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## Background Paper

# Improving medication safety in primary care. A review and consensus procedure by the LINNEAUS collaboration on patient safety in primary care

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### KEY MESSAGE:

- Medication safety is an issue of major concern in primary care.
- Most promising interventions to achieve optimization are clinical decision support, interprofessional collaboration between general practitioners and pharmacists, and tools to improve safety culture.

### ABSTRACT

**Background:** Drug treatment is an important clinical process in primary care that is associated with risk of error and adverse events.

**Objective:** To review currently available research evidence on the topic and to develop a framework, which can help to guide improvement of medication safety.

**Methods:** Systematic reviews were performed on adverse drug events (ADE), their preventability, and on available tools and methods to improve medication safety with a particular focus on information technology. Consensus methods were used to develop a framework to guide the improvement of medication safety based on the findings of our literature review.

**Results:** The median prevalence rate of ADEs in primary care patients was 12.8%. Only a median of 16.5% of ADEs were preventable and thus could be classified as medication errors. Our review of information technology interventions found that only about half of the studies found a reduction of medication errors. In both reviews, the wide range between studies emphasizes the necessity of a validated medication error classification system. Another important aspect of medication safety appears to be a general lack of safety culture in primary care, which led us to the development of the Salzburg medication safety framework (SaMSaF), based on the MaPSaF tool to improve patient safety. The tool proved to be feasible and useful in a pilot study with several GP practices.

**Conclusion:** A number of tools and interventions to investigate and enhance medication safety have been identified. Further research is necessary to implement and evaluate current concepts.

**Keywords:** Medication safety, adverse drug events, patient safety, primary care, literature review, LINNEAUS collaboration

### INTRODUCTION

Improving safety of medication use has become an important topic, not only in the hospital, but also in primary care. Due to the high frequency of drug prescriptions in primary care, the absolute number of adverse drug events (ADEs) is high, despite lower risk as compared to

the hospital setting. Adverse drug events have been reported to occur at a rate of up to 25% of patients, underlining the necessity for improvement (1). However, we know little about the causes and preventability of these ADEs. Interventions involving information technology (IT) and pharmacist-led interventions may play an important

role to improve medication safety, but their impact seems inconsistent and overall moderate (2).

A systematic review on the evaluation of outpatient CPOE (computerized provider order entry) systems concluded that evidence for the effectiveness of these systems in outpatient settings is lacking (2). A systematic review including 38 studies revealed that pharmacist-led interventions were effective in reducing hospital admissions, although the effect sizes were small (1).

Bearing in mind the lack of an overall systematic approach to medication safety in primary care, we aimed to review and collate the current knowledge on medication safety in primary care, and to develop frameworks, which guide improvement in this area.

## METHODS

In the context of the LINNEAUS collaboration project, we performed a systematic review of studies on the prevalence and preventability of adverse drug events in ambulatory care, which was published in 2011 (3). We also conducted an observational study in Austrian general practices to document the types and frequency of medication errors in primary care patients with polypharmacy (4).

Epidemiological data on adverse drug events and medication errors are difficult to interpret because different definitions and methods are used in studies. Therefore, we set out to develop a consensus statement of definitions in patient safety terms and to develop a classification system that is valid and useful for medication incident classification in primary care. We identified the existing types of interventions and currently used tools to improve medication safety in primary care in Europe in an extensive literature search (search up to 2009) (3). As many interventions used information technology (IT), we conducted a second systematic review on IT interventions targeted at the improvement of medication safety in primary care (5).

Finally, we developed a standardized workshop, the Salzburg Medication Safety Framework (SaMSaF), based on the MaPSaF-tool to improve medication safety culture (6,7).

In this paper, we report on our review of the epidemiology of ADEs, the framework that we used to classify ADEs, interventions to improve medication safety and a measure to assess safety culture in relation to medication use.

## RESULTS

### *Epidemiology of adverse drug events and medication errors in primary care*

Our systematic review (3) revealed the following results: The median ADE prevalence rate in ambulatory care patients was 12.8%, with a range from 2.8 to 34.7%. The

median rate of preventable events in all ADEs (pADEs) in ambulatory care-based studies was 16.5%, (versus 52.9% in hospital-based studies), with a range from 11–27.5%. This rate of preventable ADEs decreased with age from a median of 15.8% in children to 13.6% in adults and 9.9% in older patients.

In an observational study in Austrian general practices, we focussed on medication errors rather than adverse drug events and detected a mean of 2.7 medication errors per patient in patients with polypharmacy. These patients took an average of  $9.1 \pm 3.0$  drugs/day, and in 93.5% of the patients, at least one medication error could be detected (4).

### *Definitions and classification of medication incident*

Our systematic review and the large span of prevalence rates—due to different study designs, definitions, denominators, and settings—make clear that epidemiological as well as interventional research in medication safety requires a consensus on definitions and methodology. We therefore developed the following definitions of medication errors/ADEs and pADEs within the LINNEAUS collaboration (6), of which the most relevant are the following:

- NCC MERP definition of medication errors (7): ‘any preventable event that may cause or lead to inappropriate medication use or patient harm.’
- ADE (adverse drug event) definition of Bates et al. (8): ‘An injury resulting from medical intervention related to a drug.’
- Preventable ADE (pADE)—Adverse drug events are injuries resulting from drug use and, therefore, constitute clinical outcomes. Adverse drug events associated with a medication error are considered preventable, whereas those not associated with a medication error are considered non-preventable (9).

Based on these definitions we developed a ‘classification of medication incidents in primary care’ (CMIPC) for usage by general practitioners and pharmacists. The CMIPC included five classification categories (discrimination between ADE and pADE, severity, process level at which the incident occurred, problem type, and main cause) and showed acceptable inter-rater agreement in a validation study with GPs and pharmacists (3).

### *Interventions to improve medication safety*

In our literature search for tools and interventions to improve medication safety in Europe, we identified 16 tools and five educational interventions from nine different European countries, of which the majority were lists of inappropriate medication for the elderly or incident reporting systems.

In the systematic review of interventions to improve medication safety, we focused on randomized controlled trials (RCTs) investigating information technology for the improvement of medication safety (5). This review showed that only in five of the ten RCTs included, a reduction of medication errors was achieved. CDS (clinical decision support) systems were most effective if they focused on a limited number of relevant drugs.

The impact of CDS on the initiation of recommended medication seemed larger than on the discontinuation of inappropriate pre-existing medication (10). Physicians tended to stop the CDS tool or to override alerts if there was poor signal-to-noise ratio (i.e. there were many alerts but only a few of them of clinical relevance), if alerts were judged as irrelevant, or if they were repeatedly shown (11). Alert fatigue appears to be the most probable explanation why computer-triggered alerts were not superior to on-demand alerts. Furthermore, the positive results of pharmacist-led interventions indicate that IT interventions combined with inter-professional communication may be most effective. However, alert fatigue is also a problem in computerized decision support systems used by pharmacists to provide recommendations on drug treatments.

Another finding in our systematic review was that some errors were related to the insufficient reliability of or errors induced by information technology. These errors raise safety concerns that must be seen as a threat to patients by e-iatrogenesis (12).

*The Salzburg medication safety framework*

Our results regarding the limited effectiveness of the tools and educational interventions we studied led to the conclusion that apart from available tools there is a need to strengthen ‘safety culture’ as an important human resource for safety enhancement. We, therefore, developed a tool to improve safety culture in respect to medication safety. The Salzburg medication safety framework (SaMSaF) is based on the Manchester patient safety framework (MaPSaF), which has been developed to address general safety culture in primary care (7,13). We adapted MaPSaF to focus specifically on medication safety. SaMSaF is constructed as a workshop held in a GP surgery and sets out with all members rating the practice’s attitude towards medication safety regarding nine dimensions of quality and safety. The rating extends over five categories from ‘pathologic’ to ‘generative’ (see Figure 1). The surgery staff discusses the ratings, and interventions to improve medication safety in the particular practice are developed by the staff itself. The tool was piloted in three general practices in Salzburg and Bavaria, and results of the pilot tests found SaMSaF to be feasible and useful. Community pharmacists have developed a similar tool for use, and further research should be carried out formally to assess SaMSaF as a potential tool to improve medication safety in primary care (8).

Dimension of medication safety culture	Pathological	Reactive	Bureaucratic	Proactive	Generative
1. Overall commitment to quality					
2. Priority given to medication safety					
3. Perceptions of the causes of medication safety					
4. Investigating medication safety incidents					
5. Learning following a medication safety incident					
6. Communication about medication safety issues					
7. Personnel management and medication safety					
8. Staff education and training about medication safety issues					
9. Team working around medication safety issues					

Figure 1. The Salzburg medication safety framework (SaMSaF). SaMSaF is based on the Manchester patient safety framework (MaPSaF). Practice staff carries out a self-evaluation of their culture for each of the dimensions and rate their status in relation to this. The terms are explained in the original MaPSaF paper (13).

## DISCUSSION

### *Main findings*

The literature reviews, studies and frameworks in this paper highlight the importance of medication safety in primary care and the need to develop effective interventions to improve it. We found a substantial risk of error and adverse drug events in primary care, which translates into high numbers at the national level because of the high number of drug prescriptions in primary care. Computerized prescriber order entry systems with clinical decision support and involvement of pharmacists are two methods to improve medication safety, which can be effective but need to be improved to optimize their impact. Standardization of language is recommended to facilitate further development of the field.

### *Challenges*

One of the most important challenges will be to improve the effectiveness of CDS by reducing the alert burden to only clinically relevant alerts. Decision support systems should provide valid data on safer prescription and should, therefore, be restricted to relevant evidence-based recommendations, avoiding those of minor importance. Comprehensive valid drug databases still need to be developed or improved. Eventually, to further facilitate judgment about risk relative to benefit; CDS may also be required to integrate additional clinical data and laboratory information in order to tailor recommendations to the individual patient (4).

Another important step towards more medication safety may be the improvement of interprofessional collaboration. A recent cluster randomized trial compared the effectiveness and cost-effectiveness of a pharmacist-led IT-based intervention with simple feedback to the physicians in reducing rates of clinically important errors in medicines management in 72 English general practices. The main outcomes of interest were prescribing errors and medication monitoring errors at six and 12 months following the intervention. As a result, the prevalence of prescriptions with prescribing or monitoring errors dropped significantly, with odds ratios between 0.51 and 0.73 compared to the control group (14).

Our somewhat disappointing results regarding the effectiveness of IT-interventions and the work of the LINNEAUS Euro-PC collaboration on safety culture make it very clear that no tool or intervention of any type will be effective without physician and health professional awareness and interprofessional collaboration. A proactive or generative attitude towards patient safety is essential to motivate health professionals to use tools to improve the safety of their patients. Whether these tools comprise IT interventions, educa-

tional outreaches or other approaches, is probably of secondary importance.

## CONCLUSION

Adverse drug events in primary care are one of the most researched areas in relation to improving patient safety in primary care. There are distinct areas where the research evidence suggests that improvements can be made within the primary care setting—for example well-targeted clinical decision support systems. The importance of interprofessional working between pharmacists and general practitioners together with practice based safety culture awareness, using tools like the SaMSaF, cannot be overlooked in improving medication safety in primary care.

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