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Discrepancies between home medication and patient documentation in primary care

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1. Introduction

Medication Reconciliation is defined by the World Health Organization Collaborating Centre for Patient Safety Solutions as a process, designed to prevent medication errors and includes creating the most accurate medication list, comparing the list, updating the list and communicating the list to the next provider of care.[1] The aspect of comparing medication lists usually is the first step at a Medication Review or Medication Management and might lead to the detection of discrepancies, which indicate first drug-related problems and can result in potential patient safety interventions.[2] In the international context, the approach to Medication Reconciliation varies. The Australian Home Medicines Review for example is conducted in the private environment of the patient and includes further aspects of a Medication Review.[3] A Brown-Bag Review usually is performed in a pharmacy or practice and does not necessarily include Medication Reconciliation. Nathan et al. used a Brown-Bag Review for patient information.[4] A Brown-Bag Review at the healthcare provider's office or pharmacy carries the risk that the patient conveys only selected drugs. In a study by Sarzynski et al. this happened in the majority of cases (61%).[5] Reconciliation of the drugs actually taken by the patient with the drugs documented by the primary care physician is the general concept behind any Medication Reconciliation; collaboration of pharmacists and physicians thus is a crucial point.[6] Medication Reconciliation is widely implemented in standard care in the United States and Canada.[7] International studies have revealed the importance of Medication Reconciliation as most patients' medications do not comply with their physicians' prescription.[8–11] Frequency and intensity of detected discrepancies have been described in well over 95 studies with a great variability of classification systems.[12] The transition of care and discharge from hospital care are typical settings for Medication Reconciliation studies.[11,13–16] No study on Medication Reconciliation in ambulatory care, and reconciliation of home recorded medications with records documented by primary care physicians, could be identified. Data for Medication Reconciliation in the German health-care system is scarce.

The aims of this study were to provide comprehensive real-life data on Medication Reconciliation in ambulatory care and for multimorbid patients with polypharmacy on 1) the number of discrepancies between a primary care physician's documentation and the actual drug intake of the patient at home, 2) any patterns and the relevance of the divergent drugs, 3) whether detected DRPs can be linked to the divergent drugs in the specific patient case.

2. Methods

2.1. Data source

Analyses were based on the controlled cluster-randomized "Westphalian study on a medication therapy management and home care based intervention under gender specific aspects in elderly multimorbid patients" (WestGem), which tested a comprehensive and collaborative Medication Management as a complex intervention.[17] The study was conducted from July 2012 until June 2015 in 2 regions in North Rhine-Westphalia, Germany and was funded by the European Union and the state of North Rhine-Westphalia (Ziel 2, IuK & Gender Med.NRW, GW 2076). Patients who met the following criteria and who had given written consent to participating in the study were included:

Inclusion criteria.

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- Age ≥65 years
- A minimum of 3 chronic disorders affecting 2 different organ systems
- At least 1 cardiovascular disease
- At least 1 visit to the primary care physician in each of the preceding 3-month intervals
- Five or more long-term drug treatments (>3 months) with systemic effects
- Ability to complete questionnaires, with assistance if required

Exclusion criteria.

- Life expectancy of less than 12 months (assessed by the treating primary care physician)
- Participation in another clinical study

A detailed description of the WestGem study and published study protocol can be found elsewhere.[18] The study was entered into the current controlled trials register (ISRCTN41595373). The ethics committee at the Medical Association of Westphalia-Lippe (AKZ-2013–292-f-s) approved the study.

2.2. Data collection

Pseudonymized data were collected by using standardized and pre-tested instruments. Demographic data, diagnoses, morbidity, laboratory data and medication were noted in a case report form (CRF) by the physician or a study nurse. The actual medication taken was assessed by home-care specialists in the private environment of the patient in lieu of the pharmacists, who were restricted in personal contact to the patients due to funding regulations. Home-care specialists, who held a degree in nursing and social sciences, were engaged by municipal authorities. They were experienced in patient assessments and trained in medication aspects before and during a pilot phase. To ensure a similar quality, a standardized assessment questionnaire was developed, tested and provided by pharmacists and home-care specialists. The assessment covered the drug name, strength and identification number, prescriber, dosage, timing, indication, handling and potential splitting. Further questions were developed on potential adverse drug events, and addressed falls, pain, vertigo, chief complaints, social support, resilience and obstipation. Results were entered into a specified form and sent to the pharmacists.

2.3. Medication reconciliation and assessment

Reported actual medications taken and physician's medication lists documented in the CRF were reconciled by clinical pharmacists with expertise in Medication Management. Results per patient were documented in a database, developed during a pilot phase. Drugs were subsequently classified based on the Anatomical-Therapeutic-Chemical (ATC) code, identified discrepancies were recorded and drugs were highlighted if they were not covered by the primary care physician's documentation. Only discrepancies in the active ingredient were counted, discrepancies in dosing and handling were not added in this study, even if they were detected.

To estimate the relevance of divergent drugs, 3 categories were compiled. These were the risk for hospitalization, the risk for falls and the risk for potential drug-drug interactions. Evaluations were dichotomized as “low risk” or “high risk”. Based on a study by Nathan et al., indication clusters were formed.[4] Risk for hospitalization was based on studies of van der Hooft et al. and Budnitz et al.[19,20] The risk of falls was based on certain information of the PRISCUS-list and the Beers criteria[21,22] as well as on the following studies and reviews. Shuto et al. found blood-pressure lowering agents, Parkinson drugs, anxiolytics and hypnotics as a frequent cause of falls.[23] Woolcott et al. concluded benzodiazepines and antidepressants as very likely to increase the risk of falls and added blood-pressure lowering agents and antipsychotics as less likely.[24] Hartikainen et al. included SSRIs as high risk drugs but stated that anticonvulsants and blood-pressure lowering agents might carry only a moderate risk.[25] Antihistamines with their sedating effects and long half-lives are very likely to increase the risk of falls as well.[26] Table 1 contains the references per category, which were utilized in assessing the drugs.

Table 1
Literature for evaluation of risk categories.

Risk category	Drugs/drug classes rated as high risk	Underlying literature
Risk of hospitalization due to adverse drug reactions	anticoagulation drugs, digoxin, cytostatics, diuretics, insulin, oral antidiabetics carrying risk of hypoglycemia, NSAIDs and DMARDs	van der Hooft et al.[19] Budnitz et al.[20]
Risk of falls	antidepressants, antihistamines, benzodiazepines, Parkinson drugs	Shuto et al.[23] Woolcott et al.[24] Hartikainen et al.[25] PRISCUS-List[21] Beers criteria[22]

Drugs likely to cause relevant drug-drug interactions were more difficult to define. In this study a specific drug-drug interaction checker (ABDA-database) was used to search for interactions but detected interactions were always limited to a pair of drugs.[27] Clinical experience was requested in pondering clinical relevance. In uncertainty, general literature on interactions was consulted and results of clinical studies were included into decision-making.[28–32] Classification of DRPs was done according to the Pharmaceutical Care Network Europe (PCNE) DRP-classification system 6.2.[33]

2.4. Statistical analysis

Included in this study were all 142 patients of the intention-to-treat (ITT) collective, for whom the actual medication taken was assessed. The secondary analysis of this elaboration considered the baseline assessment of the WestGem study and was descriptive (Table 2). Besides demographic patient data, the frequency and number of discrepancies between the medication, documented by the primary care physician and the medication in use was analyzed. Drugs that were not documented by the primary care physicians were further assessed on the mentioned risks and whether any actual DRPs were related to the drugs. Divergent drugs were allocated to 5 indication clusters for further interpretation. Analyses were stratified to gender, age and whether a Medication Plan was issued by the physician. The latter was done assuming that special care on the medication was provided in patients with a Medication Plan. Age was stratified according to the following classes: <70, 70–79, 80–89 and ≥ 90 years. Analyses were done using SPSS Statistics 23 (IBM Corp, Armonk, NY, USA) and STATA 14 (StataCorp, College Station, Texas, USA).

3. Results

3.1. Patient characteristics

The study collective consisted of the ITT population with 142 patients from 12 primary care practices (70 invited, 12 signed in). The patient collective was drawn as a random sample. Practices prepared a list of 856 eligible patients, 480 were asked to participate. As a result, 162 patients signed in (4–24 per practice). The

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