

OUTCOMES IN SURGERY

Evolution of Outcomes in Cardiothoracic Surgery

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ABBREVIATIONS

HADS = hospital anxiety and depression score

HRQL = health related quality of life

OAR = open aortic repair

PROs = patient reported outcomes

QoL = quality of life

TEVAR = thoracic endovascular aortic repair

VATS = video assisted thoracic surgery

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ABSTRACT

The measurement of outcomes is a fundamental component of modern surgery to provide the foundations of surgical improvement. The conventional emphasis of clinical outcomes such as morbidity and mortality has been augmented with a growing focus on quality of life, quality of care and patient satisfaction. Outcome measures can provide cardiothoracic surgeons the opportunity to assess their results in increased precision and transparency. An initiative to increase patient awareness and education regarding their hospitals and their surgeons has meant a necessary move towards greater clarity and accountability of all surgical centres. This has seen an adaptation towards a more patient-centered approach.

Comprehensive quality measures and a framework for analyzing and interpreting these results is pivotal as is knowing *what* to measure and *how* to measure it. Innovative approaches whereby the patient measures and reports their own 'outcome' and experience are being piloted in all surgical specialties, including cardiothoracic surgery. Adopting the Donabedian model for quality measurement in three domains structure, process, and outcomes is a valid and reliable instrument for assessing patient's satisfaction and quality of care as are the wide range of validated surveys of health related quality of life, which should be routinely implemented.

BACKGROUND

The measurement of outcomes is a fundamental component of modern surgery to provide the foundations of surgical improvement. Whilst the emphasis and importance on these measurements has not changed, both the nature of the outcomes measured and the methods for doing so have evolved. The conventional emphasis of clinical outcomes such as morbidity and mortality has been augmented with a growing focus on quality of life, quality of care and patient satisfaction. These empower patients to report their own outcomes subjectively. We examine a number of these outcome measures and their importance for increasing patient centeredness, and an inclusive approach to cardiothoracic surgery.

HEALTH RELATED QUALITY OF LIFE (HRQL)

Health Related Quality of Life (HRQL) has become an increasingly recognized

end-point for assessing outcomes in cardiothoracic surgery. It provides a quantifiable score of a patient's perspective which can compliment more traditional outcome measures. The definition of 'health' is now viewed as a multidimensional construct made up of *physical, social* and *emotional* components. Taking this into account, the phrase HRQL has been used to describe an individual's perception of how the illness or treatment impacts on more than one of these key components.

The most common means of measuring HRQL is via a paper based system i.e. Questionnaires and Surveys, since interviewing patients individually is often not economically viable. These questionnaires require careful development with full clinical and psychometric validation so as to be certain that they are fit for purpose. The following steps are recommended to effectively measure HRQL as an outcome in cardiothoracic surgery:

- Literature search: identify existing scales or instruments that measure HRQL issues in this area.
- Determine the most pertinent HRQL issues that will be selected for measurement and have these reviewed by other surgeons, the multidisciplinary team and patients at this stage.
- Formulate the questions ensuring each one only addresses one single HRQL and the wording, formatting and layout all provide maximum ease for the patient to respond.
- Clinical and psychometric validation. Whilst there are no international set tests for proving validity, efforts should be made to ensure that the measurement tools are reliable, there is internal consistency and that results are reproducible.
- For research purposes, sample size and timing of the study of HRQLs are also important, as is having strategies to deal with missing data and poor compliance which can significantly affect the power of the study and introduce selection bias, compromising validity of results.

Once such study by Dick et al (2008)¹ assessed outcome and quality of life in patients treated either by thoracic endovascular aortic repair (TEVAR) or open aortic repair (OAR) for diseased descending thoracic aorta. They analysed a prospectively collected consecutive series of 136 patients presenting with surgical diseases of the descending aorta over 4 years and all patients were followed up systematically after intervention in annual intervals. Cross-sectional assessment of present-day quality of life (QoL) was performed using the validated German versions of both the Short- Form Health Survey (SF-36) and the Hospital Anxiety and Depression Score (HADS) questionnaires and Long-term QoL re-assessed using the SF-36 almost 3 years after treatment. Long-term quality of life showed no significant differences, despite all advantages of the minimally invasive approach. Similarly, anxiety and depression scores were not reduced by TEVAR, possibly reflecting a certain caution against the new technology.

A systematic review of Quality of Life (QoL) in Video assisted Thoracic Surgery (VATS) Lobectomy (2008)² divided quality of life measures into those which were subjective and objective. Subjective QoL was measured using a wide range of survey tools with the commonest being The Medical Outcomes Study Short Form 36 (SF36)³ and the European Organization for Research and Treatment of Cancer (EORTC)⁴. These subjective QoL scores were found to be lowered by pre-operative factors such as existing clinical depression, advanced age or comorbid diseases. The most significant postoperative predictor of low scores was suffering dyspnoea and those with larger resections such as pneumonectomies showed worse long term QoL. Objective criteria for measuring QoL was preferred by a number of studies and validated objective values such as reduced pulmonary function tests, return to work time, analgesia use and exercise testing were commonly used. Infections were also measured and found to be lower in those undergoing VATS procedures but large cohorts were required to detect differences.⁵ Objective measures of QoL are often preferred due to easier data collection however with more recent emphasis on the patient journey and patient experience, subjective measures are increasingly being implemented. A study by Lundberg et al.⁶ Looking at long term Health Related Quality of life after Maze Surgery in 34 patients with Atrial Fibrillation (2009) again used the Swedish Short Form-36 survey. This is internationally validated generic health scale is commonly used in arrhythmia studies. It evaluates eight health domains: physical, functioning, role-physical bodily pain, general health, vitality, social function, role-emotional and mental health scoring patients from 1-100, with higher scores representing better functional status and well-being. In this study, pre-operative patients were found to have scores much lower than those of healthy controls in all domains except the bodily pain domain. Post operatively, within 12 months for most domains QoL had returned to the equivalent of a healthy control with 'general health' improving much earlier. From this it was concluded that the maze III procedure significantly improves QoL for pts with AF during the 35 month observation time studied.

QoL is a particularly essential outcome measure in cardiothoracic surgery since it has an immediate and irreversible effect on HRQL. Having accurate measurements of HRQL domains not only aids healthcare providers to improve cost effectiveness, but influences the distribution of resources appropriately. It also arms the patient with crucial information in the decision making process, improving informed consent prior to cardiothoracic surgery. The importance of identifying factors in pre-operative period that may predispose patient to lower QoL post-operatively will help predict and prevent such outcomes. However this should be done with awareness of limitations including bias resulting from timing of testing, variability in measurement instrument used, language as well as language and cultural barriers. With careful use

however, measuring HRQL as an outcome in addition to traditional outcomes such as mortality and morbidity ensures that patients' views are taken into consideration when making decisions about their care, particularly with regard to psychosocial health as well as physical wellbeing which may have previously been overlooked, promoting a holistic approach to cardiothoracic surgery.

QUALITY OF CARE

The provision of high quality of care is not only the aim of all cardiothoracic centres and surgeons but is the universal goal for any healthcare system. High quality of care begets high quality results, and involves a delicate interaction of multiple factors at various stage of a patient's care pathway. Any single suboptimal episode can have a cascade effect on the overall quality of care, to the detriment of the patient.

Definitions of quality of care are generally quite non-specific and whilst it is usually apparent when high quality of care is being delivered, providing objective proof of high quality of care is often more difficult. The American Medical Association defines it as "[that] which consistently contributes to the improvement or maintenance of quality and/or duration of life"⁷ Alternatively there are more patient-orientated definitions such as that of BUPA hospitals United Kingdom (U.K)⁸:

"...ability to provide the service you want and need-resulting in medical treatment you can rely on and personal care you'll appreciate"

Quality of Care therefore represents an overall broad impression of healthcare delivery, but also requires some very specific and agreed measures of the treatment process or outcomes, making it a complex entity to encompass and necessitating an ordered approach.

Assessment of quality of care should include every aspect of a patient's journey through the healthcare system. In cardiothoracic surgery this would encompass community care, referral to cardiology, investigations then referral for cardiothoracic surgery with the details of pre- and post operative period. It is clear therefore that there are countless variable which could be measured.

A widely applied model of Quality of Care is that of Donabedian who describes three key areas: structure, process and outcome (Figure 1)⁹.

Structure refers to the infrastructure of the healthcare system such as availability of equipment and qualifications of staff. Process relates to the details of care such as diagnostic tests and interventions e.g. surgery. Finally outcome is the end result including the traditional measures of mortality and morbidity as quality of life measures. Donabedian went on to develop this model further to encompass seven pillars of quality: (Figure 2)¹⁰.

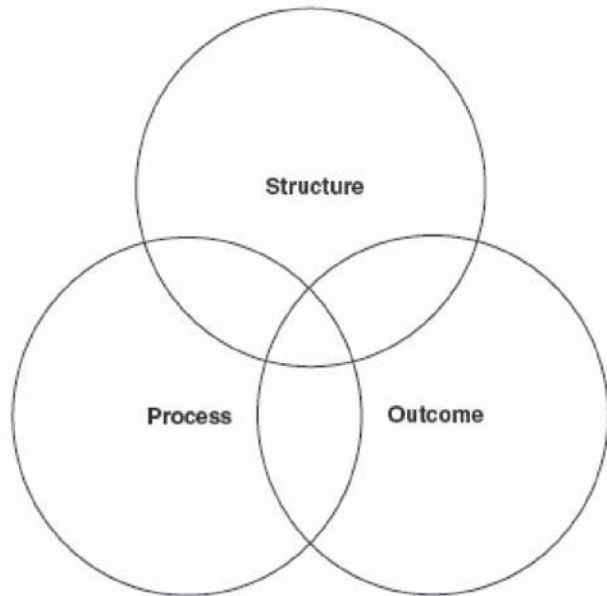


FIGURE 1. As defined by Donabedian, quality of care is defined by an interaction of three key elements.

For measuring quality of care in cardiothoracic surgery accurately the following variables should therefore be considered:

STRUCTURAL VARIABLES:

There are an infinite number of potential variables (Figure 3) however it is vital that a correlation is firmly established between these variables and quality of care. It has been demonstrated that staff:patient ratio and the ratio of doctors/nurses per bed has a significant effect on mortality in paediatric cardiac surgery.¹¹ Whereas a multicentre study done by Treggiari et al the issue of seniority of staff and proved that Intensive Care Units run by Specialist Intensivists had significantly lower mortality rates for patients with acute lung injury irrespective of severity of illness or respiratory physician involvement. (Odds ratio = 0.68; 95% CI 0.52-0.89).¹²

PROCESS MEASURES:

Benefits to measuring processes i.e. the pre-operative, surgery and post-operative aspects of cardiothoracic surgery as an assessment of quality of care are numerous. Despite the fact that often this form of measurement can be labour intensive and time consuming, (made perhaps easier with the introduction of clinical coding) there are a number of advantages. Process measures tend to be less susceptible to case-mix bias, results more accurately reflect the entire evaluated institution and population as opposed to a few outliers with poor outcomes and also they reflect current state of care as opposed to the times delay often encountered with some outcome measures.¹³

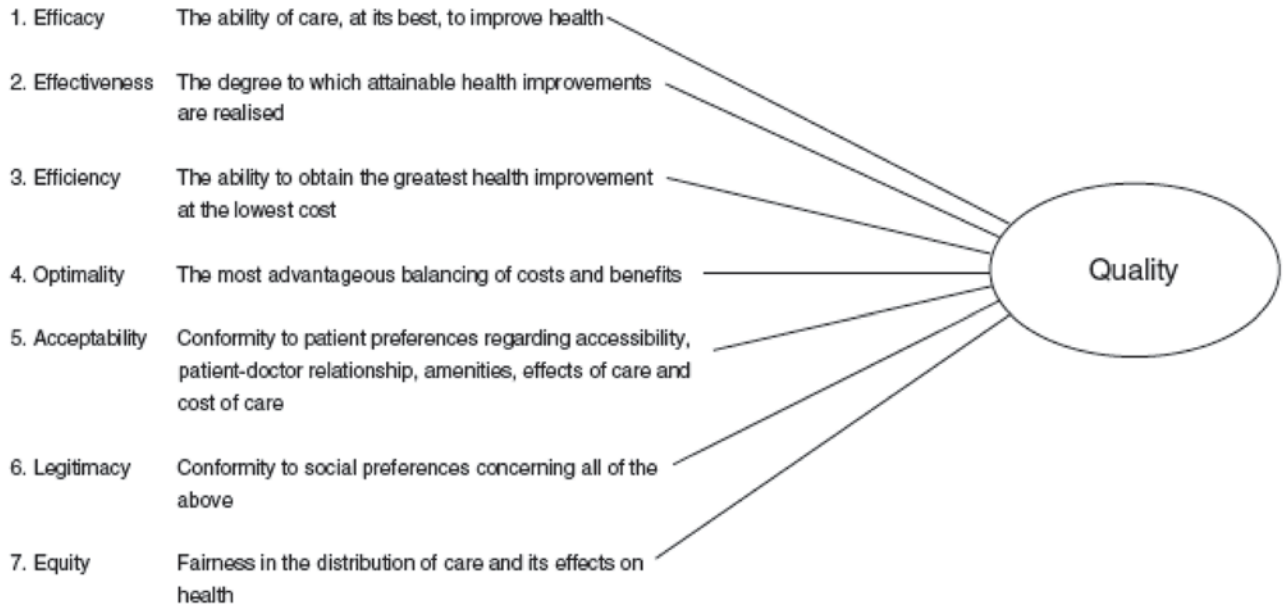


FIGURE 2. The seven pillars of quality as defined by Donabedian.

OUTCOME MEASURES:

In cardiac surgery these include traditional mortality and morbidity measures which in turn tend to publicly affect hospital rankings due to their association with quality of care as

outlined by organisations such as the Dr Foster Intelligence and “Good Hospital Guide”¹⁴ in the U.K and the Leapfrog group¹⁵ in the U.S. However confounding factors such as patient age and co-morbidities tend to have a larger influence

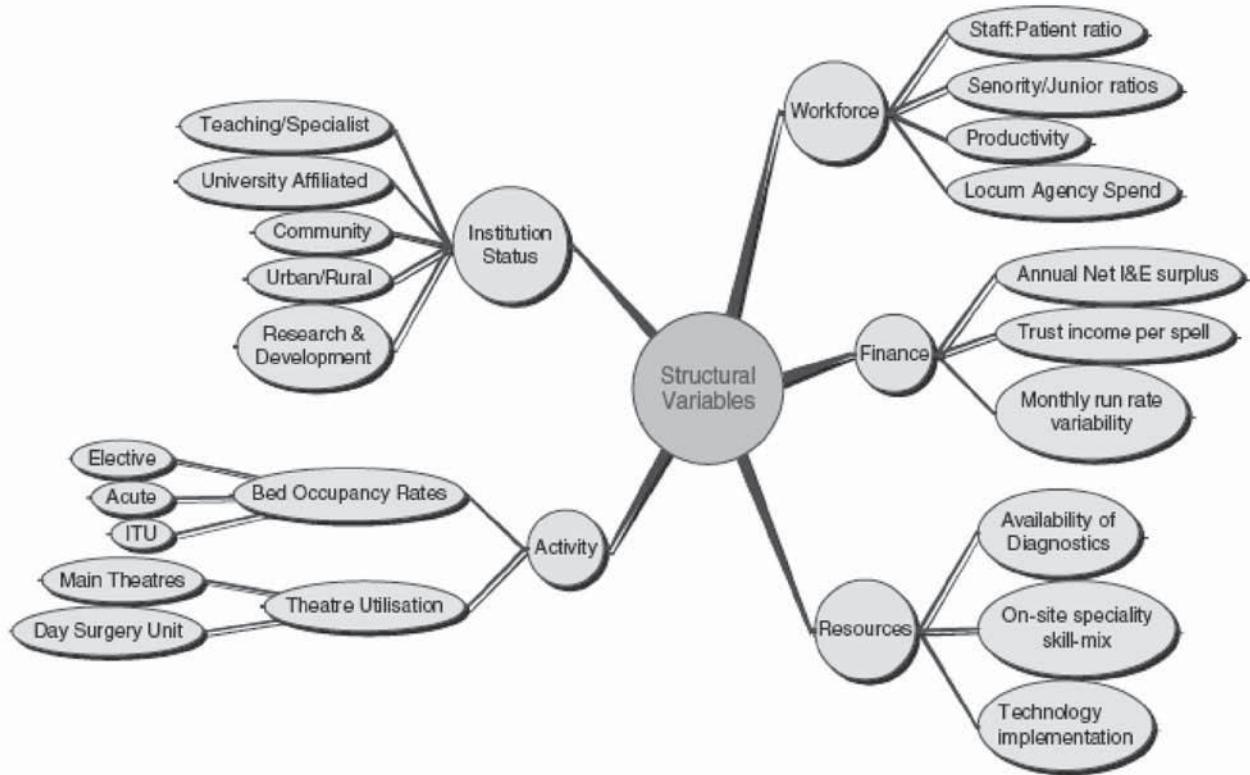


FIGURE 3. Examples of potential structural variables which influence quality of care.

on outcome than the surgery itself and so risk adjustment is crucial. To truly capture quality of care through the entire patient journey however, traditional outcome measures should be combined with some formal measure of HRQL for completeness.

HEALTHCARE ECONOMICS

The limitations of finances and resources can have a huge effect on quality of care. In the U.S issues surrounding private insurance and quality of care remain prevalent whereas in the U.K the concept of the “post code lottery” whereby the area in which you live determines the quality of services available is ever topical. The aim of all healthcare providers should therefore be to improve quality of care through maximising the efficiency of existing resources and using evidence based practise to distribute finances effectively so that improvements in quality need not necessarily cost more.

Overall, with the Donabedian model of structure, process and outcome, accurate measures of quality of care can be made in cardiothoracic surgery to produce a benchmark against which further improvement can be made. As well as identifying substandard areas, recognising areas of high quality of care boosts both the patient and surgeons confidence in the healthcare system and plays a vital role in directing funds and resources towards areas that need it most.

PATIENT SATISFACTION

Since the patient is the most important individual in the health care system, their viewpoints should be central to all that we do as health care providers. Patient satisfaction is a multi-faceted construct which can be split into two distinct areas: 1) satisfaction determinants: patient variables that can affect satisfaction e.g. patient expectations, characteristics and psychosocial determinants. 2) Satisfaction components: these measure the care actually received.¹⁶

1) SATISFACTION DETERMINANTS

- a) Patient expectations: Each patient’s expectations of healthcare can greatly colour their perception and thus satisfaction with care. This concept, first explored by D Stimson and Webb in 1975 who described three key areas to expectations: *background* which relates to the patient knowledge of their condition, *interaction* which describe their expectations of how they would interact and with the doctor/surgeon and *action* which is what they expected to done as treatment.¹⁷ It therefore follows that failing to meet expectation in any of these three categories as surgeons, would lead to patient dissatisfaction and a negative effect on the fulfilment of patient expectations.
- b) Patient Characteristics: Since patient satisfaction is a subjective measure, it is logical that it should depend on

characteristics such as age, background, culture, religion and so forth. Numerous studies, for example have shown the elderly to be more satisfied with care, demand less information and comply more willingly with medical advice¹⁸

- c) Psychosocial factors: These can affect the quality of information that is gained from the healthcare profession regarding genuine satisfaction. Theories such as the ‘Hawthorne effect’ suggest that simply carrying out the survey illustrates increased apparent concern and thereby boosts patient satisfaction.¹⁹ Also confounding factors should be accounted for such as self-interest bias where patients responding positively simply to enable the service to continue so that they may continue to receive treatment and the gratitude factor which is a big confounder in the elderly population.

2) COMPONENTS OF SATISFACTION

These refer to the specific areas of care that the patient receives and their perception of them, i.e. waiting times, communication and so forth. There are seven key areas which form the basis for most surveys according to the Fitzpatrick model²⁰:

- Interpersonal manner
- Technical quality of care
- Accessibility and convenience
- Efficacy and outcomes of care
- Continuity of care
- Physical environment of care
- Availability of care

Whilst technical ability is often felt to be the most important by surgeons, for the patient it have been proven over and over again that interpersonal manner is by far the greatest indicator of patient satisfaction. Shaufel et al (2009) analysed a series of consultations prior to cardiac surgery on patients deemed particularly high risk in accordance with EuroSCORE. They noted that ‘when handling uncertainty doctors imparted complex information about risk, warnings and recommendations, while patients sought and trusted the doctor’s advice.’²¹ They recommended increased education of cardiac surgeons to address power relations in order to emphasise shared decision making during such preoperative discussions.

In order to produce reliable results, satisfaction surveys must be carefully planned and tested. It has become increasingly accepted that measuring satisfaction with very specific surveys for a particular clinical situation so that clear areas of dissatisfaction can become quickly visible, is the best method. This is in contrast to the “overall satisfaction” rating previously used whereby patients are asked to give more general ratings and results often mask smaller, more specific areas of dissatisfaction. A study by Leo et al (2009)²² assessed satisfaction in patients undergoing thoracic surgery in a cancer centre

using the Europe Organisation for Research and Treatment of Cancer (EORTC) questionnaire series on admission and discharge. Areas of low satisfaction such as 'nurse's information provision' were then targeted and improved specifically and the survey was repeated months later showing significant improvement. This continuous cycle of auditing and improving satisfaction permits focused management of ongoing problems and promotes a flexible and proactive response to patient needs.

For the design of satisfaction survey, it is generally accepted that four key areas in the design of the survey must be taken into consideration due to their ability to influence results²³:

- 1) Choice of population: whether to survey the entire population or simply current users or a specific group as this will have a significant effect on results.
- 2) Timing: the later the survey is left the greater the change of bias as patients are susceptible to changes in perception or appreciation of care and may have forgotten things that concerned them at the time of admission.
- 3) Type of Questionnaire: The use of open and closed questioning to various degrees must be carefully moulded to the area being surveyed.
- 4) Rating of satisfaction: Patients must be able to choose from a range of levels of satisfaction options in their response since forcing answers into narrow categories means that results automatically lose value.

Understanding and measuring patient satisfaction is in cardiothoracic surgery is crucial to bettering our practise and improving not only the quality of care that we provide for our patients but also health and quality of life outcomes. Improved satisfaction leads to improved compliance with care leading to beneficial changes in health of the population and perhaps less misuse of healthcare services. Improved satisfaction in surgery also promotes fewer complaints, "second opinions" and repeat investigations which in time has greatly beneficial cost implications.

PATIENT REPORTED OUTCOMES

The measuring of patient reported outcomes (PROs) can greatly enhance the assessment of quality of care. These measures provide us with patient's views on their health condition, consultation and treatment. In this way we gain a specific and subjective assessment of their symptoms, functional status, productivity and satisfaction which are particularly useful pieces information in cardiothoracic surgery where patients are often high risk and consequences of poor outcomes significant.

In the U.K there has been a national initiative by the Department of Health to measure patient reported outcome measures (PROMS) to determine healthcare performance.²⁴ A

large U.S study by Flynn et al (2009)²⁵ examined associations between patient reported outcome measures using the Kansas City Cardiomyopathy Questionnaire (KCCQ) and the Visual Analog Scale (VAS) and clinical indicators of disease such as a 6-minute walk and peak VO₂ in a population of 2331 patients with heart failure. This showed the PROs measured with two scales were correlated with 6 minute walking distance and peak VO₂ hence such measures are advocated in how to best measure the benefit of heart failure interventions.

Overall, Patient reported Outcome measures will play an increasingly important role in cardiothoracic surgery, due to their effectiveness in monitoring the patient experience and patient journey. They can be used in a number of applications including clinical trials, economic evaluation and day to day patient care.

CONCLUSION

The development of enhanced outcome measures can provide Cardiothoracic surgeons the opportunity to assess their results in increased precision and transparency. An initiative to increase patient awareness and education regarding their hospitals and their surgeons has meant a necessary move towards greater clarity and accountability of all surgical centres. This has seen an adaptation towards a more patient-centred approach. Traditional outcome measures such as morbidity and mortality remain crucial to maintaining excellent standards. However more subjective measures based around 'quality' are evolving. Health related quality of life measurements have equipped surgeons with superior techniques to judge and improve their practice whilst allowing patients the basis to make informed choices about their care. Assessing patient satisfaction and quality of care again provides a more long term outcome measure and ensures that the patient preferences are incorporated into clinical decisions. It ensures that patient and surgeon expectations will be fulfilled in a broad range of areas related to surgical care.

Comprehensive quality measures and a framework for analyzing and interpreting these results is pivotal as is knowing *what* to measure and *how* to measure it. Innovative approaches whereby the patient measures and reports their own 'outcome' and experience are being piloted in all surgical specialties and cardiothoracic should be no exception to this. Adopting the Donabedian model for quality measurement in three domains structure, process, and outcomes is again a valid and reliable instrument for assessing patient's satisfaction and quality of care as are the wide range of validated surveys of HRQL which should be routinely implemented. We must continue to find ways to collect such data efficiently and inexpensively then analyze it effectively of we are to genuinely improve our patients' experience of cardiothoracic surgery.

OUTCOMES IN CARDIAC SURGERY

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