

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Quality indicators (QIs), a tool for kaizen (“change for better”) for clinical practice in medical care, allow quantitative assessment of daily practice and functions to bridge the evidence-practice gap. A conceptual model proposed by Avedis Donabedian has been widely used to develop QIs in various specialty areas. The Donabedian model explains the quality of medical practice based on 3 domains (structure, process, and outcome; Figure), and numerous disease-specific QIs have been proposed, including for cancer, acute myocardial infarction, and chronic obstructive pulmonary disease, as well as for specific areas, such as the intensive care unit (ICU) in cardiovascular practice. In general, a QI is initially developed and proposed by clinicians who are focused on the need to improve the quality of practice in a specific area; QI items in an area with no consensus of indicators are sometimes examined by systematic review for generalization. Using QI, clinicians are expected to improve quality of care by reviewing daily practice. In some English-speaking countries, QIs may serve as measures for “pay for performance (P4P)”, in which the QI score acts as a financial incentive. QIs can also be used to complement existing clinical guidelines to achieve specific outcomes in complex clinical situations. Indeed, in cardiovascular practice, the European Society of Cardiology, American Heart Association

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**Figure.** The Donabedian model of measuring healthcare system performance. Adapted from Brien SE et al.¹
(AHA), and other medical specialty societies have proposed QIs for specific diseases or in particular areas, including acute myocardial infarction (AMI), adults with heart failure (HF), and cardiac rehabilitation.

Because most cardiologists seem to be inexperienced with regard to the methodology used to develop QIs, knowing the development process may be of value in assessing the different publications on QI. The Delphi survey, an established methodology used to develop QIs, is used to answer many questions of interest in medical and social sciences by developing consensus around a particular issue. For example, a QI-development process using a modified four-step Delphi approach was proposed by the European Society of Gynaecological Oncology. The first step in this process is to list potential QIs from guidelines and the literature, with expert panel members then independently rating the relevance, validity, and feasibility of each QI item with no interaction. The second step involves a moderated expert panel discussion of each potential QI item. In this step, each panel member independently provides a second rating for each item after discussion (first panel meeting). In the third step, the external panel of expert reviewers rates the relevance, validity, and feasibility of each QI item with no interaction. The fourth and final step consists of a moderated expert panel discussion that integrates reviewer comments. In this step, the expert panel members independently provide a final rating for each QI item after the discussion (second panel meeting). After finishing the process, the proposed QI is examined for generalizability.

Recently, systematic reviews of specific area-focused QI sets in cardiovascular practice have been reported. For example, Goldfarb et al reported a systematic review of QIs in the cardiac ICU. In that review, 108 QIs (70 process, 18 structural, 18 outcome, 1 patient engagement, 1 covering multiple domains) were identified in 30 articles, representing 23 agencies, organizations, and societies. Goldfarb et al then surveyed the results with 14 expert cardiac intensivist-administrators (7 Americans, 7 Europeans), with the final QI set including 7 structure, 2 process, and 6 outcome measures. Interestingly, during the survey process, differences in choosing some items as important and relevant became evident between American and European expert cardiac intensivist-administrators, suggesting that the rating of a particular QI is likely to be affected by region-specific medical issues. With this in mind, QIs for focused area of practice should be developed in view of the evidence and region-specific medical issues, including the healthcare insurance system.

In this issue of the Journal, Hamatani et al report on the development of QIs for palliative care in HF patients, for whom care is less advanced than for cancer patients. Developing QIs in palliative care is deemed essential because the goal of care is to achieve quality of life (and death) for patients, which requires multidisciplinary intervention. Hamatani et al identified 44 potential QIs for further consideration and proposed a final set of 35 QI items for palliative care in HF patients (74% process, 26% structure, 0% outcome in the Donabedian model). The final set of QIs included 4 domains: (1) structure and process in disease care; (2) HF treatment and care; (3) total pain management; and (4) decision support and ethical issue management. In a practical preliminary test, Hamatani et al found that intervention by a multidisciplinary team, opioid therapy for patients with refractory dyspnea, and screening for psychological symptoms (process indicators), as well as preparation of a screening sheet for total pain and a medical manual about advanced care planning (structure domain) remained as appropriate targets to improve quality in practice with maximum potential for improvement. The next step is to examine the generalizability of the proposed QIs; after this has been done, the QI set of Hamatani et al may serve as a reference for QIs in palliative care in Japan.

Thus, QIs allow us to clarify issues to improve quality of care in specific cardiovascular practice, and QI rating is the first step to refine our practice. Most of us recognize the benefit of guiding indicators, particularly in areas of care involving multidisciplinary teams, which are now becoming mainstream in highly developed medical care. As Hamatani et al note in their article, the next step in establishing their proposed QIs will be to generalize their proposed QIs by collaborating with medical specialty societies. It is understandable that the most difficult issue would be to disseminate QIs into general practice. To this end, most medical specialty societies globally take a leading role in authorizing QIs for focused areas of clinical practice that implement their existing clinical guidelines. Establishing medical specialty society-guided QIs will meet the need of clinicians as well as other medical staff who are making an effort to implement evidenced-based principles into daily practice with a great deal of enthusiasm. In addition, standardized and well-selected QIs based on guideline-recommended management will allow us not only to refine daily practice, but also to expand necessary knowledge and practice rapidly in focused areas with urgent need.

Kaizen is not a specialty only of Japanese automobile companies: we already have a tool to refine our daily practice.

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References

1. Brien SE, Ghali WA. Public reporting of the hospital standardized mortality ratio (HSMR): Implications for the Canadian approach to safety and quality in health care. Open Med 2008; 2:e70–e73.
2. Goldfarb M, Bibas L, Newby LK, Henry TD, Katz J, van Diepen S, et al. Systematic review and directors survey of quality indicators for the cardiovascular intensive care unit. Int J Cardiol 2018; 260: 219–225.
3. Lindenauer PK, Remus D, Roman S, Rothberg MB, Benjamin EM, Ma A, et al. Public reporting and pay for performance in hospital quality improvement. N Engl J Med 2007; 356: 486–496.
4. Steg PG, James SK, Atar D, Badano LP, Blömström-Lundqvist C, Borger MA, et al. ESC guidelines for the management of acute myocardial infarction in patients presenting with ST-segment elevation. Eur Heart J 2012; 33: 2569–2619.
5. Rolli M, Patrono C, Collet JP, Mueller C, Valgimigli M, Andreotti F, et al. 2015 ESC guidelines for the management of acute coronary syndrome in patients presenting without persistent ST-segment elevation: Task Force for the Management of Acute Coronary Syndromes in Patients Presenting without Persistent ST-Segment Elevation of the European Society of Cardiology (ESC). Eur Heart J 2016; 37: 267–315.
6. Spertus JA, Bonow RO, Chan P, Diamond GA, Drozda JP Jr, Kaul S, et al. ACCF/AHA new insights into the methodology of performance measurement: A report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures. Circulation 2010; 122: 2091–2106.
7. Jneid H, Addison D, Bhatt DL, Fonarow GC, Gokak S, Grady KL, et al. 2017 AHA/ACC clinical performance and quality measures for adults with ST-elevation and non-ST-elevation myocardial infarction: A report of the American College of Cardiology/American Heart Association Task Force on Performance Measures. J Am Coll Cardiol 2017; 70: 2048–2090.
8. American Academy of Family Physicians; American Academy of Hospice and Palliative Medicine; American Nurses Association; American Society of Health-System Pharmacists; Heart Rhythm Society; Society of Hospital Medicine, Bonow RO, Ganiats TG, Beam CT, Blake K, Casey DE Jr, Goodlin SJ, et al; ACCF/AHA Task Force on Performance Measures, Peterson ED, Masoudi FA, DeLong E, Erwin JP 3rd, Fonarow GC, Golf DC Jr, et al. ACCF/AHA/AMA-PCPI 2011 performance measures for adults with heart failure: A report of the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures and the American Medical Association-Physician Consortium for Performance Improvement. J Am Coll Cardiol 2012; 59: 1812–1832.

9. Thomas RJ, King M, Lui K, Oldridge N, Piña IL, Spertus J; ACCF/AHA Task Force on Performance Measures. AACVPR/ACCF/AHA 2010 update: Performance measures on cardiac rehabilitation for referral to cardiac rehabilitation/secondary prevention services: A report of the American Association of Cardiovascular and Pulmonary Rehabilitation and the American College of Cardiology Foundation/American Heart Association Task Force on Performance Measures (Writing Committee to Develop Clinical Performance Measures for Cardiac Rehabilitation). J Cardiopulm Rehabil Prev 2010; 30: 279–288.

10. European Society of Gynaecological Oncology. Quality indicators. Published development processes. https://www.esgo.org/media/2016/10/Methodology-QUALITY-INDICATORS-Published-development-processes.pdf (accessed January 15, 2020).

11. Hamatani Y, Takada Y, Miyamoto Y, Kawano Y, Anchi Y, Shibata T, et al. Development and practical test of quality indicators for palliative care in patients with chronic heart failure. Circ J 2020; 84: 584–591.