Development and application of measurement methods focusing on medication related problems in elderly hospitalised patients
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7.1 Summary
Summary

Medical care has the danger of causing unintended harm besides serving the patient. Application of medication is one of the most commonly applied medical interventions and has contributed significantly to the increase of quality of medical practice, of life expectancy, and health of people. However, the application of medication can also cause problems, can be erroneous, and cause harm. Among medical errors, medication errors make up the largest part. Of the medical adverse events (harmful events), adverse drug events (ADEs) are the most frequent type in hospitalised patients. ADEs may occur during the normal use of medication as a result of an unavoidable pharmacological effect (side effects or Adverse Drug Reactions (ADRs)), or as a result of a medication error (preventable ADEs). ADEs are associated with extra length of hospital stay, increased morbidity and mortality, and considerable extra costs. Furthermore, a considerable part of hospital admissions are related to ADEs.

Pharmaceutical care is an essential component of the total medical care of elderly patients. However, older patients (aged >65 years) represent a vulnerable population and suffer more from medication related problems than younger adult patients, especially during hospital stay. Older patients are at a higher risk for several reasons: the coexistence of multiple morbidities and often complex care; the presence of pre-existent cognitive, social and functional limitations; altered pharmacokinetics and pharmacodynamics; the use of multiple drugs (polypharmacy) and, consequently, the risk of over- and undertreatment. Furthermore, elderly often transfer from one care setting to the other (hospital-nursing home, hospital-home) thereby increasing the risk for medication errors and adverse drug events. Continuity of care is an important point of attention.

Medication related problems can present themselves in diverse manners, as medication errors or as patient harm, and can also have very different aetiology. Consequently, there are multiple approaches to measure medication related problems and thus quality and safety of pharmaceutical care.

Medication related problems can be measured at systems level, pointing out latent factors of, for example, organisational or technical nature that contribute to medication errors or ultimately to medication related patient harm. Medication related problems can be measured at process level, for example by counting how frequent a specific process, such as a drug administration was conducted insufficiently or a therapeutic decision was made incorrectly. Finally, medication related problems can be gauged by measuring outcomes, the actual harm that was caused to patients.
The aim of this thesis was to describe the development of three measurement methods for medication related problems in elderly hospitalised patients, each with one of the three foci mentioned above and to compare the results achieved in their application.

Elderly patients, besides having an increased risk for medication related problems, present more frequently than younger patients with atypical symptoms (geriatric syndromes), making it more difficult to correctly diagnose a disease but also to timely recognize medication related problems and adverse drug events (ADEs). Compared with younger patients, patients aged 65 years or older are at a 4-fold higher risk for ADEs. Since both geriatric syndromes (like delirium and falls) and ADEs are frequently found in acutely hospitalised elderly patients we suggested a possible association or sequential time course may exist. In Chapter 2 we investigated in a prospective cohort study whether geriatric syndromes were associated with ADEs in acutely admitted elderly patients. Of the total of 641 included patients over 25% had an ADE present at admission, 26% presented with delirium and 12% with a fall. Delirium was associated with the use of antidepressants, antipsychotics and antiepileptics. In all ADEs (n=167), ADEs were associated with a fall, with non-steroidal anti-inflammatory drugs and diuretics, but not with pre-existing functioning, delirium or older age. For ADEs involving psychoactive medication (n = 35), an association was found between delirium, falls, opioids and antipsychotics in bivariate analyses. A fall just before hospitalisation (odds ratio [OR] 3.69 [95% CI: 1.41-9.67]), antipsychotics (OR 3.70 [95% CI: 1.19-11.60]) and opioids (OR 14.57 [95% CI: 2.02-105.30]) remained independently associated with an ADE involving psychoactive medication. The study demonstrated that, in a cohort of elderly hospitalised patients, a fall before admission and prevalent delirium are associated with several pharmacological groups and/or with ADE-related hospital admission.

Systems level

In an exploratory study in Chapter 3 we adapted the Bow-Tie model, a prospective risk analysis method already well-known and used in petrochemical and aviation industries, to the clinical setting for medication safety risk analysis. This model integrates causes, errors, preventive and recovery measures, and consequences and gives insight into the magnitude and causes of existing safety risks. The model was consecutively applied on the medication-use process in two hospitals (a large tertiary academic hospital and a large general teaching hospital). Multiple risk factors for medication errors and medication related harm for the hospital patient population in general were found. Based on the findings in both hospitals we defined a recommended feasible procedure for application of the model. By using a multidisciplinary panel, by specifying and prioritizing patient group or department or ward specific top events and analyzing these
safety issues in-depth by drawing Bow-Tie diagrams, the method was better applicable, more comprehensible and created more awareness of latent conditions and underlying causes at a systems level.

Process level

In Chapter 4 we describe four studies concerning process indicators. The ACOVE quality indicator (QI) set, developed in 2001 by RAND/UCLA, consists of explicitly phrased IF-THEN clinical rules (indicators) with comprehensive coverage of general medical and geriatric conditions to assess the quality of care of vulnerable elderly. The ACOVE specifically addresses undertreatment, an issue often overlooked in the elderly patient population. The indicators are intended to evaluate, by measuring adherence to these rules, whether minimal standards of care are met. In Chapter 4.1 we systematically reviewed literature to examine and analyze the various ways the ACOVE QIs have been applied in medical science since their introduction. We aimed to describe the studies within a comprehensive thematic model that reflected how the indicators were used. A total of 41 articles met our selection criteria. Studies were classified into the themes ‘Application of indicators’ (32 studies) and ‘Analysis and development of indicators’ (13 studies). ‘Application’ studies included assessing quality of care, influencing behavior of health professionals and examining the association of quality of care with other factors. ‘Analysis and development’ included studies developing new indicator sets, and those adapting and validating the original quality indicators to new settings. The ACOVE indicators were used in a wide range of applications with two main foci: the assessment of quality of care for elderly patients and investigating the feasibility of similar indicators and their adaptation to new settings. Very few of the included studies had addressed the goal of care improvement.

The original ACOVE QI set was mainly developed to assess the overall quality of care of community-dwelling vulnerable elders (as opposed to hospitalised elderly). Therefore, they need to be adapted when used in a non-US hospital setting. In addition, the ACOVE QIs depend on patient and caretaker interviews to assess the quality of care. In Chapter 4.2 we aimed to develop and validate a set of explicitly phrased QIs to measure (without the need for interviews) the quality of pharmaceutical care of elderly hospitalised patients in the Netherlands. The developed QI set was based on the ACOVE QIs, Dutch national guidelines, evidence from the literature, and expert opinion. The QI set focused on in-hospital pharmaceutical care and we evaluated whether the QIs were able to assess the quality of care using medical records and a hospital information system. In three review rounds, the QI set was adapted and judged valid on face and content validity. An 87-item QI set was accepted by the expert panel.
Of this set, 49 QIs were based on ACOVE QIs and 38 QIs were newly added. The QI set demonstrated excellent inter-rater reliability (Fleiss’ kappa values for three raters: 0.87 (95% CI: 0.67-1.00); 0.85 (95% CI: 0.70-1.00); 0.88 (95% CI: 0.75-1.00) for respectively determination of condition, drug (class) and quality indicator passed/not passed; intra-class correlation coefficient for two raters: 0.80 (95% CI : 0.63-0.90) for quality indicator passed/not passed for the QIs that were scored by only two raters and good feasibility.

In Chapter 4.3 we aimed to systematically review literature to summarize studies that assess the quality of care using QIs from or based on ACOVE, in order to evaluate the state of quality of care for the reported conditions. Seventeen studies were included with 278 QIs (original, adapted or newly developed). The quality scores showed large variation between and within conditions. Only a few conditions showed a stable pass rate range over multiple studies. Overall, pass rates for dementia (interquartile range (IQR): 11%–35%), depression (IQR: 27%–41%), osteoporosis (IQR: 34%–43%), and osteoarthritis (IQR: 29–41%) were notably low. Medication management and use (range: 81%–90%), hearing loss (77%–79%), and continuity of care (76%–80%) scored higher than other conditions. Out of the 278 QIs, 141 (50%) had mean pass rates below 50% and 121 QIs (44%) had pass rates above 50%. Twenty-three percent of the QIs scored above 75%, and 16% scored below 25%. Although much effort has been put in improving the care for elderly patients in the last years, the reported quality of care according to the ACOVE indicators used in the included studies is still relatively low.

In a retrospective cohort study in Chapter 4.4 we aimed to assess the quality of pharmaceutical care provided to elderly patients admitted to an internal medicine ward (n=200) applying the 87-item set we developed in Chapter 4.2. A secondary objective was to examine the association between the assessed quality of pharmaceutical care and 500 day survival after discharge and readmission rate within 90 days. The study showed that improvements in 3 out of 4 domains of pharmaceutical care are needed. The median pass rates for the four domains ‘Using indicated medication’, ‘Avoiding inappropriate medication’, ‘Continuity and documentation’, and ‘Medication monitoring’ were 63.6%, 100%, 20.3% and 37.3%, respectively. The 200 participating patients had a mean quality score of 42.9%, SD 13.4%. After adjustment for potential confounders no difference was found in survival 500 days after discharge between patients with a low and high quality score (hazard ratio=1.351, p= 0.237). A difference in readmission rate and mortality 90 days after discharge was not found either (p= 0.516). According to the indicators a better quality of pharmaceutical care was not associated with an improved 500-day survival and fewer readmissions within 90 days.
Outcome level

Clinical outcome measures are considered the best end point in order to measure health effects on a patient. Only by assessing what actual harm or good was done to patients one can really conclude whether a specific intervention, treatment, or action has a positive or negative effect. In the field of medication safety research adverse drug events (ADEs) are the main outcome measure. ADEs are usually defined as any injury due to the use of medication. In Chapter 5.1 we described the research protocol of the WINGS study, a multicentre interrupted time series study to assess the reduction of preventable ADE incidence in elderly internal medicine patients by on-ward pharmacy services. The WINGS study consists of a pre-intervention measurement period of ADE incidence, after which ward-oriented pharmacy services are introduced. Thereafter the effects of these services are assessed during a post-intervention measurement period. The ADEs are detected and assessed by a method with a combination of explicit and implicit elements. A structured trigger tool enhanced implicit retrospective chart review by the expert panel consisting of a pharmacist and a physician. The pharmacist and physician knowledge was meant to be complementary. Furthermore, causality and severity assessment of ADEs was structured using a 3 point scale based on the WHO-UMC system and a 5 point scale of the CTCAEv3 criteria.

In Chapter 5.2 the results of the pre-measurement of the WINGS study are described. In 250 elderly patients 269 ADEs were found. Of those ADEs 50.2% (135 ADEs) was considered preventable, i.e. caused by medication errors. Underlying medication errors were most often identified as omissions in prescribing an indicated drug, prescribing the incorrect dose (for example by not taking renal function loss into account), prescribing contra-indicated medication, and prescribing the wrong drug for the indication. Most frequently encountered drug induced harm was electrolyte disturbances, hemorrhage, central nervous system effects (like delirium), hypotension/bradycardia, delayed recovery after an infection or sustained infection, and renal insufficiency/raised creatinin. The drugs causing electrolyte disturbances were mostly diuretics/RAAS inhibitors; causing hemorrhage were coumarins, anti-platelet medication and omissions of gastroprotective medication; causing central nervous system effects were opiates, benzodiazepines, and beta-blockers; causing hypotension/bradycardia were betablockers diuretics and digoxin; causing delayed recovery after an infection or sustained infection were antibiotics; and causing renal insufficiency/raised creatinin were antibiotics, NSAIDs, RAAS inhibitors, and diuretics.

In the general discussion in Chapter 6 the results of the previous mentioned chapters are discussed in a broader context. In this chapter we focus on:
1. The three foci of measuring medication-related problems and their methodological aspects.

2. General comparison of the results obtained with the three measurement methods.

3. Implications for clinical practice and recommendations for future research.

In conclusion, elderly hospitalised patients form a patient group that is at higher risk for medication related problems compared to younger patients. In order to measure medication related problems in hospitalised elderly and to ultimately improve their pharmaceutical care we examined three possible levels of measurement one can choose. These three levels of focus (systems, process, and outcome level) were practiced in three measurement methods. As a starting point in an improvement trajectory a systems approach using the prospective risk analysis method with the Bow-Tie model is recommended. For periodical quality of care measurement and less resource intensive research it is best to use explicit process measures like our QIs (or the original ACOVE QIs). For research in which resources and time are not scarce and measuring actual patient harm is of importance, the ADE measurement method of our WINGS study is the best choice. Whereas explicit process measures, like our indicators, facilitate comparison of results of other studies using the same or comparable indicators, results of studies reporting ADEs should be compared with utmost caution. Based on the results from all three measurement methods in this thesis it can, however, be concluded that the quality of pharmaceutical care for elderly patients is still poor and needs improvement.