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

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General introduction
Medication related problems

Each patient expects the best and safest medical treatment when needed. It is the obligation of each caregiver to deliver safe and effective care. “Primum non nocere”, Latin for “first, do no harm”. In real life however, medical care has the danger of causing unintended harm besides serving the patient. In several countries the magnitude of unintended harm has been assessed and confirmed in large multi-center studies. In 1991 researchers from Harvard (USA) published the first in the row of landmark studies[1]. Other countries, such as Canada, UK, Australia, New Zealand, Denmark, and the Netherlands soon followed[2-8]. Medication has shown to be a key factor in the majority of cases of unintended harm.

Pharmaceutical care covers all processes of medical care where medication is applied and in which the pharmacist directly or indirectly plays a role. On of the most commonly applied medical interventions is the application of medication. In general drugs have 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 last but not least can cause (unintended) harm[9-11]. Among medical errors, medication errors make up the largest part and of the medical adverse events (harmful events), adverse drug events (ADEs) are the most frequent type in patients[12]. Furthermore, a considerable part of hospital admissions are related to ADEs[13]. 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 stay, increased morbidity and mortality, and considerable extra costs[11,14,15]. Since pharmaceutical care is an essential component of healthcare; prevention, monitoring and a profound understanding of medication related problems is an important condition for the consecutive improvement of the quality and safety of medical care.

Elderly

The elderly (patient) population will continue to grow in the next decades. Compared to younger patients, patients aged 65 years or older are at a four-fold higher risk for ADEs[16,17]. The following factors play an important role in the vulnerability of this population:

- elderly often use multiple drugs (polypharmacy), thereby increasing the
chance for drug-drug and drug-disease interactions, adverse drug events, or medication errors\textsuperscript{[18]}. 

- due to physiological changes, elderly often have altered pharmacokinetics and pharmacodynamics, necessitating individual drug dose adjustments.

- elderly often have multiple co-morbidities (conditions). These conditions may influence each other and influence each other’s indicated drug therapy. Due to this multi-morbidity several guidelines can be applicable to a patient and may conflict in drug therapy recommendations. Individual drug therapy adjustments are often necessary.

- elderly are treated concurrently by several medical specialists. Each doctor focuses on the care and drug therapy concerning the morbidity in which he/she is specialized\textsuperscript{[19]}. A general overview for every elderly patient is often lacking, despite the fact that many hospitals structurally have employed geriatricians.

- elderly can suffer from cognitive, social and functional problems, further increasing the risk for medication related problems. For example, if such an elder is not able to distinguish his/her medication anymore or is not able to remember the correct use of their medication.

- elderly often transfer from one care setting to the other (hospital-nursing home, hospital-home) thereby increasing the risk for drug therapy information errors and consequently medication errors and adverse drug events. Continuity of care is an important point of attention\textsuperscript{[20-22]}.

Measuring quality and safety of pharmaceutical care

There is an abundance of studies in the field of medication safety research. Especially since the nineties of the 20th Century, after the worldwide attention for patient safety after the publication of the Institute of Medicine’s report ‘To err is human\textsuperscript{[23]}, there has been a strong increase of medication safety studies. Furthermore, there is an increasing obligation to measure quality and safety. Firstly, issued by professional societies for benchmarking between institutions; secondly, by the health inspectorate for gauging whether minimal standards of care are met; and thirdly, by health insurance companies for evaluation of key hospital data and possible financial consequences. Several interventions have been developed and applied in order to improve the quality of pharmaceutical care. To measure the effect of these interventions on medication safety the application of the right measurement method is essential. In order to facilitate the right
choice for a measurement method an overview of the main foci of approach and their pros and contras is needed.

Taking Donabedian’s (figure 1) framework in mind one can postulate that there are

three different types of focus in measuring medication safety: a focus on the system (the structure), a process focus, and a focus on outcome. The model shows how the three parts of the triad are related and how outcomes are influenced by structure and processes.

In a systems focus the subject is the structure of the organisation, e.g. the manner in which the care processes are organized, the material resources (such as equipment), and the human resources (such as staffing, education). This focus is the least well-known of the triad. It examines how the system evokes people to make medication errors and ultimately cause patient harm. In most cases a person never intended to make an error, the system made it possible for this person to make the mistake. The paradigm shift of looking at the system in stead of the individual (systems approach versus persons approach) has been introduced in health-care in the last decade, taking the petrochemical and aviation industry as examples and learning from their experience in creating a safety management system. Incident reporting and analysis, an example of a systems focus and a fundamental part of a safety management system, has already been widely spread in healthcare. The experience with prospective risk analysis, generally a structured method combined with implicit experience-based input, as an adequate method to measure medication-related problems and risks is however more limited.

When considering a process focus, the ‘process’ is the actual conduction of care activities, such as prescribing medication and diagnosing disease. Most medication safety literature has a process focus. Medication errors, as errors of commission or
omission in the conduction of tasks as prescribing and administering medication, are mostly reported. Medication errors can be relatively easily detected and measured using explicit criteria and have therefore been frequently used as a measure in studies. However, medication errors have the disadvantage of the difficulty to estimate their (potential) severity. The question which part of the detected errors would ultimately have led to patient harm is not an easy one to answer.

Finally, outcome denotes the effects of the care activities on the patient’s health. Besides medication errors, many medication safety studies focus on ADEs. ADEs are a measure of outcome: actual patient harm caused by medication. Although ADEs are the most relevant measure and the best option to measure what has actually happened to the patient (did he/she benefit or did he/she suffer harm), the golden standard of ADE measurement demands a laborious review of patient record combined with implicit expert judgment. Expert panel ADE judgment is known for its reliability issues[25,26].

In addition, one can characterize measuring methods as implicit, explicit or as a combination thereof. Explicit criteria are generally applied as rigid, objective ‘black and white’ standards. Explicit methods allow little to no room for subjective interpretation and exceptions. Therefore it can be possible that specific cases are judged unjustly as incorrect. However, explicit methods can achieve very good reliability and can be implemented at low costs. Pure implicit measurement methods rely on clinical judgment, are time-consuming and costly. They generally lack a consensus-based structure. It is more difficult to obtain reliable and valid results using pure implicit criteria, however it allows individualized assessment in exceptional patient cases. The combination of both explicit and implicit criteria could result in a method that has the advantages of both strategies: a method that is objective and structured where possible, but at the same time provides the reviewer the opportunity to apply clinical judgment if necessary[24-26].

Hence, the three foci of measuring medication-related problems (system/process/outcome) have their own characteristics and their advantages and disadvantages.

Objectives of this thesis

The aim of this thesis is to describe the development of three measurement methods, each with a distinct focus (system, process and outcome), for medication related problems in elderly hospitalised patients and to compare the results achieved in their application.
Outline of this thesis

This thesis contains seven chapters. In this introductory chapter (Chapter 1) the general introduction, the objective and outline are described.

Chapter 2 details the elderly patient population and addresses the issues of acute admissions, medication related problems, and geriatric syndromes as a preceding chapter of the thesis. It describes a prospective cohort study aimed to investigate whether geriatric syndromes (atypical symptoms like falls or delirium) presented just before or at hospitalisation are associated with ADEs in acutely admitted elderly medical patients.

Chapter 3 focuses on one of the three foci of measurement of medication related problems in elderly: measuring at systems level. In this chapter we describe the development and application of prospective risk analysis method for medication safety.

Chapter 4 describes measurement of medication related problems at process level using explicit quality indicators (QIs). The Assessing Care of Vulnerable Elderly (ACOVE) quality indicators were developed in 2001 and were the first very comprehensive set of explicitly phrased quality indicators meant to measure the quality of care of various relevant conditions and processes of the care for elderly. The ACOVE QIs are unique among other methods for measurement of medication related problems in elderly because of their comprehensibility, their explicit phrasing, their reliability, their attention for undertreatment, and in that they reflect the minimal level of expected care.

Chapter 4.1 describes a systematic review in which we reviewed literature to examine and analyze the various ways the ACOVE QIs have been applied in medical science since their introduction over a decade ago. The studies found were categorized within a comprehensive thematic model.

In Chapter 4.2 we describe a study in which we developed a new QI set to assess the quality of pharmaceutical care of hospitalised elderly in the Netherlands based on the original ACOVE QIs.

Chapter 4.3 is a systematic review in which we aimed to summarize and analyze all studies that assessed the quality of care using QIs from or based upon the ACOVE in order to evaluate the state of the quality of care for the reported conditions.

In Chapter 4.4 we describe a study in which the quality of pharmaceutical care of 200
hospitalised Dutch elderly was assessed using the QI set described in Chapter 4.2. Furthermore, in this chapter we also assess whether an association exists between measured quality of care and the QIs, mortality, and readmissions.

Chapter 5 focuses on measurement of medication related problems at outcome level (ADEs).

In Chapter 5.1 we describe the research protocol of the WINGS study, a multicentre study to assess reduction of ADE incidence in elderly internal medicine patients by on-ward pharmacy services.

In Chapter 5.2 the results of the baseline measurement of the WINGS study are described.

In Chapter 6 the results presented in this thesis are discussed in a broader context. Implications for clinical practice and recommendations for future research are provided.

In Chapter 7 the summary is provided.

References

9. Barber ND, Dean BS. The incidence of medication errors and ways to reduce them. Clin


