Registration and analysis of surgical complications: Bearing the burden of broken butterflies

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‘Thread tensioner’ is missing two wings. With thread and pins the veins of his wings were constructed. *Anne ten Donkelaar.*
Chapter 1

General Introduction and
Outline of the Thesis
GENERAL INTRODUCTION

During the history of mankind, medicine attempts to alleviate human suffering. For centuries, doctors pledge loyalty to Hippocrates' oath, part of which pleads to ‘primum non nocere’ or ‘first do no harm’. However, any medical intervention that is intended to cure or alleviate sickness, may also cause harm. Particularly surgical interventions are inadvertently but inherently associated with harm. This starts with the skin incision, which may already lead to various unintended sequelae like wound infection, pain or hematoma. Furthermore in surgical patients harm may be due to for example bleeding, infection, disturbance of the normal healing process, (surgical) damage to anatomical structures, etc. Any harm should preferably be avoided, but some harm may be justified as a calculated risk if it is outweighed by the anticipated positive effect(s) of the intervention. For example, a bowel (colon) resection for cancer may require a re-anastomosis with a certain risk of leakage. Surgeons are obliged to compare the potential harm versus the intended positive results of their interventions and to communicate both aspects with their patients before an invasive diagnostic procedure or a treatment choice is made.

Definitions

The definition of harm in surgery still lacks uniformity, thereby confounding the interpretation of surgical performance and quality assessment. When observing harm, multiple terms, definitions and interpretations are used (see figure 1). The terms mostly refer to an unwanted event, process or outcome.

A ‘near miss’ is an unwanted event without negative effects on the patient’s health (incorrect process). The term ‘event’ or ‘incident’ is used when the unwanted event did affect the patients’ health (incorrect process).

An ‘adverse event’ is an unwanted outcome that occurs due to (the neglect of) a medical intervention, that negatively affects the patient’s health as such this requires their medical treatment to be adapted, or that irreparable damage is caused. An ‘adverse event’ suggests that there is a causal relationship between the unwanted outcome and the medical intervention but not whether the intervention was performed correctly. The term ‘complication’ is often interpreted erroneously, in terms of ‘incident’, ‘adverse event’, or ‘calculated risk’. Complications contain all unwanted outcomes that occur during or after a medical or surgical intervention, regardless of causal connections with factors, such as medical treatment, surgery, or comorbidities, causing irreparable damage or requiring adaptation of the medical treatment to be adapted. Complications, as opposed to adverse events, can be related to the primary disease, comorbidities, patient characteristics. If, in retrospect, certain actions could have prevented the harm, any of these types of harm will be marked as preventable.
Application of this broad definition of a ‘complication’, combined with data on the consequences for treatment, allows analysis of a wide variety of complications and provides valuable tools for quality improvement. Complications refer to unintended and unwanted outcomes and may, after analysis, be used to prevent unintended events.

**Figure 1**: Global relationship between different terms.

Based on figure from ‘Praktijkboek Patientveiligheid’, Bohn Stafleu van Loghum, 2006; chapter 1, p 10.
Registration of Complications
After the landmark publication of ‘To err is human’ of the Institute of Medicine (IOM) in 1999, patient safety became a highly discussed subject. This publication underlined that individual care providers should not solely bear the burden of harm inflicted. Complications are rather shortcomings in the healthcare systems. This shifted the subject from a legal perspective to a quality of care perspective. As a consequence, complication registration and reporting systems were considered as a pivotal step to improve the awareness of complications, to reduce their incidence, and to improve quality of care. Several registration and reporting systems have been developed since. The American College of Surgeons uses the National Surgical Quality Improvement Program (ACS-NSQIP) to monitor clinical morbidity and mortality. The Society of Thoracic Surgeons in the United States uses a complication registration system since 1989 for cardiothoracic surgery in adults (www.sts.org). In the Netherlands, the National Intensive Care Evaluation (NICE) registry has been developed especially for ICU departments, while surgical complications on general surgical wards are registered in the national surgical complication registration system (LHCR), developed by the Association of Surgeons of the Netherlands (NVvH). Also at the Department of Surgery of the Academic Medical Centre in Amsterdam complications have been documented routinely of all admitted patients from 1993 on, and using the department’s complication registration according to the LHCR system since 2002.

Improvement Initiatives
Complications can lead to unfavourable health outcomes for the patient, requiring a change in therapy or even causing irreversible damage. This might result in a prolonged hospital stay and increased costs for the patient, hospital, and society. Hence, improving the quality of care has become a priority for hospitals, which includes the registration and minimisation of complications. Comprehensive and accurate registration of complications and analysis of these data are essential to help surgeons properly inform their patients as part of the shared decision-making process and to provide surgical departments with adequate process information for internal quality control.

This thesis addresses how the completeness and efficiency of the current registration system can be improved by investigating the different approaches to improve the registration of complications in surgical patients.
CHAPTER 1      GENERAL INTRODUCTION

OUTLINE OF THE THESIS

This thesis contains two parts. The first part focuses on studies regarding the quality and quantity of the complication registration in surgery. The introduction and optimisation of a complication registry may lead to an apparently increased complication rate. This increase does not necessarily mean that the performance of medical care is insufficient, but could be interpreted as a stimulus for further scrutiny of the quality of care, or merely as a sign that these complications are gradually being better reported, as part of a learning curve (also a certain awareness phase).\textsuperscript{13,14} In Chapter 2 an analysis of the changes in complication rates and types, and their possible causes, in an academic hospital over a six-year period is described. In Chapter 3 a study is performed to assess the completeness of the departments’ complication database as used in our hospital. The completeness is assessed by comparing the database to relevant information from other available resources on complications, such as the medical and nursing files, the discharge letters relevant to that admission period, the complications documented during morning hand-offs, and the complication database.

Furthermore, previous studies have suggested that surgeons only record certain complications after discharge.\textsuperscript{15,16} The extent and impact of this potential under-recording of post-discharge complications is unknown. This is another aspect that underestimates the overall complication rate. If more information were available on all complications occurring after discharge, this would provide a more reliable representation of all surgery-related complications. In Chapter 4 a study is performed to determine which method, a telephone interview or a questionnaire by mail, is the best way to collect post-discharge complications as reported by patients. In Chapter 5 the extent and impact of the potential under-recording of post-discharge complications are determined. For this purpose the patient-reported complications are compared with surgeon-reported complications by the frequency, type, and grade of post-discharge complications.

Part 2 focuses on several initiatives for improvement of the quality of the complication data and the need for reducing complications. The trend to develop national benchmarking data, including those regarding complications in hospitalised surgical patients is growing. The reliability of benchmarking depends on the quality control of these data. Uniform interpretation and registration by the participating surgical departments is required to assemble high-quality data. The study described in Chapter 6 addresses the amount of agreement and potential differences in the application and interpretation of the definition of a complication among the surgeons and the surgical departments of seven Dutch hospitals. Surgical complications occur more frequently, are more often preventable, and their consequences can be more severe than other types of complications. A risk analysis is
essential to identify those patients at risk of developing complications. In Chapter 7 a systematic review is performed to summarise available factors that may predict surgical complications. These factors are used in Chapter 8 to develop a new trigger tool. A ‘trigger’ can be defined as a specific factor that is derived from the patient’s medical record and is associated with an increased risk of complications, like bodyweight or complexity of the procedure. A ‘trigger tool’ is a set of triggers that identifies patients who are likely to have suffered a complication and thereby indicates which patient records should be checked for complications. The accuracy of the trigger tool is compared with the current standardised clinical registry method during morning handovers.

Reducing complications has become an important goal for quality improvement initiatives to optimise patient outcomes and to reduce hospital costs. However, little is known about the cost consequences of complications. In Chapter 9 the possible financial consequences of specific complications occurring after pancreatoduodenectomy, in particular anastomotic leakage, haemorrhage, infection, as well as the severity of the complication are explored. The results of the studies presented in this thesis and consequences for changes in registration and management of complications in the future are summarised and discussed in Chapter 10.
REFERENCES


