# Methodology

# The measurement and monitoring of surgical adverse events

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# **Executive summary**

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# Background

Surgical adverse events contribute significantly to postoperative morbidity, yet the measurement and monitoring of events is often imprecise and of uncertain validity. Given the trend of decreasing length of hospital stay and the increase in use of innovative surgical techniques – particularly minimally invasive and endoscopic procedures – accurate measurement and monitoring of adverse events is crucial.

# **Objectives**

The aim of this methodological review was to identify a selection of common and potentially avoidable surgical adverse events and to assess whether they could be reliably and validly measured, to review methods for monitoring their occurrence and to identify examples of effective monitoring systems for selected events. This review is a comprehensive attempt to exam-ine the quality of the definition, measurement, reporting and monitoring of selected events that are known to cause significant postoperative morbidity and mortality.

# **Methods**

#### Selection of surgical adverse events

Four adverse events were selected on the basis of their frequency of occurrence and likelihood of evidence of measurement and monitoring:

- surgical wound infection
- anastomotic leak
- deep vein thrombosis (DVT)
- surgical mortality.

Surgical wound infection and DVT are common events that cause significant postoperative morbidity. Anastomotic leak is a less common event, but risk of fatality is associated with delay in recognition, detection and investigation. Surgical mortality was selected because of the effort known to have been invested in developing systems for monitoring surgical death, both in the UK and internationally. Systems for monitoring surgical wound infection were also included in the review.

### Literature search

Thirty separate, systematic literature searches of core health and biomedical bibliographic databases (MEDLINE, EMBASE, CINAHL, HealthSTAR and the Cochrane Library) were conducted. The reference lists of retrieved articles were reviewed to locate additional articles. A matrix was developed whereby different literature and study designs were reviewed for each of the surgical adverse events. Each article eligible for inclusion was independently reviewed by two assessors.

## **Critical appraisal**

Studies were appraised according to predetermined assessment criteria. Definitions and grading scales were assessed for: content, criterion and construct validity; repeatability; reproducibility; and practicality (surgical wound infection and anastomotic leak). Monitoring systems for surgical wound infection and surgical mortality were assessed on the following criteria:

- coverage of the system
- whether or not denominator data were collected
- whether standard and agreed definitions were used
- inclusion of risk adjustment
- issues related to data collection
- postdischarge surveillance
- output in terms of feedback and wider dissemination.

## Results

## Surgical wound infection

A total of 41 different definitions and 13 grading scales of surgical wound infection were identified from 82 studies. Definitions of surgical wound infection varied from 'presence of pus' to complex definitions such as those proposed by the Centres for Disease Control in the USA. A small body of literature has been published on the content, criterion and construct validity of different definitions, and comparisons have been made against wound assessment scales and multidimensional indices. There are examples of comprehensive hospitalbased monitoring systems of surgical wound infection, mainly under the auspices of nosocomial surveillance. To date, however, there is little evidence of systematic measurement and monitoring of surgical wound infection after hospital discharge.

#### Anastomotic leak

Over 40 definitions of anastomotic leak were extracted from 107 studies of upper gastrointestinal, hepatopancreaticobiliary and lower gastrointestinal surgery. No formal evaluations were found that assessed the validity or reliability of definitions or severity scales of anastomotic leak. One definition was proposed during a national consensus workshop, but no evidence of its use was found in the surgical literature. The lack of a single definition or gold standard hampers comparison of postoperative anastomotic leak rates between studies and institutions.

## Deep vein thrombosis

Although a critical review of the DVT literature could not be completed within the realms of this review, it was evident that a number of new techniques for the detection and diagnosis of DVT have emerged in the last 20 years. The group recommends a separate review be undertaken of the different diagnostic tests to detect DVT.

### Surgical mortality monitoring systems

The definition of surgical mortality is relatively consistent between monitoring systems, but duration of follow-up of death postdischarge varies considerably. The majority of systems report in-hospital mortality rates; only some have the potential to link deaths to national death registers. Risk assessment is an important factor and there should be a distinction between recording pre-intervention factors and postoperative complications. A variety of risk scoring systems was identified in the review. Factors associated with accurate and complete data collection include the employment of local, dedicated personnel, simple and structured prompts to ensure that clinical input is complete, and accurate and automated data capture and transfer.

# Conclusions

The use of standardised, valid and reliable definitions is fundamental to the accurate measurement and monitoring of surgical adverse events. This review found inconsistency in the quality of reporting of postoperative adverse events, limiting accurate comparison of rates over time and between institutions. The duration of follow-up for individual events will vary according to their natural history and epidemiology. Although riskadjusted aggregated rates can act as screening or warning systems for adverse events, attribution of whether events are avoidable or preventable will invariably require further investigation at the level of the individual, unit or department.

### **Recommendations for research**

- A single, standard definition of surgical wound infection is needed so that comparisons over time and between departments and institutions are valid, accurate and useful. Surgeons and other healthcare professionals should consider adopting the 1992 Centers for Disease Control (CDC) definition for superficial incisional, deep incisional and organ/space surgical site infection for hospital monitoring programmes and surgical audits. There is a need for further methodological research into the performance of the CDC definition in the UK setting.
- There is a need to formally assess the reliability of self-diagnosis of surgical wound infection by patients.
- There is a need to assess formally the reliability of case ascertainment by infection control staff.
- Work is needed to create and agree a standard, valid and reliable definition of anastomotic leak which is acceptable to surgeons.
- A systematic review is needed of the different diagnostic tests for the diagnosis of DVT.
- The following variables should be considered in any future DVT review: anatomical region (lower limb, upper limb, pelvis); patient presentation (symptomatic, asymptomatic); outcome of diagnostic test (successfully completed, inconclusive, technically inadequate, negative); length of followup; cost of test; whether or not serial screening was conducted; and recording of laboratory cut-off values for fibrinogen equivalent units.
- A critical review is needed of the surgical risk scoring used in monitoring systems.
- In the absence of automated linkage there is a need to explore the benefits and costs of monitoring in primary care.
- The growing potential for automated linkage of data from different sources (including primary care, the private sector and death registers) needs to be explored as a means of improving the ascertainment of surgical complications, including death. This linkage needs to be within the terms of data protection, privacy and human rights legislation.
- A review is needed of the extent of the use and efficiency of routine hospital data versus special collections or voluntary reporting.

# **Publication**

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# NHS R&D HTA Programme

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Although the National Coordinating Centre for Health Technology Assessment (NCCHTA) commissions research on behalf of the Methodology Programme, it is the Methodology Group that now considers and advises the Methodology Programme Director on the best research projects to pursue.

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