CHAPTER 1

Introduction

> The ultimate measure by which to judge the quality of a medical effort is whether it helps patients (and their families) as they see it. Anything done in health care that does not help a patient or family is, by definition, waste, whether or not the professions and their associations traditionally hallow it. (Berwick, 1997: Reproduced with permission of BMJ Publishing Group Ltd.)

The goal of most health care is to improve patients' health and there is a strong argument that patients themselves are the people best placed to judge how their state of health affects them. There is a growing recognition throughout the world's health care systems that the patient's perspective on health and health care is highly relevant to – and indeed, needs to be at the heart of – efforts to improve the quality and effectiveness of health care.

Information provided by patients about their health does not replace clinical measures of health and illness. But it can provide valuable, complementary information about how health problems and the effects of health care interventions are experienced by patients. These data, carefully collected and appropriately analysed, can provide crucial insights about the patients view on health, and the quality of health care, that would otherwise be missed.

There has been a considerable investment of resources by academics and clinicians, spanning the last three decades, to develop systematic, robust and valid ways of collecting self-reported health data from patients. These efforts have resulted in the availability of Patient Reported Outcomes questionnaires (PROs).

In broad terms, PROs comprise a series of structured questions that ask patients about their health from their point of view. There are now literally thousands of questionnaires available for measuring patient reported outcomes. Carefully collected PRO data from patients are likely to become a key part of how all health care is funded, provided and managed in the future.

PRO questionnaires are already very widely used in clinical trials and observational studies, alongside clinical end-points, and those data are widely recognised as providing a vital part of the evidence required in decisions to approve and make pricing and reimbursement decisions about new health care technologies. Well-established Health Technology Appraisal (HTA) bodies, charged with a responsibility to judge the effectiveness and value for money of new treatments, such as the UK's National Institute for Health and Care Excellence (NICE), require PRO evidence to be submitted as part of their deliberations (NICE, 2013). In that context, PRO data are often used to estimate the Quality Adjusted Life Years (QALYs)[1] gained by patients receiving new therapies.

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[1] QALYs are a generic measure of length and quality of life – capturing the two main outcomes/goals of health care: to prolong life and improve its quality.

Using Patient Reported Outcomes to Improve Health Care,
First Edition. John Appleby, Nancy Devlin and David Parkin.

PROs have also long been included in population health surveys, as a means of measuring population health and morbidity (see Szende *et al.*, 2014) The population norms provided by such surveys help policy makers understand what 'normal' health means, from the perspective of people of various socio-demographic backgrounds, in local communities. That provides a baseline for understanding the burden of disease from illnesses, and is used to inform priorities for resource allocation decisions.

However, the use of PROs, until very recently, tended to be limited to one-off studies of general or patient populations. The use of PROs in the real world context of health care delivery settings is relatively new.

The possibility of routinely collecting and using these data alongside the delivery of care was first recognised by the private sector in the UK. Bupa, the UK's biggest private health insurer and (at that time) owner of a network of private hospital, asked its patients to complete PRO questionnaires before and after a number of elective surgical procedures. The data were used to monitor and benchmark the quality of care by its surgical teams. The routine use of patient reported outcomes was introduced into the English National Health Service (NHS) in 2009. Known as the PROMs (Patient Reported Outcome Measures) programme, it was a landmark development in the use of PROs across an entire whole health care system. The move has attracted considerable interest elsewhere, and other health care systems are now following suit.

The economic context

Health care accounts for a substantial and growing proportion of both overall economic activity and government spending in developed economies. In 2012, for example, total (public and private) spending on health care accounted for 9.3% of the aggregate GDP for the 34 countries comprising the OECD. In the US, around one dollar in six of the entire economy is now devoted to health care. In the Netherlands, around one Euro in eight and in France and Germany, one Euro in ten. Since the 1960s, most OECD countries have seen the proportion of GDP devoted to health care more or less double. Health care also absorbs a significant proportion of government spending – especially in countries such as the UK that have predominantly tax-funded health care systems and where the NHS accounts for nearly a fifth of all government.

But what is *produced* from health care spending? What *value* does expenditure on health services generate for patients and for economies? While most other sectors of the economy generate outputs that can readily be measured and valued – quantities of goods and services, and the prices at which they are bought and sold – in contrast, health services have traditionally posed considerable challenges for the measurement of output and productivity (Office of Health Economics, 2008). For example, following the historically unprecedented increases in real spending on the NHS in the years following 2000, commentators reasonably asked: where did the money go? What was achieved by the massive increase in spending?

In stark contrast, the current economic environment in which the English NHS and other health care systems operate has changed dramatically as a result of the financial crisis and recession of 2008–2009 (Appleby *et al.,* 2014). Since that time, the NHS has had to adjust to zero or small real increases in spending (Appleby *et al.,* 2009a), against a backdrop of constantly rising demand. Notwithstanding the changed economic context, the questions remain essentially the same:

- Can we be sure that public spending on health care is justified by the outputs that it produces?
- Are scarce public sector resources being used in a way that maximises their value to patients and society?

- How do different sorts of health care services, that we could spend our money on, compare in terms of their effectiveness and value for money in improving patient health?
- How do different providers of health care compare in terms of their performance in improving patient health?

Special issues with measuring and valuing health

Assessing the output and productivity of health care poses special problems. Health care services or products themselves are easy to record and count: the number of hospital admissions, doctors' visits, surgical procedures undertaken, tooth cavities filled, prescriptions issued, and so on. But these cannot simply be added up to give an indication of what is produced overall. More importantly, they are *intermediate* outputs. Most health services are not valued in their own right, but rather because of the effects they have on something much more fundamental: health. Health is the true final output of health care.

Yet efforts to measure the health produced by health care systems such as the English NHS have been fairly rudimentary. Traditional measures have tended to focus on the prevalence of adverse outcomes, such as post-surgical mortality, hospital-acquired infections and readmission rates. It is, of course, important to know about these bad things, and they do need to be minimised. But such incidents are also relatively rare and shed little light on the great majority of health service interventions for most patients.

As a basis for assessing the value of the vast resources devoted to health care in the world's health care systems, however, these measures are hopelessly inadequate.

The purpose of a health care system is not just to minimise the harm caused by its activity, but also (and arguably, principally) to produce health and social benefits for patients and society. Despite a century of developments in medical technology, and vast improvements in the ability of medical science to prevent, diagnose and treat disease and ill health, attempts to measure the outputs of health care in terms of their impact on patients' health have barely progressed beyond Florence Nightingale's time. More than 100 years ago, she suggested a simple three-point health-related outcome measure for her patients: relieved; unrelieved; and dead (Appleby and Devlin, 2004).

Clinicians have, of course developed measures to guide and inform their clinical practice. These provide important and relevant information about the impact of health care interventions on clinically defined variables, but, while useful, they typically fail to inform wider questions crucial to measuring the *overall* output and quality of health care services.

Moreover, the many different clinical indicators used in medical practice do not always distinguish the aspects of health that patients consider important, or their relative value to patients. The observation that 'the operation was a success, but the patient died' might be an example of the dark humour of the medical profession, but it is nonetheless indicative of the gap that can exist between the views of clinicians and patients on what matters in health care.

Furthermore, the many different clinical measures used make it hard to compare health impacts across specialties. It is therefore difficult to draw any conclusions about the overall effects of spending and service delivery across different disease areas, or their ultimate effects on health outcomes. Nor is it possible to identify how those outcomes could be improved by different allocations of resources between services and patients.

In addition, although patient-reported experience measures (sometimes referred to as PREMs) can provide useful indications of patients' perspectives and views about the care they have received, by their nature these reflect experience of the *process* rather than the *outcome* of care. As the final report of the NHS Next Stage Review observes, '…just as important is the effectiveness of care from the patient's own perspective, which will be measured through patient reported outcomes measures…' (Department of Health, 2008).

It is clear that a fundamental rethink about what 'outputs' and 'outcomes' mean in health care is long overdue.

A fundamental shift in focus

Against this backdrop, there has been a marked shift internationally in thinking about what health is and how it is measured. Traditional clinical ways of measuring health and the effects of treatment are increasingly accompanied by, or indeed replaced by, PROs.

This shift in focus is most evident in the appraisal of new health care technologies, where products and practices are subject to rigorous evaluation. The United States' Food and Drug Administration (FDA), which has recently recommended the inclusion of PROs in US clinical trials (Food and Drug Administration, 2006), notes: 'The use of PRO instruments is part of a general movement toward the idea that the patient, properly queried, is the best source of information about how he or she feels' (Bren, 2006).

In parts of the English NHS, most notably in the work done by the NICE in appraising the effectiveness and cost effectiveness of new health care technologies, the use of PRO data is already commonplace. Indeed, pharmaceutical companies are required to submit evidence on PROs to support NICE's Health Technology Appraisal (HTA) process (NICE, 2013). Similar HTA processes, utilising PRO data, are also in place in a range of other countries including Canada, Sweden, Australia and New Zealand, and with interest in the development of HTA in many of the large, emerging economies shifting toward collectively funded health care systems, such as China and Brazil.

Over the course of several decades, clinical, health services and social sciences researchers have produced literally thousands of validated instruments that facilitate the consistent, reliable measurement of patient-reported health. Patients' perspectives on their health outcomes can now be measured in most clinical areas.

Routine measurement of PROs: a step forward in the NHS

An important development in this area took place in the English NHS in England in April 2009. The Department of Health introduced a requirement for the routine measurement of patient-reported health outcomes for all NHS patients in England before and after receiving surgery, via its Patient Reported Outcome Measures (PROMs) programme (Department of Health, 2007, 2008a). Box 1.2 provides some key facts about the NHS PROMs programme, and activities underway for its extension. Appendix 1 shows the PROM questionnaire that is currently completed by patients after undergoing varicose vein surgery.

Box 1.2 Key facts about the implementation of the PROMs programme in the NHS in England

Jo Partington[2]

In 2009 the routine collection of PROs from patients, both before and after NHS-funded surgery, was introduced by the English Department of Health for four elective procedures:

- hip replacement
- knee replacement

- varicose veins
- hernia

Those data are now being used in a wide range of ways including:

- To measure the outcomes of the health care system under the Government's 'Outcomes Framework'
- To performance-manage organisations providing NHS treatment, as well as incentivising good outcomes by including patient outcomes in payment mechanisms (e.g. the Hip/Knee Best Practice Tariff from April 2014).
- Regulatory bodies, such as Care Quality Commission, use PROMs programme data in their intelligence monitoring.
- Patients and their GPs can use PROMs data, published on the health and Social Care Information Centre website, to inform their choice of providers at the point of referral.

Following restructuring of the health care system, responsibility for the PROMs programme passed from the Department of Health to NHS England.

An important development has been the collection of PRO data in the GP patient survey (GPPS). Since 2011–2012, the generic PRO used in the PROMs programme, the EQ-5D, has also been included in the GPPS. Data are collected from around 900 000 patients each year, half of whom have long term conditions. The data are being used to produce new insights into questions about primary care, and the effects of multimorbidities on patient health.

Pilot studies have been undertaken to explore the possibility of extending PROMs over a wider range of conditions and treatments in the NHS, including:

- mental health, for example anxiety and depression
- cancer care
- six long-term conditions: asthma, COPD, diabetes, epilepsy, heart failure, stroke
- cancers of the breast, prostate, bowel, Non-Hodgkin's Lymphoma.

NHS England NHS England is involved in a number of pilots being analysed/evaluated in the following areas:

- revascularisation;
- cancers of the bladder, womb, cervix or ovary.

In addition, pilots are currently being developed for PROMs in

- Musculoskeletal,
- Renal replacement,
- Major trauma,
- Dementia.

In addition, work is underway for the inclusion of PROMs data collection in National Clinical Audits. In each case, the approach to potentially the extending the PROMs programme comprises the following careful process:

- identifying the appropriate PROM instruments
- piloting their use and reviewing their potential to be rolled out across the NHS
- implementing data collection and related procedures
- evaluating the programme.

Progression depends on there being sufficient evidence at each stage to support the use of PROMs. To date mandated PROMs are limited to the initial four elective procedures.

[2] Patient Reported Outcome Measures Insight Account Manager, NHS England.

The requirement to collect PRO data introduced applied to just four surgical procedures – hernia repair, hip and knee replacement and varicose veins. Those four procedures cost the NHS in England around £800 million per year. Since its introduction, around quarter of a million patients have been invited each year be to complete questionnaires both before and after surgery. All NHS providers are currently collecting these data. A very good response rate has been achieved, for example 80% in hip replacement patients. The annual cost of the current PROMs programme is estimated to represent less than 0.5% of expenditure on the relevant interventions.

The NHS PROMs programme is an extraordinary achievement, both in terms of the proven logistics of large scale data collection, and in terms of its ambition in using routinely collected health outcomes data to drive health care decision making.

However, progress in further developing the NHS PROMs programme since that date has been slow. Pilot work is under way to explore the feasibility of and case for extending routine measurement to a range of chronic conditions, including diabetes, asthma, stroke, chronic obstructive pulmonary disease (COPD) and others (see Box 1.2). Contingent on there being positive evidence to support their use, the routine collection of PRO data could be introduced across a wide range of NHS services.

PRO data are used across a range of applications, including measuring and managing hospitals in their efforts to improve patient health. Indicators of hospital performance, based on PROs, are to be included in the information provided to patients being referred for elective surgery, to assist them in choosing the hospital at which they will receive treatment.

This reflects a key theme of various changes in the NHS since the turn of the century, namely to improve the responsiveness of the NHS to patients' views, preferences and choices. Research has indicated that patients regard the relative performance of providers in improving their health as highly important in choosing where to receive surgery (Burge *et al.,* 2006), yet to date it has been the aspect of performance about which least information existed.

The PROMs initiative is a truly remarkable development for the NHS – and a first internationally: the NHS will be the first health care system in the world to measure what it produces in terms of *health*, rather than in terms of the production of *health care*. The intention is that, in addition to clinical measures of outcome, PROs will enable patient perspectives to be taken into account in key aspects of the NHS, including:

- informing the choices patients make with regard to their treatment and its providers
- measuring and benchmarking the performance of health care providers
- linking the payment received by providers to their performance in improving patient health
- understanding and managing referral from primary to secondary care
- facilitating cooperation between clinicians and managers in the delivery of care
- enabling health care professionals to monitor and improve health care practices
- regulating for safety and quality in health care services.

As the potential scope of the PROMs programme in the NHS could extend beyond elective surgery, these data will offer a powerful new means of managing the performance of the NHS.

Getting the most out of patient reported outcomes

The aim of this book is to provoke and encourage thinking about the wide range of ways in which PRO data, routinely collected in the context of health service delivery, can be used to inform decisions.

- What opportunities do these data present?
- What are the limitations of PROs and what are the possible pitfalls in the use and over-interpretation of data produced from them?
- What work needs to be done in order to get the most out of PRO data?
- What have been the experiences of the English NHS with its PROs programme and what can be learned from that by other health care systems?

In the next chapter, we provide an overview and explanation of PRO instruments. Then in Chapter 3 we look first at how PRO data might be used by patients in choosing both *where* to receive treatment, and also *what* treatment is best for them; and then we consider other ways in which the data now being collected can be used to transform decision making in the NHS (and, by extension, in any health care system anywhere in the world).

We then consider, in Chapter 4, how clinicians might use these data. Drawing on the experience of the Canadian and New Zealand health care systems, we consider whether there is scope for using PRO data to guide referral practices, to ensure that the people who receive health care are those that will benefit from it the most.

Following on from this, Chapter 5 discusses how providers can use the data to benchmark and improve clinical performance within their own organisations, drawing on the example of Bupa.

In Chapter 6, we look at how PROs might be used by those who commission health care on behalf of patients to assess value for money and purchase health care services that maximise improvement in the health of the communities they serve. We also consider the possibility of commissioners directly linking provider reimbursement to PROs performance.

Chapter 7 shows how measuring improvements in patient health can address high-level questions about productivity and performance in the NHS.

We conclude by asking the question ‘Where next for PROs?’ Routine use of PROs has the potential to put the views and values of patients squarely at the heart of health care systems management and clinical thinking about the provision of health care services. Our aim is to help ensure that these benefits are realised and that the NHS and other health care systems maximise the benefit to patients that collecting these data makes possible.

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