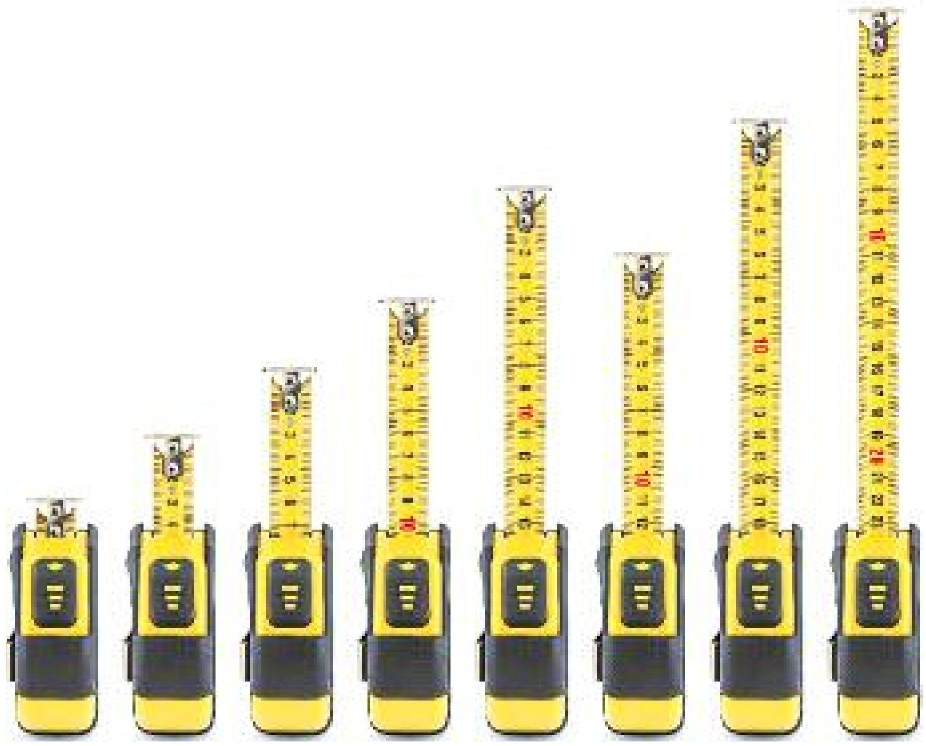
Measuring health outcomes: The foundation of contemporary healthcare decision-making

Paul Kind
Academic Unit of Health Economics, Institute for Health Sciences, University of Leeds, England

Correspondence to:
Paul Kind
University of Leeds
Wolsey Building, Clarendon Way
Leeds LS9 5NL, England
p.kind@leeds.ac.uk

Abstract

Healthcare professionals and patients are (or should be) interested in understanding the benefits of health care. We should be able to know the expected treatment benefits and to see quantifiable evidence that supports those expectations. Such information is a requirement in all clinical studies and there have long been calls for the systematic recording of health outcomes. Without such information how will healthcare professionals differentiate between treatments that yield health benefits – and those that do not? Key to the measurement of outcomes in healthcare is an understanding as to what is meant by "health", a concept that continues to evade a universally agreed definition. The measurement of health outcomes provides three key pieces of information – it identifies whether or not anything has changed, the direction of any change and its magnitude. New approaches to measuring health outcomes herald new ways of managing and delivering healthcare in the twenty-first century.



Whether as health professionals delivering care or as patients receiving it; whether as researchers working at the frontiers of science or administrators working in healthcare provider units – all of us are directly or indirectly interested in health, if not currently then with increased likelihood as we grow older. But what exactly is meant by "health"? How is it defined? It is paradoxical that this universal concept lacks a universally agreed understanding of its meaning. This is in marked contrast to the physical parameters that characterise the science that underpins the practice of healthcare itself. Standardised units of measure are found everywhere, from body weight to blood pressure, lung function, nerve signal transmission, cardiac output, blood chemistry. The 1946 Constitution of the World Health Organization (WHO)[1] opens with a definition of health as "state of complete physical, mental and social well-being and not merely the absence of disease or infirmity", but this raises many other questions, for example what is meant by "well-being" and how can we establish when it is "complete"? The three nominated facets of health included within the WHO definition make no allowance for cultural and ethnic factors that need to be taken into account when thinking about health. Traditional Chinese medicine recognises many signs and symptoms that have significance in establishing a patient's health status, but which are discounted by physicians trained elsewhere. Social organisation, practice and values change over time allowing new health-related issues to emerge. Contraceptive practice, gender identity, cosmetic appearance, domestic violence are recent additions to the health lexicon. At one level all such considerations could be judged to be philosophical, but healthcare today relies predominantly on empirical evidence and in order for us to measure it, we need clarity about what it is that we are observing and agreement about the

> The 1946 Constitution of the World Health Organization opens with a definition of health as "state of complete physical, mental and social well-being and not merely the absence of disease or infirmity."

metrics to be used to quantify those observations.

For the purposes of what follows here, it is necessary only to accept the principle that we can (and should) think about health as a quantifiable concept. Several different approaches of varying degrees of legitimacy have been proposed for measuring health, but none has acquired the distinction of being recognised as the standard. All forms of measurement begin with description. Diagnostic systems such as ICD-11 represent a sophisticated mechanism through which we can define the health (or rather ill-health) of a patient.[2] An individual patient can be categorised with a diagnostic code or codes, establishing information which can be important in its own right. Knowledge of a diagnosis can help guide decisions about clinical investigation and treatment. By aggregating data based on ICD codes we can establish the prevalence of conditions of interest in the population at large. Even at the level of the hospital or provider unit we can use such information to compare workload and monitor performance.

> A fundamental question that is central to all healthcare decisions, for individual patients or collectively for a population, is that of deciding whether healthcare interventions "work."

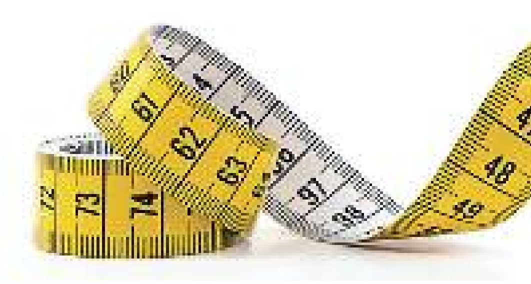
More than 150 years ago, Florence Nightingale published a classification of health status that was to be applied to all patients leaving her care.[3] This system that describes patients as being *relieved* (better), *unrelieved* (same), or *dead* has a level of sophistication that continues to challenge us all today, namely the ability to systematically identify and record patient's status following treatment. A fundamental question that is central to all healthcare decisions, for individual patients or collectively for a population, is that of deciding whether healthcare interventions "work". There is an understandable tendency to always see healthcare in a positive light. Nothing stimulates a community more than the threatened loss of a local healthcare service, but against a background of limited resources (including personnel, capacity and budgets) there is a need to assess evidence regarding the effectiveness and cost-effectiveness of healthcare interventions.

Advances in medical practice do sometimes come with undesirable consequences. A recent UK study of medical device-related pressure ulcers revealed more than 7,200 cases of iatrogenic harm, i.e., harm caused by a medical intervention or investigation.[4] Well-established practice too is not without its risks. A Canadian study[5] of older patients admitted for in-patient care found that acute illness and hospitalisation are associated with significant potential harm notably from so-called "pyjama paralysis" in which patients remain confined to bed rather than being mobilised. Sometimes healthcare systems fail. In 1998, a UK general practitioner was found guilty of the murder of more than 200 of his patients.[6] A review of perioperative deaths published in 1987 identified organisational shortcomings that adversely affected patient outcomes but also instances of terminally ill patients undergoing surgery that would not have improved their condition.[7]

In considering the role of health outcomes, we need first to understand why it is that we provide health care in the first place. In its most dramatic form we can see how interventions might save lives; beyond that we might expect health care to relieve symptoms, to maintain or improve aspects of function and potentially to extend life through early detection. Generally speaking, we intervene with patients in order to improve the expected trajectory of health that would otherwise occur without it. Sometimes there is a clear association between the intervention and the expected benefits so that we can observe and quantify the extent to which changes occur. Much depends, however, on the nature of the benefits. Relieving the painful effects of arthritis could be easily classified as being a health benefit, but there is less consensus about, say, providing cosmetic surgery for the removal of unwanted tattoos where the benefits might be regarded as being largely non-health in nature. This returns us to the unanswered issue concerning a definition of health. Indeed, the issue is much wider than one might suppose since the boundaries of healthcare are subject to change, most obviously when dealing with older citizens who present with health *and* social care needs. There is increasing interest in broadening the focus from a relatively narrowly defined concern with health to that of quality of life, well-being, life satisfaction or happiness; all of these share the same limitations of being ill-defined and lacking any standard method for their observation.

In the 1900s early proponents such as Ernest Codman proposed what we now call health outcome measurements Donabedian[8] described "end results hospitals" in which patients are followed up "long enough to determine whether the treatment given has permanently relieved the condition or symptoms complained of".[9] Archibald Cochrane in his seminal monograph on efficiency and effectiveness declared that we should always "assume that a treatment is ineffective unless there is evidence to the contrary".[10] For many conditions there exist disease classification systems that are widely used to represent patient health status but which in fact describe disease staging. Systems such as the TNM and Dukes classification in colon cancer are typical and categorise patients solely in terms of their disease. They are silent with respect to all other aspects of the patient experience and although they are readily understood by clinicians such indicators are at best only partial indicators of patient health. The clue here lies in the use of such indicators. Clinicians are by virtue of their training and experience likely to assess a patient's health status in terms of the parameters that they have grown accustomed to handling. The patient for their part may judge their condition or illness from an entirely different perspective. Neither viewpoint is correct; neither dominates the other.

If we understand the rationale for intervening, then we should be able to select a target metric that we expect to influence; if we then track that metric over time we will be able to derive quantifiable evidence of "health" outcomes in terms of its direction and magnitude. For example, in tackling obesity a planned weight loss programme may result in measurable change expressed in terms of standardised units of measure. In such a situation we would need to weigh the patient before and after the intervention using the same weighing machine at both time points. We can then use these observations to compute the *difference* in weight. The sign of that difference indicates the *direction* of change and the arithmetic difference indicates the *magnitude* of that change. These then are the basic attributes



of all measures of health status.

The development of new approaches to the measurement of health status had its origins in the mid-1960s, reflecting growing concern about the superiority of the healthcare professional in deciding such matters. New terms appeared in the clinical and health services research literature, notably quality of life or more accurately health-related quality of life. Today these same measures have been relabelled under the somewhat unfortunate heading of patient reported outcomes (PROs)[11] – unfortunate, as these measure health status at a single point in time *not* outcomes; they can only indirectly assess outcomes since they require repeated (before/after) observations from which we subsequently infer a change in health status.

Defined originally as being "any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else" PROs mirror the growing recognition of the patients' voice in measuring the benefits of treatment. The most important feature of this class of measures is that information should come directly from the patient. This requirement has far-reaching implications – most notably for health economists. The evaluation of treatment in the twenty-first century is not restricted to questions of safety and efficacy but has to be seen in a wider context. There are inevitable limits to all healthcare systems and there is widespread acceptance of the need for evidence of cost-effectiveness to help inform decisions and to set priorities. Measuring health outcomes is fundamental to such cost-effectiveness analysis and health economists have placed their own technical requirements on how health benefits should be described and valued. In particular, they hold to a position that the value of health outcomes should be determined by the society as a whole – *not* by patients or others who might be classed as beneficiaries. What was already a volatile cocktail of ill-defined concepts has now become an ever more complex science with competing views about its own technology.

However, at its core, health outcome measurement, which we can define as being "a quantifiable change in health status resulting from the provision or withholding of healthcare", is a process of observation that is common to all those concerned with the planning, financing, management, and delivery of healthcare. It is an integral part of all clinical studies and helps guide investment decisions made by pharmaceutical companies. It provides information that should be available to patients and consumers of healthcare. Absorbed into routine clinical practice it provides intelligence that can help refine decisions about preferred treatment options; the absence of health outcomes data creates space for the continuation of clinical practice of unproven benefit. In short, the need for health outcome measurement has never been greater and its potential value is limited only by the creativity and imagination of those willing and able to generate it.

Conflicts of interest

The author is a founder-member of the EuroQoL Group.

References

1. Constitution of WHO: principles. https://www.who.int/about/mission/en/.
2. ICD-11: Classifying disease to map the way we live and die. http://www.who.int/health-topics/international-classification-of-diseases.
3. Nightingale F. Notes on hospitals: Being two papers read before the National Association for the Promotion of Social Science, at Liverpool, in October 1858. Cambridge University Press; 2013.
4. Young M. Medical device-related pressure ulcers: a clear case of iatrogenic harm. *Br J Nurs.* 2018;27(15)S6–S13.
5. Surkan MJ, Gibson W. Interventions to mobilize elderly patients and reduce length of hospital stay. *Can J Cardiol.* 2018 Jul;34(7):881–8. doi: 10.1016/j.cjca.2018.04.033. Epub 2018 May 9.
6. The Shipman Inquiry. https://en.wikipedia.org/wiki/The_Shipman_Inquiry.
7. Buck N, Devlin HB, Lunn JN. The report of a confidential enquiry into perioperative death. Nuffield Trust; 1987.
8. Donabedian A. The end results of health care: Ernest Codman's contribution to quality assessment and beyond. Milbank Q. 1989;67(2):233–56; discussion 257–67.
9. Codman EA. A Study in Hospital Efficiency: As Demonstrated by the Case Report of First Five Years of Private Hospital. Boston: Thomas Todd Co.; 1918: 4– 10,108,162 reprinted *Clin Orthop Relat Res* (2013) 471:1778–1783 DOI 10.1007/s11999-012-2751-3.
10. Cochrane AL. Effectiveness and efficiency: Random reflections on health services. London, UK: Nuffield Provincial Hospital Trust; 1972.
11. Patient-reported outcome measures: Use in medical product development to support labeling claims. 2009. US Department of Health and Human Services Food and Drug Administration. http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

Author information

Paul Kind is a founder member and past President of the EuroQoL Group. He has spent the past 40 years on research concerned with measuring the value of health for economic and clinical evaluation. He is the 2017 recipient of the Avedis Donabedian Outcomes Research Lifetime Achievement Award presented by ISPOR.