Pharmaceutical care in surgical patients: Tools for measurement and intervention
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CHAPTER 1
INTRODUCTION AND OUTLINE THESIS
Nowadays, much attention is paid to the quality and safety of pharmaceutical care in hospitalised patients. Although the term 'pharmaceutical care' is widely used, there are different definitions and interpretations to explain what this kind of health care actually incorporates. The country, local culture and language, the type of pharmacy practice, and, as has recently been suggested, the type of patient are of influence in explicitly defining pharmaceutical care. In general, it can be stated that pharmaceutical care is the patient-focused care related to medication, which is provided by a (hospital) pharmacist and the (hospital) pharmacy team with the aim of improving the outcomes of pharmacotherapy and therefore reducing medication-related harm.

In the Dutch hospital pharmacy setting, a shift from product to patient-centered care is seen. Also, mainly providing pharmaceutical care from a central pharmacy is shifted to more and more pharmaceutical care provided directly at the hospital wards. An example is the development of 'satellite pharmacies' on the wards, where predominantly preparation of parenteral medication is taken place. Also, more hospital pharmacists participate in multi-disciplinary teams to optimize patients' (pharmaceutical) care. This type of providing pharmaceutical care can be defined as clinical pharmacy or more specifically ward-based pharmacy.

Provision of pharmaceutical care in hospitals concerns several medication-related processes, e.g. prescribing/ordering, transcribing, dispensing, administering, monitoring, and discharge/across setting. Medication use, as a result of these processes, is a major cause of unintended patient harm. Medication-related harm is widely known as adverse drug events (ADEs). If medication-related harm is caused by an error in the medication-related processes, it is called a preventable ADE (pADE). However, not all ADEs are preventable (e.g. adverse drug reactions), whereas not all medication errors lead to harm (e.g. potential ADEs) (figure 1).
**Pharmaceutical Care**

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**Adverse Drug Events**

Provision of pharmaceutical care in hospitals concerns several medication-related processes, e.g. prescribing/ordering, transcribing, dispensing, administering, monitoring, and discharge/setting. Medication use, as a result of these processes, is a major cause of unintended patient harm. Medication-related harm is widely known as adverse drug events (ADEs). If medication-related harm is caused by an error in the medication-related processes, it is called a preventable ADE (pADE). However, not all ADEs are preventable (e.g. adverse drug reactions), whereas not all medication errors lead to harm (e.g. potential ADEs) (figure 1).

![Figure 1. Definitions adverse drug events and medication errors (adapted from Morimoto et al.)](image-url)
A systematic review has shown that 15.1% of all in-hospital adverse events, is medication-related (i.e. ADEs)\(^9\). Furthermore, another review shows that the incidence of ADEs during hospital admission ranges from 1.7 to 51.8 ADEs per 100 admissions. Many of these ADEs can be prevented (14.8%–59%)\(^12\). A more recent study by Morimoto et al.\(^13\) on the incidence of ADEs has been performed in medical, surgical and Intensive Care Unit (ICU) patients. This study finds 32.9 ADEs per 100 admissions in medical patients, 27.7 ADEs per 100 admissions in surgical patients, and 21.6 ADEs per 100 admissions in ICU patients; and that 14% of the ADEs are preventable (141/1010 ADEs).

Besides incidence of (preventable) ADEs, knowledge about the nature of ADEs, i.e. ADE severity and type of medication accountable for the ADEs, is essential for future pharmaceutical care improvements. Most ADEs are classified as mild or moderate (>80%), and anti-infective agents, cardiovascular agents and antineoplastic agents are most frequently (>50%) related to ADEs\(^2\). Other have found comparable results: 61% of ADEs are significant, 33% serious and 7% life-threatening or lethal\(^13\). Antibiotics are frequently related to ADEs. Electrolytes, NSAIDs and antibiotics are predominantly accountable for the preventable ADEs\(^12,13\).

Many studies on ADE cover mixed patient populations or medical patients only. No detailed information is available on the nature of ADEs in surgical patients only.

**Pharmaceutical Care in Surgery**

Studies on the incidence and nature of ADEs focus predominantly on general medical wards, ICUs and paediatric wards\(^14-19\). However, medication-related harm can also be expected on surgical wards. Admission for surgery is frequently associated with in-hospital adverse events due to the surgical intervention itself (almost 40%)\(^1\). Moreover, surgical patients frequently use medication prone for ADEs\(^12,14,20,21\). For example, surgical patients use antibiotics and analgesics during the surgical intervention and post-operatively. Also, surgical patients are subjected to multiple in-hospital transfers along the surgical pathway\(^22\) (figure 2), with associated handovers and possible errors in communication, which are prone to adverse events\(^23\). In contrast to medical patients, surgical patients are physically transferred from the admission ward to various locations such as the holding area before surgery, the operating room, the recovery room or the ICU, back to the hospital ward, and eventually discharged home or to a rehabilitation facility. Each location has different caregivers and medication decisions from different viewpoints\(^22\). Therefore, providing pharmaceutical care in surgical patients is considerably different from that of medical patients. It is consequently conceivable that errors can occur in the medication processes in surgical wards. Thus, due to co-morbidity and surgery related medication and multiple surgery pathway related transfers, surgical patients are at risk for medication-related harm. However, until now, no studies are available which give insight in the incidence and nature of ADEs or the quality of pharmaceutical care in solely the surgical population.
Many studies on ADE cover mixed patient populations or medical patients only. No detailed studies are available which give insight in the quality of care. QIs are often used as a process measure, such as the QI set to assess the quality of care. These methods have different benefits and disadvantages in efficiency and accuracy when quantifying medication-related harm. The gold standard to assess ADEs does not yet exist. A widely used and accepted detection method is the trigger tool method. The primary advantage of the trigger tool method is the more efficient and less labour-intensive quantification of ADEs in comparison with the other detection methods. The trigger tool method identifies adverse (drug) events based on ‘triggers’ or clues in the patients’ medical record. This method was described by the Institute for Healthcare Improvement (IHI) to detect adverse (drug) events in a variety of medical in- and outpatient populations. However, the trigger tool does not include a critical appraisal of the causal relationship between the found ‘trigger’ and the used medication. To identify the presence and impact of an ADE, a review and interpretation of an individual case is crucial. Several methods of causality assessment have been described, i.e. expert judgement, algorithms and probabilistic methods. No trigger tool with a standardized causality assessment method exists for the specific assessment of ADEs in surgical patients.

Compared to outcome measures, process measures elucidate suboptimal care in the process and are influenced directly by implementations of care improvements. Furthermore, these measures are easier to recognize in an earlier stage than outcome measures and are more efficient in assessing the quality of care. QIs are often used as a process measure, such as the QI set to assess the care of vulnerable elderly patients (ACOVE). Higashi et al. have measured the quality of pharmacologic care of vulnerable elderly patients. Also for elderly surgical patients a set of care quality...
indicators has been developed\textsuperscript{38}. However, only few of these indicators are directly related to the medication processes on the surgical wards. ADEs assessment and QIs will provide information about the quality of pharmaceutical care from different angles. They can therefore complement each other in assessing and monitoring the quality of pharmaceutical care.

**TOOLS FOR INTERVENTION TO IMPROVE PHARMACEUTICAL CARE**

Hospitals are aware of the occurrence of ADEs and already incorporate several medication safety improvements in their medication-related processes, such as Computerized Physician Order Entry (CPOE) systems with or without Clinical Decision Support (CDS) to prevent prescribing errors\textsuperscript{25,39}, bar-code technology to prevent transcription and administering errors\textsuperscript{40}, and/or one of the medication safety improvements introduced by the WHO Joint Commission International\textsuperscript{41} and IHI\textsuperscript{42}. Examples are improvement for look-alike/sound-alike medication names to prevent dispensing and administering errors, and medication reconciliation to prevent discharge/across-setting errors.

However, adverse drug events remain a serious problem in hospitals. Even in highly computerized hospitals using CPOE systems with CDS, preventable ADEs still occur\textsuperscript{43}. Implementation of clinical pharmacy services has been shown effective in reducing medication errors as well as medication-related harm in several non-surgical patient populations\textsuperscript{44-48}. Preventable ADEs were reduced by 66\%\textsuperscript{45}, 78\%\textsuperscript{46} and 51\%\textsuperscript{48}.

In conclusion, information is lacking on the quality of pharmaceutical care in surgical patients. This thesis describes tools for measurement and interventions to assess and improve the pharmaceutical care in surgical patients.

**OBJECTIVE THESIS**

The objective of this research was to evaluate and improve medication-related harm in surgical patients using developed measurement and intervention tools for pharmaceutical care.

**OUTLINE THESIS**

This thesis contains thirteen chapters subdivided into three sections. Part I of the thesis ‘Development’ – Adverse drug events in surgical patients’ provides the scientific basis and study design of the SUREPILL (Surgery & Pharmacy In Liaison)-study that evaluates the efficacy of ward-based pharmacy on ADEs (chapter 2), a review of literature on the occurrence and nature of ADEs in surgical patients (chapter 3), and the development and testing of a targeted method for standardized assessment of ADEs in surgical patients (chapter 4).

Part II of the thesis focuses on the assessment of pharmaceutical care by using ADEs and QIs. Chapter 5 describes a prospective study on the incidence and nature of ADEs in surgical patients of three Dutch
hospitals. Chapter 6 describes the quality of pharmaceutical care assessed in surgical patients of a Dutch academic hospital with developed medication-related quality indicators. The final part of the thesis, part III, describes the improvement of pharmaceutical care by ward-based pharmacy interventions in surgical patients. First, the development and implementation of the ward-based pharmacy intervention strategy is described (chapter 7). Thereafter, the effect of this ward-based pharmacy intervention strategy on preventable ADEs is evaluated in a prospective cohort study with ward randomisation (chapter 8).

Next, a summarizing discussion (chapter 9) is provided, where the results of these studies are summarized and discussed along with future perspectives to improve the quality of pharmaceutical care in surgical patients.
REFERENCES


