New outcome measures in perioperative care

ABSTRACT

Improvements in outcome measurement are needed to produce quality improvement in perioperative care. However, problems with the collection and use of outcome data persist in research and clinical practice. This is being addressed by several national programmes and initiatives to standardize and integrate outcome measurement.

The use of different outcome measures is changing and there has been a transition towards patient-focused measures. Traditional measures of quality in perioperative care include mortality, morbidity and resource utilization measures. Patient-focused measures include patient-reported outcome measures and measures of patient experience. Each of these has advantages and disadvantages in different situations.

The routine collection, analysis and dissemination of data relating to perioperative outcome is beneficial to patients, clinicians, hospitals, commissioners, regulators and researchers.

The global surgical epidemic is described in the first article of this symposium (https://doi.org/10.12968/hmed.2017.78.11.612), with mortality estimated at up to 1 million patients per year (Weiser et al, 2008). The death and complication rates of major surgical procedures are a substantial global public health concern, but the available data give a very limited picture of the scale of the problem. The majority of patients do not die during the immediate perioperative period and changes in health following surgery are frequently missed by commonly collected outcome data.

In the context of the global surgery epidemic there is an established need to demonstrate quality improvement in perioperative care. The increasing health-care demand coincides with resource limitation and expenditure must be justified by objective measures. Simultaneously, there has been a shift in how quality is defined and measured. Increasingly, traditional measures with outcomes of interest to clinicians are being accompanied or replaced by patient-focused measures.

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Measuring outcomes

To improve perioperative care, a robust and standardized system is needed to measure surgical outcomes which are important to patients as well as health-care providers, researchers and policy makers. The benefits of this include greater transparency and accountability, enabling clinicians to improve their practice and empowering patients to make informed choices about their care. In addition, it provides information for service improvement and quality assurance of operations and facilitates rational decisions about resource distribution within a health-care system.

Traditional perioperative outcome measures that are used to determine quality of perioperative care are defined by the interests of clinicians. Outcomes such as short-term mortality, length of hospital stay and unplanned hospital re-admission rates, while undeniably important, pay little attention to a patient's perspective on the effect that surgery has on his/her quality of life. Furthermore, problems with the collection and reporting of outcome measures limit their usefulness in clinical practice.

Improving outcome reporting

The need for national reporting of perioperative outcomes is recognized. Many major surgical procedures are included within a programme of national clinical audits which are used to quality assure care through the measurement and public reporting of compliance with recommendations for good practice in care delivery, and risk-adjusted surgical outcome. Examples include the national bowel cancer and emergency laparotomy audits and the National Joint Registry. The purpose of the measurement programme requires careful consideration: initiatives whose principal purpose is research, quality improvement or quality assurance may require different measures and reporting structures, although there is potential benefit to using data originally collected for one purpose to support another (Allwood, 2014).

Heterogeneity of outcome measures used in clinical trials is a significant problem that limits the conclusions that can be made. For a finding to influence practice it must have outcomes that are relevant and important to the many stakeholders involved in health care, including patients. Incomplete or selective reporting of outcomes leads to outcome reporting bias that affects the conclusion in a substantial proportion of Cochrane reviews (Kirkham et al, 2010). There have been several attempts to develop and use an agreed standardized collection of outcomes, described as

a core outcome set, in several specialties. The Core Outcome Measures in Effectiveness Trials Initiative (COMET; www.comet-initiative.org) works towards developing consensus in this area. The proposed benefit of this work is that outcome measures will be standardized between trials and reflect endpoints that are useful for service users.

The COMPAC initiative (Core Outcome Measures for Perioperative and Anaesthesia Care) is in its advanced stages, having completed a comprehensive systematic review of the literature, and now undertaking survey and interview work with patients to develop a core set of outcomes appropriate for use in perioperative trials, which are important to both clinicians and patients. A parallel initiative, the Standardised Endpoints in Perioperative Care (StEP) collaborative, is working towards achieving consensus over how a particular outcome should be measures in clinical trials (e.g. how do we define postoperative pulmonary complications?). Both of these initiatives should lead to clarity in measurement which will benefit the conduct of clinical research, and ultimately therefore benefit patients (Boney et al, 2016; Myles et al, 2016).

Mortality

Surgical mortality is an important outcome measure used by patients and health-care providers in assessing the quality of perioperative care. Mortality rates frequently appear as the main outcome measure in the scientific literature. The use of mortality as a sole outcome measure has limitations, however, as advances in surgical and anaesthetic techniques over time have led to significant reductions in short-term mortality and therefore this measure is increasingly viewed as an inadequate measure of quality in perioperative practice (Ho et al, 2006).

Nevertheless, mortality has several advantages as a quality metric because it is a dichotomous variable and clinically important. Mortality data can be easily collated and compared across specialties. In England and Wales inpatient mortality is recorded in the Hospital Episode Statistics database and all mortality data are collected by the Office for National Statistics.

The interpretation of mortality as an outcome is highly dependent on the timeframe of measurement. The inpatient, 28- or 30-day and 1-year mortality are commonly reported definitions but are not reliably related to each other. It is unreliable to compare the results of studies or audits in which different mortality definitions are used.

In studies which use longer term mortality as their outcome measure, loss to follow up after discharge from hospital is a problem. In addition, mortality may be attributable to the effect of pre-existing comorbidities rather than the surgical episode itself.

Morbidity

While many trials of perioperative interventions have failed to demonstrate an improvement in short-term perioperative mortality, there are many that show an improvement in postoperative morbidity and resource utilization measures (Hamilton et al, 2011).

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Perioperative morbidity is independently associated with poor long-term outcomes. The occurrence of a 30-day postoperative complication is a better predictor of survival after major surgery than preoperative patient risk and intraoperative factors. For this reason, it is likely that short-term mortality data may not fully reflect the health-care impact of the surgical episode (Khuri et al, 2005). A 2014 cohort study (Moonesinghe et al, 2014) demonstrated that patients with prolonged postoperative morbidity are at an increased risk of death for up to 3 years after surgery. This signal has been repeatedly demonstrated across surgical specialties and international boundaries (Toner and Hamilton, 2013).

Morbidity is frequently described in the surgical literature, although the quality of reporting is poor. The inconsistency of reporting and the lack of accepted principles of accrual, display, and analysis of complication data argue strongly for the creation and generalized use of standards for reporting this information (Martin et al, 2002). There are currently several alternative systems of morbidity classification in use.

The Clavien–Dindo classification for surgical complications was published in 2004 (Dindo et al, 2004). It consists of seven grades, and the therapy used to correct a specific complication is the basis of this classification in order to rank a complication in an objective and reproducible manner.

The National Surgical Quality Improvement Program is a surgical outcome database of the American College of Surgeons designed to measure risk-adjusted outcomes of surgical interventions to compare results between hospitals. This is achieved with a validated risk adjustment using a logistic regression model. This risk adjustment allows unbiased comparison of results between hospitals of different sizes serving different patient populations (Fuchshuber et al, 2012).

The Postoperative Morbidity Survey (Grocott et al, 2007) has nine domains which were derived based on being complications of a type and severity that would delay hospital discharge. The complications are defined by data that would be easy to collect and subject to minimal inter-observer variability. Currently, the Postoperative Morbidity Survey is used widely in clinical studies in adult patients, and along with the Clavien–Dindo classification has been incorporated into the national Perioperative Quality Improvement Programme (see later).

Table 1. Range of dimensions assessed by patient-based outcome measures	
Physical function	Mobility, dexterity, range of movement, physical activity
	Activities of daily living: ability to eat, wash dress
Symptoms	Pain
	Energy, vitality, fatigue
	Nausea
	Sleep and rest
	Appetite
Global judgements of health	
Psychological wellbeing	Psychological illness: anxiety, depression
	Coping, positive wellbeing and adjustment, sense of control, self-esteem
Social wellbeing	Family and intimate relations
	Social contact, integration and social opportunities
	Leisure activities
	Sexual activity and satisfaction
Cognitive functioning	Cognition
	Memory
	Alertness
	Confusion
	Concentration
	Ability to communicate
Role activities	Employment
	Financial concerns
	Household management
Personal constructs	Satisfaction with bodily appearance
	Stigma and stigmatizing conditions
	Life satisfaction
	Spirituality
Satisfaction with care	
From Fitzpatrick et al (1998)	

Failure to rescue

The relationship between postoperative complications and mortality is complex and associated with both patient and hospital factors. Failure to rescue refers to the proportion of deaths in patients who have suffered postoperative complications. The relevance of this outcome measure is based on the observation that the factors affecting overall mortality and complication rate are different to those affecting likelihood of death following a complication (Silber et al, 1992). For example, a hospital with the highest complication rate (as a result of having a high-risk patient population) may not have the highest death rate. This reflects the importance of high quality care following the occurrence of a complication and failure to rescue may be used to indicate the quality of perioperative care.

Resource utilization measures

Other commonly used outcome metrics in perioperative care are length of inpatient hospital stay and readmission rates. Resource utilization measures can be misleading as different hospitals use different systems of care for the same procedure and delayed discharge can reflect unmet social care requirements.

Readmission rates within 30 days of discharge are often used as a measure for quality of hospital care. Reducing hospital readmission rates is a clinical and policy priority, but little is known about variation in rates of readmission after major surgery and whether these rates at a given hospital are related to other markers of the quality of surgical care. Nearly one in seven patients hospitalized for a major surgical procedure is readmitted to the hospital within 30 days after discharge. Hospitals with high surgical volume and low surgical mortality have lower rates of surgical readmission than other hospitals (Tsai et al, 2013). Recovery from surgery is not limited to the inpatient episode, and the concept of 'post-hospital syndrome' has been used to describes the critical period of impaired health following discharge (Krumholz, 2013). The post-hospital syndrome can lead to readmission, and although this outcome can be collected, it only includes a small proportion of patients affected.

Patient-reported outcome measures

There are many ways to measure success in health care and although technical measures of health-care output and outcome are important they do not address the patient perspective. There are several factors contributing to a move towards patient-reported outcomes in the UK. There is an ongoing political commitment towards patient-centred care and the NHS is required to justify its spending and demonstrate value for patients and society. Within this context, information obtained directly from patients is increasingly used by patients, clinicians, researchers and commissioners.

Patient-reported outcome measures are obtained directly from patients in response to how they feel about their health and health-related quality of life (*Table 1*). They do not generally address patient experience or satisfaction with health-care services and they do not include clinician impression of patient outcome. Most patient-reported outcome measures are short questionnaires which are measured before and at some point (often 6 months) after a procedure to assess its impact. Patient-reported outcome measures can include aspects of generic health status, preference-based and condition-specific measures.

The Department of Health patient-reported outcome measures programme was launched in England in April 2009 and incorporates patient-reported outcome measures into routine care. This has initially been applied to four surgical procedures: hip and knee replacement, hernia repair and varicose vein surgery. A pilot study has been completed looking at the feasibility of using patient-reported outcome measures in long-term conditions including asthma, chronic obstructive pulmonary disease, diabetes, epilepsy, heart failure and cerebrovascular disease (Peters et al, 2013).

Patient-reported outcome measures may be condition-specific or generic and incorporate score-based and value-based questionnaires. There are thousands of such tools available and choice depends on quality in terms of reliability and validity but also practical aspects of use. Patient-reported outcome measures can be administered by interview or distantly, including online (Wilson et al, 2014).

The 36-Item Short Form Health Survey (SF-36) (Ware and Sherbourne, 1992) is a 36-item questionnaire of generic quality of life measures. The SF-36 is widely used worldwide and results in a summary score for physical and mental health components.

The European Quality of Life instrument (EQ-5D) (EuroQol Group, 1990) is a generic tool that is currently used in the UK patient-reported outcome measures programme. It contains assessment of health across five domains:

1. Anxiety or depression
2. Mobility
3. Pain or discomfort
4. Self-care
5. Usual activities.

Each domain is assessed with a single question on a three-point scale. The tool also includes the EQ thermometer, which is a visual analogue scale asking the patient to describe his/her current health on a scale of 100 (best health imaginable) to 0 (worst). The scale has been subsequently modified (EQ-5D-5L) (Herdman et al, 2011) to include a five-point scale in each domain, with more sensitivity to detect change in health over time.

Both the EQ-5D and SF-36 have a considerable literature demonstrating their validity, reliability and sensitivity for a range of health conditions. They also have the advantage of being able to compare patient-reported outcomes between different conditions. For specific patient groups and conditions these tools may miss important aspects of health status; in these cases, condition-specific patient-reported outcome measures may have improved characteristics. There are eight criteria that should apply to the use of a candidate patient-reported outcome measure in a clinical trial: appropriateness, reliability, validity, responsiveness, precision, interpretability, acceptability and feasibility (Fitzpatrick et al, 1998).

The QoR-40 (Myles et al, 2000) is a 40-item questionnaire that measures quality of recovery after surgery and anaesthesia. It includes five dimensions: patient support, comfort, emotions, physical independence and pain. The QoR-40 has been extensively validated in a variety of clinical and research settings. This tool has subsequently been modified to a shorter version, the QoR-15, that can be administered in a mean ± standard deviation time of 2.4±0.8 minutes (Stark et al, 2013).

> “To balance the competing needs for generalizability and precision the use of a combination of generic and condition-specific tools is recommended.”

To balance the competing needs for generalizability and precision the use of a combination of generic and condition-specific tools is recommended. The tools used by the NHS patient-reported outcome measures programme were chosen after consultation and pilot testing (Browne et al, 2007) and include a generic tool in all cases and a condition-specific tool where one of sufficient quality was available. For example, the hip replacement patient-reported outcome measure uses the EQ-5D and Oxford Hip Score.

In the 2010 King's Fund report *Getting the most out of PROMs* (Devlin and Appleby, 2010), the benefits and potentials of more widespread use of patient-reported outcome measures are described. Currently, national patient-reported outcome measure data are presented at hospital level and are used by patients to guide their choice of hospital and treatment. The information is used by hospitals to manage clinical quality and by clinicians to guide decision making. Other stakeholders include commissioners, who use patient-reported outcome measures for econometric evaluation (such as the calculation of quality-adjusted life years), and national regulators who use them to measure output and productivity. Patient-reported outcome measures have been used in the independent health-care sector since 1998, initially to identify poorly performing clinicians and subsequently to identify and share best practice (Vallance-Owen et al, 2004).

Although the use of patient-reported outcome measures has increased the national patient-reported outcome measures programme covers just 3.3% of elective care in the NHS (Devlin and Appleby, 2010). There are challenges extending this to other populations, such as emergency care. This may reflect difficulties collecting data when clinical care is urgent, patients have difficulty answering questions as a result of pain or illness, or baseline data not being available (Mason et al, 2015). In a systematic review of patient-reported outcome measures in trials of unplanned general surgery (Stevens et al, 2015) the authors identified a lack of high quality data and a high incidence of methodological concerns. There is evidence that patients who are more unwell are less likely to participate in patient-reported outcome measures and their exclusion is likely to result in bias. In populations

KEY POINTS

- The use of outcome measures in perioperative care is changing and new measures are being used alongside or instead of traditional measures.
- There is a strong signal that short-term postoperative morbidity is associated with long-term outcome.
- Patient-reported outcome measures are being used in research and routine care.
- Efforts to standardize outcome measurement in perioperative care are ongoing.

that cannot self-report the use of proxy reporters (such as family members or carers) may be considered. The reliability of proxy reporting has been investigated in several studies with mixed results (Fitzpatrick et al, 1998). Patient-reported outcome measures can be used in other populations that may have difficulty answering generic questions, e.g. paediatrics (Gibbons et al, 2009), with appropriately validated tools.

Disability refers to the impact of a health impairment on a person's ability to work, care for him-/herself, and interact with society. Disability-free survival is a key aim of surgery and although this measure is important to patients and clinicians it may not be captured with other quality of life or quality of recovery measures. The World Health Organization Disability Assessment Schedule has been validated for use with postoperative patients in several specialties (Shulman et al, 2015).

Patient experience

There is increasing interest in including patient experience of care as well as of outcomes. Tools that collect this information are described as patient-reported experience measures and it is recognized that this information is integral to patient-centred care.

The NHS patient survey programme was established in 2001 and systematically gathers the views of patients about their care. This has included the national inpatient survey since 2002 which includes a few measures of experience related to perioperative care (DeCourcy et al, 2012). The first Sprint National Anaesthesia Project (SNAP-1) was a nationwide observational study that obtained patient-reported outcome and experience measures for adult patients undergoing anaesthesia over a 48-hour period in 2014 (Walker et al, 2016). This found a disconnect between short-term patient reported outcome (discomfort) after surgery (which was high) and patient satisfaction (which was also high). This observation strengthens the case for using combinations of measures reporting experience, satisfaction and outcome, to provide a comprehensive quality assessment of care from the patient perspective. To that end, there are ongoing attempts to integrate assessment of outcome and experience into a single tool. The Outcomes and Experience Questionnaire (Gibbons et al, 2015) is one attempt to address this and combines short instrument questions from each of these domains.

The Perioperative Quality Improvement Programme

The Perioperative Quality Improvement Programme (www.pqip.org.uk) is an initiative launched in 2016 by the Health Services Research Centre based at the Royal College of Anaesthetists. This multidisciplinary programme aims to eventually involve all hospitals undertaking major inpatient surgery throughout the NHS. Outcome measurement includes complications, patient-reported outcomes and failure to rescue and includes follow up using patient-centred outcome measures to 1 year postoperatively, as well as longer term survival. The aim of this programme is to support clinical care by incorporating ongoing reporting of these outcomes, as well as key clinical processes, back to local teams to facilitate quality improvement.

Conclusions

The limitations of traditional outcome measures and non-standardized outcome reporting are increasingly recognized and there are ongoing effort to improve this.

There is an ongoing fundamental shift in how quality in health care is defined and this is reflected by a change in how outcome measures are used and reported. Increasingly, traditional measures of the effect of treatment are being accompanied or replaced by patient-reported outcomes. Outcome measures in perioperative care are changing as part of a transition towards patient-centred care.

The routine collection, analysis and dissemination of data relating to outcome measures is beneficial to patients, clinicians, hospitals, commissioners, regulators and researchers. BJHM

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