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

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General discussion
Introduction

Pharmaceutical care is an essential component of the 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\cite{1-4}.

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. They can be measured at systems level, pointing out latent factors of for example organizational or technical nature that contribute to medication errors or ultimately to medication related patient harm; at process level, for example by counting how frequently a specific process, such as a drug administration, was conducted insufficiently or a therapeutic decision was made incorrectly; or 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 above mentioned foci, and to compare the results achieved in their application.

In this final chapter the comparison of the results of the individual studies is made and the results are placed in a broader perspective. Finally, this chapter will conclude with implications and recommendations for clinical practice and directions for future research.

Measurement of medication related problems in elderly

Medication related problems at admission and typical aspects of the elderly population

Many medication related problems originate from before hospitalisation. Besides having an increased risk for medication related problems, elderly patients present themselves more frequently than younger patients with atypical symptoms (geriatric syndromes), making it more difficult to correctly diagnose underlying 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\cite{1}. Since both geriatric syndromes (like delirium and falls) and ADEs are frequent-
ly found in acutely hospitalised elderly patients we suggested a possible association or sequential time course may exist. Therefore, in Chapter 2, we investigated whether geriatric syndromes were associated with ADEs in acutely admitted elderly patients. In this chapter we confirmed that elderly form a high-risk patient group as over 25% of the studied acutely admitted elderly had an ADE present at admission. We also underscored the importance of taking geriatric syndromes and atypical disease into account because 26% of the patients presented with delirium and 12% with a fall. ADEs were associated with a fall, with non-steroidal anti-inflammatory drugs and diuretics, but not with pre-existing functioning, delirium or older age. And, when focusing only on ADEs caused by psychoactive drugs, a fall just before hospitalisation, antipsychotics and opioids were independently associated with an ADE. To prevent elderly patients from unnecessary admissions, more proactive, preventative initiatives should be undertaken, especially in primary care. This could lead to a timely identification of ADEs revealing themselves as an atypical illness presentation, namely with a fall or delirium as a geriatric syndrome, or could even lead to the prevention of acute hospital admission. Additionally, geriatric syndromes presenting in hospital patients need a more systematic and holistic approach to recognize them in time as potential ‘atypical’ presentations of an ADE. Geriatric syndromes, especially falls, may indicate important warning signs and thus may require additional evaluations to understand potential underlying pathological processes, like the use of harmful medications.

Medication related problems during hospital stay

Three foci and their methodological aspects

Medication related problems can be measured at three levels.

1. At systems level. The goal of this approach is to point out structural risk factors (in the organisation) that can lead to medication errors or ultimately to an ADE (and hence patient harm). Prospective risk analysis methods have a systems focus and can be used for detecting ‘gaps’ in the medication-use process that contribute to medication related problems and incidents. One of the benefits of this approach is the determination of so-called ‘latent conditions’ of organizational or technical nature that contribute to an increased risk of medication related harm (for example under-staffing, ineffective safety checks or an insufficient training program for new employees). When these latent factors are resolved or improved, potentially numerous medication incidents and a large amount of patient harm can be prevented on a structural basis. In Chapter 3 we describe the adaptation of the Bow-Tie model for prospective risk analysis in medication safety in hospitals. This
model, already well-known in petrochemical and aviation industry, was applied on the medication-use process in two hospitals. We defined a recommended procedure for application of the model. By using a multidisciplinary panel, by specifying and prioritizing patient group or department 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. Although we did not specifically focus on elderly hospitalised patients in this chapter, multiple risk factors for medication errors and medication related harm for the hospital patient population in general were found that also apply to the elderly patient. Latent conditions in the medication-use process apply to almost all patients; it is the combination of a specific incident with the patient type and drug type that defines the consequential harm. As elderly patients are less resilient than younger patients (as mentioned earlier due to multimorbidity, pharmacokinetik and pharmacodynamic changes, polypharmacy, cognitive, social and functional limitations) and often receive complex care, extra safety barriers or strengthening of existing barriers should be considered to prevent or to mitigate harm. The Bow-Tie model can assist in this effort. Furthermore, the system is of influence on processes and outcomes. A bad organisational structure will lead to processes that are conducted wrongly and ultimately to bad outcome like patient harm. By identifying and improving these organisational weaknesses or latent conditions, many medication errors of diverse nature and bad patient outcomes like adverse drug events can be prevented. For this reason, and also because of the multidisciplinary awareness, the Bow-Tie model can be best used as a starting point in an improvement trajectory.

2. At process level. Processes can be amended and measured more easily than outcomes can. Also, in contrast to outcomes, process indicators do not need to be adjusted for potential confounders. Process indicators, consisting of a nominator and denominator, can be defined in a meticulous selection process using scientific evidence and expert opinion. These process indicators can be phrased very explicitly, thereby reducing subjective judgment when applied on medical patient information. This results in good kappa values for interrater reliability. Furthermore, due to this aspect, several indicators can be scored in a relatively small amount of time with no necessary expert knowledge. Hence, this aspect also enables the use of non-physicians or non-pharmacists to score process indicators. Also, the principle of process indicators offers an opportunity to carefully define a comprehensive selection of different areas on which the indicators focus with no limitation on the number and content of indicators.

The ACOVE quality indicator (QI) set, developed in 2001 by RAND/UCLA,
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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\(^5\). 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 showed that these process indicators have formed the basis for many studies that could be categorized in two main themes: studies that applied the QIs to measure quality of care and studies that described the development and feasibility of QI sets. The ACOVE QIs inspired various applications (mostly for the assessment of quality of care) and hold promise of forming a common ground for aligning diverse research efforts.

The original ACOVE QIs were developed to assess overall quality of care of community dwelling elderly in the US healthcare setting. To be able to assess the quality of pharmaceutical care of hospitalised elderly in the Netherlands we developed a new valid and reliable QI set based upon the original ACOVE QIs (Chapter 4.2). Our QI set consisted of 87 indicators of which 49 were ACOVE and 38 were newly added. We have further improved both feasibility and reliability in comparison to the original ACOVE QIs by making patient or caretaker interviews to score the indicators of our set unnecessary. The inter-rater agreement kappa values ranged from 0.85-0.88, hence showing almost perfect agreement.

3. At 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. However, as mentioned earlier, in contrast to processes, outcomes are less amendable and more difficult to measure and generally have to be adjusted for potential confounders. 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. Especially ADEs that are caused by medication errors are important because of their preventability. As opposed to unpreventable ADEs (adverse drug reactions (ADRs) or side effects), that occur during normal and correct use of medication as a result of an unavoidable pharmacological effect, preventable ADEs are associated with substantial morbidity, increased mortality, a longer length of stay in hospital and increased costs\(^6-8\).

In Chapter 5.1 we describe the research protocol of the WINGS study, a multi-
centre study to assess reduction of ADE incidence in elderly internal medicine patients by on-ward pharmacy services. We chose a clinical outcome (ADEs) as a primary endpoint because only a few studies had investigated the effect of on-ward pharmacy services on clinical outcomes[9]. Furthermore, limited data exist regarding ADE incidence in elderly in the inpatient setting although elderly patients have a higher risk of experiencing an ADE.

While measuring preventable ADEs has the benefit of giving an idea of the actual preventable harm that was caused by medication related problems, it is their measurement that has its drawbacks. The golden standard for ADE detection is screening of medical records by research workers and subsequent review of suspected records by an expert panel. This expert panel usually decides by consensus whether an ADE occurred, judges on the type of ADE and estimates the severity. This strategy is laborious and due to the fact that it relies on subjective clinical judgment, it is notorious for its lack of reproducibility and its poor inter-rater agreement. However, for ADE measurement strict explicit algorithms or rules like the process indicators we used in Chapter 4 cannot be applied as strict algorithms like these process indicators hamper sensitivity in ADE measurement[10]. For ADE detection clinical judgment by experienced experts is necessary, thereby accepting a more laborious and implicit method. However, a combination of both an implicit clinical judgment and an explicit decision algorithm can improve results[11]. In the study method we describe in Chapter 5.1 we combined the necessary implicit clinical judgment by experts in order to achieve sufficient sensitivity with an adapted version of the explicit structured causality assessment system used for adverse drug reactions by the WHO-UMC[12].

General comparison of results of three measurement methods

At systems level

The application of the Bow-Tie model for prospective risk analysis in the medication-use process in two hospitals gave insight into many hospital wide risks that affect all patients (Chapter 3). As mentioned earlier, those general risks impose potentially more danger for elderly patients due to their vulnerability and lesser resilience compared to younger patients. Prescription errors, prescribing the wrong drug for the indication but also prescribing the wrong dosage, were considered to be one of the main risks in the medication-use process. Compared to younger patients, prescribing the correct indicated drug for elderly is more challenging due to multi-morbidity and sometimes conflicting guidelines and therapy for co-morbidities. Furthermore, prescribing the correct dose
is more complex because of the need to frequently adjust the dose due to organ function loss (kidney, liver) or increased effect by pharmacodynamic sensitivity. Pro-active on-ward participation of a hospital pharmacist was considered an important safety barrier that should be implemented in the future. The effect of that future safety barrier on ADEs in elderly was examined in the WINGS study. In this thesis we describe the research method of the WINGS study (Chapter 5.1) and the results of the baseline measurement (Chapter 5.2).

Another large risk from patient transfers (between different care settings, admission and discharge, between care takers) and information exchange about medication. Continuity of care and continuity of information is very important in order to provide safe and correct pharmaceutical care. It is well-known that patient transfers pose a great risk for error and information loss\cite{13-14}. For this aspect too, elderly are at higher risk due to polypharmacy, their complex care, due to multiple treating medical specialists and sometimes multiple care institutions that concurrently or consecutively care for a patient. Furthermore, elderly sometimes have to cope with cognitive impairment and social isolation making it more difficult for the patient to manage his/her medication use. Hence, all the more reason for healthcare providers to address this issue, especially since the elderly patient group will continue to grow. The importance of continuity of care is further underscored by the fact that it forms one of the four main domains of care on which our quality indicator set focuses (Chapter 4.2 and 4.4.).

At process level

ACOVE QIs formed the starting point for many studies in which quality of care for elderly was assessed. In those studies the original ACOVE QIs or adaptations thereof were used to gauge whether the minimally accepted care for one or more specific conditions was delivered. Our systematic review (Chapter 4.3) showed that in 17 studies published after the development of the ACOVE criteria measured quality of care for elderly was still relatively low. Also, when we applied our ACOVE-based QI set in a Dutch elderly patient population we showed that the quality of in-hospital pharmaceutical care for elderly was insufficient (Chapter 4.4). Patients received an average of 42.9% of the care recommended by the indicators. Especially, in order of magnitude, in the domains of continuity of care (median pass rate of only 20.3%), monitoring of drug therapy (median pass rate of 37.3%), and prescription of indicated medication (median pass rate of 63.6%) we showed that there is a strong need to improve the quality of care. These results are worrisome as the ACOVE and our criteria represent the minimal standard of care. The findings about continuity of care and prescribing indicated medication correspond to the main risks found in Chapter 3.
At outcome level

In Chapter 5.2 the results of the baseline 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, prescribing contra-indicated medication, and prescribing the wrong drug for the indication. These findings are in line with the main risk found in our study focusing on the medication-use process in Chapter 3 (prescribing the wrong drug and dose), and one of the three out of four domains in pharmaceutical care that our QI set pointed out as insufficient and needing improvement in Chapter 4.4. However, whereas the QI set gave insight into specific therapy that was omitted (calcium and bisphosphonates for osteoporosis; secondary prophylaxis of a transient ischemic attack with thrombocyte aggregation inhibitors) the screening of patient records for ADEs pointed out apparent ‘harm’ that a patient suffered from. Most frequent were electrolyte disturbances, hemorrhage, central nervous system effects (like delirium), hypotension/bradycardia, delayed recovery after an infection or sustained infection, and renal insufficiency/raised creatinin. This difference in findings can be explained by the focus of each measurement method. The QIs of Chapter 4 tested whether a clinical rule was followed, thus whether the process was conducted correctly or erroneous. The results of such a method will give insight into medication related process errors. This in contrast to screening records for ADEs where one will get insight into harmful medication related outcomes and less about the underlying preventable errors, unless one specifically examines causality and preventability. Causality and preventability, however, were part of our screening method described in Chapter 5. Hence, our ADE measurement method of the WINGS study made it possible to define the medication that was related to an ADE and its underlying medication error. For the earlier mentioned ADEs that had the highest incidence, the most involved medication was: diuretics/RAAS inhibitors causing electrolyte disturbances; coumarins, anti-platelet medication and omissions of gastroprotective medication causing hemorrhage; opiates, benzodiazepines and beta-blockers causing central nervous system effects; betablockers, diuretics and digoxin causing hypotension/bradycardia; the omission of antibiotics causing delayed recovery after an infection or sustained infection; and antibiotics, NSAIDs, RAAS inhibitors and diuretics causing renal insufficiency/raised creatinin. Therapy of elderly with these drugs should therefore receive extra attention and should be monitored carefully.
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Conclusion

Elderly hospitalised patients are indeed a patient group that is at higher risk compared to younger patients for medication related problems. In order to measure their medication related problems and ultimately improve the quality and safety of pharmaceutical care we examined three levels of measurement focus. These three levels of focus (systems, process and outcome level) were practiced in three measurement methods. We did not only describe the development and characteristics of the three measurement methods, but also the results found.

With respect to the aim of this thesis we can conclude that each focus of measurement has its unique characteristics. This is reflected in the general results obtained with each method and the indications for improvement one obtains. Therefore it is necessary to choose a measurement method bearing the aim of a quality improvement project or research study in mind. Furthermore, the use of two or more methods could also be an option, as the methods can be complementary. It can be said that the best and most complete picture of the quality of pharmaceutical care can be obtained using aspects of the three approaches. However, based on our studies recommendations on applying the individual measurement methods can be given. As a starting point in an improvement trajectory a systems approach using the prospective risk analysis method of 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). The QIs can be applied at low cost and because of the explicit phrasing no experts are needed to conduct the measurements. Furthermore, by using process measures one will acquire insight into tangible parts of processes that need improvement which thereafter can be amended swiftly. For research in which resources and time are not scarce and measuring actual patient harm in detail is of importance (such as in a study that examines the effect of a specific intervention on patient outcomes), 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 due to differences in applied criteria and definitions.

Despite the differences in characteristics of each applied measurement method, the results of the three methods were in concordance regarding the fact that the quality of (pharmaceutical) care for elderly patients is still poor and needs improvement.

Based on the results discussed in this thesis, we summarize implications for clinical
practice and provide suggestions for future research, all in order to improve quality of pharmaceutical care of the elderly and to reduce medication related problems.

Implications for clinical practice and medication related problems research in elderly

- Elderly patients are a patient group at higher risk for medication related problems. Due to the growing number of elderly and their increasing age healthcare should focus on safer care for these patients.

- To prevent elderly patients from unnecessary admissions more proactive, preventative initiatives should be undertaken, starting in primary care. This could lead to a timely identification of ADEs revealing themselves as an atypical illness presentation, namely a fall or a delirium as a geriatric syndrome, or even to prevention of an acute hospital admission.

- As geriatric syndromes, especially falls, may indicate important warning signs for underlying problems with medication, they need a more systematic and holistic approach to recognize them in time as an atypical presentation of an ADE.

- (Internist-) geriatricians and hospital pharmacists are the obvious professionals to deliver this care. Collaboration between these two groups is necessary.

- When an elderly patient presents his or herself with atypical disease during acute admissions, ADEs should be considered as a differential diagnosis.

- In measurement of medication related problems in elderly patients and the subsequent definition of improvement strategies there are three options for focus: at systems level, at process level, and at outcome level

- Use prospective risk analysis utilizing the Bow-Tie method as a starting point to align/focus improvement projects in a multidisciplinary fashion (systems level).

- For periodical quality of care measurement and relatively less laborious quality of care measurement as part of studies QIs are well suited. Due to their explicit phrasing, ACOVE like QIs could be automated using IT making their application even less resource intensive (process level).

- Due to the laborious nature of ADE measurement it is more suitable for research
purposes than for general periodical quality measurements. It is the most clinical
relevant measure as it reflects actual patient harm due to medication. The lack
of reliability in ADE measurement and judgment, however, forms an important
drawback (outcome level).

- There is an opportunity to use ACOVE(-based) QIs pro-actively to steer health-
care professionals to deliver the right care at the right time; for example by
incorporating the QIs in clinical decision support tools.

- Pharmaceutical in-hospital care for elderly in the Netherlands, as measured with
our QI set, but also the care for elderly in general internationally, is insufficient.
Continuity of care, medication monitoring and prescribing indicated medication
should be improved.

- ADEs occur frequently in Dutch elderly inpatients. On-ward pharmacy services
and a collaborative approach by hospital pharmacist and geriatrician can possibly
reduce the preventable ADEs.

- ADE measurement suffers from poor reliability. Much depends on the ADE
screening method used and subjective judgments, based on clinical opinion, of
experts. Therefore comparison of results between studies should be done with
cautions.

- All three measurement methods, with each a different focus, point out that espe-
cially prescribing indicated medication in the correct dose and continuity of care
for elderly patients need improvement.

Future Research

- Study the proactive application of QIs to directly improve care, for example in
clinical decision support systems to influence and support physicians. It is worth-
while to shift focus from assessment to improvement in the application of QIs.

- Study the application of our QI set in one or more larger cohorts of elderly hospi-
talised patients for further validation. This can possibly result in further selection
(and thus also discarding) of indicators based on eligibility. Furthermore, a more
reliable image can be gained about the quality of in-hospital pharmaceutical care of
the Dutch elderly patient.
• Study the effect of collaborative hospital-pharmacist and (internist-)geriatrician lead improvement initiatives on the quality of care for elderly, especially focusing on continuity of care, prescribing medication, medication monitoring, and acute admissions.

• Study the effect of interventions to increase the awareness of doctors, both in and outside of the hospital, that medication related problems and ADEs can present with atypical symptoms. The effect can be measured by the number of acute admissions due to medication.

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