Pharmacists' Documentation of Interventions in Seamless Care

PharmDISC

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To my lovely family

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LIST OF ABBREVIATIONS

ADE	Adverse Drug Event
ADR	Adverse Drug Reaction
ASHP	American Society of Hospital Pharmacists
CLEO	CLinical Economic and Organisational
COREQ	Consolidated Criteria for Reporting Qualitative Research
DART	Drug Associated Risk Tool
DRP	Drug-Related Problem
ESCP	European Society of Clinical Pharmacy
FIP	International Pharmaceutical Federation
FPH	Foederatio Pharmaceutica Helvetiae
GPP	Good Pharmacy Practice
GSASA	Swiss Association of public health administration and hospital pharmacists
IT	Information Technology
κ	Fleiss' Kappa coefficient
PCNE	Pharmaceutical Care Network Europe
PCRG	Pharmaceutical Care Research Group
PE	Prescription Encounter
PharmDISC	Pharmacists' Documentation of Intervention in Seamless Care
PI	Pharmaceutical Intervention
PMC	Polymedication-check
vs	versus
WHO	World Health Organization

SUMMARY

Patient transition across care settings represent a high-risk period for the occurrence of drug-related problems (DRP), such as discrepancies. These DRPs often result in patient readmission, resulting in higher costs of care in public health. A DRP is commonly defined as an event or circumstance involving drug therapy that actually, or potentially, interferes with the desired health outcomes. In both community and hospital settings, there is evidence that interventions initiated by pharmacists can reduce the occurrence of DRPs. For this thesis, we defined a ‘‘pharmaceutical intervention’’ as a recommendation initiated by a pharmacist in response to a DRP occurring in an individual patient in any phase of the medication process. The pharmaceutical intervention aims at optimising pharmacotherapy, in terms of efficacy, safety, economic, and humanistic aspects.

The exchange of information (e.g. on pharmaceutical interventions) between primary and secondary care remains, however, a major challenge. The access to complete and accurate patient medical information and good communication is essential for the healthcare professionals to ensure safe and efficient care to the patients. In the current practice, the medication management at the time of admission and discharge from hospital is not seamlessly guaranteed through complete documentation and communication of clinical pharmaceutical interventions between inpatient and outpatient care. Seamless care is defined as any process which optimises efficiency, quality, and safety of medication management at transitions to establish a continuum of care.

These pharmaceutical interventions should no longer be loose fragments, but should be brought together like a mosaic in an overall concept and documented in a form that enables the most seamlessly possible exchange of information at the hospital discharge of patient in the outpatient situation. To accomplish this task**,** the **first step** is to document the pharmaceutical interventions in their respective care setting by developing valid structured instruments in order to depict the practice. Such documentation of care represents the evidence of practice. It is therefore essential to be recorded in a standardised and structured manner. Classification, as essential part of documentation, enables a precise representation of what has been done (e.g. pharmaceutical interventions) by categorising key elements in a standardised manner, and as a consequence, facilitates the transfer of information.

Once the pharmaceutical interventions are documented in the respective healthcare setting, the information exchange between the hospital and the community pharmacy and vice versa still remains challenging. Improving information exchange regarding pharmaceutical interventions could enable a more efficient and safer transfer of patients between inpatient and outpatient care. Thus as a **second**

step, an aligned classification system in both settings would facilitate a standardised documentation of pharmaceutical interventions.

Hence, validated, structured, and standardised classification systems for pharmaceutical interventions, which fulfil both requirements of comprehensiveness and easy application with little time expenditure in daily clinical practice, are rare. Furthermore, there was no national consensus in Switzerland on how to record pharmaceutical interventions in a standardised manner to obtain data allowing epidemiological studies for research and political purposes. Therefore, we recognised the need of proper instruments able to depict the practice in their representative setting.

The goal of this thesis was to create structured instruments for daily practice to improve the continuity of documentation and communication of pharmaceutical interventions during transitions of care. We approached this goal through

a) developing and validating classification systems for pharmaceutical interventions (one for hospital and one for community setting)
b) testing their feasibility in daily practice in observational studies
c) exploring pharmacists' satisfaction and opinions on documentation of pharmaceutical interventions
d) analysing the documented pharmaceutical interventions
e) investigating with an observation study the dispensing process of prescribed medicines in daily practice of community pharmacies, focusing on counselling activities
f) assessing pharmacist's opinions on patient counselling and on transfer of documented pharmaceutical interventions

In the first project of this thesis (**Project A**), we developed together with the working group in clinical pharmacy of the Swiss Society of Public Health Administration and Hospital pharmacists (GSASA) an intervention oriented classification system for the hospital setting, the GSASA system. Study **A1** aimed at validating the GSASA system. The GSASA system includes 5 categories (problem, type of problem, cause of intervention, intervention, and outcome of the intervention) and 41 subcategories. Total interrater reliability was moderate (Fleiss' Kappa coefficient K=0.52). Interrater reliability and acceptability of the GSASA system were comparable to those of the well-established Pharmaceutical Care Network Europe (PCNE) system V6.2.

In 2011, GSASA proposed the GSASA classification system of pharmaceutical interventions to all Swiss hospitals that are members of this society, and encouraged its application. One and a half years later,

the implementation of the GSASA system was evaluated to assess implementation outcome such as the number of hospital pharmacies using the system, to analyse the pooled data retrieved from Swiss hospitals, and to explore the user satisfaction (**A2**). Forty-four chief hospitals pharmacists responded by online questionnaire about the use and satisfaction with the classification system. Eleven of 12 hospitals using the GSASA system provided us voluntary all classification data, covering an observation period of 121.5 months. Of a total of 9'543 recorded pharmaceutical interventions, 8.8% were not fully classifiable (n=840). In general, users were satisfied (3.8±0.9, Likert-scale 1-5) with the GSASA system, especially with its adequate time expenditure (4.1±1.0). Ten users (83.3%) reported to need less than two minutes and two (16.7%) up to four minutes to classify one intervention. The extent to which the system is used and the good acceptance within a short time after implementation are promising results to use it as basis for a further development.

The aim of next study (**A3**) of the project was to design an innovative seamless concept of classification of pharmaceutical interventions in patient care. The basic structure of the GSASA classification system, currently used in hospitals, should be adopted as far as possible. As a first exploratory trial to test the suitability of the GSASA system in ambulatory settings, we analysed 65 protocols of medication reviews (Polymedication-Check, PMC) performed by community pharmacists, and all 190 interventions could be classified using the GSASA system (median of 3 per PMC). However, the system does not provide detailed information about certain interventions. We identified the need for a new classification system which allows high flexibility in documenting pharmaceutical interventions. According to the complexity of the case, the available information, the type of medication review, and the need for follow-up, different levels of classification may be indicated. This classification system should be suitable for both, community and hospital pharmacy practices to facilitate continuity of care.

The second project of the thesis (**Project B**) reports the development process of the Pharmacists' Documentation of Interventions in Seamless Care (PharmDISC) system which was split into two parts and four stages: Part 1 covered the development and piloting stages (**B1**), while Part 2 covered the evaluation and implementation stages (**B2**).

The aim of Part 1 (**B1**) was to develop an intervention oriented classification system for community setting, the PharmDISC system, based on the GSASA system for the hospital setting (development stage), and to validate (interrater reliability, appropriateness, interpretability) it in an academic environment (piloting stage). In a prospective observational study in community pharmacies, 77 master students in pharmacy consecutively collected each 10 first prescriptions requiring a pharmaceutical intervention and classified these interventions with the PharmDISC system. The

classification system includes 5 categories and 52 subcategories. Most of the 725 pharmaceutical interventions (n=686, 94.6%) were completely classified. The PharmDISC system reached an overall substantial users agreement (K=0.61). Additionally, with a focus group of nine pharmacists (six community and three hospital pharmacists), we assessed their opinions on the documentation of pharmaceutical interventions, and assessed face and content validity of the PharmDISC system. Despite some arising points for optimisation, the pharmacists were satisfied with the PharmDISC system. They recognised the importance of documentation of pharmaceutical interventions and believed that this may allow traceability, facilitate communication within the team and other healthcare professionals, and increase quality of care. Refinement based on the pharmacists' suggestions resulted in a final version to be tested in an observational study with community pharmacists.

In Part 2 of the PharmDISC development process (**B2**), the PharmDISC was tested on interrater reliability, appropriateness, interpretability, acceptability, feasibility, and validity in the daily life environment of community pharmacies (evaluation stage) and first implementation aspects were explored (implementation stage). In an observational study, 21 pharmacists each classified 30 prescriptions requiring a pharmaceutical intervention with the PharmDISC system on 5 selected days within a 5-weeks period. The participating pharmacists were trained with an online training and could use a descriptive manual of the PharmDISC system to support them in the classification of pharmaceutical interventions. The PharmDISC system reached an average substantial user agreement (K=0.66). Of 519 documented pharmaceutical interventions, 430 (82.9%) were completely classified. Most users found the system comprehensive and practical. The PharmDISC system raised the awareness regarding drug-related problems for most users. To facilitate its implementation, an electronic version that automatically connects to the prescription together with a task manager for pharmaceutical interventions needing follow-up was suggested. Barriers could be time expenditure and lack of understanding the benefits.

A subanalysis (**B3**) based on the data obtained from the validation results (**B2**) allowed characterising the pharmaceutical interventions performed during dispensing of prescribed medicines in community pharmacies, and identifying the frequent problems with the prescribed medicines. Pharmacists performed individualised pharmaceutical interventions to solve or prevent DRPs concerning prescribed medicines. Pharmacists mainly intervened to substitute a drug (n=132, 30.7%), adjust a dose (n=57, 13.3%), and clarify/complete information (n=48, 11.2%). In 138 (32.1%) cases, the pharmacists contacted the prescriber whereas in 292 cases (67.9%), only the pharmacist was involved (alone n=59, with the patient n=222, with the caregiver n=11). Direct patient-pharmacist interaction during the dispensing was essential to detect patient-reported problems with prescribed medicines.

In the third project of the thesis (**Project C**), we observed on site the whole dispensing process of prescribed medicines, focusing on counselling activities, in order to depict the current practice in community pharmacies (**C1**). One master student in pharmacy performed non-participant observations during one day at each of the 18 included community pharmacy. Within 556 prescription encounters, counselling was provided to 367 (66.0%) customer on 2.9 ±3.1 themes per prescription encounter (first 4.9±3.0; refill 1.0±1.7, $p<0.001$), predominantly about drug administration, use and dose. We identified factors influencing counselling provision at patient, prescription and pharmacy level. Significantly more counselling was provided by pharmacists, to customers with a first prescription, with a prescription requiring a pharmaceutical intervention, to carers who filled the prescription for a patient, to new customers, and to customers who did not refuse counselling. While pharmacists intervened frequently, only few additional activities and no further services were offered.

Additionally, at the end of the observation day (**C1**), an interview (**C2**) was conducted with one pharmacist of each participating pharmacy to assess pharmacists' opinions on patient counselling during dispensing of prescribed medicines in daily community pharmacy practice, and on documentation and transfer of pharmaceutical interventions. For the eighteen interviewed pharmacists, most important themes to be discussed at first prescription dispensing were indication, administration, and anamnesis and at refill prescription dispensing, adherence, therapy benefits, and adverse effects. The most frequently counselling triggers that pharmacists expressed were patient's knowledge gap, patient's motivation/interest, drug-drug interaction, polypharmacy/polymorbidity and special patient population. Barriers were refusal by patients, communication problems, lack of medical data, and lack of time. Pharmacists occasionally documented their pharmaceutical interventions, however almost always not in a standardised way. Pharmacists found important to transfer the performed pharmaceutical interventions to the other involved healthcare providers, but some barriers (e.g. too time-consuming, overwork) could hinder it. Therefore, a simple and fast in use computerised documentation system, with an additional intervention history option, could be a promising approach.

In summary, this thesis showed the following:

The GSASA system

- The GSASA classification system appeared to be reliable and promising for the documentation of pharmaceutical interventions in daily practice (practical and less time-consuming). Its validation was successful in terms of appropriateness, interpretability, validity, acceptability, feasibility, and reliability (**A1**).
- After 18 months of introduction (2013), the GSASA classification system is already widely accepted in Swiss hospitals, suggesting to be suitable also to daily life settings. Most pharmaceutical interventions can be classified with adequate time effort and overall users' satisfaction is good. The extent to which the system is used and the good acceptance within a short time after implementation are promising results to use it as basis for a further development (**A2**).
- The GSASA classification system was tested in primary care and proved to be suitable also to classify interventions of medication reviews performed by community pharmacists in primary care; however, further refinements were necessary to improve the precision of the system. Thus, the development of one classification system suitable for both, primary and secondary care, flexible for addressing different levels of complexity, and easily integrable in daily practice and in electronic patient file was recognised as a promising approach (**A3**).

The PharmDISC system

- In a focus group interview, pharmacists recognised the importance of the documentation of pharmaceutical interventions and were convinced that this may allow traceability, facilitate communication within the team and other healthcare professionals, and eventually would increase quality of care (**B1**).
- Substantial interrater reliability and high rating of acceptability and feasibility indicates that the new PharmDISC system is a valid system for the documentation of pharmaceutical interventions in daily practice of community pharmacies. The pharmacists were satisfied with the system and considered it helpful, easy to use, and practical for daily work. They appraised

the fact that by using an intervention oriented classification system, their awareness of DRPs and concurrently the intervention rate increased (**B2**).

- The developed descriptive manual of the PharmDISC system and the online training were helpful elements for an accurate use of the PharmDISC system and are promising utilities to enhance its implementation (**B2**).

Depicting real-life daily practice

- The high number of pharmaceutical interventions following DRPs and patient-reported problems highlights the importance of a direct patient-pharmacist interaction when dispensing prescribed medicines (**B3**).
- The observation of the dispensing process of prescribed medicines allowed to depict the community pharmacy practice from the customers' perspective (at the counter). However, counselling was not equally provided, indicating that prescription encounters need different degrees of counselling. A more transparent practice and patient-centered counselling is necessary to better meet the patients' needs on information. While pharmacists intervened frequently, only few additional activities and no further services were offered (**C1**).
- Factors influencing counselling provision were identified at patient, prescription and pharmacy level. Significantly more counselling was provided by pharmacists, to customers with a first prescription, to customers with a prescription requiring a pharmaceutical intervention, to carers who filled the prescription for a patient, to new customers, and to customers who did not refuse counselling (**C1**).
- A discrepancy in counselling content by observation compared to pharmacists' opinions was revealed. Observations show a focus on product-centered themes (e.g. drug administration, dose), whereas pharmacists' interviews highlight the importance of patient-centered themes (e.g. benefit, adherence). This might indicate that pharmacists are aware but hindered by barriers to practice according to good pharmacy practice guidelines (**C2**).
- Pharmacists recognised the importance of the documentation of pharmaceutical interventions and their transfer to others healthcare providers, but reported also possible reasons of non-transfer (e.g. minor relevant of pharmaceutical interventions, overwork) (**C2**).
- A simple and fast in use computerised documentation system, with an additional intervention history option, could be a promising approach according to the positive reactions and the needs of the pharmacists. As stated by the pharmacists, its implementation should increase the appreciation and visibility of pharmacists' work, facilitate data handling by saving time and

costs, ensure seamless care by improving collaboration among healthcare providers, and ultimately improve the therapy outcomes (**C2**).

GENERAL INTRODUCTION AND RATIONALE

Drug-related problems and pharmaceutical interventions

A drug-related problem (DRP) is commonly defined as an event or circumstance involving drug therapy that actually, or potentially, interferes with the desired health outcomes [1]. Many studies have shown that DRPs are very common in the hospital and community settings [2-4]. A DRP can be a risk to the patient (potential problem) or cause harm (manifest problem) as an adverse drug event (ADE) or an adverse drug reaction (ADR). Multiple causes for DRPs are known such as medication error, poor documentation, failures in communication, inappropriate processes in the healthcare setting or the patient's behaviour. A systematic review analysing DRPs in hospitals showed that problems associated with pharmacotherapy lead to a prolonged hospital stay and increased healthcare costs. On average 8% of hospitalised patients suffer from an ADE or ADR, and 5 to 10% of all prescriptions or drug administrations are incorrect [5].

In community setting, the pharmacists also frequently identify DRPs and consequently intervene to solve or prevent them. A Swiss study showed that in community pharmacies, more than half (53.4%) of the 616 prescriptions resulted in a DRP [4]. Common DRPs observed in community pharmacies are drug-drug interactions, inappropriate drug choice, and missing/unclear information regarding the prescription [4, 6]. Especially with initial prescriptions which also include hospital discharge prescriptions, it is of great importance that patients are properly instructed and that the right drug is used in the right dose at the right time during the right duration. It is also essential that no DRPs arise and that the drug therapy is not interrupted or conducted incorrectly. The introduction of a newly prescribed drug to the treatment plan is an unusual situation for a patient who may have only recently been confronted with a new diagnosis or the necessity for a new drug. The risk of DRPs may be increased in this situation [7, 8].

In both hospital and community settings, there is evidence that interventions initiated by pharmacists can reduce the occurrence of DRPs [5, 9, 10]. In this thesis, we defined a ''pharmaceutical intervention'' as a recommendation initiated by a pharmacist in response to a DRP occurring in an individual patient in any phase of the medication process. These intervention aims at optimising pharmacotherapy, in terms of efficacy, safety, economic, and humanistic aspects [11].

Seamless care

Patient transitions such as hospital admissions, hospital internal transitions, transfer to an external institution or transfer from inpatient to outpatient care are currently not appropriately organised in a seamless care approach, particularly concerning the medication management. Seamless care is defined as any process which optimises efficiency, quality, and safety of medication management at transitions to establish a continuum of care [12, 13]. Continuity of care is crucial to ensure safe and efficient care transitions [14], especially for high-risk and/or elderly patients [15]. Provision of pharmaceutical care and clinical pharmacy when present in the hospital focus their activities mainly on the processes during hospitalisation, making, however, an important contribution to the safe and efficient recovery of the patients.

Patient transition across care settings represent a high-risk period for the occurrence of DRPs, such as discrepancies (medication omission, discontinuation and incomplete prescription requiring clarification) [16-22]. These DRPs often result in adverse drug events, ranging from minor symptoms to impairment or death, and in patient readmission [20, 22-24], resulting in higher costs of care in public health [25]. According to the literature, unintentional medication discrepancies were observed in 24-91% of the patients at hospital admission and/or discharge [16, 19]. Particularly in the case of high-risk patients, such as patients with polypharmacy, with four and more comorbidities, with impaired cognition, and who are non-adherent to the prescribed medicines, around half of the hospital admissions (46%) due to preventable DRPs could be avoided [26].

An observational study in 3 German hospitals revealed that almost two-thirds of the 300 recruited hospitalised patients are confronted with 3 or more medication changes during hospitalisation [27]. The patient knowledge and understanding of their hospital discharge medication, especially by medication changes, is a decisive factor for positive health outcome. A study reported that half of the long-term medication of 130 patients during the hospital stay has been modified by the healthcare providers with dose adjustment, drug discontinuation/restart, and/or substitution [28]. There is also a necessity on the part of the patients to better understand their drug therapy [29]. By educating patients, medication safety as well as patient satisfaction can be improved subsequently. According to the study by Williams et al. 60% of unplanned rehabilitation could be avoided by more efficient interventions during hospitalisation [30]. Various strategies such as development of services (e.g. medication reconciliation/review), education and implementation of guidelines for healthcare providers, development of information technologies to share data across settings of care, have been developed to improve the quality of care and to achieve better patient outcomes [16, 31-33].

However, the exchange of information between primary and secondary care on the patient medication remains a major challenge. Improved information exchange can only be achieved through collaboration among the different healthcare providers [34], and especially through better networking of the pharmacists involved in the perihospital phase.

The access to complete and accurate patient medical information and good communication between healthcare professionals is essential to ensure safe and efficient patient care [21, 22, 35, 36] and to coordinate effective medication management, particularly when several healthcare provider are involved [37]. In current practice, the medication management at the time of admission and discharge from the hospital is not seamlessly guaranteed through complete documentation and communication of clinical pharmaceutical interventions between inpatient and outpatient care. In addition, collaboration between hospital pharmacists, community pharmacists and the medical team is not sufficiently established at present. Gaps in transfer of information and communication between secondary and primary care could negatively influence patient safety and continuity of care [34]. Moreover, healthcare providers in primary care are often not informed about patient medical conditions and outcomes [38], and unaware of medication changes following hospital discharge [39]. The patient transfer from inpatient to outpatient care could be organised in a more efficient and safer way, if information about the performed pharmaceutical interventions would be exchanged. Currently, the reasons of clinically relevant changes in medication are rarely clearly communicated and the pharmaceutical interventions lose their value.

An illustrative example

> *During hospitalisation, a hospital pharmacist discovered a DRP in patient drug therapy and makes a recommendation, which is implemented in collaboration with the physician. This pharmaceutical intervention led to a change in the patient medication. After hospital discharge, the patient filled the hospital discharge prescription in the community pharmacy. The community pharmacist changed the prescribed medication back to the medication the patient took before hospitalisation, according to his/her medication history, prior prescriptions, and eventually by contacting the general practitioner. Because of insufficient documentation and communication, the results of the interprofessional work and the implemented pharmaceutical intervention during the hospital stay were lost*.

At **hospital admission**, DRPs already occur and these consequently lower the quality of the hospital stay and jeopardise the patient unnecessarily [22]. A standardised document allowing the assessment of the best possible medication history [40] could be helpful to assemble information merging from secondary and primary care. In Switzerland, as part of the national quality strategy of the Federal

Office, the Swiss Foundation of Patient Safety carries out a first pilot program of the project 'progress! Safe Medication at Interfaces'.

At **hospital discharge**, patients often find themselves confronted with new drugs, new diagnoses, and new worries, as a result creating uncertainty. Both hospital and community pharmacists could contribute to medication safety and quality of life of the patients before, during and after the hospital stay. The seamless care approach currently developed in different PhD projects of the Pharmaceutical Care Research Group (PCRG) follows two strategies (Fig. 1):

A) **Hospital Setting**: identification of drug-related risks in patients [26, 42], provision of intensive pharmaceutical care and prospective planning of hospital discharge and care for a safe transfer to the next involved healthcare providers [14].

B) **Community setting**: recording of the hospital discharge plan, processing of non-solved DRPs, check if there is a need for medication reconciliation/review and the prospective planning of care until the next visit to the physician, offer of follow-up services.

These two strategies must be carried out in a complementary way and the community pharmacy should take on subsidiary responsibility in case of gaps in the discharge plan. Indeed, the readmission rate and number of adverse effects can be decreased by implementing a discharge order reconciliation [31], home medication review (e.g. follow-up at home of high-risk elderly patients after hospital discharge [43]) or others strategies including both predischarge and postdischarge interventions [32]. In this way, the quality of care and patient safety can be improved. According to current practice, this can be performed by a medication review, named Polymedication-check, in Swiss community pharmacies [44].

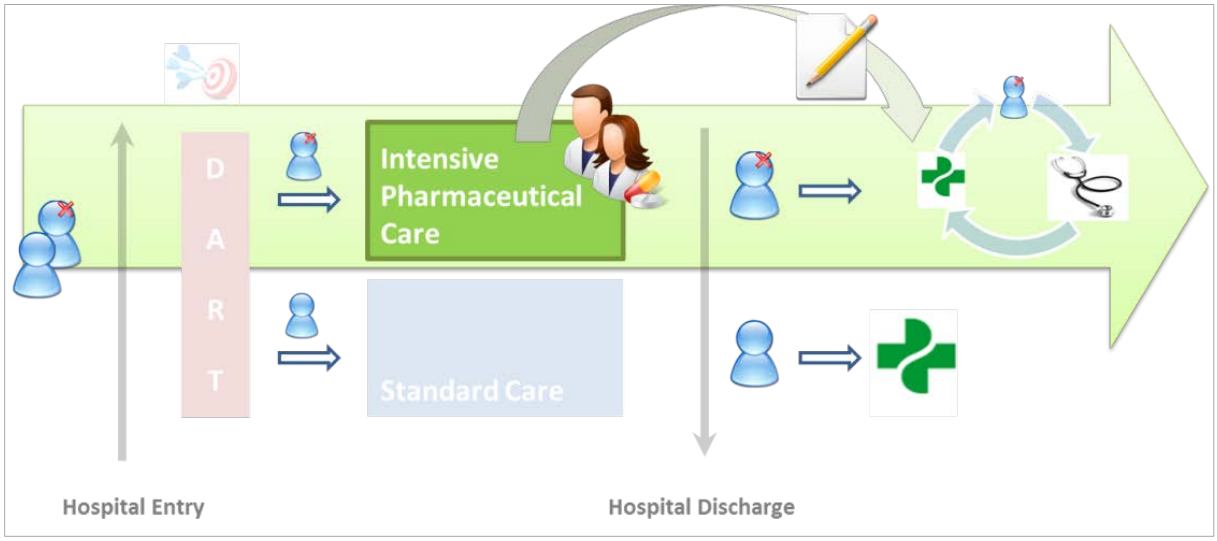


Fig. 1: Field of pharmaceutical activities during and after hospitalisation to ensure continuity of care. At admission, the high-risk patients are identified with the Drug Associated Risk Tool (DART) [42, 45], and receive intensive pharmaceutical care during the hospital stay and a discharge plan for the community pharmacy, which perform a medication reconciliation and ensure the follow-up care.

These strategies and pharmaceutical interventions should no longer be loose fragments, but should be brought together like a mosaic in an overall concept and documented in a form that enables the most seamlessly possible exchange of information at the hospital discharge of patient in the outpatient situation. To accomplish this task, the first step is to document the pharmaceutical interventions in their respective care setting by developing valid instruments in order to picture the practice.

Documentation of pharmaceutical care

Pharmaceutical care is commonly defined as the pharmacist's contribution to the care of individuals to optimise medicines use and improve health outcomes (e.g. cure/prevention of the disease, elimination/reduction of patients' symptomatology, stabilisation of the disease process) [46, 47]. Pharmaceutical care implies an effective cooperation with the patient and other involved healthcare providers to design a therapeutic plan together that improves treatment outcomes [47]. In order to support continuity of care, the pharmacists accept responsibility for the patients and the quality of their care, implicating the **necessity of documentation and communication** of the activities/interventions which have been done [47]. As Cipolle et al. said, "if you aren't documenting the care you provide in comprehensive manner, then you don't have a practice" [48]. Pharmacists are accustomed to record prescriptions, however many lack experience in documenting patient care

activities [49]. Documentation is all the more important given that the current practice is changing towards an increasing provision of patient-centered care and cognitive pharmaceutical services [47, 50]. Pharmacists acquired accordingly more responsibilities, and concurrently documentation has become central in daily pharmacy practice [37, 51].

Already today, pharmacists participate actively in the medication management, and subsequently contribute to the improvement of patient care, whereas documentation and communication of these activities to patients and other healthcare providers is often lacking [34, 51]. Nevertheless, the joint International Pharmaceutical Federation and World Health Organization (FIP/WHO) published guidelines on Good Pharmacy Practice (GPP) [37]. GPP requires that each element of pharmacy activities is relevant to the patient and is effectively communicated to all involved persons. The common saying "if it wasn't documented, it wasn't done" applies for all healthcare providers, also for pharmacists if they want to be a full member of the healthcare system [51]. Therefore, documentation of pharmacists' activities is and must be an essential part to the pharmaceutical care practice [47]. As an example, the American Society of Hospital Pharmacists (ASHP) has already published guidelines on documentation of pharmaceutical care in patient medical records [52].

In order to improve the treatment outcomes and reduce health costs, pharmaceutical care involves a broad range of activities such as detecting, preventing and solving DRPs, counselling, and medication review [46]. In fact, daily practice of pharmacists comprises a wide variety of interventions regarding DRPs. The documentation of these pharmaceutical interventions increases the pharmacists' attention to the drug-related needs of patients, enhances counselling skills and improves pharmaceutical care in general [53]. It also highlights the pharmacists' role in ensuring the safe use of medicines [54, 55]. Indeed, a prerequisite for high-quality pharmaceutical care is an effective documentation allowing the evaluation of the intervention outcome [56]. In other terms, the documentation of care represents the evidence of practice [57]. It is therefore essential to record activities/interventions in a concise, standardised and structured manner, and each documentation should contain similar key elements [51, 58]. To accomplish this task, the **classification**, as essential part of the documentation, enables a precise representation of what has been done (e.g. pharmaceutical interventions) by categorising key elements in a standardised manner, and as a consequence, facilitates the transfer of information.

Once the pharmaceutical interventions are documented in the respective healthcare setting, the information exchange between the hospital and the community pharmacy can often be challenging. Improving information exchange regarding pharmaceutical interventions could enable a more efficient and safer transfer of patients between inpatient and outpatient care. An aligned classification system in both settings would facilitate a standardised documentation of pharmaceutical interventions.

Classification systems for pharmaceutical interventions

Increasingly, hospital and community pharmacists are involved in detecting and solving DRPs on a regular basis. In daily life, they come across technical (e.g. illegible prescriptions) and clinical issues (e.g. drug-drug interaction) requiring a pharmaceutical intervention (e.g. dose adjustment).

The use of a classification system would help in the assessment of pharmaceutical interventions and the collection of DRPs in a structured way, and support continuity of care through the promotion of mutual information [9]. Additionally, such data on pharmacists' activities could be used for epidemiological studies. Such standardised documentation highlights the pharmacist's role in the safe, appropriate, and cost-effective use of drugs [54, 55], and increases the pharmacist's vigilance for the patients' drug-related needs [53].

In the literature, several classification systems have been proposed. An international review identified twenty different types of DRP classification system [59]. Their structure and content differ in terms of category size and type [59-61]. Most instruments, such as APS-Doc [62], DOCUMENT [63], and PI-Doc [64], were considered too time-consuming in practice. Another system, the PCNE classification system V6.2 [65], was originally developed for research in community pharmacy setting and has a strong focus on patient behaviour, therefore making it less appropriate for the hospital setting. Typical hospital medication errors such as application errors, incompatibilities, and incorrect transcription cannot be classified [9]. The large number of subcategories (n=71) renders the tool very comprehensive, but hinders its application in a daily routine setting. Allenet et al. validated an instrument for the documentation of clinical pharmacists' interventions (SFPC system), which proved to be suitable for daily practice [66]. However, this simple system lacks subcategories to document detailed information, and the cause of the DRPs is not assessed. Most systems have not been routinely implemented in practice to date, as they are generally too time consuming, too comprehensive, poorly defined, or only partially validated [60], and none has been used in parallel in community pharmacy and hospital settings.

Published classification systems underline different foci; most classification systems concentrate on DRPs [59] and one on the cause of DRPs [61]. A review of the application of DRP classification systems reported a large variability in the definition of DRPs [59]. To get around this problem, a classification system **focusing on interventions** has the advantage to enable a more objective assessment, thus increasing the quality and reliability of data reporting. Moreover, this is in line with the key characteristics of a clinical documentation that aims at recording what the healthcare provider does (e.g. pharmaceutical interventions), why she/he does it (cause of the intervention) and what outcomes are reached (outcome of the intervention) [51].

Validation of a classification system is necessary, not only to ensure that one code reflects a unique DRP, but to guarantee that this coding is understandable to the users. Validation confirms, through the provision of objective evidence, that the requirements for a specific use or application are fulfilled [67]. The literature describes the following criteria for validating DRP classification systems [68]:

a) appropriateness (is the classification content appropriate to the questions the application seeks to address?)

b) acceptability (is the classification acceptable to the users?)

c) feasibility (is the application easy to use?)

d) interpretability (how well can the classification codes be interpreted?)

e) reliability (does the classification generate results that are reproducible and internally consistent?)

f) validity (does the classification measure what it claims to measure?)

g) responsiveness (does the classification offer options to follow up interventions and monitor outcomes of interventions?)

Hence, validated, structured, and standardised classification systems for pharmaceutical interventions, which fulfil both requirements of comprehensive classification and simple use in daily clinical practice, are rare. Furthermore, there is no national consensus in Switzerland on how to record pharmaceutical interventions in a standardised manner to obtain data allowing epidemiological studies for research and political purposes. Therefore, we recognised the need of proper instruments able to depict the practice in their representative setting.

Depicting real-life daily practice

It has been shown that pharmacists play an effective role in detecting, preventing and solving DRPs and in patient counselling on medicines to support patients to make the best use of medicines [37, 69]. In order to investigate the extent to which this role is followed, depicting daily practice can help to evaluate quality of care, to uncover the gaps in the real world of pharmacy practice, and consequently tailor accordingly the necessary interventions. The description and assessment of clinical, organisational and economic impacts of pharmacy activities can help to develop them [70]. Several methods can be used:

- Pharmacists' role in detecting, preventing, and solving DRPs can be illustrated by the **documentation** of their pharmaceutical interventions (e.g. thanks to a classification system). Documentation is a self-reported method for collecting data, enabling to illustrate pharmacists' activities in community and hospital pharmacies. It has been reported that such documentation

makes pharmacists more attentive regarding the patients' drug-related needs and enhances the development of counseling skills and pharmaceutical care [53].

- As part of pharmaceutical care, patient counselling and dispensing of prescribed medicines and are the pharmacist's key activities to ensure the safe and effective use of medicines [37, 69]. During dispensing, community pharmacists help the patient to make the best use of prescribed medicines by providing written and oral information responding to the patient needs [71], which contribute to positive treatment outcomes [72]. Patient counselling on medicines has been shown to be effective in improving medicines adherence [73, 74], and in identifying DRPs [75]. However, insufficient information about medicines can lead to patient non-adherence to the drug therapy and negative health outcomes. For these reasons, **observation** is an adequate method to describe the pharmacists' role in patient counselling on prescribed medicines and to depict the current dispensing practice in community pharmacies. Observations give the possibility to describe customers' behaviour and discover how daily pharmacy practice works [76]. It is a useful way to study quality of services and consistency of care. In the literature, observations described interactions between pharmacy staff, patients and other healthcare providers [77], questions pharmacy staff ask, patient counselling, and recommendation of products [78-80].

Goal of the thesis

The goal of this thesis was to create structured instruments for daily practice to improve the continuity of documentation and communication of pharmaceutical interventions during transitions of care. With a structured seamless documentation and communication (Pharmacists' Documentation of Interventions in Seamless Care, **PharmDISC**) between inpatient and outpatient care, the information could be available for the healthcare providers, the pharmaceutical interventions trackable and the patient informed about the changes of the drug therapy, thus improving the health outcomes (Fig. 2). This could ensure a safe and facilitated exchange of information on medication changes, patient conditions, and care issues between secondary and primary healthcare providers. With better documentation and communication, better pharmaceutical and seamless care should be provided and consequently medication management and health outcomes for the patients improved.

We identified the need for documentation in daily practice and created an innovative classification system suitable for both, community and hospital pharmacy practices to facilitate continuity of care and to increase patient safety while transferring between care settings. The aims were as follows:

- to develop and validate a classification of pharmaceutical interventions for a cross-sectoral use and its proper instruments (classification systems in secondary and primary care)
- to evaluate its feasibility in practice
- to depict real-life daily pharmacy practice

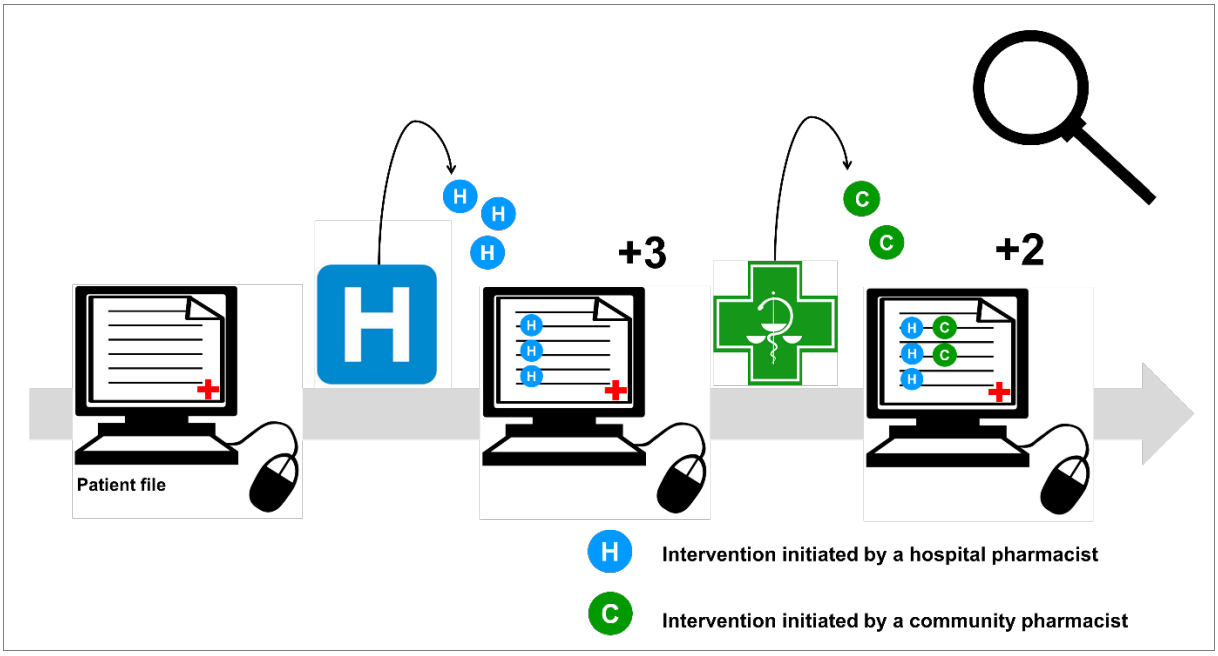


Fig. 2 Continuity of documentation: looking at the patient pathway during hospital stay, three pharmaceutical interventions were documented into the electronic patient file; and after discharge, two interventions initiated by a community pharmacist were added to the same file, using the similarly structured classification, thus enabling to depict real-life daily practice (represented with the magnifying glass).

Approach

The goal of this thesis was to create structured instruments for daily practice to improve the continuity of documentation and communication of pharmaceutical interventions at transitions of care. We approached this goal in three main projects:

Project A An intervention oriented classification system for the hospital setting: the GSASA system

As a first step towards the development of a classification of pharmaceutical interventions for a cross-sectoral use in secondary and primary care, we developed, in the first project of this thesis (**Project A**), an intervention oriented classification system for the hospital setting, the GSASA system. This project contains the three following studies:

A1 **Demonstrating the clinical pharmacist's activity: validation of an intervention oriented classification system** (publication in *Int J Clin Pharm* 2015;37:1162–1171 [81])

To develop and validate a classification system for pharmaceutical interventions and to compare it with the well-established Pharmaceutical Care Network Europe (PCNE) system V6.2 [65].

A2 **Evaluation of the implementation of a classification system for pharmaceutical interventions** (short research report [82])

To evaluate the implementation of this classification system in daily practice one and a half years after its introduction, and to analyse the pooled data retrieved from Swiss hospitals.

A3 **Classification of pharmaceutical interventions in patient care: an innovative seamless concept** (short research report [83])

To develop a new seamless concept for classification of pharmaceutical interventions suitable for both, primary and secondary care, integrable into patient files, and supporting seamless care.

Project B An intervention oriented classification system for the community setting: the PharmDISC system

To create an aligned classification system in both hospital and community settings, the basic structure of the GSASA classification system should be adopted as far as possible. In the second project (**Project B**), we developed an intervention oriented classification system for the community setting, the PharmDISC system, based on the GSASA system for the hospital setting. An initial validation was conducted in an academic environment and the final validation in the daily real-life environment of community pharmacies. The development process of the PharmDISC system was split into two parts and four stages: Part 1 covered the development and piloting stages (**B1**), while Part 2 covered the evaluation and implementation stages (**B2**). Thereafter, a subanalysis (**B3**) based on the data obtained from the validation results (**B2**), allowed for characterising frequent pharmaceutical interventions occurring in daily practice, and identifying frequent patient-reported problems.

Project B comprises three studies:

B1 **Documentation of pharmaceutical care: development of an intervention oriented classification system** (publication in *Int J Clin Pharm,* 2017;39(2):354-363 [84])

To develop an intervention oriented classification system for community pharmacies named PharmDISC based on the hospital system; to test it on interrater reliability, appropriateness, interpretability, and face and content validity; to assess pharmacists' opinions.

B2 **Documentation of pharmaceutical care - validation of an intervention oriented classification system** (publication in *J Eval Clin Pract,* submitted, under review [85])

To validate the PharmDISC system in terms of interrater reliability, appropriateness, interpretability, acceptability, feasibility, and validity; to explore first implementation aspects.

B3 **Pharmaceutical interventions on prescribed medicines in community pharmacies: focus on patient problems** (short research report in *Int J Clin Pharm,* submitted, in revision)

To describe pharmaceutical interventions performed by community pharmacists during the dispensing process of prescribed medicines and to investigate their response to patient-reported problems.

Project C Patient counselling on prescribed medicines in Swiss community pharmacies

Patient-reported problems concerning prescribed medicines were frequently detected by direct patient-pharmacist interaction in daily practice and resulted in a pharmaceutical intervention (**B3**). As one of the last healthcare provider before the patients take their medicines, pharmacists play an important role in patient counselling and education on medicines and in supporting the patients to make the best use of medicines. Therefore, the third project (**Project C**) aims at investigating the role of the pharmacy staff in patient counselling on prescribed medicines. Firstly, we observed the dispensing process of prescribed medicines at the counter, focusing on counselling activities, in order to depict the actual practice in community pharmacies (**C1**). Secondly, an interview (**C2**) was conducted with one pharmacist of each participating pharmacy to assess pharmacists' opinions on patient counselling at dispensing of prescribed medicines in daily community pharmacy practice, and on documentation and transfer of pharmaceutical interventions.

Project C contains two studies:

C1 **Dispensing of prescribed medicines in community pharmacies - Observed counselling, interventions and services** (publication in preparation)

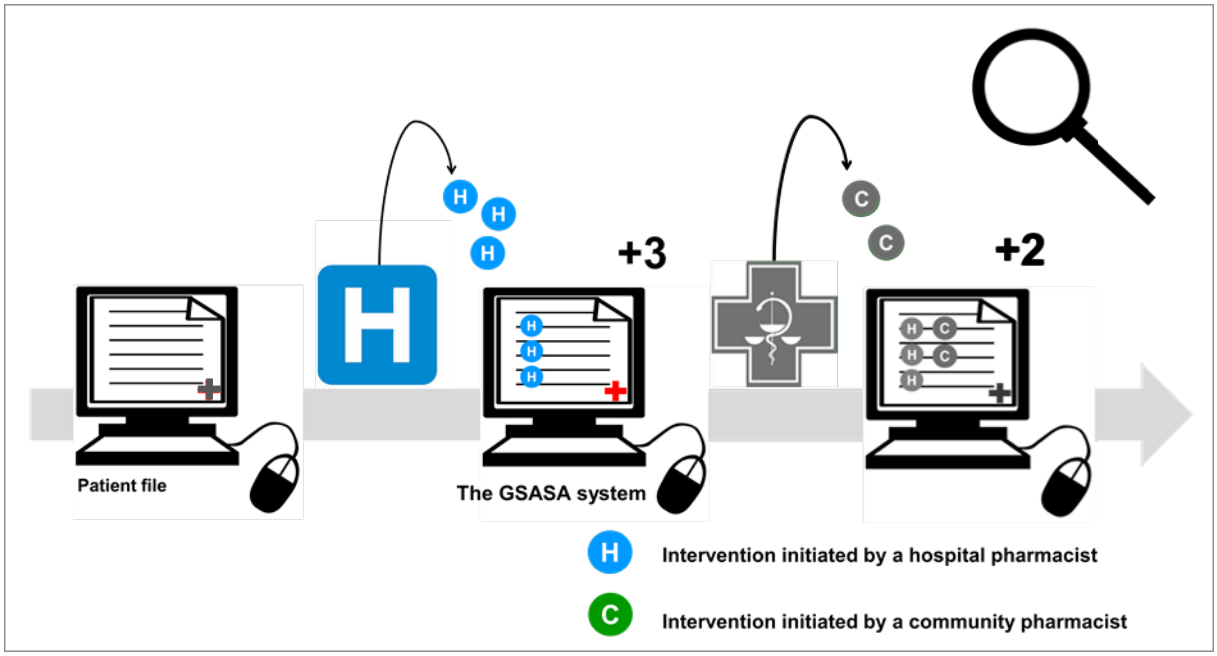
To describe the observed dispensing process of prescribed medicines at the counter in daily community pharmacy practice, focusing on counselling activities.

C2 **Dispensing of prescribed medicines in community pharmacies – Observation deviates from pharmacists' opinions** (research report)

To assess pharmacists' opinions on patient counselling at dispensing of prescribed medicines in daily community pharmacy practice, and on documentation and transfer of pharmaceutical interventions

PROJECT A

An intervention oriented classification system for the hospital setting: the GSASA system



A1 Demonstrating the clinical pharmacist's activity: validation of an intervention oriented classification system

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Abstract

Background Clinical pharmacists are increasingly involved in detecting and solving drug-related problems. In order to document their performance, a convenient tool to code pharmaceutical interventions in daily practice is desirable. The Swiss Society of Public Health Administration and Hospital Pharmacists (GSASA) proposed to implement a new classification system for pharmaceutical interventions.

Objectives To develop and validate a classification system for pharmaceutical interventions and to compare it with the well-established Pharmaceutical Care Network Europe (PCNE) system.

Setting Rehabilitation clinic, geriatric and orthopaedic wards of a 427-bed teaching hospital.

Methods Development of the GSASA classification started with expert panel discussions and the validation of the first version (GSASA V1). In order to assess appropriateness, interpretability, and validity, clinical pharmacists documented during a 6-week period all interventions using GSASA V1 and PCNE version 6.2 (V6.2). Acceptability and feasibility were tested by an 8-item questionnaire with 5-point Likert scale (1=strongly disagree, 5=strongly agree), and interrater reliability (Fleiss-Kappa coefficients κ) was determined. After revision, the second version (V2) was assessed again for reliability.

Main outcome measures User's agreement/satisfaction, comprehensiveness/reliability of the classification system.

Results The GSASA V1 includes 4 categories and 35 subcategories. Of 115 interventions classified with GSASA V1, 93 (80.9 %) could be completely classified in all categories. This explains that 3 of 6 users could be not satisfied with the comprehensiveness of GSASA V1 (mean user agreement 2.7 ± 0.8). The questionnaire showed that all users could find GSASA V1 (4.0 ± 0.0) easier to use than PCNE V6.2 (3.0 ± 0.9). Users were generally satisfied with the GSASA V1 (3.5 ± 0.8), especially with the adequate time expenditure (4.0 ± 0.7). Interrater reliability and acceptability of GSASA V1 were comparable to those of the PCNE V6.2. The agreement among the GSASA V1 users was substantial for the categories 'problem' (κ = 0.66), 'intervention' (κ = 0.74), and 'outcome' (κ = 0.63), while moderate agreement for the category 'cause' was obtained (κ = 0.53). The final system GSASA V2 includes 5 categories (addition of 'type of problem') and 41 subcategories. Total interrater reliability was moderate (κ = 0.52).

Conclusion The GSASA classification system appeared to be reliable and promising for documentation of pharmaceutical interventions in daily practice (practical and less time-consuming). The system is validated in terms of appropriateness, interpretability, validity, acceptability, feasibility, and reliability.

Keywords

Classification system; Clinical pharmacy; Drug-related problems; Pharmaceutical care; Pharmaceutical interventions; Validation

Impact of findings on practice statements

- The new classification system GSASA V2 may serve as a helpful tool in daily practice to classify DRPs and clinical interventions undertaken by pharmacists.
- Classification of DRPs together with according interventions enables demonstration of the performance/impact of clinical pharmacy services.
- This classification system could be a helpful instrument to collect and quantify data on pharmaceutical interventions, thus enabling the merging of data for epidemiological studies.

Introduction

Drug-related problems (DRPs) are common in hospitalised patients. As defined by the Pharmaceutical Care Network Europe (PCNE), a DRP is an event or circumstance involving drug therapy that actually, or potentially, interferes with the desired health outcomes [1]. A drug-related problem can be a risk to the patient (potential problem) or cause harm (manifest problem) as an adverse drug event (ADE) or an adverse drug reaction (ADR). Multiple causes for DRPs are known such as medication error, poor documentation, failures in communication, inappropriate processes in the health care setting or the patient's behaviour. A systematic review analysing DRPs in hospitals showed that problems associated with pharmacotherapy lead to a prolonged hospital stay and increased healthcare costs. Medication errors occurred in 5.7 % of all episodes of drug administrations, and 6.1 % of hospitalised patients experienced an ADE or ADR [5].

Increasingly, clinical pharmacists are involved in detecting and solving DRPs on a regular basis. Utilisation of a classification system would aid in the collection of DRPs and the assessment of pharmaceutical interventions; support continuity of care through the promotion of mutual information [9]; and, additionally, such data on pharmacists' activities could be used for epidemiological studies. In the literature several classification systems have been proposed. Most instruments, such as APS-Doc [62], DOCUMENT [63], and PI-Doc [64], were considered too time-consuming in practice. Another such system, the PCNE classification system [65], was originally developed for a research and community pharmacy setting and has a strong focus on patient behaviour, therefore making it less appropriate for the hospital setting. Typical hospital medication errors such as application errors, incompatibilities, and incorrect transcription cannot be classified [9]. The large number of subcategories (n = 71) renders the tool very comprehensive, but hinders its application in a daily routine setting. Allenet et al. validated an instrument for the documentation of clinical pharmacists' interventions (SFPC system), which proved to be suitable for daily practice [66]. However, this simple system lacks subcategories to document detailed information, and the cause of the DRPs is not assessed. Hence, validated, structured, and standardised classification systems for pharmaceutical interventions, which fulfil both requirements of comprehensive classification and simple use in daily clinical practice, are rare.

Validation confirms, through the provision of objective evidence, that the requirements for a specific use or application are fulfilled [67]. Validation of a classification system is necessary, not only to ensure that one code reflects a unique DRP, but to guarantee that this coding is understandable to user. The literature describes the following criteria for validating DRP classification systems: (1) appropriateness (is the classification content appropriate to the questions the application seeks to address?) (2) acceptability (is the classification acceptable to the users?) (3) feasibility (is the application easy to

use?) (4) interpretability (how well can the classification codes be interpreted?) (5) reliability (does the classification generate results that are reproducible and internally consistent?) (6) validity (does the classification measure what it claims to measure?) (7) responsiveness (does the classification offer options to follow up interventions and monitor outcomes of interventions?) [68].

Up to now, there was no national consensus in Switzerland on how to demonstrate the clinical pharmacist activities to obtain data allowing epidemiological studies for research and political purposes. The working group on clinical pharmacy of the Swiss Society of Public Health Administration and Hospital Pharmacists (GSASA), comprising eight French- and German-speaking clinical pharmacists, recognised the need for the development of a new standardised and practical tool. To ease the recording of interventions in inpatients during daily practice, a tool was developed, which seeks to combine the advantages of existing systems such as SFPC (validated, practical, and based on hospital setting) and PCNE (validated, logical basic structure with the categories cause and intervention) systems. The classification system focused on interventions to enable a more objective assessment, and increased quality and reliability of data recording. We used the PCNE system, which is validated, well-established and internationally used, as a benchmark for our new intervention oriented classification system [9, 60].

Aim of the study

The aim of the study was to develop a classification system for drug-related problems and pharmaceutical interventions, and to validate this system using inpatients and against the PCNE classification system V6.2.

Ethical Approval

According to the requirements of the Swiss federal law on human research this study is exempt from ethical approval.

Methods

Overview of development process

Figure 1 illustrates the process involved in developing the new GSASA classification system, which comprised four main steps. The topics were based on those of the PCNE classification system, while the structure followed that of the French classification system [66]. The first version (GSASA V1) of the classification system was developed by an expert panel of eight clinical pharmacists (GSASA working

group on clinical pharmacy). After validation, a second version was developed (GSASA V2) which was revalidated.

We defined a ‘‘pharmaceutical intervention’’ as a recommendation initiated by a pharmacist in response to a DRP occurring in an individual patient in any phase of the medication process. The intervention aims at optimising pharmacotherapy, in terms of efficacy, safety, economic, and humanistic aspects [11].

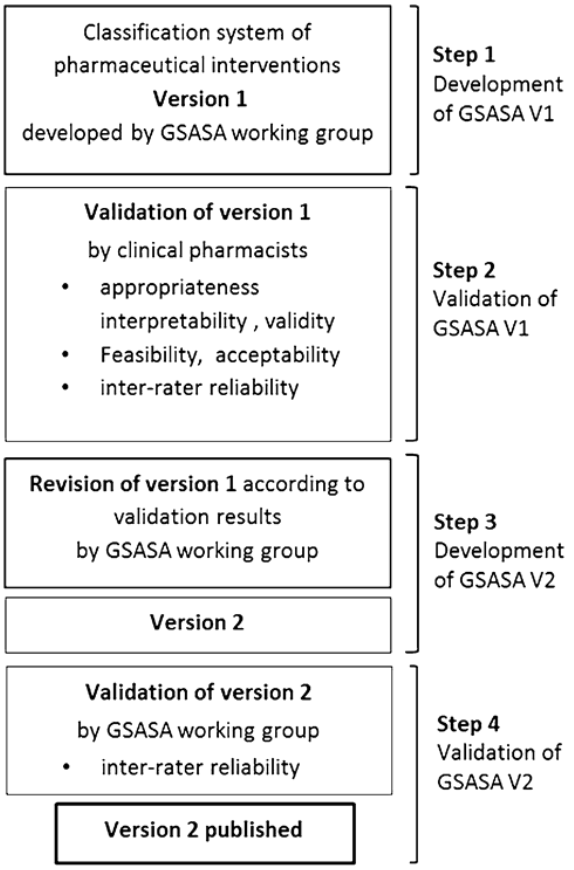

Fig. 1 Process of developing the classification system

Step 1: Development of classification system GSASA V1

The GSASA working group (=expert panel) comprised four French and four German speaking clinical pharmacists (n = 8) from 8 different hospitals, whose professional experience in clinical pharmacy ranged from 3 to 14 years. Seven of them had previously used a DRP classification system. The fi version, developed by the aforementioned GSASA working group, was based on the PCNE classification system for DRPs [65] and the instrument for documentation of clinical pharmacists’ interventions of the French Society of Clinical Pharmacy [66]. Any discrepancies were resolved by discussion.

Step 2: Validation of classification system GSASA V1

Version 1 was validated assessing appropriateness, interpretability, validity, feasibility, acceptability, and interrater reliability.

Appropriateness, interpretability, and validity

We measured appropriateness, interpretability, and validity of the classification systems by assessing the proportion of completely classified interventions. Classification was considered complete when all categories were filled out. At a 427-bed teaching hospital, six experienced clinical pharmacists used the GSASA V1 during a 6-week period to classify the interventions they performed themselves from their routine ward rounds (in geriatric ward, rehabilitation clinic, and orthopaedic ward). Additionally, they classified the same data with PCNE V6.2, and entered the classification codes into a Microsoft Excel sheet. For each DRP, only one choice per category was possible. Special attention was paid to the cases that could not be completely classified.

The pharmacists received training prior to data collection. Training mainly comprised classification of model cases according to standardised documentation forms of PCNE and GSASA, followed by plenum discussions. Validated model cases in a German translation were used [4]. The collected data were analysed by descriptive statistics.

Acceptability and feasibility

In order to evaluate acceptability and feasibility of both classification systems, an 8-item questionnaire, which has been used in an earlier study, was completed by the six pharmacists [4, 86].

The extent of their agreement or disagreement was assessed by a 5-point Likert scale (1 = strongly disagree, 2 = dis- agree, 3 = neutral, 4 = agree, 5 = strongly agree). Time spent for classification and the free text comments was then evaluated. A Mann–Whitney U test was used for statistical evaluation. The significance level was accepted at $p < 0.05$.

Interrater reliability

Three of the six senior clinical pharmacists assessed the reliability of the classification systems. Each had more than 5 years of professional experience in clinical pharmacy, and had worked with DRP classification systems before. They classified 10 model cases using GSASA V1 and PCNE V6.2. The model cases consisted of five validated model cases taken from the literature [87], and five model cases developed for the validation of PCNE V5.0 taken from the German translation. Drug names were only modified to suit the Swiss market. We randomised the order of model cases and classification systems,

and each rater received the same instructions. For both classification systems, only one choice per category was possible to classify each detected problem. For the four categories of both classification systems (detected problem, cause, intervention, outcome of intervention) Fleiss kappa was calculated using a Microsoft Excel template [88]. Resulting values were interpreted according to Landis and Koch [89] as 'almost perfect' (Fleiss' K 0.81–1.00), 'substantial' (0.61–0.80), 'moderate' (0.41–0.60), 'fair'(0.21–0.40), 'slight' (0.00–0.20), and 'poor' (<0.00). A kappa higher than 0.40 indicates that the system is reliable.

Step 3: Development of classification system GSASA V2

Revision of version 1

The GSASA working group reviewed the results of the validation of GSASA V1. Conclusions were drawn and discussed until consensus was reached.

Translation

The GSASA working group translated the German GSASA V2 into French during an open discussion. For the purpose of this paper, we additionally translated version 2 into English.

Step 4: Reliability of classification system GSASA V2

Interrater reliability

The GSASA working group assessed the interrater reliability of the German and French versions of GSASA V2 as described in step 2. They classified the same 10 model cases using the GSASA V2.

Results

Step 1: Development of classification system GSASA V1

The first version included 4 main categories and a total of 35 subcategories, i.e., detected problem (3 subcategories), cause of intervention (17 subcategories), intervention (10 subcategories), and outcome of intervention (5 subcategories).

Step 2: Validation of classification system GSASA V1

Appropriateness, interpretability, and validity

DRPs were collected from daily work on the wards during a 6-week period. We classified 115 DRPs with PCNE V6.2 and GSASA V1. The proportion of the classified cases and the categories involved are shown

in Table 1. In both classification systems, the majority of the cases could be completely classified (PCNE 81.7 %, GSASA 80.9 %).

Table 1 Proportion of classified cases per system and per category

	PCNE V6.2		GSASA V1	
	n	%	n	%
All cases	115	100	115	100
Completely* classified cases	94	81.7	93	80.9
Per category				
Problem	106	92.2	99	86.1
Cause	108	93.9	110	95.6
Intervention	110	95.6	114	99.1
Outcome	115	100	115	100

* Classification was considered complete when all categories were filled out

Acceptability and feasibility

The six pharmacists completed an 8-item questionnaire on the usability of PCNE V6.2 and GSASA V1 using a 5-point Likert scale. Data was compared using Mann–Whitney U Test. The results of the questionnaire were not statistically significant. Table 2 shows the differences of the results for acceptability and feasibility of the two classification systems (questions 1–7).

Question 8 allowed the pharmacists to record their comments and suggestions. The subcategories 'untreated indications' and 'documentation errors' were missing in the category 'problem', 'duplication' and 'insufficient effect of drug treatment/inappropriate drug' in the category 'cause' and 'recommendations of laboratory test' in the category 'intervention'.

Table 2 Users' agreement on the classification systems adapted from AbuRuz et a

	GSASA V1		PCNE V6.2	
	Mean ± SD	Median	Mean ± SD	Median
(1) The classification system was comprehensive and included all drug-related problems I identified (n = 6)	2.7 ± 0.8	2.5	3.8 ± 1.0	4
(2) I did not have problems finding out the proper classification of drug-related problem I identified (n = 6)	3.2 ± 0.8	3	3.0 ± 0.9	3
(3) The classification system was easy to use and practical (n = 6)	4.0 ± 0.0	4	3.0 ± 0.9	3
(4) I will use the classification in my practice in the future (n = 6)	3.8 ± 0.8	4	4.0 ± 0.6	4
(5) In general, I am satisfied with the classification system (n = 6)	3.5 ± 0.5	3.5	4.0 ± 0.6	4
(6) The expenditure of time to classify the problems was adequate (n = 6)	3.5 ± 0.8	4	2.7 ± 0.8	2.5
(7) The classification would be a good tool to document the activities of hospital pharmacy/clinical pharmacy (n = 5)	4.0 ± 0.7	4	3.6 ± 0.5	4

Interrater reliability

Figure 2 illustrates the interrater reliability of the four classification categories, i.e., problem (GSASA V1 K = 0.66, PCNE V6.2 K = 0.32), cause (GSASA K = 0.53, PCNE K = 0.44), intervention (GSASA K = 0.74, PCNE K = 0.40), and outcome (GSASA K = 0.63, PCNE K = 0.52). The three pharmacists showed a fair agreement for the category 'problem' and a moderate agreement for the other categories of the PCNE classification system. In comparison, GSASA V1 reached a moderate agreement for the category 'cause' and a substantial agreement for the other categories.

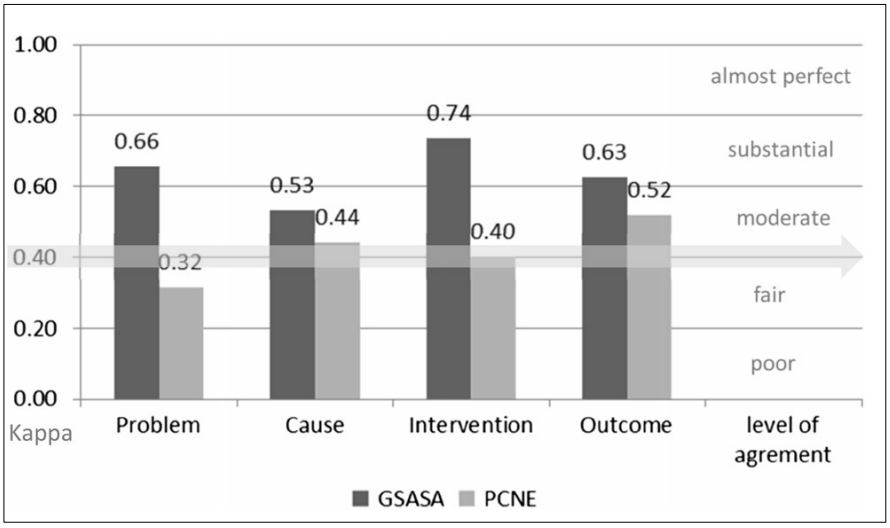

Fig. 2 K-Coefficients of PCNE V6.2 and GSASA V1 classification systems for the four categories, based on standard cases (n = 10) classified by raters (n = 3)

Step 3: Development of classification system GSASA V2

The results of the validation of GSASA V1 and the suggestions from the six users were discussed in the expert group, and resulted in the addition of one new category 'type of problem' and seven new subcategories, and in the modification of three subcategories. The subcategory 'untreated indication' was moved from the category 'cause' to 'problem'. The major change concerned the category 'detected problem'. In order to precisely describe the DRPs, we included two additional subcategories to this category, and introduced the new category 'type of problem' to differentiate potential and manifest DRPs. Table 2 describes the English version 2 and the modifications with respect to version 1. The resulting classification system GSASA V2 includes 5 categories with a total of 41 subcategories as follows: detected problem (5 subcategories), type of problem (potential/manifest) (2 subcategories), cause of intervention (18 subcategories), intervention (11 subcategories), and outcome of intervention (5 subcategories) (see Table 3). Only one choice per category is possible. Therefore, if a detected

problem involved multiple interventions, each intervention required the use of a new form or line in the Excel sheet. An example to illustrate this classification is given in Figure 3.

Table 3 Description manual of the classification system GSASA V2 and illustrations with examples (bolded text category or subcategory added for version 2, italicized text subcategory modified)

Code	Category	Code	Subcategory	Subcategory description	Example
1	Detected problem	1.1	Treatment effectiveness	Any problem or circumstance which may modify the effectiveness of a medication (type of problem: potential), or any signs or symptoms (type of problem: manifest) suggesting lacking or unsatisfactory effectiveness	No effect of the quinolone therapy due to formation of non-absorbable complexes with multivalent cations
		1.2	**Untreated indication**	Preventive, therapeutic, or concomitant medication not prescribed for a valid indication	No laxative prescribed together with opioid therapy
		1.3	Safety of treatment	Any problem or circumstance which may expose the patient to an increased risk for an adverse drug event (type of problem: potential) or any signs or symptoms (type of problem: manifest) suggesting a lacking or unsatisfactory medication safety	Risk of torsades de pointes due to combination of amiodarone and clarithromycine
		1.4	Treatment costs	Any issue associated with the cost of a drug treatment (e.g., high price, reimbursement, cost-effectiveness, patient's economic situation, generic substitution)	Switch original product to generic (generic substitution) because of lower treatment costs; i.v antibiotics administration longer than necessary
		1.5	**Patient dissatisfaction**	Any complaint or concern regarding drug therapy expressed by the patient or the caregivers/relatives	Patient complains about high number of prescribed drugs, about swallowing difficulties, lack of information, etc
2	**Type of problem**	**2.1**	**Manifest**	Patient shows signs or symptoms of an adverse drug event, therapy failure or non-treatment. Problem is present → Reactive, corrective intervention	Electrocardiogram shows QT interval prolongation induced by clarithromycine in combination with amiodarone
		2.2	**Potential**	Patient is at risk for an adverse event but does not present signs or symptoms of adverse clinical outcomes Problem is in the future → Preventive intervention	Loss of cardio protective effect of acetylsalicylic acid (ASS) in combination with ibuprofen causes an increased risk for myocardial infarction
3	Cause of intervention	Therapy choice			
		3.1a	No concordance with guidelines or contraindication	Drug selection does not comply with treatment guidelines	ASS is not prescribed in a patient after myocardial infarction
				Patient shows a contraindication to the therapy due to his medical conditions	Metformin contraindicated in patient with renal failure
		3.1b	*Drug not indicated or duplication*	Drug use without an indication or inappropriate use of two drugs from the same therapeutic class	Potassium supplementation in spite of normal blood level
					Combination of ACE inhibitor and angiotensin receptor blocker
		3.1c	Interaction	Combination of a drug with another drug or with food representing a potential or manifest negative outcome	Calcium in combination with levothyroxine
		3.1d	Adverse effect	Response to a drug that is noxious and unintended and occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease, or for modification of physiological function	Tremor as sign for lithium toxicity
		3.1e	**Incomplete patient documentation**	Lack of patient information in case notes/ laboratory results	Allergies not reported in patient cases
		Drug choice			
		3.2	Inappropriate dosage form	Wrong drug administration route or method, or wrong form, or incompatibility	Sustained release tablets crushed for the administration through feeding tube

Table 3 continued

Code	Category	Code	Subcategory	Subcategory description	Example
		Dose choice			
		3.3a	Underdose	Prescribed dose too low	Pantoprazol 20 mg in duodenal ulcer
		3.3b	Overdose	Prescribed dose too high	Prescribed dose of acetaminophen exceeds maximal daily dose
		3.3c	Inappropriate monitoring	Inappropriate process of observing, recording and detecting the effects or safety of a therapy, incl. therapeutic drug monitoring (TDM)	No thyroid hormones control in substituted hypothyroidism Wrong timing of blood collection for determination of drug serum levels
		3.3d	**Dose not adjusted to organ function**	No dose adjustment required due to organ impairment (renal/liver failure, etc.) and pathological changes	High dose allopurinol was prescribed daily in renal impairment
		Therapy duration			
		3.4	Inappropriate therapy duration	Duration of therapy too long or too short	Folic acid substitution in spite of adequate serum levels Too short antibiotic therapy; too long topical application of a cortisone cream
		Drug use			
		3.5a	Treatment not received	Any problem or circumstance which prohibited the patient to get the treatment originally prescribed	The nurse forgot to administer a prescribed dose
		3.5b	*Inappropriate timing or frequency of administration*	Wrong timing of drug intake regarding circadian rhythm or food intake, or no respect of the dosing interval	Bisphosphonate intake with breakfast Nitrate-free interval too short
		Logistics			
		3.6a	Prescribed drug not available	Drug not in stock, drug shortage or any other logistic problems in drug provision	Drug prescribed, but not in stock
		3.6b	Error in medication process	Any error appearing during drug prescription, transcription, distribution or administration	No transfer of the indicated drug from the prescription sheet to the case notes (transcription error)
		Patient			
		3.7	Insufficient compliance	Patient does not take his medication as prescribed	Patient forgot to intake a prescribed drug
		Others			
		3.8a	Insufficient knowledge of caregivers	Caregivers (e.g., nurse, physician) lack information about therapy or disease	Physician does not know about a drug–drug interaction
		3.8b	Insufficient knowledge of the patient	Patient lacks information about their medication or disease	Patient does not know how to use an asthma device
4	Intervention	4.1	Therapy started/ restarted	Introduce a drug to the treatment plan	Restart oral anticoagulants after bridging with heparin
		4.2	Therapy stopped	Withdraw a drug without substitution by another drug	Stop proton pump inhibitor, which was prescribed without indication/ risk factors
		4.3	Substitution	Replace a drug by another for the same indication	Switch from esomeprazole to pantoprazole
		4.4	Dose adjustment	Adjust drug dose or therapy duration regarding medical and personal conditions	Reduce enalapril dose due to renal insufficiency
		4.5	Therapy monitoring	Observe, record, or detect the effects of a drug administered to an individual, by indication of safety or efficacy, incl. TDM	Suggest medical analysis of uric acid in suspicion of gout Suggest TDM in a patient treated with vancomycin

Table 3 continued

Code	Category	Code	Subcategory	Subcategory description	Example
		4.6	Change of administration route	Find an appropriate drug administration route	Switch intravenuous antibiotic therapy to oral therapy
		4.7	Optimisation of administration	Change the treatment plan to suit patient or to optimise drug response, regarding e.g., meal interval, posture, fasting intake, swallowing difficulties	Recommend bisphosphonate intake on empty stomach and in upright position
		4.8	Counselling of patient, training	Advice and educate patient about his medicines	Instruct the use of an asthma device
		4.9	Information to caregivers	Inform caregivers about any problem or circumstance	Explain a potential drug–drug interaction
		4.10	Clarification in the case notes	Complete or correct patient notes	Clarify a prescribed drug without indication in the case notes
		4.11	**Report to pharmacovigilance centre**	Report ADR of medicines to a reporting centre/health authorities	Report a case of agranulocytosis observed under metamizol therapy
5	Outcome of intervention	5.1	Accepted	Recommendation of intervention approved by physician and implemented	Drug without indication is stopped
		5.2	*Partially accepted without implementation*	Recommendation of intervention partially approved by physician but not implemented or not possible to implement	Drug without indication is evaluated (search for diagnosis or clarify with the patient), or physician accepted the recommendation but not the patient
		5.3	Not accepted	Physician does not agree with recommendation	Drug without indication is continued without clarification
		5.4	Not known	Outcome of intervention not known	No feedback after written recommendation
		5.5	Not applicable	Intervention needing no approval or implementation	Information given to the caregiver

Fig. 3 Example of a pharmaceutical intervention classified as a drug-related problem according to classification system GSASA V2

The case

An immunosuppressed patient is treated for gout with allopurinol 100 mg. According to his chronic renal failure (creatinine concentration in serum 200 µmol/L, GFR 25 mL/min), a daily dose of <100 mg is appropriate. The physician agreed with the recommendation of monitoring the uric acid levels and adapting the dose according to the laboratory data.

The classification GSASA V2

1) detected problem: Safety of treatment (code 1.3)
2) type of problem: Potential (code 2.2)
3) cause of intervention: Dose not adjusted to organ function (code 3.3d)
4) intervention: Therapy monitoring (code 4.5)
5) outcome of intervention: Accepted (code 5.1)

Step 4: Reliability of classification system GSASA V2

Interrater reliability

The working group assessed the level of agreement of the version V2 in German and French (Table 4). They classified the same 10 cases used in step 2. Interrater reliability was moderate (K = 0.52) for all categories.

Table 4 Level of agreement of the GSASA V2 among experts (n = 8), 10 standard cases

	Kappa coefficient (agreement)		
	French-speaking experts (n = 4)	German-speaking experts (n = 4)	All experts (n = 8)
Detected problem	0.58 (moderate)	0.26 (fair)	0.43 (moderate)
Type of problem	0.48 (moderate)	0.66 (substantial)	0.57 (moderate)
Cause of intervention	0.53 (moderate)	0.56 (moderate)	0.55 (moderate)
Intervention	0.77 (substantial)	0.40 (moderate)	0.58 (moderate)
Outcome of intervention	0.44 (moderate)	0.51 (moderate)	0.48 (moderate)
Average agreement	0.56 (moderate)	0.48 (moderate)	0.52 (moderate)

Discussion

Our study showed that most (80.9 %) of the 115 pharmaceutical interventions could be documented with the first GSASA classification system V1 and a similar ratio of 81.7 % with the PCNE classification V6.2, our benchmark. Moreover, we found comparable interrater reliability and acceptability for the GSASA and PCNE systems. On the other hand, the comparative evaluation of the two systems revealed differences with respect to usability. Indeed, the category 'intervention' of the GSASA system allowed a more complete classification of the cases than the PCNE. This reveals that our system respected his original approach, which was focusing on recording the interventions.

The structure of the two systems could also explain these differences. The four main categories of GSASA V1 corresponded with the ones of PCNE V6.2. However, PCNE V6.2 contained a twofold larger choice of subcategories (n = 71) than GSASA V1 (n = 35) enabling the precise classification of most DRPs. Consequently, users could find the PCNE instrument to be more comprehensive than the GSASA system, knowing that, due to the small number of raters, the comparison of both tools showed no statistically significant results. In contrast, the GSASA system could be easier to use and more practical than the PCNE system. Time is an essential element for the acceptance of a classification system. In routine settings, application of the GSASA system in clinical practice demonstrated this tool to be less time-consuming than the PCNE system. This important factor should increase the chances of a

successful and systematic use of the GSASA system. By addition or modification of several subcategories, the number of non-classifiable cases should decrease. In this way, the usefulness/comprehensiveness of the GSASA system could be enhanced without affecting its well-established practical use. In summary, the validation of the two existing systems showed an acceptable performance in enabling documentation and a better acceptability and feasibility of the GSASA system. The comments of the users provided helpful input for further improvement and the development of the classification system GSASA V2.

The goal of this development process was to create a classification system that permits the classification of DRPs detected and the recording of any pharmaceutical intervention. Van Mil et al. describe essential characteristics of classification systems [60]. Accurate classification of a detected problem should lead to only one choice per category. Therefore, the comprehensiveness of our instrument allows its systematic use and the consistency in the documentation of the interventions. Its detailed description manual, illustrated with practical examples, should enable homogenous data collection. In this way, the classification system would allow to collect and pool data from different sites, and by this generating a representative overview of clinical pharmacy activities within a given region. As a disadvantage, our instrument allows limited entry of details on individual cases. However, its open structure enables to enter additional and important information about the coded interventions.

The classification GSASA V1 reached good interrater reliability. Indeed, the four classification categories of GSASA V1 (κ = 0.64, which indicated a substantial agreement) was more reliable than the four categories of PCNE V6.2 (κ = 0.42, moderate agreement). Interrater reliability of GSASA V2 (κ = 0.52) was acceptable, although the κ-coefficients were lower than those calculated for the initial version. This decrease of the interrater agreement can be explained by the extension of the classification system from 4 to 5 categories. Additionally, the raters for the second version were more heterogeneous in terms of language, professional experience, and clinical background. Due to minor changes in GSASA V1 only interrater reliability was repeated when revalidating GSASA V2.

Average interrater agreement for GSASA V2 was moderate (κ = 0.52). This Kappa value was similar to that of the DOCUMENT [63] instrument (κ = 0.53), a recent validated system for classifying DRPs and clinical interventions in community pharmacy. Similarly, the APS-Doc system obtained a substantial agreement for the categories and a moderate agreement for the subcategories [62]. Considering that (a) the pharmacists involved in our study had only little experience with the GSASA system, (b) they had never used a description manual to aid in DRPs classification, and (c) that Kappa value higher than 0.40 indicates the internally acceptability and the good comprehensiveness of the classification

system, these results fulfil the minimum requirement for an acceptable classification system. In the future, the use of the descriptive manual to assist with the classification should improve the Kappa score.

This study involved several limitations. As in most classification systems, subcategories are not mutually exclusive. The GSASA system shows similarities with the PCNE and SFPC systems, which it stemmed from. The validation and reliability of GSASA V1 were based on a small number of pharmacists (n = 6 and 3, respectively), thus we cannot exclude a selection bias. Many raters were involved in the different stages in the development process. Therefore, we cannot ensure the generalisability of the system. We limited the validation of GSASA V2 on reliability as only minor changes were required in the first version. We considered most results of GSASA V1 validation as transferable to GSASA V2. In order to enable its implementation we tested the classification system in a limited number of users (n = 8). All were qualified clinical pharmacists, each classifying 10 cases. On-going projects aim to evaluate the implementation and the user's satisfaction of GSASA V2 in daily practice and to analyse the pooled data retrieved from Swiss hospitals. In addition, we are currently adapting the system to also suit the community pharmacy setting and to support seamless documentation and transition from secondary to primary care.

Conclusion

The intervention oriented classification system GSASA V2 appeared to be valid and easy to use in daily clinical practice. The system is validated in terms of appropriateness, interpretability, validity, acceptability, feasibility, and reliability. The description manual assists in categorisation and hereby will increase the quality of data due to an appropriate use of the standardised classification system. Systematic use of the procedure will provide information on the performance of clinical pharmacy services on the whole. On-going epidemiological research aims to merge all interventions classified with the classification system GSASA V2 in Switzerland and to evaluate its implementation.

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Conflicts of interest

The authors declare that they have no conflicts of interest.

Supplementary data: the GSASA V2 classification form (in German)

Pharmazeutischer Interventionsbogen

Datum : Medikament :

ABTEILUNG
- ☐ 1)Medizin
- ☐ 2)Chirurgie
- ☐ 3)Geriatrie
- ☐ 4)Orthopädie
- ☐ 5)Psychiatrie
- ☐ 6)Intensivstation Erwachsene
- ☐ 7)Intensivstation Pädiatrie
- ☐ 8)Pädiatrie
- ☐ 9)Rehabilitationszentrum
- ☐ 10)Andere...

1-Erfasstes Problem
- ☐ 1)Effekt der Behandlung
- ☐ 2)Nicht behandelte Indikation
- ☐ 3)Risiko durch Behandlung
- ☐ 4)Behandlungskosten
- ☐ 5)Unzufriedenheit des Patienten

2-Problemtyp
- ☐ 1)Manifest
- ☐ 2)Potentiell

3-Grund der Intervention (1 Möglichkeit)

Wahl der Behandlung:
- ☐ 1a)Keine Übereinstimmung mit den Richtlinien/Kontraindikation
- ☐ 1b)Medikament nicht indiziert oder Duplikation
- ☐ 1c)Interaktion
- ☐ 1d)Unerwünschter Effekt
- ☐ 1e)Lückenhafte Patientendokumentation

Wahl der galenischen Form
- ☐ 2)Ungeeignete/r Verabreichungsweg/-form

Wahl der Dosis:
- ☐ 3a)Unterdosierung
- ☐ 3b)Überdosierung
- ☐ 3c)Unzweckmässiges Monitoring
- ☐ 3d)Keine Dosisanpassung bei pathologischen Veränderungen (Nieren-, Leberinsuffizienz, etc.)

Dauer der Behandlung:
- ☐ 4)Unangemessene Dauer der Behandlung

Anwendung des Medikaments:
- ☐ 5a)Behandlung nicht erhalten
- ☐ 5b)Zeitpunkt oder Frequenz der Verabreichung ungeeignet

Logistik:
- ☐ 6a)Verschriebenes Medikament nicht verfügbar
- ☐ 6b)Fehler im Medikationsprozess

Patient:
- ☐ 7)Ungenügende Compliance

Andere:
- ☐ 8a)Ungenügender Kenntnisstand des Pflegepersonals
- ☐ 8b)Ungenügender Kenntnisstand des Patienten

4-Intervention (1-Möglichkeit)
- ☐ 1)Beginn/ Wiederbeginn der Behandlung
- ☐ 2)Abbruch der Behandlung
- ☐ 3)Substitution/ Austausch
- ☐ 4)Dosisanpassung
- ☐ 5)Therapie Monitoring
- ☐ 6)Änderung des Verabreichungswegs
- ☐ 7)Optimierung der Verabreichungsmodalitäten
- ☐ 8)Beratung des Patienten, Schulung
- ☐ 9)Information des Pflegepersonals
- ☐ 10)Klärung in der Krankengeschichte
- ☐ 11)Pharmakovigilance-Meldung

5-Resultat der Intervention
- ☐ 1)Akzeptiert
- ☐ 2)Teilweise akzeptiert ohne Umsetzung der Empfehlung
- ☐ 3)Nicht akzeptiert
- ☐ 4)Verlauf unbekannt
- ☐ 5)Nicht anwendbar

AG Klinische Aktivitäten - Pharmazeutischer Interventionsbogen V1-11.2011

A2 Evaluation of the implementation of a classification system for pharmaceutical interventions

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Short research report

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International Journal of Clinical Pharmacy 2013 35: 1251 [82]

Background and Objectives

The Swiss Society of Public Health Administration and Hospital pharmacists (GSASA) introduced in 2011 a new GSASA classification system for pharmaceutical interventions in Swiss hospitals. The instrument (Fig. 1), developed and validated in a previous research, comprises five main categories (problem, type of problem, cause, intervention, and outcome) [81]. Our objectives were to evaluate the implementation of this classification system in daily practice, and to analyse the pooled data retrieved from Swiss hospitals.

Setting and methods

Chief hospitals pharmacists (n=47) were asked by online questionnaire (part of the Questionnaire Mapping clinical Pharmacy in Swiss Practice [90]) about the use and satisfaction with their classification system. Users of the GSASA system were asked to voluntarily provide their data containing all interventions classified with this system during daily work (example fig. 1). We evaluated users' satisfaction about comprehensiveness, feasibility, and acceptability with a 5-point Likert scale.

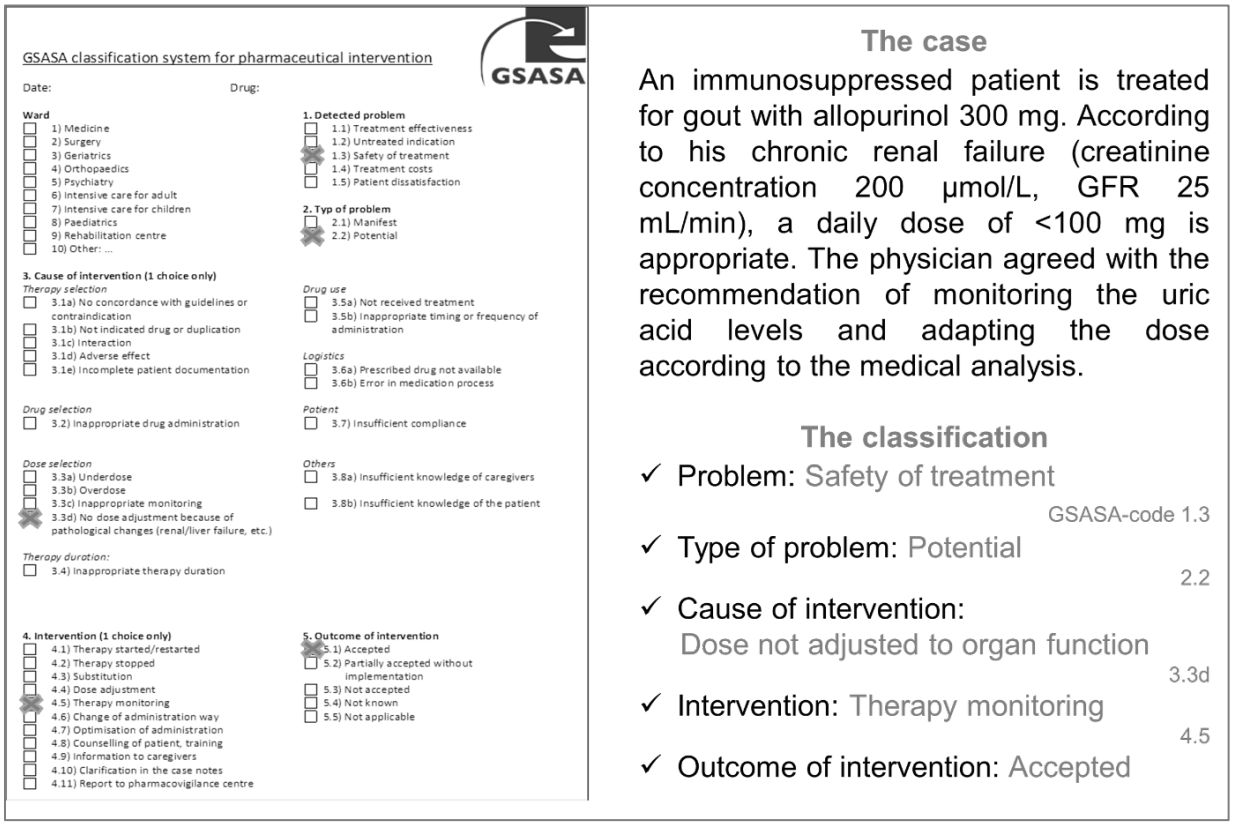


Fig. 1 Example of a pharmaceutical intervention classified with the GSASA classification system

Results

The questionnaire was completed by 44 chief pharmacists (94%), therefrom 33 hospitals offer regularly clinical pharmacy services (75%) and 7 planned it (16%)[90].Figure 2 shows the types of classification system used in Swiss hospitals. All hospitals using the GSASA system provided regular clinical pharmacy services.

Fig. 2 How hospital pharmacists classify their interventions? (n=44)

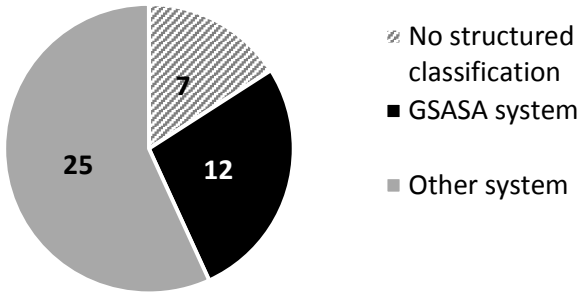
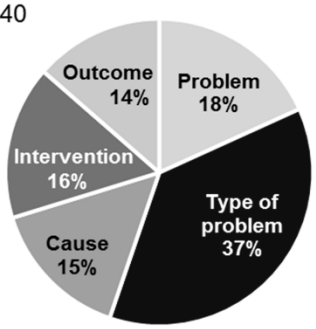


Fig. 3: Not coded aspects of drug-related problem in GSASA categories
n=840



Eleven of 12 hospitals using the GSASA system provided us all classification data thus covering an observation period of 121.5 months (sum of the months per hospital). In total, 9'543 interventions were recorded. Of all interventions, 840 (8.8%) were not fully categorised because of missing aspects (Fig. 3).

Figure 4 illustrates the users' satisfaction:

1. Six of twelve users were not fully satisfied with the **comprehensiveness** of the system (mean user agreement 2.9±1.1). The users suggested additional subcategories (examples):

- Problem: Problem based on electronic prescription
- Cause: i.v. drug incompatibility, incorrect prescription
- Intervention: Information to physician
- Outcome: Refused by the patient

2. Users found the system **easy to use** in daily work (3.8±1.0).

3. In general, users were **satisfied** (3.8±0.9) with the GSASA system, especially (4.) with the **adequate time expenditure** (4.1±1.0). Ten users reported to need less than 2 minutes (83%) and 2 (17%) up to 4 minutes to classify one intervention.

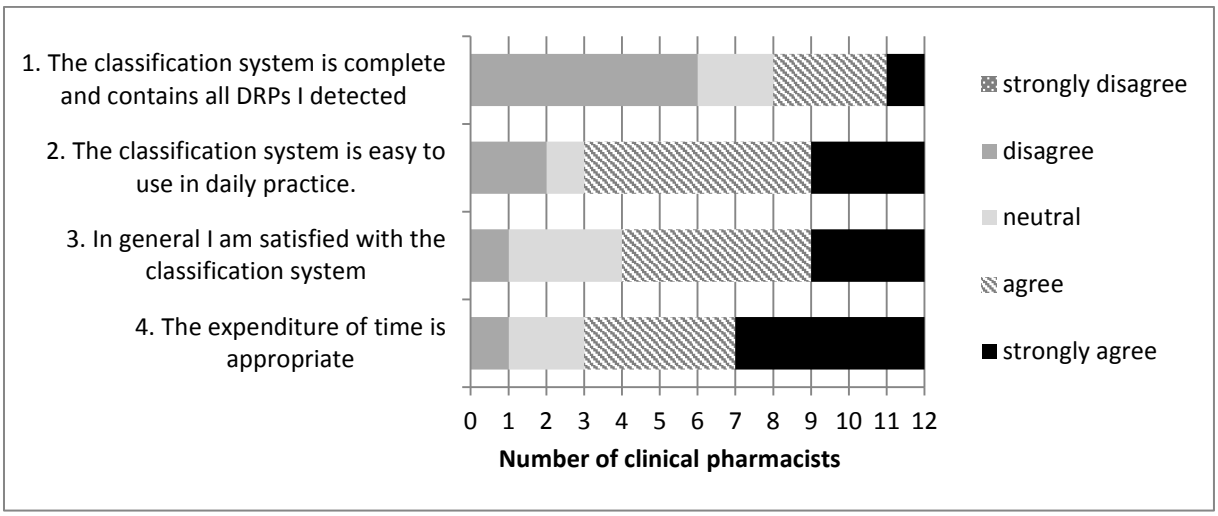


Fig. 4 Satisfaction of the users (n=12) with the GSASA classification system

Discussion and conclusion

After one year, the GSASA classification system is already widely accepted in Swiss hospitals. This instrument proved to be suitable also to daily life setting. Most pharmaceutical interventions can be classified with adequate time effort. Overall users' satisfaction is good. Further refinements are necessary to improve the precision of the system (additional subcategories, clarification of existing subcategories). The extent to which the system is used and the good acceptance within a short time after implementation are promising results to use it as basis for a further development.

Appendix

A1.1 Questionnaire Mapping clinical Pharmacy in Swiss Practice, incl. evaluation of the implementation of the GSASA system

A3 Classification of pharmaceutical interventions in patient care: an innovative seamless concept

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Short research report

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International Journal of Clinical Pharmacy 2014 36: 847 [83]

Background

In patient care, we defined a "pharmaceutical intervention" as a recommendation initiated by a pharmacist in response to a drug-related problem in an individual patient occurring in any phase of the medication process.

In daily practice, classification helps to document interventions, and data provide a pool for epidemiological studies. Most existing instruments have not been routinely implemented in practice yet and none has been used in parallel in community pharmacy and hospital settings.

In Switzerland, a classification system of pharmaceutical interventions was implemented in several hospitals [81, 82], while in community pharmacies no standardised classification is used. In order to ease seamless care and to promote mutual information, the structure of the classification system should be similar but provide different levels of details depending on the complexity of the pharmaceutical interventions, and support medication management along the patient pathway.

Objectives

To develop an innovative seamless concept for classification of pharmaceutical interventions suitable for both, primary and secondary care, integrable into patient files, and supporting seamless care (Fig.1).

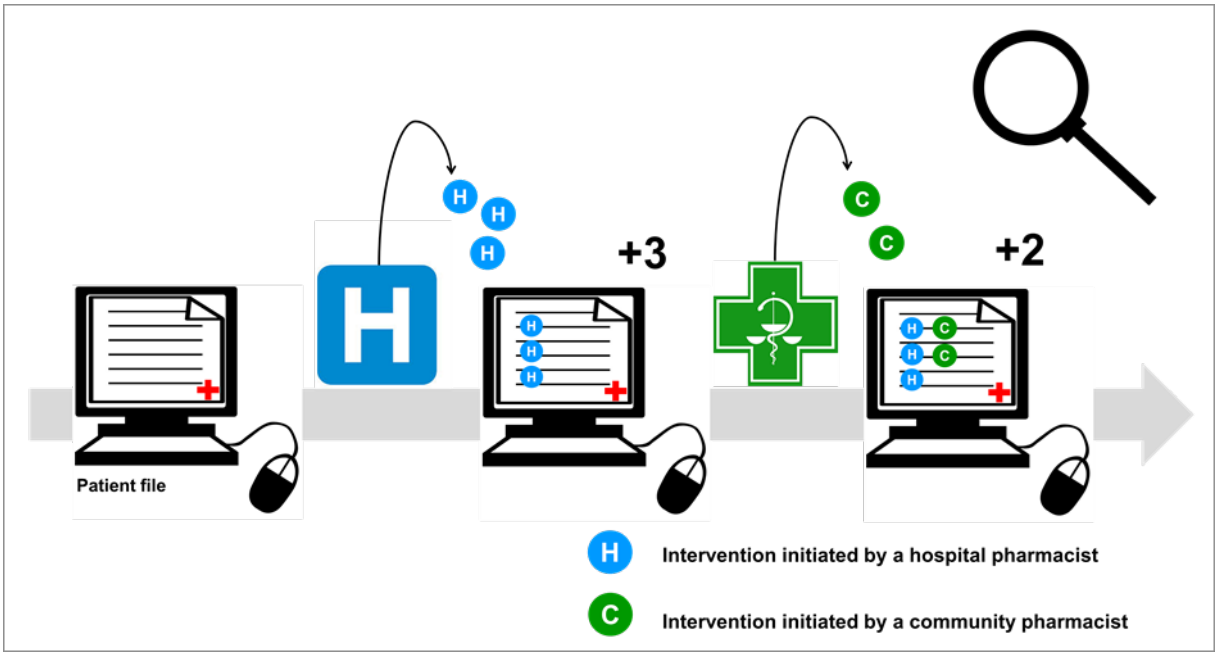


Fig. 1 Continuity of documentation: looking at the patient pathway during hospital stay, tree interventions were documented into the electronic patient file; and after discharge, two interventions initiated by a community pharmacist were added to the same file, using the similarly structured classification.

Design and Methods

Previously, we developed and validated a new classification system for the hospital setting (GSASA system), starting with an expert panel discussion [81]. During the adaptation of the system for the use in community pharmacies, further discussion rounds followed and relevant classification systems were retrieved by literature research.

As a first exploratory trial to test the suitability of the GSASA system in ambulatory settings, we analysed protocols of medication reviews (Polymedication-Check, PMC [44]) performed by community pharmacists and we classified the interventions using the GSASA system.

Results

We identified the need for a new classification system which allows high flexibility in documenting pharmaceutical interventions. According to the complexity of the case, the available information, the type of medication review, and the need for follow-up, different levels of classification may be indicated. This instrument should be suitable for both, community and hospital pharmacy practices to facilitate continuity of care.

During a total of 65 medication reviews, 190 pharmaceutical interventions were documented. All of them could be classified with the GSASA system (median of 3 per PMC). However, the system does not provide detailed information about certain interventions. Figure 2 illustrates the pharmaceutical interventions. Pharmacists intervene mainly by 'patient counselling, training' (69; 36.3 %), 'optimisation of administration' (45; 23.7 %), 'dose adjustment' (13; 6.8 %) and 'therapy monitoring' (13; 6.8 %).

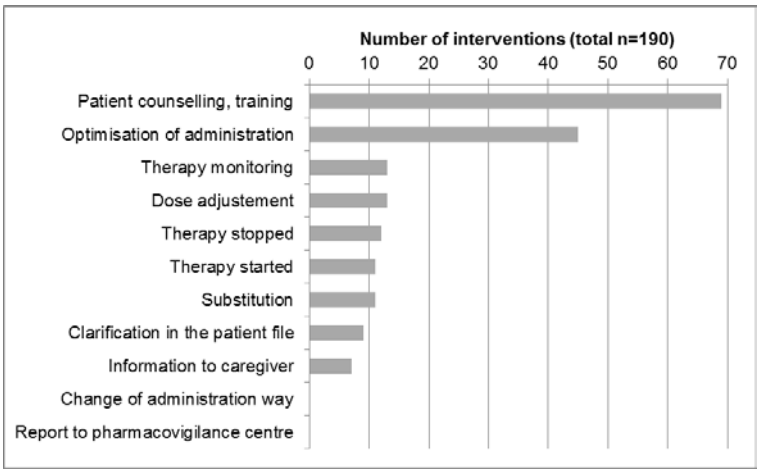


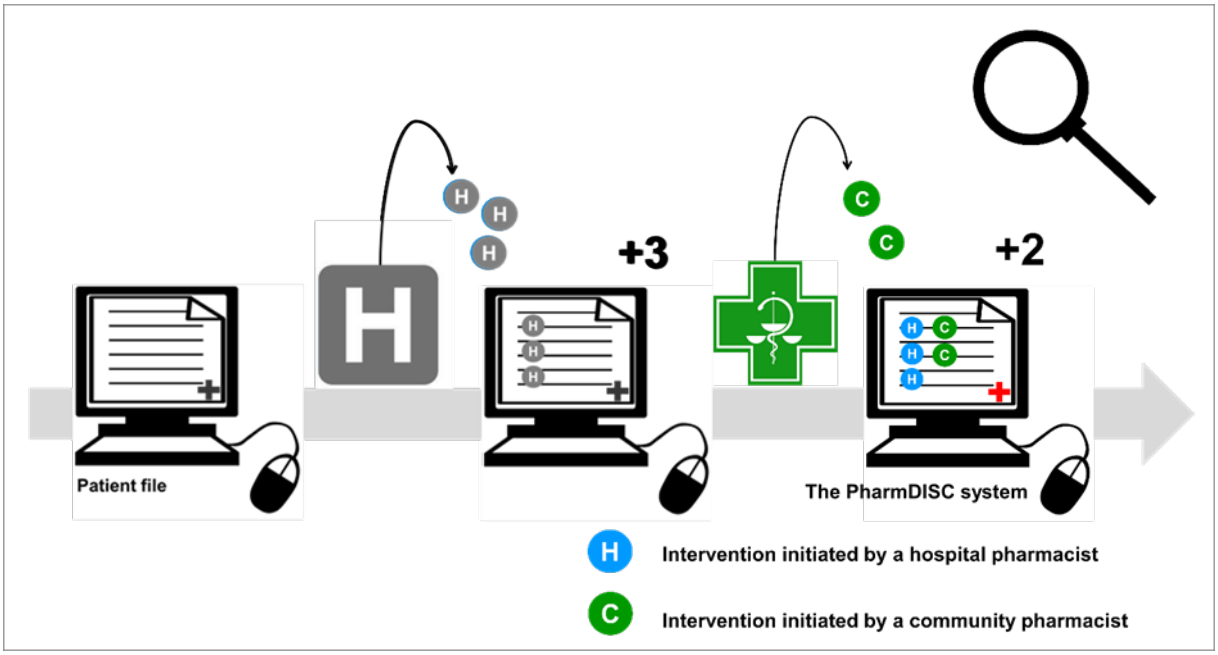
Fig. 2 Pharmaceutical interventions (n=190) documented during 65 medication reviews

Conclusions and implications

The GSASA classification system proved to be suitable also to classify interventions of medication reviews performed in primary care; however further refinements are necessary to improve the precision of the system. Thus, the development of one classification system suitable for both, primary and secondary care, flexible for addressing different levels of complexity, and easily integrable in daily practice and in electronic patient file is a promising approach.

PROJECT B

An intervention oriented classification system for the community setting: the PharmDISC system



B1 Documentation of pharmaceutical care: development of an intervention oriented classification system

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Abstract

Background A standardised classification system of pharmaceutical interventions (PI) is currently in use in several Swiss hospitals, whereas none exists for community pharmacies to date. To promote information exchange between both settings, a compatible structure of the classification system is needed.

Objective To develop an intervention oriented classification system for community pharmacies named PharmDISC based on the hospital system; to test it on interrater reliability, appropriateness, interpretability, and face and content validity; to assess pharmacists' opinions.

Setting Seventy-seven Swiss community pharmacies.

Method Based on previous studies, a modified classification system was developed. Fifth-year pharmacy students (n=77) received a two-hour training and classified three model PIs with which Fleiss-Kappa coefficients K were calculated to determine interrater reliability. In the community pharmacies, each student consecutively collected 10 prescriptions that required a PI. A focus group interview was conducted with pharmacists (n=9). The anonymised transcript was analysed using thematic analysis.

Main outcome measure Number of classified PIs, interrater reliability, pharmacists' opinions/suggestions.

Results The classification system includes 5 categories and 52 subcategories. Most of the 725 PIs (94.6%) were completely classified. The PharmDISC system reached an overall substantial users agreement (K=0.61). Despite some points for optimisation, the pharmacists were satisfied with the PharmDISC system. They recognised the importance of PI documentation and believed that this may allow traceability, facilitate communication within the team and other healthcare professionals, and increase quality of care.

Conclusion The PharmDISC system was valid and reached substantial interrater reliability. Refinement based on the pharmacists' suggestions resulted in a final version to be tested in an observational study with community pharmacists.

Key words

Classification system, pharmaceutical intervention, drug-related problem, mixed method, community pharmacy practice, pharmaceutical care

Impact of findings on practice statements

- The intervention oriented classification system PharmDISC may serve as a helpful instrument to document pharmaceutical interventions in daily community pharmacy practice.
- The data collected with the PharmDISC system could improve visibility of the pharmacists' activities among other healthcare professionals, patients, and authorities.
- The documentation of pharmaceutical interventions could contribute to quality management by enhancing traceability and information flow within teams and towards other healthcare professionals.

Introduction

The medication process is complex and involves a variety of individuals such as patients, carers, prescribers, and pharmacists. It is therefore not surprising that frequent medication issues occur. A drug-related problem (DRP) is defined as an "event or circumstance involving drug therapy that actually or potentially interferes with desired health outcomes" [1]. Common DRPs observed in community pharmacies are drug-drug interactions, inappropriate drug choice, and missing/unclear information regarding the prescription [4, 6]. A Swiss study showed that in community pharmacies, 53.4% of 329 prescriptions resulted in a DRP [4]. In daily practice, pharmacists face not only technical (e.g. illegible prescription) but also clinical issues (e.g. drug-drug interaction) requiring a pharmaceutical intervention (PI), such as changing the dosage form or adapting the dose [91]. A PI is defined as a recommendation initiated by a pharmacist in response to a DRP in an individual patient occurring in any phase of the medication process [11, 81]. A classification system is a helpful tool to document PIs in a structured way. Such documentation highlights the pharmacist's role in the safe, appropriate, and cost-effective use of drugs [54, 55], and increases the pharmacist's vigilance for the patients' drug-related needs [53]. The documentation of PIs also provides a valuable source for pharmaceutical care research [60, 63], improves communication between involved healthcare professionals [63], and facilitates political and economic discussions [55, 64]. A documentation of PIs is written evidence that the care was conducted in compliance with good pharmacy practice standards. An important part of the pharmacist's activities is patient counselling at the time of dispensing medicines. Recording DRPs is an essential part of the documentation of counselling outcomes. Common systems and aims must be developed to enable the pharmacy profession to refine and enhance its counselling role [92].

Several DRP classification systems have been developed, either for research purposes, or for the application in practice. Their structure and content differs in terms of category size and type [59-61]. However, most existing classification systems focus mainly on DRPs, such as the Pharmaceutical Care Network Europe (PCNE) system [65], the third Consensus of Granada on DRPs and negatives outcomes associated with medication [93], and the PI-Doc® system [54]. Most systems have not been routinely implemented in practice to date, as they are generally too time consuming, too comprehensive, poorly defined, or partially validated [60].

Solving technical issues is part of the community pharmacists' daily work, but is often not represented in the classification system. Although the PI-Doc® system provides a distinct classification for some technical and logistical DRPs and PIs [64], they are captured in both the DRP and PI category which lengthens the system. Another classification system illustrates the step-wise approach of DRP management and separates the clinical from the technical DRPs, but was exclusive to prescriptions

[94]. While classification systems are mostly developed either for the clinical [62, 66] or the community pharmacy setting [63], no system has been developed for parallel use in both settings. In several Swiss hospitals, an intervention oriented classification system, the Swiss Association of Public Health Administration and Hospital Pharmacists (GSASA) system [81], has been implemented and is routinely used. However, there is no standardised classification system for community pharmacies.

Once a PI is documented in the respective healthcare setting, the exchange of information between the hospital and the community pharmacy is challenging. Our aim is to enable a more efficient and safer transfer of patients between inpatient and outpatient care by improving the exchange of information regarding PIs. Implementing a compatible classification system in both settings would allow for standardised PI documentation and improve the medication management. To achieve this goal, a sound and reliable PI classification form is essential. We identified the need for a classification system that provides high flexibility in documenting PIs. Depending on the PI complexity, the available information, and the need for follow-up, different levels of classification may be required. The objectives of this study were to adapt the existing GSASA system [81] for the community pharmacy setting and to perform an initial validation. Our system, termed the Pharmacists' Documentation of Interventions in Seamless Care (PharmDISC) system, is intended for the documentation of DRPs that result in a PI.

Aim of the study

The aim of this study was to develop and test the PharmDISC classification system on interrater reliability, appropriateness, interpretability, and face and content validity, and to assess pharmacists' opinions on the documentation of PIs.

Ethical approval

The study was approved by the Ethics Committee of Northwest and Central Switzerland (EKNZ 2014-102) on 30.03.2014.

Methods

PharmDISC development

The development process of the PharmDISC system was split into two parts and four stages [95]: Part 1 covered the development and piloting stages, while Part 2 covered the evaluation and

implementation stages (Table 1). This publication is focused on Part 1 of the PharmDISC development process exclusively. Part 2 is reported separately [85].

Table 1 PharmDISC development process [95]: from research to practice

Documentation of pharmaceutical interventions				
	Part 1: Development of PharmDISC		**Part 2**: Validation of PharmDISC	
Stage	Development	Piloting	Evaluation	Implementation
Methods	1. Exploratory trial: analysis of medication review protocols (modification of GSASA system to PharmDISC) 2. Expert panel discussion	1. Interrater reliability study 2. Appropriateness, interpretability and validity study 3. Face and content validity study	1. Interrater reliability study 2. Appropriateness, interpretability and validity study 3. Acceptability and feasibility study	1.Questionnaire (barriers, facilitators) Outlook: quick classification of frequent interventions
Output	Version 1.0	Version 1.1	Version 2.0	Version 2.1 (e-Version)

Development stage

In the initial exploratory trial, we tested the suitability of the GSASA system in a community pharmacy setting. We analysed protocols of medication reviews (Polymedication-Check) provided by community pharmacists. Three investigators independently classified all reported PIs using the GSASA system. Based on the outcome of this exploratory trial as well as on findings from previous studies [4], we modified the GSASA system [81] to generate the PharmDISC system version 1.0 that was intended for use in the piloting phase. Furthermore, in an expert panel discussion with five community pharmacists and one hospital pharmacist, experiences using the new classification system were exchanged.

Piloting stage

The piloting stage combined a quantitative and qualitative approach in a mixed method study. It was performed within an academic environment to obtain first validation results and to further develop the PharmDISC system in preparation of testing the final version in the daily practice in community pharmacies.

1. Interrater reliability study

A total of 77 fifth-year pharmacy students received two hours of training and instructions on the PharmDISC classification form. The training started with two model PIs which were classified with the PharmDISC system using a voting web application. Another three model PIs were classified with the PharmDISC system to determine interrater reliability. All model PIs were taken from the literature [87]

and adapted to Swiss community pharmacy practice. Fleiss-Kappa coefficients K were calculated for the categories using a Microsoft Excel template [88]. Resulting K-values were interpreted according to Landis and Koch [89] as 'almost perfect' (Fleiss' K 0.81-1.00), 'substantial' (0.61-0.80), 'moderate' (0.41-0.60), 'fair' (0.21-0.40), 'slight' (0.00-0.20), and 'poor' (<0.00) interrater reliability. As reported by Ganso et al, a K-value greater than 0.40 suggests a reliable system necessary for a relevant agreement in clinical practice [87].

2. Appropriateness, interpretability and validity study

This prospective observational study aimed to validate the PharmDISC system in terms of appropriateness, interpretability and validity, and to evaluate its suitability in community pharmacy practice. The study design was based on a previous study that classified DRPs with a modified PCNE system [4]. The main outcome measure was the proportion of completely classified PIs. The classification was considered complete when all categories A-E (i.e. problem, type of problem, cause, intervention, communication and outcome) were filled in. Beside the PI classification, we recorded patient and prescription characteristics. We conducted this study during 6 weeks from February to March 2014 in 77 community pharmacies in which the 77 fifth-year pharmacy students from the interrater reliability study were conducting their one-year internship.

Each of the 77 fifth-year pharmacy students was required to consecutively collect ten prescriptions necessitating a PI. The role of the students was to document the PI together with the pharmacists who performed the PI. Prescriptions of patients aged 18 or older were eligible if they contained at least two prescribed drugs, thereof at least one new prescription (new drug, altered dosage form and/or changed dosage). Prescriptions for contraceptives, not reimbursed by the Swiss health insurance, were excluded. Each case was documented with a short description, a copy of the prescription, and classification forms for each PI. This allowed the plausibility and coherence of the documentation to be verified and validated by the investigator in retrospect. Each PI classification was documented on a separate PharmDISC classification form. Statistical analyses were performed using IBM SPSS Statistics for Windows, version 22 (released 2013, Armonk, NY: IBM Corp).

3. Face and content validity

In a next validation step, we collected suggestions from experienced community and hospital pharmacists to establish face validity. For content validity, the pharmacists judged the extent as to which the PharmDISC system covered all of the relevant issues.

We used the focus group technique as a method to explore the pharmacists' opinions regarding the importance of PI documentation and to further develop the PharmDISC system. The focus group consisted of nine experienced pharmacists practicing in different institutions. The participants

consisted of six community pharmacists (three with previous experience using a classification system), and three hospital pharmacists who routinely work with a classification system during ward rounds. Participants were specifically chosen to include practicing and experienced pharmacists directly involved in patient medication management.

The focus group was moderated by the associate professor ML (male, PhD, clinical pharmacist), an experienced qualitative researcher [42]. At the time of this study, the moderator worked with three of the participants.

To familiarize with the PharmDISC system (version 1.0), the participants were first required to document a model PI. This PI was subsequently discussed in the focus group at the University of Basel in a seminar room. As shown in the predefined focus group framework (Fig. 1), the interview was structured in four questions. The opening question of the importance of documentation allowed the participants to express two to three reasons on paper sheets, which were discussed. In question 2, the core content, structure and order of the PharmDISC system were discussed to assess face and content validity. The participants had the possibility to accept, reject or revise each item with coloured voting cards. Two investigators counted and recorded the votes (DS, KH). An agreement of > 50% among the participants was counted as approval of the item. Question 3 discussed different levels of detail of the PharmDISC system depending on the PI complexity. Lastly, question 4 allowed identifying barriers and facilitators for the implementation of a classification system in the daily community pharmacy practice. The focus group lasted 2 hours 40 minutes and was recorded on audio tape, transcribed and anonymised as written text by an investigator (KM). Notes were taken during the interview by three investigators (KM, DS, KH). The transcripts were qualitatively analysed using an explorative theme analysis guided by the predefined framework and by using the software MAXQDA, version 12 (VERBI GmbH, Berlin, Germany). The transcripts were not returned to the participants for proof-reading, but were reviewed by a second investigator. The focus group was reported according to the Consolidated Criteria for Reporting Qualitative Research (COREQ) checklist [96].

Aim / question	Methods	Analysis
1 Goal of the documentation "Why is it important to document what we are doing?"	• Individual expression of 2-3 reasons on paper sheets • Discussion	• Thematic analysis
2 Review of the PharmDISC system according to core content (categories and subcategories), structure, and order of the system with regards to the practice and the implementation	• 1st round: voting with colour cards (green=accepted, yellow = need revision, red=rejected) • 2nd round: discussion, based on the yellow cards	• Quantitative analysis • Suggestions for optimisation leading to changes of the PharmDISC system
3 Definition of different levels of detail of the PharmDISC system depending on the complexity of the pharmaceutical intervention	• Discussion	• Thematic analysis
4 Identification of barriers and facilitators for the implementation	• Discussion	• Thematic analysis

Fig. 1 Framework for the focus group interview

Results

Development stage

We adapted the GSASA system to allow its application in community pharmacies [81]. Figure 2 illustrates the changes that formed the PharmDISC system version 1.0, most of which were based on previous studies [4, 81] and the exclusion of hospital-specific items. The modification concerning the quality of prescribing was adopted from the modified PCNE system [4]. Further changes originated from the exploratory trial using the GSASA system and from protocols of medication reviews that were written by community pharmacists. From a total of 65 medication reviews, 190 PIs were documented (median of 3 PIs per review), all of which were classified with the GSASA system. The pharmacists intervened mainly for 'patient counselling/training' (n=69, 36.3%) and 'optimisation of administration' (n=45, 23.7%). However, the system did not provide detailed information on certain interventions. Therefore, we added two subcategories in category D, namely 'application instruction (training)', and 'delivery of a compliance aid incl. counselling'. Moreover, the expert panel of community and hospital pharmacists proposed three new subcategories and some optimisation in wording to improve the comprehension of the classification system. The resulting PharmDISC system (version 1.0) included 5 categories (i.e. problem, type of problem, cause, intervention and outcome) and 52 subcategories.

PharmDISC: Classification of pharmaceutical interventions

Drug/s: .....

A Problem

- □ 1. Treatment effectiveness
- □ 2. Untreated indication
- □ 3. Safety of treatment
- □ 4. Treatment costs
- □ 5. Dissatisfaction / problems of the patient

B Type of problem

- □ 1. Manifest, reactive
- □ 2. Potential, preventive

C Cause of intervention

1. Therapy choice

- □ 1. No concordance with guidelines, only suboptimal therapy possible
- □ 2. Contraindication
- □ 3. Interaction
- □ 4. Drug not indicated
- □ 5. Duplication
- □ 6. Adverse effect
- □ 7. Incomplete patient documentation / missing information

2. Drug choice

- □ 1. Inappropriate dosage form

3. Dose choice

- □ 1. Underdose
- □ 2. Overdose
- □ 3. Inappropriate monitoring
- □ 4. Dose not adjusted to organ function

4. Drug use

- □ 1. Inappropriate timing or frequency of administration
- □ 2. Inappropriate use method

5. Therapy duration

- □ 1. Inappropriate therapy duration

6. Logistics

- □ 1. Prescribed drug not available
- □ 2. Error in medication process

7. Patient

- □ 1. Insufficient adherence
- □ 2. Insufficient knowledge
- □ 3. Burden due to therapy

8. Prescription quality

- □ 1. Missing / unclear package size/ therapy duration
- □ 2. Missing / unclear dosage strength / galenic form
- □ 3. Illegible prescription
- □ 4. Unclear drug name, although legible
- □ 5. Missing / unclear dosage / application instruction
- □ 6. Missing prescription of necessary application aid(s) / complementary product(s)

D Intervention

- □ 1. Counselling of patient
- □ 2. Application instruction (training)
- □ 3. Delivery of an adherence aid inclusive counselling
- □ 4. Therapy started
- □ 5. Therapy stopped / no delivery
- □ 6. Substitution
- □ 7. Dose adjustment
- □ 8. Therapy monitoring
- □ 9. Optimisation of administration
- □ 10. Change of administration way
- □ 11. Adjustment of the delivery amount (e.g. package size, quantity of packages)
- □ 12. Information to the physician
- □ 13. Clarification in the case notes (e.g. history)
- □ 14. Report to pharmacovigilance centre

E Outcome of the intervention

- □ 1. Accepted and implemented
- □ 2. Partially accepted or accepted without implementation
- □ 3. Not accepted
- □ 4. Not known
- □ 5. Not applicable

Fig. 2 The PharmDISC system (version 1.0): The changes highlighted in grey text originate from expert panel discussions, in grey frames from modified PCNE system [4], in black frames from exploratory trial based on GSASA system and protocols of medication review performed in community pharmacy, in black text from evaluation of GSASA system)

Piloting stage

1. Interrater reliability study

The PharmDISC system (version 1.0) reached a substantial user agreement for the categories B (κ=0.70) and D (κ=0.76), while a moderate agreement for the categories A (κ=0.53) and C (κ=0.45) was obtained. All κ-values of the five categories were above the threshold of 0.40 and are therefore considered at least moderate [87]. For the category E, the used template was not able to calculate a κ-value because of the high relative agreement (P=0.96), which is described as an almost perfect agreement.

2. Appropriateness, interpretability and validity study

A total of 826 PI forms were analysed of which 101 were excluded due to deficient documentation or did not fulfil the inclusion criteria as shown in the data management flow chart in Fig. 3. Out of the 725 (100%) usable PI classification forms, 39 (5.4%) could not be fully classified in all classification categories due to missing data or manually added subcategories. Data were missing mostly for the category A followed by the categories C and B, while categories D and E were always completed. A total of 25 new subcategories were manually added by the users. Most of these were added in the category C (n=15) especially concerning the price and generic substitution. In the category D, the proposed subcategories (n=6) mainly concerned the contact with the persons involved.

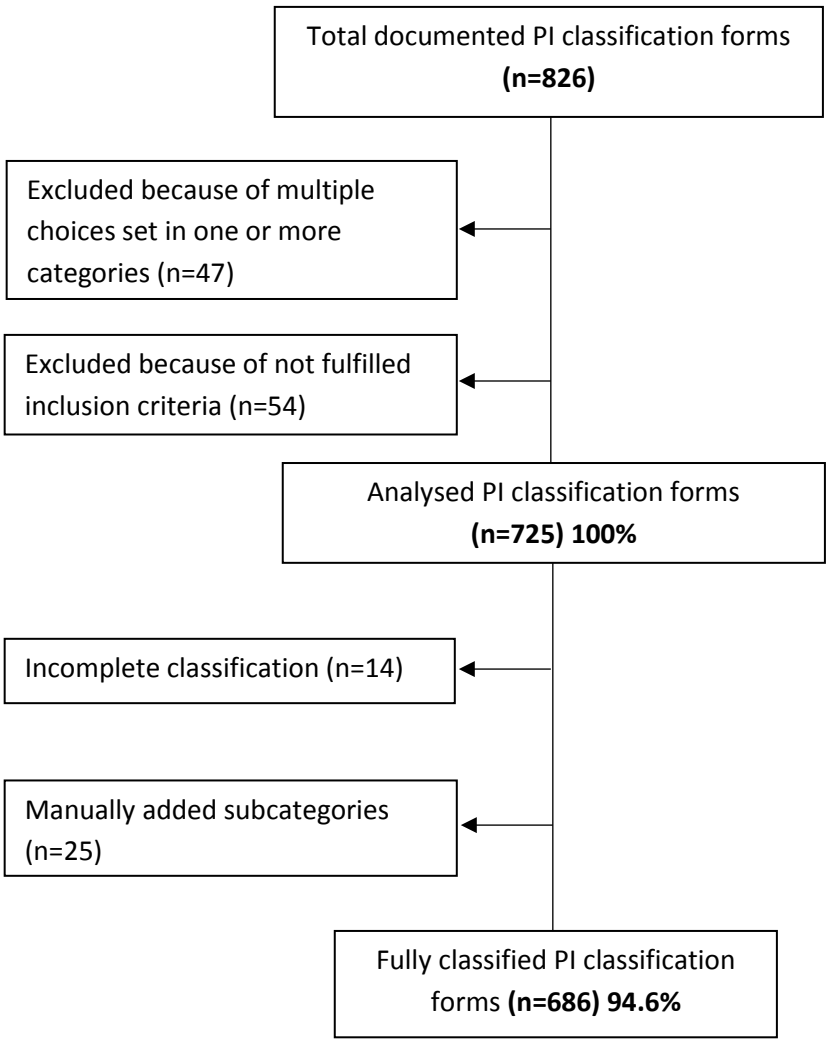

Fig. 3 Data management flow chart

Based on the results and suggestions collected in this study, we created a refined version of the PharmDISC system (version 1.1, supplementary Fig.). Major changes between PharmDISC version 1.0 (Fig. 2) and version 1.1 are shown in Table 2a.

Table 2 Comparison of the PharmDISC version 1.0 and version 1.1: major changes introduced following a) the appropriateness, interpretability and validity study, and b) the face and content validity study

	PharmDISC version 1.0 (Fig. 2)	PharmDISC version 1.1 (suppl. Fig.)
a) Appropriateness, interpretability and validity study		
General		Wording "only one choice" per category A, B, C, D, F added
Category C		Two subcategories added: C5.4 Financial burden C7.4 Formal/regulatory reason
	C8.1 Missing/ unclear package size/ therapy duration C8.2 Missing/ unclear dosage strength/ galenic form C8.5 Missing/ unclear dosage/ application instruction	Three subcategories merged into: C7.1 Incomplete/ unclear prescription
	C8.3 Illegible prescription C8.4 Unclear drug name, although legible	Two subcategories merged into: C7.2 Illegible prescription
	C8.6 Missing prescription of necessary application aid(s) / complementary products.	Reworded for clarity: C7.3 Missing prescription of necessary application aid(s)
Category D	D12 information to the physician	Replaced by a checkbox to indicate if the PI was performed by the pharmacist alone or in collaboration with the physician
b) Face and content validity study		
Category C	C4 Drug use C5 Therapy duration	Two subcategories merged into: C4 Drug use
Category D	D12 Information to physician D13 Clarification in patient notes	Reworded for clarity: D11 Transmission of information D10 Clarification/ addition of information
	D14 Report to pharmacovigilance centre	Removed
Category E		New category (between categories D Intervention and F Outcome) added: E communication: person(s) involved (multiple choice possible)

3. Face and content validity

Nine pharmacists joined the focus group and were asked to express their opinion on the PharmDISC system (version 1.0) and the PI documentation.

Question 1: The participants recognised the importance of documenting PIs. They believed that this may facilitate communication within the pharmacy team and with other healthcare professionals, allow traceability, improve the information-flow, and increase patient safety and quality of care. Most participants were of the opinion that by documenting PIs, thus making the pharmacist's performance quantifiable, stronger arguments can be made in political discussions. Table 3 shows a compilation of the major emerging themes for Question 1.

Table 3 Statements of experienced pharmacists illustrating and emphasising the importance for documenting PIs in the specified major themes from the focus group interview (Question 1).

Theme	**Example**
Communication	Respondent (R) 9: *"I have mainly listed communication. Precisely [documentation of intervention can] ease communication within the team, but also with other healthcare professionals. And I believe it is important to document, to facilitate or even standardise communication that everybody knows what we are talking about. That we understand each other."*
Organisation	R8: *"We employ about 30 people with many in and out in our pharmacy with about 60-70% full-time job equivalent. It takes a lot of coordination, a lot of structure and every team that undergoes changes also needs to know what the other team has been doing. It's very important that this is documented. Not only for the team, but also for the information flow, the documentation transfer e.g., to the doctors, to the team of the emergency department."*
Traceability	R3: *"[Documentation is important to allow] reproducibility at a later date, that the same mistakes are not repeated, or that we do not have to struggle with the same problems."*
Information-flow	R5: "*[Documentation is important] to enable a seamless information flow between the team and healthcare professionals."* R5: *"It may well be that in the future, perhaps when the patient data would somehow be centralised, that we could eventually have access to this information."*
Quality management	R4: *"We can perform statistics that we operate for ourselves and show a certain level of development. We see if there are certain trends. When we record everything, we can see if our interventions are beneficial or not, so we can optimize our practice in the long term."*
Drug safety	R6: *"[Documentation could enable to] identify common and severe problems, to implement actions before, during and after the prescription to ensure safe and effective use of drugs."*
Pharmacists' performance	R2: *"[Documentation of intervention is important] to map the importance of our own work."*
Quantifiability	R5: *"As part of the development of a service society, our services will be fully recognisable and quantifiable."* R1: *"It is important that we can actually show everything we do. We do so much, but we cannot prove it. We just do it. But when a politician asks, well, what are you going to say. We cannot provide any figures on our daily interventions. But we simply do it. We really should also have data to show which situations always need an intervention at the pharmacy, and what we change, and what we optimise. Providing data in black and white from research projects or everyday life at the pharmacy is exceptionally important."*
Politics	R1: *"This is a GMP principle: 'If something is not documented, it has never been done.' This is a basis for political discussions to present the performance of the pharmacists and change the field. This could determine the quality management and the frequent interventions, we could draw any possible consequences from it."*

Question 2: The interview aimed to refine and validate the PharmDISC classification system (version 1.0) leading to the creation of a new version (version 1.1, supplementary Fig). From a total of 51 subcategories, 47 were accepted (92.2%, mean agreement 91%), 4 needed revision (7.8%), and none were rejected. The major change was the addition of a category 'communication: persons involved' (Table 2b). Pharmacist R9 suggested: *"An entire category is missing. Communication or a blank space where in which you could write 'I have discussed with the physician or the patient'"*.

Question 3: The pharmacists suggested to differentiate between types of PIs for the classification, in other words to align the classification level of detail with the complexity of the PI:

R7: *"It depends on the type of intervention. I have a pharmacy software with only pharmaceutical records that allows to briefly document interventions such as adjustment of drug package size with a line or with key words. In contrast, when I need to talk to two specialists for a dose adjustment, then a more precise documentation is necessary. It really depends on the complexity."*

Question 4: The pharmacists suggested factors which could enhance the implementation of the PharmDISC system in daily community pharmacy practice. A notable suggestion was the automatic integration of the PI classification form into the patient file:

R1: *"It should be integrated into the software. That when you close the prescription assessment in your software, the question 'Was there an intervention?' pops up. This appears automatically and you have to choose 'yes' or 'no'."*

The pharmacists further discussed the involvement of pharmacy technicians to complement the pharmacists. This would require the team to be trained and a descriptive manual for the PharmDISC system. A person in charge should be determined who, besides analysing the obtained data, has the ability to motivate and teach the team how to use the PharmDISC system. This approach could facilitate the implementation of the PharmDISC system and overcome issues such as lack of motivation or understanding from team members:

R6: *"Someone who is responsible and who understands the importance of it. Every week he/she discusses the results with the team and sometimes he/she can bring an example."*

R8: *"There are some interventions, like delivery of adherence aid, which the pharmacy technician can carry out, and others, depending of the intervention type intervention, have to be handed over to the pharmacist."*

Discussion

The findings of the study confirmed that the PharmDISC system was valid and reliable. Further qualitative results indicated an overall favourable acceptance of the system. This positively answered the research question, which was to investigate whether the PharmDISC system is suitable to classify PIs in community pharmacies.

The PharmDISC system (version 1.0) reached good interrater reliability. The average user agreement was substantial (K=0.61). All K-coefficients of the classification categories were above the threshold of K=0.40, indicating that the results were widely independent of the observers and that the categories were mutually exclusive. Furthermore, the PharmDISC system reached higher interrater reliability than both, the GSASA system (K=0.53) [81] and the DOCUMENT system (K=0.53) [63]. This shows that the modifications made to the GSASA system were suitable for the community pharmacy setting. The study showed that the majority (94.6%) of the 725 PIs were completely documented with the PharmDISC system which demonstrated its clarity and completeness. These results demonstrated that the PharmDISC system fulfilled the requirements of a valid and reliable classification system.

To our knowledge, this is the first development of a classification system that combines a quantitative and qualitative approach in a mixed methods study. Integrating data from different sources is a challenging and labour-intensive task, but the application of diverse methods provides in-depth and complementary information, and can compensate for inherent weaknesses in single study designs [97, 98]. The Medical Research Council framework [95] proposed the application of diverse methodologies for each stage, which was the case in our piloting stage. Both, the observational study and interrater reliability study provided the quantitative baseline which was used in a qualitative phase to gain the pharmacists' opinion using a focus group. Although only a limited number of highly motivated and qualified pharmacists participated in the focus group, the findings highlight the factors which positively influenced the PI documentation, while limited insight in possible opposing factors was addressed.

The focus group confirmed the need for a classification system which is compatible with the electronic patient file by pointing out the importance of PI traceability. Similar observations in a survey with community pharmacies in the United States were made, in which the advantages of a computerised system compared with paper charts were highlighted [99]. Pharmacists wished to distinguish the type of intervention depending of the PI complexity. This could be solved by separating technical and clinical PIs. Technical PIs such (e.g. generic substitution) are routine and non-complex PIs that require little time expenditure as opposed to clinical PIs (e.g. dose adjustment). We also discovered that pharmacists are highly motivated to document PIs, as it provides a tangible proof of their work, improves the communication within the team and with other healthcare professionals, and maintains

quality management. They also mentioned that issues with the quality of PI documentation (e.g. repeated mistakes) could be improved by the analysis of frequent PIs. Conclusions of such analyses could be included in team training and learning. The increased visibility and transparency of PI-related activities by the pharmacist could provide strong arguments when negotiating a remuneration-based service for PI documentation, which is currently in effect in Australia with the DOCUMENT system [63].

Points for optimisation of the PharmDISC system were discovered in this study. The community pharmacists frequently misinterpreted the subcategory 'information to the physician' as the PI. Therefore, a clear distinction between the PI itself and the communication was needed. Communication was also a predominant topic discussed in the focus group, finally leading to the creation of a category 'communication: person involved' (e.g. introduction of a drug is correctly classified as 'therapy started' and not as 'information to the physician' although this PI needs communication with the physician, which is additionally documented in category 'communication'). In Switzerland, the pharmacist is required to inform the prescriber in the case of any change in the prescribed medicines. In Germany, the validation study of the PI-Doc® system showed that the prescriber was contacted in 60.5% of the cases [54]. It could be more convenient to refer all patient to the prescriber once DRPs are detected. It seems that Swiss community pharmacists in most cases decide to initiate the intervention themselves, but in collaboration with the prescriber. With respect to the practice of pharmaceutical care, pharmacists should take responsibility for the patient's drug-related needs together with other healthcare professionals [100].

In this piloting stage of the project (Part 1), we refined and validated the PharmDISC system within an academic environment, where the PI documentation was performed by trained pharmacy students. The pharmacists understood the importance of PI documentation. The next step is to validate the herein established PharmDISC system (version 1.1) in real-life daily practice in community pharmacies. Therefore, Part 2 of the PharmDISC development process highlights the evaluation stage by performing an observational study with practicing community pharmacists, and enabling discussions of implementation aspects.

Conclusion

The hospital-specific GSASA classification system for PIs was modified into the PharmDISC system for the application in community pharmacies. The PharmDISC system proved to be valid and reached substantial interrater reliability. Almost all PIs could be classified using the PharmDISC system. The system was refined based on the results from the piloting stage and the pharmacists' suggestions, resulting in a final version which will be tested in an observational study with community pharmacists. As stated by the pharmacists, PI documentation should enhance traceability and information flow within team and with other healthcare professionals, improving so the visibility of pharmacists' activities. Documentation can also have a teaching and learning effect and therefore increase quality and performance.

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Conflict of interest

None.

Appendix

A2.1.1 Study protocol for Ethics committee

A2.1.2 Study information sheet for the master pharmacy students

A2.1.3 Case Report Form PharmDISC Part 1

A2.1.4 Two model pharmaceutical interventions, adapted from Ganso et al. for the training with the online voting (Movo.ch)

A2.1.5 Three model pharmaceutical interventions, adapted from Ganso et al.

Supplementary Fig.: The PharmDISC system (version 1.1)

PharmDISC: Classification of pharmaceutical interventions

A Problem (1 choice)
- □ 1. Treatment effectiveness
- □ 2. Untreated indication
- □ 3. Safety of treatment
- □ 4. Treatment costs
- □ 5. Patient dissatisfaction/ problems

B Type of problem (1 choice)
- □ 1. Manifest, reactive
- □ 2. Potential, preventive

C Cause of intervention (1 choice)

1. Therapy choice
- □ 1. No concordance with guidelines, only suboptimal therapy possible
- □ 2. Contraindication
- □ 3. Interaction
- □ 4. Drug not indicated
- □ 5. Duplication
- □ 6. Adverse effect
- □ 7. Missing patient documentation

2. Drug choice
- □ 1. Inappropriate dosage form / administration route

3. Dose choice
- □ 1. Underdose
- □ 2. Overdose
- □ 3. Inappropriate monitoring
- □ 4. Dose not adjusted to organ function (e.g., renal/ liver failure, age)

4. Drug use
- □ 1. Inappropriate timing or frequency of admin.
- □ 2. Inappropriate application
- □ 3. Inappropriate therapy duration

5. Patient
- □ 1. Insufficient compliance
- □ 2. Insufficient knowledge
- □ 3. Concerns about the treatment
- □ 4. Financial burden

6. Logistics
- □ 1. Prescribed drug not available
- □ 2. Error in medication process

7. Prescription quality
- □ 1. Incomplete / unclear prescription
- □ 2. Illegible prescription
- □ 3. Missing prescription of necessary application aid(s)
- □ 4. Formal / regulatory reason

Technical

D Intervention (1 choice)
- □ 1. Substitution
- □ 2. Dose adjustment
- □ 3. Adjustment of package size / quantity
- □ 4. Optimisation of administration / route
- □ 5. Therapy stopped / no delivery
- □ 6. Therapy started / continued
- □ 7. In-depth counselling of patient
- □ 8. Application instruction (training)
- □ 9. Delivery of compliance aid incl. counselling
- □ 10. Clarification / addition of information
- □ 11. Transmission of information
- □ 12. Proposition of therapy monitoring

E Communication: involved person(s) (multiple choice possible)
- □ 1. Only pharmacist
- □ 2. physician
- □ 3. Caregiver / home care
- □ 4. Patient / relative

F Outcome of the intervention (1 choice)
- □ 1. Accepted and implemented
- □ 2. Partially accepted or accepted without implementation
- □ 3. Not accepted
- □ 4. Not known
- □ 5. Not applicable

B2 Documentation of pharmaceutical care: validation of an intervention oriented classification system

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Abstract

Rationale, aims and objectives During the dispensing process, pharmacists may come across technical and clinical issues requiring a pharmaceutical intervention (PI). An intervention oriented classification system is a helpful tool to document these PIs in a structured manner. Therefore, we developed the PharmDISC classification system (Pharmacists' Documentation of Interventions in Seamless Care). The aim of this study was to evaluate the PharmDISC system in the daily practice environment (in terms of interrater reliability, appropriateness, interpretability, acceptability, feasibility, and validity); to assess its user satisfaction, the descriptive manual, and the online training; and to explore first implementation aspects.

Method Twenty-one pharmacists from different community pharmacies each classified 30 prescriptions requiring a PI with the PharmDISC system on five selected days within five-weeks. Interrater reliability was determined using model PIs and Fleiss's kappa coefficients (K) were calculated. User satisfaction was assessed by questionnaire with a 4-point Likert scale. The main outcome measures were: interrater reliability (K); appropriateness, interpretability, validity (ratio of completely classified PIs/all PIs); feasibility, and acceptability (user satisfaction and suggestions).

Results The PharmDISC system reached an average substantial agreement (K=0.66). Of documented 519 PIs, 430 (82.9%) were completely classified. Most users found the system comprehensive [median user agreement 3 (2/3.25 quartiles)] and practical [3(2.75/3)]. The PharmDISC system raised the awareness regarding drug-related problems for most users (n=16). To facilitate its implementation, an electronic version that automatically connects to the prescription together with a task manager for PIs needing follow-up was suggested. Barriers could be time expenditure and lack of understanding the benefits.

Conclusion Substantial interrater reliability and acceptable user satisfaction indicate that the PharmDISC system is a valid system to document PIs in daily community pharmacy practice.

Key words

Evaluation; healthcare; patient-centered care; medical error

Introduction

The daily practice of pharmacists comprises a wide variety of interventions regarding drug-related problems (DRPs). The classification and documentation of pharmaceutical interventions (PIs) increases the pharmacists' attention to the drug-related needs of patients, enhances counselling skills and improves pharmaceutical care [53]. It also highlights the pharmacists' role in ensuring the safe use of medicines [54, 55]. Indeed, a prerequisite for high-quality pharmaceutical care is an effective documentation allowing the evaluation of the PI outcome [56]. In other terms, the documentation of care represents the evidence of practice [57]. It is therefore essential to be recorded in a standardised and structured manner.

Once PIs are documented in the respective healthcare setting, the information exchange between the hospital and the community pharmacy and vice versa can often be challenging. Improving information exchange regarding PIs could enable a more efficient and safer transfer of patients between inpatient and outpatient care. An aligned classification system in both settings would facilitate a standardized documentation of PIs. Most existing classification systems focus on DRP enabling documentation of all DRPs (potential and manifest). However, in daily practice and especially in seamless care, only those DRPs become relevant that were also addressed through PIs. Therefore, we identified the need for a PI classification system in community pharmacies and created the Pharmacists' Documentation of Interventions in Seamless Care (PharmDISC) system, adapted to an existing system used in Swiss hospitals [81]. This system allows a comprehensive classification of prescription-focused as well as patient-centered PIs. The PharmDISC system is intervention oriented and contains 6 categories (problem, type of problem, cause, intervention, communication, and outcome) and 53 subcategories for classification. The development process of the PharmDISC system was split into two parts and four stages following an established development framework (Table 1) [95]. Part 1 covered the development and the piloting stage and was reported separately [84]. In this piloting stage of the project, the PharmDISC system was refined and validated within an academic environment, where the PI documentation was performed by trained pharmacy students (n=77). To assess face and content validity, a focus group interview was performed and revealed that the pharmacists (n=9) understood the importance of PI documentation. The next step was to validate and evaluate the herein established PharmDISC system (version 1.1) in real-life daily practice in community pharmacies.[84] Hence, this publication is focused on Part 2 that includes the evaluation stage and implementation aspects. The validation of a classification system is necessary to confirm "through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled" [101]. For evaluating patient-based outcome measures, Fitzpatrick et al. defined eight criteria to consider: appropriateness, reliability, validity, responsiveness, precision, interpretability, acceptability, and

feasibility. These measures are originally defined for the validation of DRP classification [68, 102], but they are without restriction applicable to a PI classification as well.

Table 1 PharmDISC development process [95]: from research to practice

Documentation of pharmaceutical interventions				
	Part 1: Development of PharmDISC		**Part 2**: Validation of PharmDISC	
Stage	Development	Piloting	Evaluation	Implementation
Methods	1. Exploratory trial: analysis of medication review protocols (modification of GSASA system to PharmDISC) 2. Expert panel discussion	1. Interrater reliability study 2. Appropriateness, interpretability and validity study 3. Face and content validity study	1. Interrater reliability study 2. Appropriateness, interpretability and validity study 3. Acceptability and feasibility study	1.Questionnaire (barriers, facilitators) Outlook: quick classification of frequent interventions
Output	Version 1.0	Version 1.1	Version 2.0	Version 2.1 (e-Version)

The aim of this study was to validate the PharmDISC system in the daily practice environment (in terms of interrater reliability, appropriateness, interpretability, acceptability, feasibility, and validity); to assess its user satisfaction, the descriptive manual, and the online training; and to explore first implementation aspects.

Methods

Setting

A prospective observational study was conducted in Swiss community pharmacies to evaluate the practicability of the PharmDISC system (version 1.1) in daily practice and to validate it. This study was approved by the ethics committee of the Northwest and Central Switzerland (EKNZ:2014-102). The study coordination center was located at the University of Basel in the German-speaking part of Switzerland which collaborated with the community pharmacy of the Department of Ambulatory Care & Community Medicine, Lausanne, in the French-speaking part of Switzerland. All documents and study materials were available in German and French. The translation of the German PharmDISC system to the French version was based on a previous study [81]. All community pharmacists of the expert list for the state exams of the Universities of Basel and Lausanne/Geneva were contacted by e-mail and asked to participate in the study. The aim was to recruit twenty pharmacists using convenience sampling.

Training

The study participants completed an online training prior to PI documentation. The training consisted of two videos that were available from the online study platform. The first video was a fifteen-minute Microsoft Power Point Presentation narrated by a trainer that described the study procedure and material, and provided instructions for the correct use of the PharmDISC system. The second three-minute video presented a role play demonstration of the documentation of a PI. The two model PIs [87], showed in the videos, were modified to suit the community pharmacy setting. The study documents were also available on the online study platform.

Study

The validation of the PharmDISC system (version 1.1) was performed in a stepwise approach:

1. Interrater reliability

To describe the extent of independent agreement between raters, interrater reliability was determined using three model PIs [87]. After online training, the model PIs were classified by each pharmacist prior to real-world data collection. Fleiss's kappa coefficients (K) were calculated using a Microsoft Office Excel template [88]. Resulting K-values were interpreted according to Landis and Koch [89]as almost perfect (K=0.81-1.00), substantial (0.61-0.80), moderate (0.41-0.60), fair (0.21-0.40), slight (0.00-0.20), and poor (<0.00) agreement. A K-value greater than 0.40 suggests a reliable system necessary for a relevant agreement in clinical practice [87].

2. Appropriateness, interpretability and validity

We measured appropriateness, interpretability, and validity of the PharmDISC system by assessing the ratio of completely classified PIs to all PIs. In addition, we collected users' suggestions for optimization and comments on classification difficulties. Classification was considered completed when all six categories were filled in. Each participating pharmacist consecutively collected 30 prescriptions requiring a PI on five selected days within five weeks from March to April 2015. The dates chosen were communicated to the study center and each PI was classified on the same day as the prescription was collected. There were no inclusion criteria for the prescriptions. Each PI was documented with a short description, the anonymized prescription copy, a three-month medication history and the PI classification form. We developed a descriptive manual which defined the PharmDISC system with examples reflecting the community pharmacy practice (Table 4). This supported the users in the PI classification, thus increasing consistency and comprehensibility. All PI classification forms were validated and statistically analyzed using IBM SPSS Statistics for Windows, version 22 (released 2013, Armonk, NY:IBM Corp).

3. Acceptability and feasibility

Feasibility and acceptability were evaluated with a 47-item online user satisfaction questionnaire (FlexiForm® version 2.6.9, University of Basel, Switzerland), which was split into four sections. In section 1 (18 questions), pharmacists expressed their opinion on the PharmDISC system. Most questions of section 1 were adapted from AbuRuz et al. [81, 86]. In section 2 (10 questions), the users evaluated the online training, in section 3 (6 questions) the descriptive manual, and in section 4 (13 questions) the overall project. Most questions in sections 2-4 were adapted from the literature [103-105]. Table 2 illustrates the evaluation framework, based on the four steps proposed by Kirkpatrick [106]: reaction (35 questions), learning (3), behavior (8) and results (1). The extent of the agreement was assessed by 4-point Likert scale (1=strongly disagree, 4=strongly agree). An option answer 'no comment' was also available.

Table 2 Description of the evaluation steps, adapted from Kirkpatrick et al. [106]

Step	Description	example of a question/statement
Step 1 Reaction	Evaluates the feelings of the participants, how well they liked and accepted the project/training.	"The topics of the online training were relevant."
Step 2 Learning	Determines how much was learned.	"After the online training I felt confident to use the PharmDISC system."
Step 3 Behavior	Evaluates if participants change their behavior after the project/training.	"Classifying PIs in this study motivated me to document PIs in the future."
Step 4 Results	Evaluates if the project/training had any influence on the results (e.g. increase in quality and/or quantity of production).	"I intervene now more in the dispensing process of medicines than before the study."

In view of a future implementation of the PharmDISC system in community pharmacies, we surveyed the pharmacists about potential barriers and facilitators that influence implementation. We also obtained feedback from the pharmacists on the usefulness of the online training and the descriptive manual. The answers and comments were collected and qualitatively analyzed

Results

We approached 57 community pharmacists (33 German-speaking and 24 French-speaking). Twenty-one pharmacists (11 German-speaking and 10 French-speaking), all working in separate pharmacies, participated in the study (participation rate 36.8%). Their professional experience ranged from 3.0 to 20.8 years. Twelve pharmacies were located in urban areas (57.1%) and nine in the rural areas (42.9%). Seventeen were independent pharmacies (80.9%) while four belonged to a pharmacy chain (19.1%).

1. Interrater reliability

Nineteen pharmacists classified three model PIs to assess the level of user-agreement for each category of the PharmDISC system (version 1.1) [Fig.1]. Two pharmacists did not participate in this part of the study due to time constraints. An overall substantial agreement (average K=0.66) was achieved for the classification categories A-E. Category E (K= 0.29) was the only category reaching a K-value less than 0.40. For the last category F 'outcome', the calculation template was not able to calculate a K-coefficient because of the high relative agreement (P=1.00), describing an almost perfect agreement.

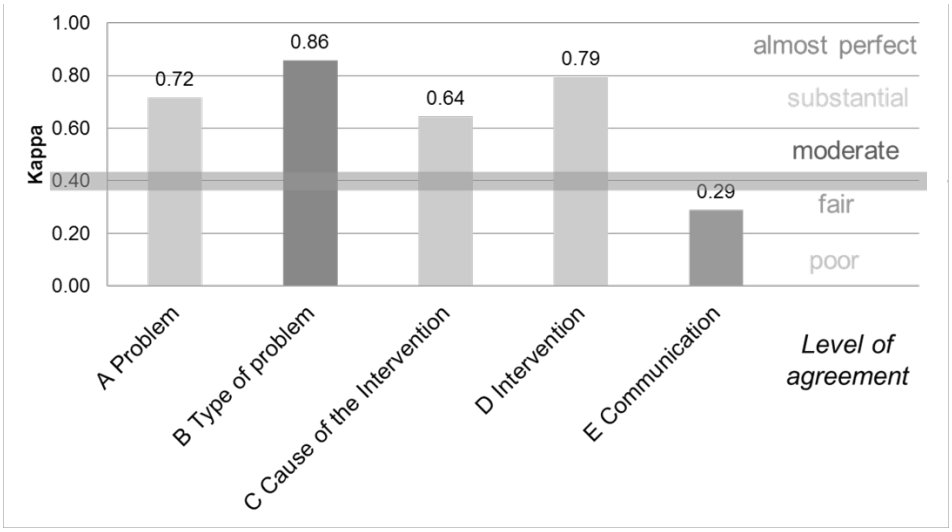

Fig. 1 User-agreement based on three model PIs rated by 19 users for each classification category of the PhamDISC system expressed as K-coefficients. A K-value greater than 0.40 is considered necessary for a valid classification system.

2. Appropriateness, interpretability, and validity

To evaluate appropriateness, interpretability, and validity, the pharmacists classified prescriptions requiring a PI on five days within five weeks. Table 3 illustrates a typical PI performed in community pharmacy. A total of 535 PIs from 365 prescriptions were documented by 21 pharmacists. Sixteen PIs were excluded because they were either not drug-related or data validation was not possible. Of 519 analyzed PIs, 430 (82.9%) were completely classified in all categories (Table 4). In 89 cases (17.1%), the

instructions for the completion of the PI classification form were not respected (i.e. categories with no data and/or statement for optimization such as new subcategories). Categories with no data (n=64, 12.3%) were observed in the categories A (n=26), B (n=25), and other categories (n=13).

The pharmacists proposed 19 new subcategories to address classification difficulties they encountered and provided 16 statements for optimization in a free text box. The proposed subcategories were mainly related to technical issues (prescription error [n=9], technical/formal problems [n=8], financial burden for the healthcare system [n=2]) for which the classification in category A was challenging.

Table 3 Illustration of a typical PI classified in this study in a community pharmacy with the PharmDISC system

The pharmaceutical intervention	***The classification PharmDISC***	
	Category	**Subcategory**
A mother visited the pharmacy with a prescription for her 18-month old daughter. One measuring spoon (=5 mL) Dextromethorphan syrup was prescribed 2 to 3 times daily.	**A** Problem	**A3** safety of treatment
	B Type of problem	**B2** potential, preventive
During the dispensing process, the pharmacist noticed that the dose of Dextromethorphan is too high for this age (<2 years old).	**C** Cause of the Intervention	**C3.2** Overdose
The pharmacist adjusted the dose according to the Swiss drug formulary to a half measuring spoon (=2.5 mL) twice daily in the morning and the evening.	**D** Intervention	**D1** Dose adjustment
The mother accepted the dose adjustment and thanked.	**E** Communication **F** Outcome of intervention	**E4** Patient/relatives **F1** Accepted and implemented

.

Table 4: Descriptive manual of the PharmDISC system for the documentation of PIs with examples, and with frequencies [n=430 PIs] (bolded text added to version 2.0, italicised text modified to version 2.0)

Code	Category	Code	Subcategory	Subcategory description	Example	Frequency n (%)
A	Problem (1 choice)	A1	Treatment effectiveness	Any problem or circumstance which may modify the effectiveness of a medication (type of problem: potential), or any signs or symptoms (type of problem: manifest) suggesting lacking or unsatisfactory effectiveness	No effect of the quinolone therapy due to formation of non-absorbable complexes with multivalent cations (e.g., Ca^{2+}, Mg^{2+})	172 (40.0%)
		A2	Untreated indication	Preventive, therapeutic, or concomitant medication not prescribed for a valid indication	No laxative prescribed together with opioid therapy	8 (1.9%)
		A3	Safety of treatment	Any problem or circumstance which may expose the patient to an increased risk for an adverse drug event (type of problem: potential) or any signs or symptoms (type of problem: manifest) suggesting a lacking or unsatisfactory medication safety	Risk of torsades de pointes due to combination of amiodarone and clarithromycin	98 (22.8%)
		A4	Treatment costs	Any issue associated with the cost of a drug treatment (e.g., high price, reimbursement, cost-effectiveness, patient's economic situation, generic substitution)	Switch original product to generic (generic substitution) because of lower treatment costs	53 (12.3%)
		A5	Patient dissatisfaction / problems	Any complaint or concern regarding drug therapy expressed by the patient or the caregivers/relatives	Patient complains about high number of prescribed drugs, about swallowing difficulties, lack of information, etc.	99 (23.0%)
		A6	**Technical / formal problem**	Any problem regarding the pharmacy logistics, the prescription quality or other technical and formal problem	The pharmacy does not have the prescribed drug in stock. The drug dosage was missing on the prescription.	-
B	Type of problem (1 choice)	B1	Manifest, reactive	Patient shows signs or symptoms of an adverse drug event, therapy failure or non-treatment. Problem is present → reactive, corrective intervention	Occurrence of vaginal mycosis after antibiotic therapy	192 (44.7%)
		B2	Potential, preventive	Patient is at risk for an adverse event but does not present signs or symptoms of adverse clinical outcomes. Problem is in the future → preventive intervention	Loss of cardio protective effect of acetylsalicylic acid (ASS) in combination with ibuprofen causes an increased risk for myocardial infarction	238 (55.3%)

Code	Category	Code	Subcategory	Subcategory description	Example	Frequency
C	Cause of intervention Clinical cause	Therapy choice				67 (15.6%)
		C1.1	No concordance with guidelines, only suboptimal therapy possible	Drug selection does not comply with treatment guidelines.	Contrary to the guidelines, ASS is not prescribed in a patient after myocardial infarction.	13 (3.0%)
		C1.2	Contraindication	Patient has a contraindication to the therapy due to his medical conditions.	Metformin contraindicated in patient with renal failure. (Creatinine clearance <30 ml/min).	3 (0.7%)
		C1.3	Interaction	Combination of a drug with another drug or with food representing a potential or manifest negative outcome.	Calcium in combination with levothyroxine	25 (5.8%)
		C1.4	Drug not indicated	Drug use without an indication.	PPI continued although anticoagulation therapy was stopped.	4 (0.9%)
		C1.5	Duplication	Inappropriate use of two drugs from the same therapeutic class.	Combination of ACE inhibitor and angiotensin receptor blocker. Original and generic drug concomitantly prescribed.	11 (2.6%)
		C1.6	Adverse effect	Response to a drug that is noxious and unintended and occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease, or for modification of physiological function.	Symptoms of myalgia under statin therapy.	8 (1.9%)
		C1.7	Missing patient documentation	Lack of patient information in case notes / laboratory results.	Allergies not reported in patient cases.	3 (0.7%)
		Drug choice				20 (4.7%)
		C2.1	Inappropriate dosage form / administration route	Wrong drug administration route or method, or wrong form, or incompatibility.	Sustained release tablets crushed for the administration through feeding tube.	20 (4.7%)

Code	Category	Code	Subcategory	Subcategory description	Example	Frequency
		Dose choice				40 (9.3%)
		C3.1	Underdose	Prescribed dose too low	Pantoprazole 20 mg in acute duodenal ulcer.	19 (4.4%)
		C3.2	Overdose	Prescribed dose too high	Prescribed dose of acetaminophen exceeds maximal daily dose.	20 (4.6%)
		C3.3	Inappropriate monitoring	Inappropriate process of observing, recording and detecting the effects or safety of a therapy, incl. therapeutic drug monitoring (TDM).	No thyroid hormones control in substituted hypothyroidism.	0 (0.0%)
		C3.4	Dose not adjusted to organ function (e.g., renal/liver failure, age)	Dose adjustment required due to organ impairment (renal/liver failure, etc.) or advanced age.	High dose allopurinol (300 mg/d) was prescribed daily in renal impairment.	1 (0.2%)
		Drug use				50 (11.6%)
		C4.1	Inappropriate timing or frequency of administration	Wrong timing of drug intake regarding circadian rhythm or food intake, or no respect of the dosing interval.	Bisphosphonate intake with breakfast; Nitrate-free period for nitroglycerin patch is too short.	16 (3.7%)
		C4.2	Inappropriate application	Misapplication / incorrect use of drug, e.g., with an application aid.	Application of an asthma inhaler without prior shaking the aerosol.	18 (4.2%)
		C4.3	Inappropriate therapy duration	Duration of therapy too long or too short	Too long application of a cortisone cream after healing. Too short treatment with amorolfine (Loceryl) for nail mycosis.	16 (3.7%)
		Patient				114 (26.5%)
		C5.1	Insufficient adherence	Patient does not take his medication as prescribed.	Patient forgot to intake a prescribed drug.	9 (2.1%)
		C5.2	Insufficient knowledge	Patient lacks information about their medication or disease.	Patient does not know how to use an asthma device.	30 (7.0%)
		C5.3	Concerns about the treatment	Patient is concerned about his/her treatment.	Patient is concerned about the number of prescribed drugs.	26 (6.0%)
		C5.4	Financial burden *(*Patient / *public health*)	The costs of treatment are a financial burden for the patient or the public health.	The original product is substituted by a generic drug.	49 (11.4%)

Code	Category	C Subcategory		Subcategory description	Example	Frequency
	Technical cause					
		Logistics				61 (14.2%)
		C6.1	Prescribed drug not available	Drug not in stock, drug shortage or any other logistic problems in drug provision.	Drug is currently undeliverable and is not in stock at the wholesaler.	53 (12.3%)
		C6.2	Error in medication process	Any error appearing during drug prescription, transcription, distribution or administration.	Erroneous delivery of an incorrect dosage strength or wrong package size.	8 (1.9%)
		Prescription quality				78 (18.1%)
		C7.1	Incomplete / unclear prescription	Missing or unclear information on the medical prescription.	The dosage is not specified on the prescription.	59 (13.7%)
		C7.2	Illegible prescription	The writing on the prescription is illegible.	The drug name is illegible.	4 (0.9%)
		C7.3	Missing prescription of necessary application aid(s)	The necessary tools for the correct drug application are not prescribed.	Missing spacer for a steroid-containing metered dose inhaler	4 (0.9%)
		C7.4	Formal / regulatory reason	Formal or regulatory errors concerning prescription.	Oxycodone was not prescribed on a special prescription for narcotic substances; forged prescription	11 (2.6%)
D	Intervention (1 choice)	D1	Substitution	Replace a drug by another for the same therapeutic indication.	Switch from esomeprazole to pantoprazole.	132 (30.7%)
		D2	Dose adjustment	Adjust drug dose or therapy duration regarding medical and personal conditions.	Adjust acetaminophen dose relative to the body weight of an infant.	57 (13.3%)
		D3	Adjustment of package size / quantity	Adjust package size or the number of package.	Delivery of two packages of antibiotic suspension in order to ensure a sufficient therapy duration	30 (7.0%)
		D4	Optimisation of administration / route	Change the treatment plan to suit patient or to optimise drug response, regarding e.g., meal interval, posture, fasting intake, swallowing difficulties. Find an appropriate drug administration route.	Recommend bisphosphonate intake on empty stomach and in upright position. Switch intravenous antibiotic therapy to oral therapy.	47 (10.9%)

Code	Category	Code	Subcategory	Subcategory description	Example	Frequency
		D5	Therapy stopped / no delivery	Withdraw a drug without substitution by another drug; or drug is not delivered.	Stop proton pump inhibitor (PPI), which was prescribed without indication/risk factors.	15 (3.5%)
		D6	Therapy started / continued	Introduce a drug to the treatment plan.	Start laxative therapy with concurrent opioid analgesics.	26 (6.0%)
		D7	In-depth counselling of patient	Comprehensively advise the patient about his/her medications or diseases.	Counsel patient on drug indication to increase the acceptance of a regular application.	39 (9.1%)
		D8	Application instruction (training)	Train and educate patient on the correct use of prescribed medicines.	Instruct on the use of an asthma device following misapplication.	14 (3.3%)
		D9	Delivery of adherence aid incl. counselling	Deliver an adherence aid and advise patient to improve adherence/compliance.	Instruct and deliver a weekly pill dispenser following adherence problems.	2 (0.5%)
		D10	Clarification / addition of information	Clarify, complete or correct information in patient notes.	Add new diagnosed penicillin allergy in patient notes.	48 (11.2%)
		D11	Transmission of information	Report/communicate information to the patient or other health personnel regarding medications or diseases.	Communicate an adverse drug reaction in a report to the physician.	16 (3.7%)
		D12	Proposition of therapy monitoring	Initiate the observation, record, or detection of the effects of a drug administered to an individual, by indication of safety or efficacy, incl. TDM.	Recommend regular blood pressure measurement; increased blood glucose measurements by patient after dose adjustment of insulin.	4 (0.9%)
E	Communication: involved person *Except pharmacist* (Multiple choice possible)	E1	*Nobody*	Pharmacist intervenes in an independent manner without consultation.	Complete the patient case record with the information on drug allergy.	59 (13.7%)
		E2	Physician	Communication with physician. Pharmacist consults the physician to intervene.	Recommend the physician to start a therapy with a PPI, to reduce the gastrointestinal bleeding risk under anticoagulation treatment.	138 (32.1%)
		E3	Caregiver / home care	Communication with caregiver/home care. Pharmacist involved the nursing staff, care giver or home care in an intervention.	Remind the caregiver to administer levothyroxine under fasting conditions.	14 (3.3%)
		E4	Patient / relative	Communication with patient/relative. Pharmacist involved the patient or relative in an intervention.	The patient agreed to switch the original product to generic drug.	294 (68.4%)

Code	Category	Code	Subcategory	Subcategory description	Example	
F	Outcome of Intervention (1 choice)	F1	Accepted and implemented	Recommendation of intervention approved by the person involved and implemented.	Drug without indication is stopped (e.g., discontinuation of PPI after a treatment with NSAID).	381 (88.6%)
		F2	Partially accepted or accepted without implementation	Recommendation of intervention partially approved by the person involved but not implemented or not possible to implement.	Discontinuation of a PPI without indication: physician approved the recommendation with good cause, but he/she does not have plausible explication for PPI therapy (e.g., reflux) or physician accepted the recommendation but not the patient.	12 (2.8%)
		F3	Not accepted	The person involved does not agree with the recommendation.	Drug without indication is continued without clarification.	16 (3.7%)
		F4	Not known	Outcome of intervention not known.	No feedback after written recommendation.	14 (3.3%)
		F5	Not applicable	Intervention needing no approval or implementation.	Information given to the physician.	7 (1.6%)
	Short case description / comments	-	-	Free text comments or place for a description of the case.	Dextromethorphan dose too high (5ml, 2-3 times/day) for an 18-month child, dose reduction to twice daily in the morning and the evening a half measuring spoon (=2.5 mL). Accepted.	-

3. Acceptability and feasibility

Acceptability and feasibility were evaluated with a 47-item questionnaire on user satisfaction. Eighteen pharmacists (return rate 85.7%) expressed their opinion on the PharmDISC system and this study. Three pharmacists did not respond due to time constraints and holidays. The results of the four sections of the questionnaire are provided below.

Section 1, evaluation of the PharmDISC system: Most users found the PharmDISC system comprehensive [median user agreement 3(2/3.25 quartiles)], practical [3(2.75/3)] and were in general satisfied [3(2/3)] (Fig. 2). Time expenditure was considered adequate [3(2.75/4)]. Most pharmacists showed willingness to use the system once integrated in pharmacy software [4(3/4)].

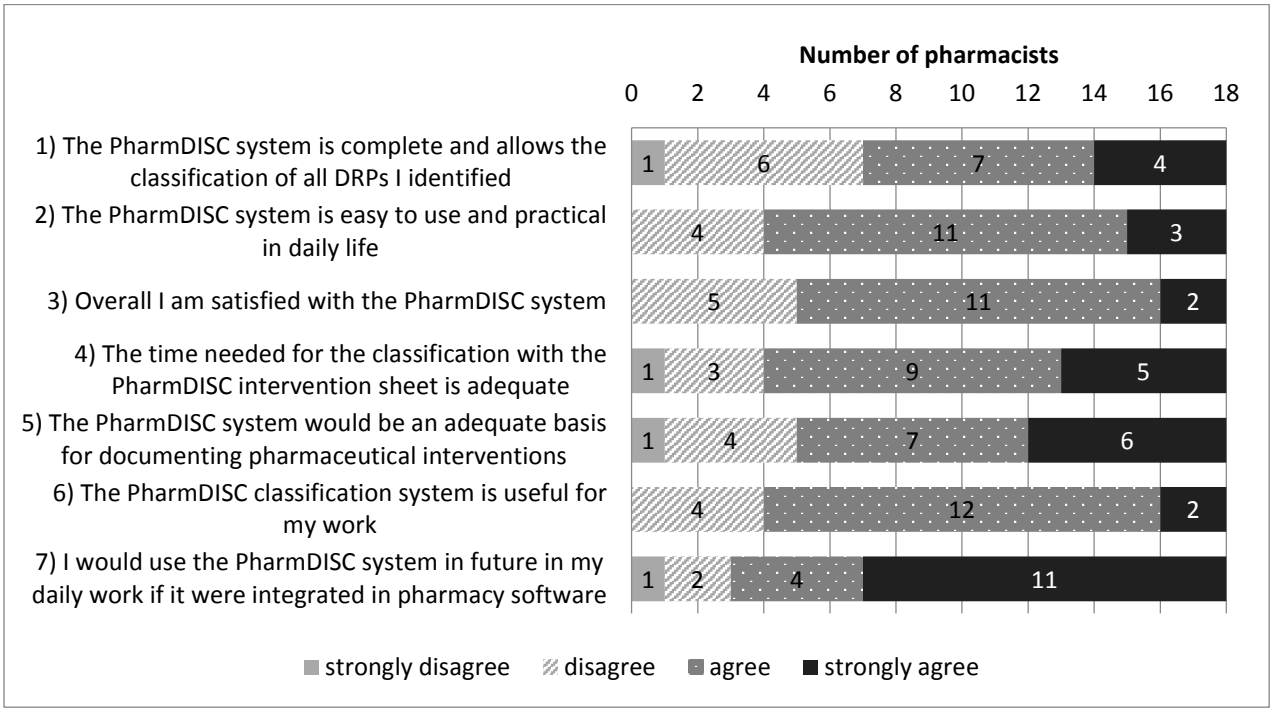

Fig. 2 Pharmacists' satisfaction with the PharmDISC system, n=18; all questions belonged to Step 1 "Reaction"

Within the questionnaire, pharmacists proposed optimisations that triggered a few changes to the PharmDISC system as illustrated in Table 2. The version 2.0 comprised 6 categories and 54 subcategories (Fig. 3).

PharmDISC : Documentation of pharmaceutical interventions

A Problem (1 choice)
- □ 1. Treatment effectiveness
- □ 2. Untreated indication
- □ 3. Safety of treatment
- □ 4. Treatment costs
- □ 5. Patient dissatisfaction / problems
- □ 6. Technical / formal problem

B Type of problem (1 choice)
- □ 1. Manifest, reactive
- □ 2. Potential, preventive

C Cause of intervention (1 choice)

1. Therapy choice
- □ 1. No concordance with guidelines, only suboptimal therapy possible
- □ 2. Contraindication
- □ 3. Interaction
- □ 4. Drug not indicated
- □ 5. Duplication
- □ 6. Adverse effect
- □ 7. Missing patient documentation

2. Drug choice
- □ 1. Inappropriate dosage form / administration route

3. Dose choice
- □ 1. Underdose
- □ 2. Overdose
- □ 3. Inappropriate monitoring
- □ 4. Dose not adjusted to organ function (e.g., renal/ liver failure, age)

4. Drug use
- □ 1. Inappropriate timing or frequency of admin.
- □ 2. Inappropriate application
- □ 3. Inappropriate therapy duration

5. Patient
- □ 1. Insufficient adherence
- □ 2. Insufficient knowledge
- □ 3. Concerns about the treatment
- □ 4. Financial burden (patient/ public health)

6. Logistics
- □ 1. Prescribed drug not available
- □ 2. Error in medication process

7. Prescription quality
- □ 1. Incomplete / unclear prescription
- □ 2. Illegible prescription
- □ 3. Missing prescription of necessary application aid(s)
- □ 4. Formal / regulatory reason

Technical

D Intervention (1 choice)
- □ 1. Substitution
- □ 2. Dose adjustment
- □ 3. Adjustment of package size / quantity
- □ 4. Optimisation of administration / route
- □ 5. Therapy stopped / no delivery
- □ 6. Therapy started / continued
- □ 7. In-depth counselling of patient
- □ 8. Application instruction (training)
- □ 9. Delivery of adherence aid incl. counselling
- □ 10. Clarification / addition of information
- □ 11. Transmission of information
- □ 12. Proposition of therapy monitoring

E Communication: involved person(s) except of pharmacist (multiple choice possible)
- □ 1. nobody
- □ 2. physician
- □ 3. Caregiver / home care
- □ 4. Patient / relative

F Outcome of the intervention (1 choice)
- □ 1. Accepted and implemented
- □ 2. Partially accepted or accepted without implementation
- □ 3. Not accepted
- □ 4. Not known
- □ 5. Not applicable

Short case description / comments

Fig. 3 The PI classification form of the PharmDISC system (version 2.0)

Section 2, evaluation of the online training: The pharmacists were very satisfied with the online training [4(3.5/4)] (Fig. 4). One pharmacist suggested that it would have been helpful to have a printed version of the online training.

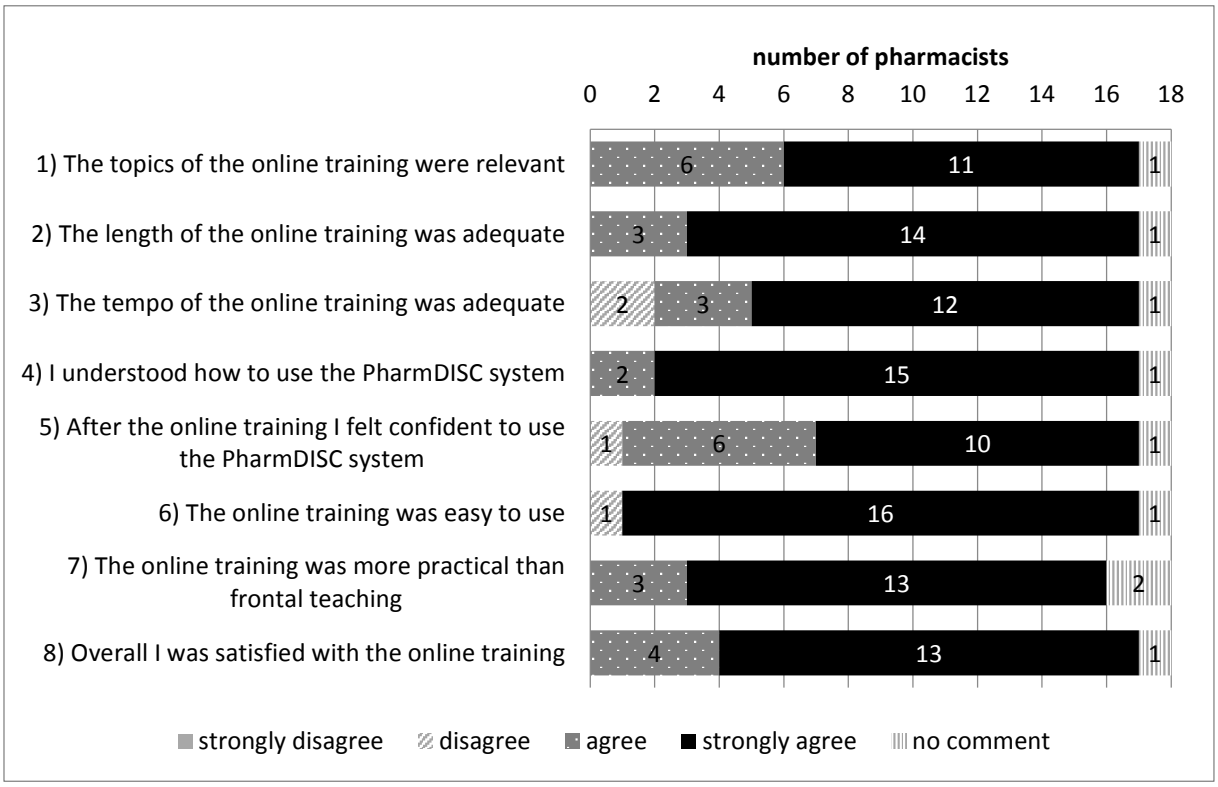

Fig. 4 Pharmacists' satisfaction with the online training, n=18; all questions belonging to Step 1 "Reaction", except questions 4-5 to Step 2 "Learning".

Section 3, evaluation of the descriptive manual: According to the pharmacists' opinion, the descriptions and examples of the descriptive manual (Table 4) were helpful [4(3/4)] and relevant [4(3/4)]. The pharmacists were overall satisfied with the manual [4(3/4)] and its length was generally considered adequate [4(3/4)], while some wished for more examples.

Section 4, evaluation of the overall project: All participants recognized the importance of PI documentation [4(4/4)]. Classifying PIs motivated the pharmacists to document PIs in the future [3(3/4)]. They believed that they did not intervene more during the dispensing process than prior to the study [2(2/2.5)]. However, through documenting their PIs, sixteen pharmacists agreed that they became more aware of what they were accomplishing in daily practice [3(3/4)].

To facilitate the implementation of the PharmDISC system, the pharmacists wished for an electronic version with additional functionalities such as an automatic connection to the prescription, a task manager for PIs needing follow-up and a section for comments. Barriers for implementation mentioned by the pharmacists were time expenditure, lack of understanding of the benefits and

missing persistent motivation of the whole pharmacy team to systematically document all PIs. A pharmacist commented: "Pharmacy staff perform lots of interventions without realizing it. A raised awareness of the intervention undertaken in daily practice and a change in behavior/habits is needed."

Discussion

The two-phase development process of our intervention oriented classification system (named PharmDISC) followed a translational approach by adapting the existing hospital-specific PI system to the requirements of community pharmacies.[81, 84] In this second development phase, we validated the PharmDISC system by means of interrater reliability, appropriateness, interpretability, acceptability, feasibility, and validity and explored first implementation aspects.

With the PharmDISC system version 1.1, we demonstrated favorable interrater reliability for all but one classification categories (average K=0.66), that was on average higher than previously obtained with version 1.0 (average K=0.61) [84]. This improvement was likely due to refinements in the updated version as well as the introduction of the descriptive manual that may have facilitated PI classification. For the DOCUMENT system, a recently validated system for DRPs and clinical interventions in community pharmacies [63], a moderate level of agreement (K=0.53) was found while the PharmDISC system reached a substantial agreement.

The validation study showed that the PharmDISC system was suitable to document PIs in community pharmacies, with 82.9% of PIs completely classified in all categories. Throughout the validation phase, the participating pharmacists provided valuable comments that were evaluated in terms of frequency and relevance. Selected comments led to further modifications of the PharmDISC system (e.g. rewording of category E Communication to increase clarity because of the low K-value). Other comments related to classification issues, where the PIs were nonetheless correctly classified, were disregarded.

One strength of this study is that because the validation was performed in two regions of Switzerland with different languages and cultures, we expect that the PharmDISC system would be suitable for other countries. Moreover, different methods for the validation were used, according to the validation criteria proposed by Fitzpatrick [68]. The main limitation was the inclusion of highly motivated and qualified pharmacists to participate in the study. To foster its generalizability, the PharmDISC system should be further tested in studies enrolling a broader range of community pharmacists. The ongoing studies using the PharmDISC system by other research groups are consequently very welcomed. Furthermore, the pharmacists stopped documentation after 30 PIs instead of documenting all interventions triggered by 30 prescriptions as required in the study protocol, suggesting that this

instruction was not clear enough. In addition, we were not able to ensure that the collection of prescriptions was done consecutively, and there might have been a selection bias.

Although all validation results of the PharmDISC system fulfilled the requirement for an acceptable classification system, its implementation into the daily routine of a community pharmacy remains a challenge. However, we expect that the PharmDISC system is viable for future implementation for several reasons:

a) In contrast to the classification of manifest or potential DRPs, which require an interpretation by the practitioner, the PharmDISC system is focused on the documentation of actual PIs allowing for an objective assessment.

b) The PharmDISC system offers a flexible and comprehensive classification system for PIs of varying complexity that, consequently, is able to capture both prescription-focused as well as patient-centered PIs. Cipolle et al. proposed both focus points to be accounted for in medication management services; the prescription-focused approach is linked to the dispensing process, while the patient-centered approach is based on pharmaceutical care practice [107]. In the PharmDISC system, the complex and time-consuming patient-centered aspects are related to clinical issues, while the less complex PIs are related to technical issues.

c) The descriptive manual, rated as helpful and relevant, provided clear definitions of PIs which should have aided in uniformly classifying PIs, another requirement for classification systems [61].

d) The pharmacists noted that with increasing familiarity with the PharmDISC system over the course of the study, the faster and more comprehensive their PI classification became.

e) Little time was necessary for the pharmacists to get accustomed with the PharmDISC system. This correlated with the pharmacists' positive opinion on the use of the PharmDISC system. Furthermore, most pharmacists were willing to use the system, but only once integrated into the pharmacy software. This determined the need for a computerized classification system.

f) The online training was appreciated by the pharmacists. It is therefore important to offer online training to any future user of the PharmDISC system.

g) The documentation of PIs may raise the awareness for DRPs and consequently increase the intervention rate and patient safety. It has been reported that PI documentation makes pharmacists more attentive regarding the patients' drug-related needs and enhances the development of counseling skills and pharmaceutical care [53].

With respect to seamless care, an electronic PI classification in hospitals (e.g. for Switzerland with the GSASA system [81]) and in community pharmacies (with the PharmDISC system) could in future

facilitate the exchange of information between both settings. Such an exchange is known to ensure continuity of care, communication between healthcare professionals, safe transfer of information and patient safety [108, 109]. A Belgian study showed that their newly developed discharge medication plan was rated as valuable for the continuity of care by community pharmacists, however, they requested additional information such as medication modifications [110]. This is covered with the PharmDISC system as such additional information is included.

Next steps towards implementation will include further descriptive analyses on the nature of common PIs with the aim to develop an electronic quick classification with a variety of prefilled classification forms. This could save time and improve the quality of PI documentation, which would further facilitate the implementation in community pharmacies. Quick classification combined with the descriptive manual and the online training would optimally facilitate the implementation. Currently, the PharmDISC system is used in several studies in Switzerland and in Belgian to further test its practicability in different situations, which may lead to modifications of the PharmDISC system specific to the setting.

Conclusions

Substantial interrater reliability and high rating of acceptability and feasibility indicates that the new PharmDISC system is a valid system for PI documentation in community pharmacy practice. The pharmacists were satisfied with the system and considered it helpful, easy to use, and practical for daily work. They appraised the fact that by using an intervention oriented classification system, their awareness of DRPs and consequently the intervention rate increased.

Acknowledgements

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Funding

No grants from any external funding body were received to conduct this study.

Conflict of interest

The authors declare that they have no conflicts of interest.

Appendix

A2.2.1 Invitation letter for the participation in the study

A2.2.2 Study protocol for the participating pharmacists

A2.2.3 Three model pharmaceutical interventions, adapted from Ganso et al

A2.2.4 Case Report Form PharmDISC Part 2

A2.2.5 Online training: slides to the video presenting the study

A2.2.6 Example used in the role play video of the online training

A2.2.7 Print screen of the online platform for the participating pharmacists

B3 Pharmaceutical interventions on prescribed medicines in community pharmacies: focus on patient-reported problems

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Abstract

Background: During dispensing of prescribed medicines, pharmacists frequently encounter technical and clinical problems that require a pharmaceutical intervention (PI).

Objective: To describe the PIs during dispensing of prescribed medicines in community pharmacies, and to investigate patient-reported problems with the prescribed medicines.

Method: Twenty-one pharmacists each collected 30 prescriptions requiring a PI on five selected days within a five-week period. All PIs were classified using the PharmDISC system.

Results: Of all 430 PIs, 242 PIs (56.3%) had a clinical cause and 188 PIs (43.7%) a technical cause. Patient-reported problems (n=99, 23.0%) were common. Pharmacists mainly intervened to substitute a drug (n=132, 30.7%), adjust a dose (n=57, 13.3%), and clarify/complete information (n=48, 11.2%). In 138 (32.1%) cases, the pharmacists contacted the prescriber whereas in 292 cases (67.9%), only the pharmacist was involved (alone n=59, with the patient n=222, with the caregiver n=11). A total of 243 PIs (56.5%) resulted in a change of the prescription. The implementation rate of PIs reached 88.6%.

Conclusion: During dispensing, pharmacists performed individualised PIs to solve or prevent drug-related problems concerning prescribed medicines. The high frequency of PIs following patient-reported problems highlight the importance of direct patient-pharmacist interaction when dispensing prescribed medicines.

Impact of findings on practice statements

- Pharmacists, as one of the last healthcare professionals interacting with patients prior to medication, add a relevant contribution in improving treatment outcomes by intervening in DRPs, particularly during the dispensing of prescribed medicines.
- Direct contact between pharmacists and patients during dispensing is essential to reveal the patient's problems, concerns or dissatisfaction with prescribed medicines.

Key words

Pharmaceutical intervention; drug-related problem; community pharmacy practice; pharmaceutical care; classification system

Introduction

During the dispensing of prescribed medicines, community pharmacists frequently encounter technical and clinical issues resulting in a pharmaceutical intervention (PI). A PI is defined as a recommendation initiated by a pharmacist in response to a drug-related problem (DRP) in an individual patient occurring in any phase of the medication process [81]. In a medicines optimisation approach, the ultimate goal of pharmacists is to improve treatment outcomes. This is achieved by the exploring the patients' experience, to choosing evidence based medicines and ensuring that the overall therapy is as safe as possible [111]. The pharmacist's professional knowledge is essential to perform PIs aimed to improve pharmacotherapy and facilitate the collaboration with the patient and/or with other healthcare professionals [112]. The PI documentation could highlight the pharmacists' activities that include proactively identifying, solving, and preventing DRPs during dispensing in community pharmacies [113, 114].

In prior research, we identified the need for a classification system for community pharmacies focusing on PIs. We subsequently developed and validated the Pharmacists' Documentation of Interventions in Seamless Care (PharmDISC) system [85]. While the frequency and nature of DRPs detected in pharmacy practice have been exhaustively described [6], little is known on how community pharmacists handle these DRPs and how they intervene for patient-reported problems. Therefore, we performed a subanalysis with data from the PharmDISC validation study [85]; the documented PIs from that study allowed reliable and consistent analyses.

Aim of the study

The aim of this study was to describe PIs performed by community pharmacists during the dispensing of prescribed medicines and to investigate their response to patient-reported problems.

Ethical approval

This study was approved by the ethics committee of the Northwest and Central Switzerland (EKNZ:2014-102).

Method

A prospective observational study was conducted in Swiss community pharmacies. The study design has been described previously [85]. Each pharmacist consecutively collected 30 prescriptions requiring a PI on five selected days within five weeks in March and April 2015. The PIs were classified with the PharmDISC system [85], allowing information to be recorded with respect to the problem, type of problem, cause, intervention, persons involved, and outcome. In addition to the PharmDISC documentation (PI classification form), a short description, an anonymised prescription copy, and a three-month medication history were collected. All documentation was checked for consistency and plausibility for each PI. A descriptive manual and an online training were available for the participants [85]. The data were analysed using IBM SPSS Statistics for Windows, Version 22 (Armonk, NY:IBM Corp).

Results

Twenty-one (11 German-speaking and 10 French-speaking) pharmacists participated in the study. Of the 519 PIs documented with the PharmDISC system, 430 (82.9%) were completely classified in all categories. Eighty-nine PI classification forms did not fulfil all requirements for a complete classification and were therefore excluded from the analysis.

The patients for which a PI was documented were mostly female (n=233, 63.8%) regular customers (n=269, 81.1%) with a mean age of 55.9±23.5 years. The number of medicines per prescription ranged from 1 to 21 (mean 3.4±3.3). The 430 eligible PIs originated from 365 prescriptions (mean 1.2±0.48 PIs per prescription, range 1-4). Of these, 313 (85.8%) PIs were ambulatory, 45 (12.3%) based on a hospital discharge and 7 (1.9%) unknown.

The problems triggering PIs comprised treatment effectiveness (n=172, 40.0%), patient-reported problems (n=99, 23.0%), safety of treatment (n=98, 22.8%), treatment cost (n=53, 12.3%) and untreated indication (n=8, 1.9%). The cause of the PI was clinical for 242 PIs (56.3%) and technical for 188 PIs (43.7%). The pharmacists mainly intervened to substitute a drug (n=132, 30.7%), adjust a dose (n=57, 13.3%), and clarify/complete information (n=48, 11.2%) [Table 1].

Pharmacist-prescriber interaction was necessary in 138 (32.1%) cases, whereas the pharmacist alone was involved in 292 (67.9%) of PIs (alone n=59, with the patient n=222, with the caregiver n=11). Overall, 243 PIs (56.5%) resulted in a change of the prescription. PIs were in 88.6% cases approved by the involved person and consequently implemented.

The number of medicines per prescription increased with the age (correlation $r=0.233$, $p<0.001$) and also with the number of PIs per prescription ($r=0.236$, $p<0.001$).

Table 1 Most frequent pharmaceutical interventions (n=430) on prescribed medicines in community pharmacies and their clinical or technical cause

	Intervention	n (%)	**Cause**	n (%)	**Problem**	n (%)	**Outcome**	n (%)	**Example**
Clinical n=242	Substitution	34 (14.0)	Inappropriate dosage form/admin	8 (23.5)	**Patient dissatis-faction/ problem**	8 (100.0)	Accepted and implemented	8 (100.0)	Patient preferred to take ibuprofen tablets instead of pellets. Pharmacist substituted the dosage form.
			Concerns about treatment	9 (26.5)	**Patient dissatis-faction/ problem**	7 (77.8)	Accepted and implemented	7 (100.0)	A patient with generalised itching did not tolerate the newly prescribed dimetindene gel, the pharmacist proposed dimetindene drops.
	Dose adjustment	47 (19.4)	Underdose	17 (36.2)	Treatment effectiveness	13 (76.5)	Accepted and implemented	12 (92.3)	The pharmacist detected a lower prescribed dose of lamotrigine than in prior prescription. The physician readapted the dose based on pharmacist's recommendation.
			Overdose	10 (21.3)	Safety of treatment	8 (80.0)	Accepted and implemented	7 (87.5)	Dextromethorphan dose was too high (12.5mg, 2-3 times/day) for an 18-month child. The pharmacist reduced the dose (6.25mg) to twice daily in the morning and the evening.
	In-depth counselling patient	36 (14.9)	Insufficient knowledge (patient)	15 (41.7)	**Patient dissatis-faction/ problem**	8 (53.3)	Accepted and implemented	6 (75.0)	Patient supposed that acetaminophen causes his stomach trouble and wanted acetylsalicylic acid instead. The pharmacist clarified the confusion.
Technical n=188	Substitution	98 (52.1)	Financial burden	44 (44.9)	Treatment costs	43 (97.7)	Accepted and implemented	40 (93.0)	The patient agreed to switch the original product to generic escitalopram to safe costs.
			Prescribed drug not available	46 (46.9)	Treatment effectiveness	35 (76.1)	Accepted and implemented	34 (97.1)	Drug is currently undeliverable and not in stock at the wholesaler, but the pharmacist proposed an alternative.
					Patient dissatis-faction/ problem	11 (23.9)	Accepted and implemented	11 (100.0)	The pharmacy does not have the prescribed drug in stock, but the pharmacist proposed an alternative dosage form.
	Optimisation of admin./route	12 (6.4)	Incomplete/unclear prescription	8 (66.6)	Treatment effectiveness	7 (87.5)	Accepted and implemented	7 (100.0)	Correct timing of magnesium administration was not specified. Due to drug-drug interaction, magnesium should be taken at lunch time, and the levothyroxine 30 minutes before breakfast.
	Clarification/ addition of info	33 (17.6)	Incomplete/unclear prescription	24 (72.7)	Treatment effectiveness	14 (58.3)	Accepted and implemented	11 (78.6)	The dose of the combination product valsartan + hydrochlorothiazide was not specified on the prescription. The pharmacist clarified the correct dose with the prescriber.

Patient-reported problems

Patient-reported problems resulted in a PI in 99 cases (23.0%). Of these, 76 PIs had a clinical cause (Fig. 1) while 23 PIs had a technical cause. In 15 (15.2%) cases, the contact with the prescriber was necessary whereas 61 (84.8%) of PIs only involved the pharmacist (alone n=15, with the patient n=68, with the caregiver n=1). The PIs resulted in 66 cases (66.7%) to a change of the prescription, and of these, 52 cases (78.8%) were solved without the prescriber.

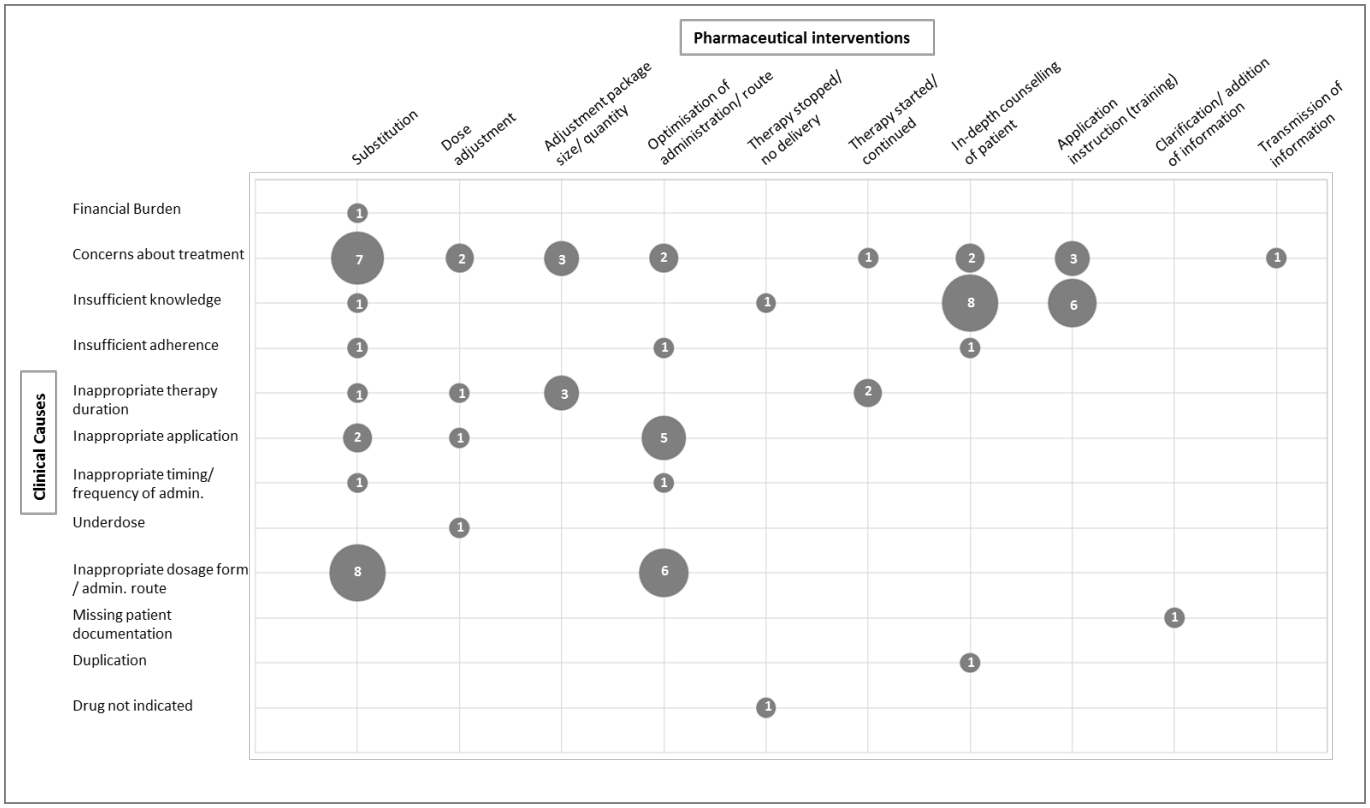

Fig. 1 Patient-reported problems with clinical causes and corresponding pharmaceutical interventions (n=76). The size of the circle represents its frequency.

Discussion

This subanalysis demonstrated that community pharmacists applied a medicines optimisation approach for a broad range of PIs which was facilitate by direct patient interaction. The PIs were mostly accepted by the involved person and implemented in practice. Individual assessment of each PI, the pharmacist's professional expertise, and the collaboration between the patient, caregiver or physician were needed to fully address the patients' needs. This ensured a safe and appropriate use of medicines - all while controlling treatment costs.

Almost a quarter of the PIs were related to patients who reported problems with their prescribed medicines at the time of dispensing. It is known that after the prescription is handed over by the prescriber, problems for the patients may still remain. The prescriber possibly provides insufficient information that does not meet the patient's needs. A Canadian study has previously revealed the discrepancies between the patient's need for information on prescribed medicines and the information provided by pharmacists and physicians [115]. Direct contact between the healthcare professional and the patient is essential to detect these problems. By addressing these problems, adherence to medical treatment and consequently patient outcomes could be improved. Indeed, Horne et al reported that the patient's beliefs and concerns are related to adherence, meaning that lower concerns correlated with higher adherence [116].

Another possible reason for remaining patient-related problems is that some concerns regarding therapy or the need for supplementary information may arise at a time after the consultation with the prescriber has taken place. The same Canadian study revealed that patients found it more convenient to receive information and counselling from the pharmacists rather than from the physician. This is likely a consequence of easy accessibility of the pharmacists and the challenge to contact the physician who often has time constraints [115]. Our findings confirm that patient-reported problems with prescribed medicines can frequently be addressed by community pharmacists. As one of the last healthcare professionals before patients take their medicines, pharmacists provide a relevant contribution in improving treatment outcomes by intervening in DRPs during the dispensing of prescribed medicines.

As this study collected data in two regions of Switzerland with different languages and cultures, the results provide a robust assessment that can likely be transferred to other regions. The main limitation was the inclusion of highly motivated and qualified pharmacists who participated in the study. We were not able to ensure the consecutive collection of prescriptions, which might have caused a selection bias. This would explain the high frequency of PIs compared to another observational study

that was conducted in Swiss community pharmacies which recorded all 38'663 patient visits with prescriptions during four weeks, revealing mean intervention rates of 1.90% related to 736 technical and of 0.77% related to 257 clinical DRPs [94].

Conclusion

By intervening during the dispensing of prescribed medicines, community pharmacists contribute to the safe, appropriate and cost-effective use of drugs. They have the opportunity to support the patient to make the best use of prescribed medicines by performing individualised PIs. The high number of PIs following patient-reported problems highlights the importance of a direct patient-pharmacist contact when dispensing prescribed medicines.

Acknowledgements

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Funding

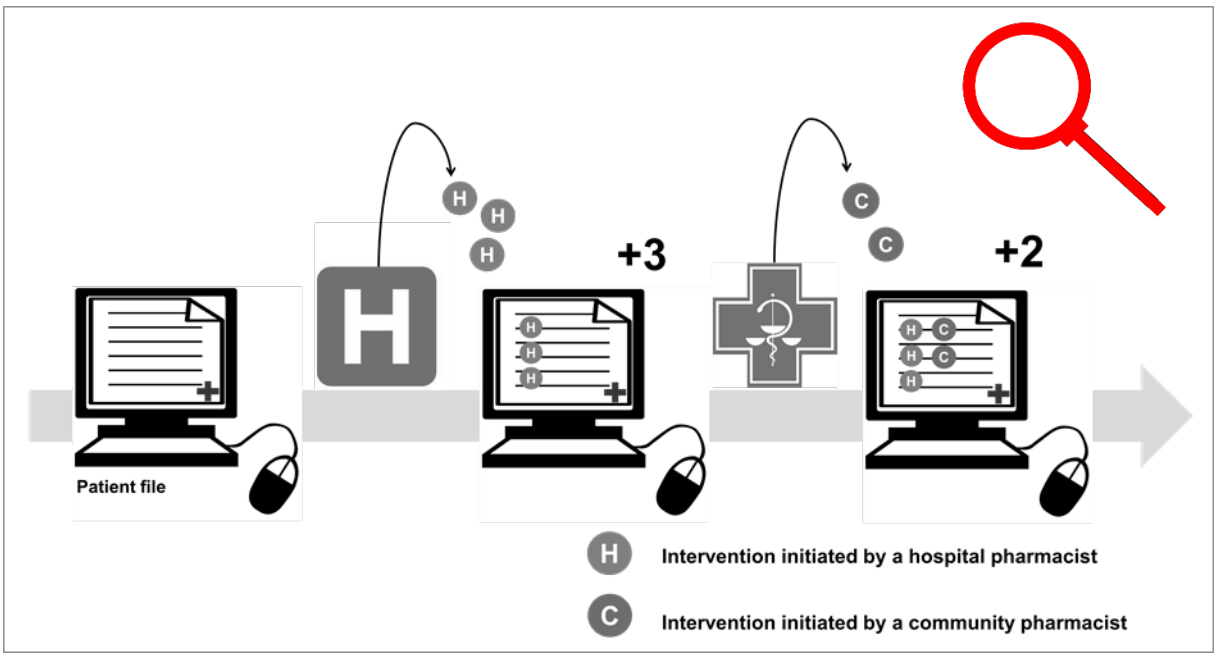
None.

Conflict of interest

None.

PROJECT C

Patient counselling on prescribed medicines in Swiss community pharmacies



C1 Dispensing of prescribed medicines in community pharmacies - Observed counselling, interventions and services

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Publication in preparation with

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Abstract

Background As part of pharmaceutical care, dispensing of prescribed medicines and patient counselling are the pharmacist's key activities to ensure the safe and effective use of medicines. To our knowledge, the dispensing process of prescribed medicines including all activities from the prescription reception to the medicines distribution has not been described in Swiss community pharmacies yet.

Objective To describe the observed dispensing process of prescribed medicines at the counter in daily community pharmacy practice, focusing on counselling activities.

Setting and Method: Community pharmacies in Basel, Switzerland, were randomly invited for study participation. One master student in pharmacy performed non-participant observations during one day at each included community pharmacy. At dispensing, patient characteristics, counselling content, and additional activities were documented on a structured checklist with predefined themes. Pharmaceutical interventions were documented and classified systematically. All data were analysed with descriptive statistical methods.

Main outcome measures: Number and nature of counselled themes, interventions and additional activities. Factors influencing counselling provision.

Results: In March and April 2016, 18 of 49 invited community pharmacies participated in the study. A total of 556 prescription encounters (PE) were analysed (269 first prescriptions; 287 refill prescriptions). Patients mostly collected their medicines personally (n=451, 81%), were regular customers (n=523, 94.1%) and on average 53.8±23.4 years old. Counselling was provided to 367 (66.0%) customers on 2.9 ±3.1 themes per PE (first 4.9±3.0; refill 1.0±1.7, $p<0.001$). The PE lasted on average 4.5±3.0 minutes (first 5.2±3.1; refill 3.9±2.7, $p<0.001$). Pharmacy staff mainly counselled on administration (first 465; refill 73), dose (188; 46), and use (152; 36) and provided an individualised label (189; 55). However, 148 patients (26.6%) refused counselling. Significantly more counselling was provided by pharmacists vs other staff members, with a first prescription vs refill, prescription requiring a pharmaceutical intervention, prescription filled by carers vs patient, to new vs regular customer and to customer who did not vs did refused counselling. During 144 PEs (101 first PEs; 41 refill PEs, $p<0.001$), 203 interventions were documented (intervention rate 25.9%), such as drug substitution (n=89), clarification of information (n=64) and adjustment of package size/quantity (n=39). Pharmacists proposed few additional activities (e.g. 3 follow up offers), while no cognitive pharmaceutical service was performed.

Conclusions: The observation of the dispensing process of prescribed medicines allowed to depict the community pharmacy practice in the customers' perspective (at the counter) and to identify factors influencing counselling provision at patient, prescription and pharmacy level. Counselling was not equally provided, indicating that pharmacy staff counsels at different degrees during PEs. A more transparent practice and patient-centered counselling is necessary to better meet the patients' needs on information. While pharmacists intervened frequently, only few additional activities and no further services were offered.

Key words

Community pharmacy practice, dispensing, counselling, pharmaceutical intervention, pharmaceutical care, observation

Impact of findings on practice statements/practice implications

- Pharmacists, as one of the last healthcare professionals interacting with patients prior to medication, help the patient to make the best use of prescribed medicines by providing counselling and intervening in drug-related problems during the dispensing of prescribed medicines.
- We suggest more transparency trough better communication of the pharmaceutical activities performed in the back office and a more patient-centered counselling to meet patients' needs.
- Factors influencing counselling provision are indicators to help in prioritising prescriptions needing in-depth counselling.

Introduction

Pharmaceutical care has been defined as "the pharmacist's contribution to the care of individuals in order to optimize medicines use and improve health outcomes provided" [46]. As part of pharmaceutical care, dispensing of prescribed medicines and patient counselling are the pharmacist's key activities to ensure the safe and effective use of medicines [37, 69]. Dispensing includes all activities between the reception of the prescription and the distribution of medicines to the patient with the provision of information [69]. During dispensing, community pharmacists help the patient to make the best use of prescribed medicines by providing written and oral information responding to the patient needs [71], which contribute to positive treatment outcomes [72]. Patients have the opportunity to receive counselling and education about their health problems and medicines in several care situations, especially in community pharmacies at the time of dispensing prescribed medicines [72]. Patient counselling about their medicines (e.g. administration, risk and benefit) has been shown to be effective in improving medicines adherence [73, 74], and in identifying drug-related problems (DRPs) [75]. In contrast, insufficient information about medicines can lead to patient non-adherence to the drug therapy and negative health outcomes.

The joint International Pharmaceutical Federation and World Health Organization (FIP/WHO) guidelines on Good Pharmacy Practice (GPP) describes the pharmacists' function of dispensing medicines concerning counselling as "providing advice to ensure that the patient receives and understands sufficient written and oral information to derive maximum benefit for the treatment"[37]. Prescription dispensing at the community pharmacy is an important contact point for patient counselling [75]. Patients regularly pick up their prescribed medicines in community pharmacies [117], hence pharmacy staff is usually one of last healthcare providers, who interacts with patients prior to medication and who has the possibility to inform and counsel them [118, 119]. The joint FIP/WHO GPP suggests also minimum national standards that should be established for this function.

In Switzerland, the Swiss Association of Pharmacists published recommendations for pharmaceutical counselling [120]. Additionally, a service–based remuneration system for community pharmacies is established since 2001 [121]; some cognitive pharmaceutical services are reimbursed by the health insurance (Table 1) [50, 122]. The counselling provided during dispensing of prescribed medicines is remunerated by the 'Drug check' and 'Delivery check'. Moreover, in Switzerland, prescribers can issue refill prescriptions for up to 12 months for patients with an ongoing long-term therapy.

Table 1 A selection of remunerated cognitive pharmaceutical services in Swiss community pharmacies, adapted from Hersberger et al. [50]

Pharmacy services	Description	Fee (EUR)
Drug check	fixed fee for checking each dispensed item on dosage, limitations, interactions, risk factors, contraindications, misuse and eventual possibility of repeat dispensing, and for patient counselling, eventual contact with prescriber, choice of optimized package size, and immediate provision	4.00
Delivery check	fixed fee for checking medication history for interactions and accumulation, including self-medication	3.00
Generic substitution	Pharmacists have been allowed to substitute generic drugs for originals with the patient's agreement and when the doctor does not oppose it.	40% of the difference to the original
Polymedication check	Medication review to support adherence for patient on more than four drugs taken over more than three months. If patient agrees, but independently from the prescriber.	45.00
Adherence fee	For preparation of a weekly pill organizer/blister pack for an outpatient with chronic condition and taking at least 3 different drugs	20.00/week

Literature on counselling in community pharmacies describes the communication patient-provider about the medicines use [123, 124] and compare the counselling practice to the guidelines [117, 125]. A Swiss study described counselling by community pharmacy staff at patient contacts, with focus on adherence [126]. To our knowledge, the dispensing process of prescribed medicines including all activities from the prescription presentation to the medicines distribution has not been described in Swiss community pharmacies yet. For this reason, our study aimed at observing what activities a prescription triggered at the time of dispensing.

Aim

To describe the observed dispensing process of prescribed medicines at the counter in daily community pharmacy practice, focusing on counselling activities.

Ethical Approval

The study was approved by the Ethics Committee of Northwest and Central Switzerland (EKNZ BASEC UBE-req. 16/00011) on 25.01.2016.

Methods

We conducted a non-participant observation study in community pharmacies to illustrate the observed dispensing process of prescribed medicines. The main outcome measures were the number and type of themes counselled, the factors influencing counselling provision, and number, frequency, and type of pharmaceutical interventions, and additional activities.

Data collection

Community pharmacies in Basel, Switzerland, were randomly invited for study participation according to a prior study [126]. One master student in pharmacy performed non-participant observations during one day at each included community pharmacy from March to April 2016. After a quick briefing on the study, the pharmacy staff were neither actively involved in the study process nor disturbed in their practice. At dispensing of prescribed medicines, counselling content (information exchanged over the counter between customer and pharmacy staff), patient characteristics (age, sex, customer status), and additional activities (offer of a further activity) were documented on a structured checklist with predefined themes for each prescription encounter (PE). A PE lasted from the customer's greetings to closing salutations; thereupon, the next customer (patient or carer) was observed. Each customer filling a prescription in the community pharmacy was included in the study. Customers were excluded if ordered medicines were picked up without counselling or if only over-the-counter (OTC) products were requested. Customers were not informed about the study to avoid any influence on the counselling activities.

The checklist was modified from a previous study [127] and enabled ad hoc coding of nine categories and 61 predefined themes: pharmacy staff involved (n=1 theme), patient (n=4), prescription (n=7), counselling (n=34), intervention (n=2), physician contact (n=2), situation (n=6), and additional activities (n=5). The category counselling included 34 counselling themes that were considered as best practice and was based on the 'Drug check' of the Swiss service–based remuneration system [121]. Other counselling themes originated from the literature [117, 128, 129], the requirement of the Omnibus Budget Reconciliation Act (OBRA, 1990) [130], the recommendations for internal audits of the Swiss Pharmacists' Association [131], and from expert discussions with five community pharmacists. The checklist enabled to distinguish between the active and passive involvement of the pharmacy staff and the customer during the PEs. After piloting, the checklist was refined. A copy of the prescription and a list of repeat medicines were additionally collected and used to test the documentation of the observed PEs on consistency and plausibility. Observation time and characteristics of the pharmacies and their staff were recorded.

The pharmaceutical interventions were systematically documented with the PharmDISC system, which records information about the problem, type of problem, cause, intervention, person involved and the outcome of the intervention [85].

At the end of the observation day, a semi-structured interview concerning the pharmacists' opinion on the counselling, triggers, facilitators and barriers was conducted at each community pharmacy with one pharmacist per pharmacy. The results of the interviews are reported separately.

Data analysis

All coded data were quantified and analysed descriptively using IBM SPSS Statistics for Windows, Version 24 (IBM Corp., Armonk, NY). For the determination of factors influencing counselling provision, counselling theme ratios (sum of each counselling theme counseled by the pharmacy staff divided by all medicines dispensed on one prescription) were calculated. A mean counselling theme ratio of 100% represents the maximum of all possible counselling themes counselled for each dispensed medicine. A single factor variance–analysis, Chi-Quadrat, Spearman and Mann-Whitney U tests were used to compare variables. A p-value <0.05 was considered statistically significant.

Results

Of a total of 49 invited community pharmacies, 18 participated in the study. Reasons for participation refusal were no interest (n=7), lack of personal resources (n=4) or time (n=4), holidays (n=2), not enough prescriptions (n=1), or unknown (n=13). All pharmacies were located in the urban area of Basel. Thirteen were independent pharmacies (72.2%), while five belonged to a pharmacy chain (27.8%). They were on average open during 10.25±1.5 hours and were observed during 8±0.6 hours (78.0% observed time) per day and pharmacy. The mean number of working staff per pharmacy at the observation day was 5.8±2.6 (1.7±0.9 pharmacists, 2.8±1.7 pharmacy technicians, 1.0±0.3 apprendices, and 0.2±0.7 pharmacists in training).

During the total observation time of 145.5 hours (18 observation days), 571 PEs (mean 31.2±6.4 per pharmacy, range 22-45) were documented. Fifteen PEs had to be excluded because no medicines were dispensed (n=9, e.g. drug not in stock), spoken language was foreign (n=3), ordered medicines were picked-up (n=1), physician ordered medication (n=1), no document about the dispensed medicines was available (n=1). A total of 556 PEs (269 first PEs and 287 refill PEs) constituted the sample for statistical analysis (each PE involved one customer).

Table 2 illustrates patient, prescription, and pharmacy characteristics. The number of medicines per prescription varied from 1 to 25, resulting in an average of 3.2 ±3.2.

Table 2 Patient, prescription, and pharmacy staff characteristics

Prescription encounter	All (n=556)	First (n=269)	Refill (n=287)
Patient			
Female n (%)	337 (60.6)	162 (60.2)	175 (61.0)
Mean age (years) ± SD	53.8 ± 23.4	45.6 ± 23.9	61.4 ± 20.2
Regular customer n (%)	523 (94.1)	242 (90.0)	281 (97.9)
Carer filled a prescription for a patient n (%)	105 (18.9)	62 (23.0)	43 (15.0)
Prescription			
Ambulatory n (%)	468 (84.2)	212 (78.8)	256 (89.2)
Hospital discharge n (%)	88 (15.8)	57 (21.2)	31 (10.8)
Pharmacy staff			
Pharmacist n (%)	149 (26.8)	70 (26.0)	79 (27.5)
Pharmacy technician n (%)	267 (48.0)	124 (46.1)	143 (49.8)
Apprentice n (%)	86 (15.5)	45 (16.7)	41 (14.3)
Pharmacist in training n (%)	13 (2.3)	8 (3.0)	5 (1.7)
Druggist n (%)	8 (1.4)	1 (0.4)	7 (2.4)
Combination of pharmacy staff n (%)	33 (5.9)	21 (7.8)	12 (4.2)

Counselling

The PEs lasted on average 4.5±3.0 minutes (first 5.2±3.1; refill 3.9±2.7, p<0.001), ranging from 1.0 to 23.0 minutes. In 106 PEs (19.1%), pharmacy staff offered counselling by asking if the patient already knew the medicines or if they have any questions (general questions that were intended to verify patient knowledge). Within the 556 PEs, counselling was provided to 367 (66.0%) customers (first 249 and refill 118, p<0.001). Of these 367 customers, 68 (12.2%) received counselling on one theme (out of the 34 counselling themes), 52 (9.4%) on two themes, 132 (36.0%) on three to five themes, and 115 (20.7%) on five to thirteen themes (Fig. 1). Pharmacy staff did not provide any counselling in 169 refill PEs and in 20 first PEs. On average, customers were counselled on 2.9 ±3.1 themes per PE (first 4.9±3.0; refill 1.0±1.7, p<0.001). Customers who refused counselling (148 PEs [26.6%]; 51 first PEs vs 97 refill PEs, p<0.001) were significantly more often approached for counselling at first PEs than refill PEs (3.7±2.9 theme vs. 1.7±1.9, p<0.001).

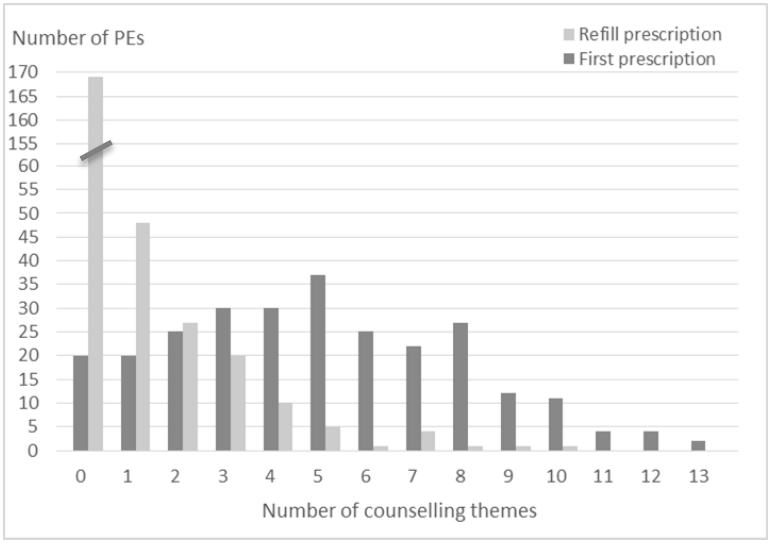


Fig 1 Number of themes counselled by the pharmacy staff per PE during first (n=269) and refill PEs (n=287).

Table 3 illustrates the number of the counselling themes and their initiator. Pharmacy staff mainly counselled on administration (in first PEs 465 times and in refill PEs 73 times), dose (188; 46), and use (152; 36) and provided a label (189; 55). Of the 34 counselling themes, 8 were never addressed.

Table 3 Number of counselling themes and their initiators. Bold p-value (p<0.05) are considered as statistically significant

Counselling themes (n=34)	First prescription encounters (n=269)					Refill prescription encounters (n=287)					P–Value (first vs refill PE of themes counseled by pharmacy staff)
	Theme counseled (pharmacy staff) n (%)	Theme discussed (pharmacy or customer) n (%)	Pharmacy staff as Initiator n (%)	Customer as initiator n (%)	Initiator not known n (%)	Theme counseled (pharmacy staff) n (%)	Theme discussed (any person) n (%)	Pharmacy staff as Initiator n (%)	Customer as initiator n (%)	Initiator not known n (%)	
Anamnesis (total)	100 (37.2)	101 (37.5)	99. (98.0)	1 (1.0)	1 (1.0)	8 (2.8)	9 (3.1)	8 (88.9)	1 (11.1)	0 (0)	
1. Medicines	34 (12.6)	35 (13.0)	33 (94.3)	1 (2.9)	1 (2.9)	3 (1.0)	4 (1.4)	3 (75.0)	1 (25.0)	0 (0)	**<0.001**
2. Diseases	9 (3.3)	9 (3.3)	9 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	**0.001**
3. Allergy	34 (12.6)	34 (12.6)	34 (100)	0 (0)	0 (0)	3 (1.0)	3 (1.0)	3 (100)	0 (0)	0 (0)	**<0.001**
4. Pregnancy/lactation	8 (3.0)	8 (3.0)	8 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	**0.003**
5. Familiar	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	-
6. Lifestyle	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	-
7. Clinical parameter	15 (5.6)	15 (5.6)	15 (100)	0 (0)	0 (0)	2 (0.7)	2 (0.7)	2 (100)	0 (0)	0 (0)	**0.001**
8. Dose	188 (69.9)	191 (71.0)	180 (94.2)	8 (4.2)	3 (1.6)	46 (16.0)	50 (17.4)	46 (92.0)	4 (8.0)	0 (0)	**<0.001**
Drug use (total)	152 (56.5)	153 (56.9)	143 (93.5)	9 (5.9)	1 (0.6)	36 (12.5)	38 (13.2)	36 (94.7)	2 (5.7)	0 (0)	
9. Use	129 (48.0)	130 (48.3)	121 (93.1)	8 (6.2)	1 (0.8)	34 (11.8)	36 (12.5)	34 (94.4)	2 (5.6)	0 (0)	**<0.001**
10. Duration of use (single application)	14 (5.2)	14 (5.2)	13 (92.9)	1 (7.1)	0 (0)	1 (0.3)	1 (0.3)	1 (100)	0 (0)	0 (0)	**<0.001**
11. Instruction/training of use	9 (3.3)	9 (3.3)	9 (100)	0 (0)	0 (0)	1 (0.3)	1 (0.3)	1 (100)	0 (0)	0 (0)	**0.009**
Drug administration (total)	465 (172.9)	475 (176.6)	437 (92.0)	26 (5.5)	13 (2.7)	73 (25.4)	80 (27.9)	69 (86.3)	8 (10.0)	3 (3.7)	
12. Frequency of administration	159 (59.1)	163 (60.6)	154 (94.5)	6 (3.7)	3 (1.8)	34 (11.8)	37 (12.9)	33 (89.2)	3 (8.1)	1 (2.7)	**<0.001**
13. Therapy duration	90 (33.5)	91 (33.8)	85 (93.4)	4 (4.4)	2 (2.2)	13 (4.5)	13 (4.5)	11 (84.6)	1 (7.7)	1 (7.7)	**<0.001**
14. Timing of administration	120 (44.6)	125 (46.5)	111 (88.8)	6 (4.8)	8 (6.4)	20 (7.0)	24 (8.4)	19 (79.2)	4 (16.7)	1 (4.2)	**<0.001**
15. Modality of administration	96 (35.7)	97 (36.1)	87 (89.7)	10 (10.3)	0 (0)	6 (2.1)	6 (2.1)	6 (100)	0 (0)	0 (0)	**<0.001**

Counselling themes (n=34)	First prescription encounters (n=269)					Refill prescription encounters (n=287)					P–Value (first vs refill PE of themes counseled by pharmacy staff)
	Theme counseled (pharmacy staff) n (%)	Theme discussed (pharmacy or customer) n (%)	Pharmacy staff as Initiator n (%)	Customer as initiator n (%)	Initiator not known n (%)	Theme counseled (pharmacy staff) n (%)	Theme discussed (any person) n (%)	Pharmacy staff as Initiator n (%)	Customer as initiator n (%)	Initiator not known n (%)	
Written information											
16. Label	189 (70.3)	189 (70.3)	188 (99.5)	1 (0.5)	0 (0)	55 (19.2)	55 (19.2)	55 (100)	0 (0)	0 (0)	**<0.001**
17. Flyer	8 (3.0)	8 (3.0)	8 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	**0.003**
18. Schedule	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	-
19. Document	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	-
20. Indication	108 (40.1)	111 (41.3)	98 (88.3)	11 (9.9)	2 (1.8)	21 (7.3)	25 (8.7)	20 (80)	5 (20)	0 (0)	**<0.001**
21. Effect	51 (19.0)	52 (19.3)	49 (94.2)	3 (5.8)	0 (0)	7 (2.4)	7 (2.4)	6 (85.7)	1 (14.3)	0 (0)	**<0.001**
22. Mechanism of action	1 (0.4)	1 (0.4)	1 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0.480
23. Benefit/purpose of therapy	3 (1.1)	4 (1.5)	3 (75)	1 (25.0)	0 (0)	8 (2.8)	9 (3.1)	7 (77.8)	2 (22.2)	0 (0)	0.226
24. Adverse effect	18 (6.7)	18 (6.7)	16 (88.9)	1 (5.6)	1 (5.6)	6 (2.1)	7 (2.4)	6 (85.7)	1 (14.3)	0 (0)	**0.011**
25. Red flag	3 (1.1)	3 (1.1)	3 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0.110
26. Drug-drug interaction	17 (6.3)	18 (6.7)	13 (72.2)	5 (27.8)	0 (0)	4 (1.4)	4 (1.4)	4 (100)	0 (0)	0 (0)	**0.003**
27. Contraindication	1 (0.4)	1 (0.4)	1 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0.480
Appropriate action in case of:											
28. Missed dose	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	-
29. Underdose	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	-
30. Overdose	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	-
31. Storage	5 (1.9)	5 (1.9)	5 (100)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	**0.025**
32. Information transfer	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	-
33. Adherence	12 (4.5)	12 (4.5)	12 (100)	0 (0)	0 (0)	23 (8.0)	23 (8.0)	22 (95.7)	1 (4.3)	0 (0)	0.116
34. Self-/monitoring	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (0.3)	1 (0.3)	1 (100)	0 (0)	0 (0)	1.000

Patient involvement

The customer was actively involved in 193 (34.7%) of PEs by providing information (149, 77.2%), asking questions (25 PEs, 13.0%) or a combination of both (19, 9.8%). During first PEs, the customer was more often actively involved than during refill PEs (48.7% vs. 21.6%, p<0.001). Table 4 illustrates the questions customers ask during first PEs. At refill PEs, customers asked five questions concerning therapy duration, indication, effect, benefit/purpose of therapy and adherence.

Table 4 Questions customers ask during first PEs, n=46 questions

	n	%
Questions on	**46**	**100.0**
Modality of administration	9	19.6
Drug use	7	15.2
Timing of administration	6	13.0
Indication	6	13.0
Dose	4	8.7
Drug-drug interaction	4	8.7
Therapy duration	3	6.5
Effect	2	4.3
Frequency of administration	2	4.3
Adverse effect	1	2.2
Duration of use	1	2.2
Written information (label)	1	2.2

Factors influencing counselling provision

Patient level

New compared to regular customer received more counselling from the pharmacy staff (mean counselling theme ratio 11.9% vs. 5.0%, p<0.001) [Table 5]. Carers who filled the prescription for a patient vs patients who filled the prescription themselves were more counselled by the pharmacy staff (6.7% vs. 5.1%, p<0.05). Customers who did not vs did refuse counselling received also more counselling (6.2% vs. 3.5%, p<0.001).

Prescription level

The type of prescription also influenced the rate of counselling. Significantly more counselling was provided with a first compared with a refill prescription (mean theme counselling ratio 9.6% vs. 1.5%, p<0.001), and with prescription requiring a pharmaceutical intervention vs. no intervention (7.9% vs. 4.6%, p<0.001).

Pharmacy level

Pharmacists provided information on significantly more themes per PE than pharmacy technicians (3.5 vs. 2.6 themes, p<0.05), druggists (3.5 vs. 1.9, p<0.05), and apprentices (3.5 vs. 2.3, p<0.05). However,

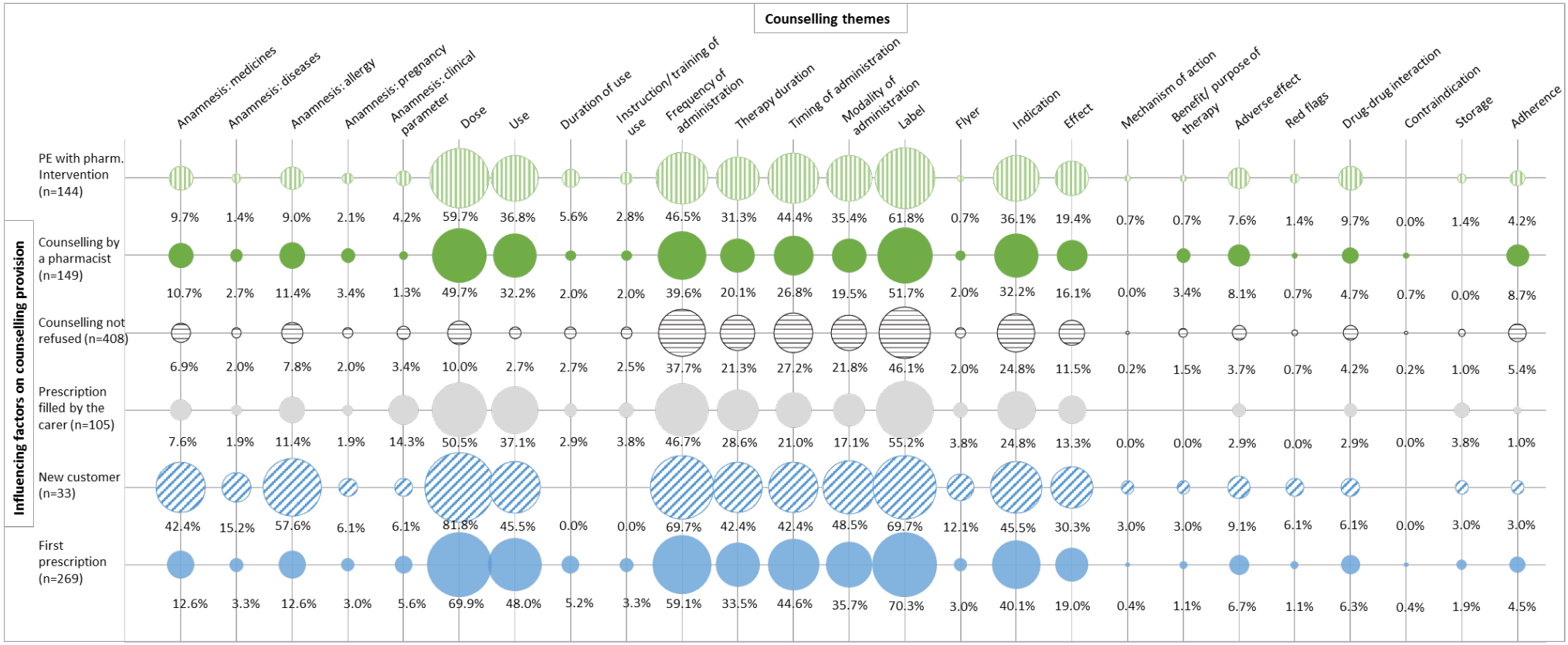
no significant difference between pharmacists and pharmacists in training (3.5 vs. 3.2, p=0.849) and between pharmacists and a combination of a pharmacist and another staff member (3.5 vs. 4.2, p=0.194) was reported.

Table 5 Mean counselling theme ratios of factors influencing counselling provision. Bold p-value are statistically significant.

Variable 1		Mean counselling theme ratio [%] average ± SD	**Variable 2**		Mean counselling theme ratio [%] average ± SD	**P–value**
Patient						
Regular customer	[n=523]	5.0 ± 6.1	New customer	[n=33]	11.9 ± 6.3	**<0.001**
Female patient	[n=337]	5.2 ± 6.1	Male patient [N=219]		5.8 ± 6.5	0.436
Counselling not refused	[n=408]	6.2 ± 6.7	Counseling refused	[n=148]	3.5 ± 4.6	**0.001**
Prescription filled by the patient	[n=451]	5.1 ± 6.2	Prescription filled by the carer	[n=105]	6.7 ± 6.7	**0.026**
Prescription						
First prescription	[n=269]	9.6 ± 6.2	Refill prescription	[n=287]	1.5 ± 3.1	**<0.001**
Ambulatory prescription	[n=468]	5.3 ± 6.2	Discharge prescription	[n=83]	6.7 ± 6.7	0.088
Prescription with interventions	[n=144]	7.9 ± 6.6	No intervention	[n=412]	4.6 ± 6.0	**<0.001**
Hand written prescription	[n=247]	7.5 ± 6.7	Printed prescription	[n=117]	7.0 ± 6.3	0.599
All medicines directly dispensed	[n=495]	5.7 ± 6.4	Some medicines picked up later	[n=61]	3.2 ± 4.6	**0.004**
> 1 medicine dispensed	[n=290]	5.7 ± 5.9	1 medicine dispensed	[n=266]	5.2 ± 6.7	**0.027**
>1 medicine on prescription	[n=353]	5.0 ± 5.8	1 medicine on prescription	[n=182]	6.5 ± 7.2	0.129
Pharmacy staff: counselling provided by						
a pharmacist	[n=149]	6.3 ± 6.6	a pharmacy technician	[n=267]	5.0 ± 6.1	**0.018**
			a druggist	[n=8]	2.4 ± 6.8	**0.019**
			an apprentice	[n=86]	4.6 ± 5.4	**0.045**
			a combination of a pharmacist and a other staff member	[n=33]	7.6 ± 7.8	0.476
			a pharmacist in training	[n=13]	6.7 ± 5.7	0.651
Situation						
Stress factor by waiting customers	[n=89]	6.5 ± 6.6	No waiting customer	[n=467]	5.3 ± 6.2	0.059
Silent environment	[n=500]	5.4 ± 6.4	Loud environment	[n=56]	5.6 ± 5.9	0.582
No disruption during counselling	[n=550]	5.5 ± 6.3	Disruption during counselling	[n=6]	3.9 ± 4.8	0.610
No communication problem	[n=548]	5.4 ± 6.3	Communication problem	[n=8]	6.9 ± 6.5	0.525

The detection of factors influencing counselling provision, allowed illustrating visual patterns of counselling (Fig. 2).

Fig. 2 Patterns of counselling: frequency of counselling themes as a function of the factors influencing counselling provision. These factors were selected in terms of significance. The size of the circle represents its frequency with respect to the factors influencing counselling provision.



Pharmaceutical interventions

During all 18 observation days, 203 pharmaceutical interventions were documented at 144 PEs (103 first PEs vs. 41 refill PEs, p<0.001; intervention rate 25.9%), with an average per prescription of 1.4±0.7 (range 1-4). Pharmacists mainly intervened by substituting a drug (89, 43.8%), clarifying information (64, 31.5%), and by adjusting the package size/quantity (39, 19.2%). Table 6 illustrates the most frequent pharmaceutical interventions. The cause of the PI was technical for 180 pharmaceutical interventions (88.7%) and clinical for 23 pharmaceutical interventions (11.3%). Pharmacist-prescriber interaction was necessary for 11 pharmaceutical interventions (5.4%), whereas the pharmacist alone involved in 192 (94.6%) pharmaceutical interventions (alone n=65, with the patient n=127).

Table 6 The most frequently observed pharmaceutical interventions, their cause, type of problem and problem (documented with the PharmDISC system)

Intervention	Cause of intervention	Type of problem	Problem	n (%)
Total interventions				203 (100.0)
	Technical			180 (88.7)
Clarification/addition of information	Incomplete/unclear prescription	Manifest, reactive	Technical/formal problem	55 (27.1)
Substitution (generic)	Financial burden	Manifest, reactive	Treatment costs	49 (24.1)
Substitution	Prescribed drug not available	Manifest, reactive	Technical/formal problem	31 (15.3)
Adjustment of package size/quantity	Financial burden	Manifest, reactive	Treatment costs	18 (8.9)
Adjustment of package size/quantity	Financial burden	Manifest, reactive	Patient dissatisfaction/ problems	9 (4.4)
	Clinical			23 (11.3)
Adjustment of package size/quantity	Concerns about the treatment	Manifest, reactive	Patient dissatisfaction/ problems	3 (1.5)
Substitution	No concordance with guidelines, only suboptimal therapy possible	Potential, preventive	Safety of treatment	2 (1)
Substitution	Concerns about the treatment	Manifest, reactive	Patient dissatisfaction/ problems	2 (1)
Therapy stopped/no delivery	Interaction	Potential, preventive	Safety of treatment	2 (1)
In–depth counseling of patient	Interaction	Potential, preventive	Safety of treatment	2 (1)

The number of pharmaceutical interventions per PE increased with the number of counselled themes per PE (correlation r=0.270, p<0.001) and the number of dispensed medicines per PE (r=0.236, p<0.001). The number of pharmaceutical interventions per PE did not increase with the patient age (r=–0.018, p=0.687) and the work experience of the pharmacy staff (r=0.032, p=0.470).

Additional activities

Of all PEs, 10 PEs resulted in a phone call with the physician (4 first and 6 refill PEs), 5 in a referral to the physician (4 first and 1 refill PEs), 1 refill PE in refusal of dispensing, and 1 first PE in a consultation in a private room. The pharmacists reconstituted seven suspension, and offered three follow up. At 11 PEs (11 first, 0 refill, $p<0.001$), counselling on non-pharmacological measures (e.g. balanced nutrition) was provided.

Discussion

This observation study allowed depicting the dispensing process of prescribed medicines in Swiss community pharmacies in the manner how the patients received counselling at the counter.

Counselling

When counselling was provided, moderate to good practice of counselling was observed, indicating that the pharmacy staff assumed in certain cases the responsibility to ensure that the patient received sufficient oral and written information on prescribed medicines to make the best use of them [37]. Counselling was given to 66.0% of the customers receiving prescribed medicines, which is slightly more than in a previous observation study (57.3%) performed in 2010 [126]. A review of worldwide counselling practices on prescribed medicines reported counselling rates from 12 to 100%, when observation methods were used [124]. This indicates a variation in frequency of pharmaceutical care provision. The customers were counselled on one to thirteen different themes (out of the 34 predefined counselling themes) per PE. Written information as an individualised label to reinforce verbal communication was provided in 43% of the cases.

Although a quarter of customers refused counselling, one-third of the customers did not received any counselling. Possibly, our study design did not take into account the long-term relationship between the pharmacy staff and the patient as a regular customer, which lead to substandard scores because they know each other. This is in line with what we observed; new customers received more counselling that regular customers. We could not assess what happened before the observed PE and which information was already exchanged during prior PEs. However, this study depicted how the patient received the counselling at the counter; we observed that pharmacists were involved by direct patient contact in only a quarter of all PEs. Pharmacists' activities such as drug interaction-check and

investigation of the medication history that have been done in the back office are neither visible nor communicated to the customer. Pharmacy staff should be more transparent about their activities through openness and better communication with the customer in daily practice.

The counselling was more based on product-centered (e.g. dose, use, and administration) than patient-centered information (e.g. adherence, therapy benefit, and adverse effect), similarly to other studies [124, 126, 132]. In reference to Figure 2, the counselling patterns illustrates well the gaps in patient-centered counselling. Especially for patients refilling prescribed medicines, low counselling ratios were observed. Not addressing the patient-centered counselling themes to the customers showed that the pharmacists missed the opportunity to improve patients' adherence to their drug therapy [133]. It is known that patients often stop taking their newly prescribed medicines in the first six month of therapy (medication non-persistence), because of concerns about medication (e.g. adverse effect), the lack of perceived need for it (e.g. poor understanding of medicines/disease) and medication affordability [134, 135]. Therefore, remunerated cognitive pharmaceutical services (e.g. 'Polymedication check', 'Adherence fee') were introduced in Switzerland since 2010 [50], but during the observation, none of these services were performed.

Patient involvement

We showed that the pharmacy staff was mostly the initiator of the discussion, confirming the findings of another study [117]. A systematic review revealed a mainly passive role of the patient in conversations with healthcare providers [136], even though some guidelines encourage an interactive communication [72]. This is in line with what we observed; customers asked only few questions. However, these questions give the opportunity to the pharmacy staff to tailor information on patients' needs [133]. Lack of privacy at the counter [137], lack of interest in pharmacy counselling [138-140], and patients' underestimation of pharmacists' role in healthcare are possible reasons for patients' difficulties in asking questions [132, 141, 142]. Nevertheless, the patients' initiative would be important, knowing that the outcome of a dialogue depends on the person who initiates the discussion [76]. Indeed, in patient-centered care, the patient always comes first and its needs should drive the PE [107]. Therefore, the patient should be encouraged in PEs to be more active in the discussion. Furthermore, we observed that sometimes pharmacy staff offered counselling by asking only general questions (e.g. do you know this medicine already?), limiting the counselling provision and the patient involvement, and consequently not taking into account the patients' needs. It has been shown that the counselling provided to the patients did not completely meet their need for information [143]. A study exploring advice-giving behaviour in British community pharmacies reported that the counselling was mostly based on product use and that the customers wished information about the drug

effectiveness while the pharmacists provided information on drug safety. The authors proposed a protocol to guide pharmacy staff that includes the customer perspective [132]. To meet patient needs, the pharmacists should better listen to the patients' problems and provide individualised counselling and information [144].

Factors influencing counselling provision

Counselling was not equally provided, indicating that pharmacy staff use different degrees of counselling at PEs. If extended counselling at each first and refill PE is not possible in daily practice, pharmacy staff should target counselling for specific situations. However, it is important to notice that each PE offers the pharmacists the opportunity to interact with the patient and hence to detect DRPs and patients' concerns. The study findings highlight some factors influencing counselling provision at patient, prescription and pharmacy level. These indicators could help in prioritising prescriptions needing in-depth counselling.

Patient level

- New customers were more likely to receive counselling from the pharmacy staff than regular customers. The counselling patterns revealed that the pharmacy staff performed more likely an anamnesis (medicine, diseases, and allergy) with the new customers, while the counselling patterns of the other factors influencing counselling provision were comparable (Fig. 2). Similarly to a review [124], the pharmacy staff mainly provided information on administration, dose and use, what also the counselling patterns demonstrates.
- Customers who did not refuse counselling received more counselling. Refusing counselling did not mean that the patient did not receive any counselling, but such refusing is known as an important barrier for the provision of counselling [126]. Lack of the patients' interest is a common phenomenon during counseling in community pharmacy [138, 139], up to 41–63% patients decline a counseling offer [140, 146], leading to low counseling ratios [140].
- Carers who filled a prescription for a patient received more information on the prescribed medicines than the patients themselves. Possibly the carer was not present at the consultation with the prescriber and did not receive information on the patient's drug therapy.

Prescription level

- Customers with a first prescription received more counselling than the customers with a refill prescription. In a first PE, it is important to ensure that the patient receives the knowledge for using their medicines correctly [126]. Correct drug use is ensured by counseling on therapy duration treatment, dosage, and optimal timing of drug intake [147]. At refill PE, pharmacists

could suppose that patients with chronic medication were already informed about their use [148]. They could be also regular customers that need less clarification. Previous studies showed that pharmacy staff classified the communication with patients to be more difficult during refill PE than during first PE [149, 150]. It has been shown that patients' expectations towards the counselling are different in first and refill PEs. More interest during first PE may facilitate an extensive counselling [140]. This is in line with our findings: during first PEs, patients showed more interest in counseling than during refill PEs because two third of the counselling refusals were observed during refill PEs.

- Prescriptions that resulted in a pharmaceutical intervention required more counselling than prescriptions without any intervention. These prescriptions involved mandatorily the pharmacist, who is known to give more counselling than other pharmacy staff member and hence, the PE required more counselling to inform the patient about the DRP.

Pharmacist level

- Pharmacists provided more counselling to customers than the other pharmacy staff members. Other studies reported this factor [126, 148, 151]. A reason could be that pharmacists have a larger knowledge about drug therapy. The practice of dispensing prescribed medicines should be homogenised in the pharmacy staff, for example by training and using a protocol to guide pharmacy staff [132].

Lack of counselling provision might reflect insufficient knowledge or skills of the pharmacy staff. Counselling quality can be improved by developing counselling skills through education (e.g. role-play with standardised patients [152]), patient-centered communication (concordance of provided care with patients' preferences and needs) [153, 154] and the application of established guidelines on Good Pharmacy Practice [37].

Pharmaceutical interventions

Our findings confirm that the community pharmacists were effective in detecting, preventing, and solving DRPs [6, 133]. By intervening during dispensing, pharmacists contributed to the safe, appropriate, and cost-effective use of drugs. Individual judgement and professional knowledge of the pharmacists and the collaboration with the patient, carer or prescriber was needed to respond satisfactorily to the patient needs. We assessed a comparable rate of pharmaceutical interventions (25.9%) to a German study describing DRPs at time of dispensing prescribed medicines which reported an intervention rate of 18.0% [6].

Additional activities

Pharmacy staff proposed only few additional activities during PE, missing the opportunity to offer additional care and ensure continuity of care to optimise patient therapy and health outcomes. Nevertheless, each refill prescription is an opportunity for the pharmacists to offer follow-up and further cognitive pharmaceutical services. Although these services are remunerated in Switzerland [50], none of the pharmacists proposed to the customer a medication review (e.g. 'Polymedication check') and an adherence aid (e.g. 'Adherence fee'). However, they performed often 'Generic substitution' for newly prescribed medicines. This limited observed provision of pharmaceutical care in community pharmacies confirms the results of other studies [146, 151, 155] and indicates that the implementation of these cognitive pharmaceutical services is still challenging.

Strengths and limitations

Our approach to describe the dispensing process of prescribed medicines at the counter was non-participant observation, which is a useful way to study quality of services and consistency of care [156]. In the literature, observations allowed to describe customers' behaviour and practice from real daily life [157], thus avoiding the biases of self-report methods [147]. Our observation method was based on ad hoc taking notes of exchanged information and transcribing into quantitative information. The documentation of the observed PEs has been tested on consistency and plausibility. The data was collected in eighteen randomly selected pharmacies, while the study was restricted to one region in Switzerland. The principal limitation was the presence of an observer which could positively influence the counselling performance of the pharmacy staff by triggering them to be more aware of their way of approaching customers (the Hawthorne effect) [158]. In order to minimise this effect, our observer became accustomed with the pharmacy staff prior data collection to make them feel at ease. Moreover, the observation lasted a whole working day, which allowed observing the normal practice over time. Simulated client methods such as mystery shopping could minimise observation bias, but present limitations of their own. The extracted information corresponds to a small part (snapshot) of healthcare practice only and is therefore hard to generalise to other health situations [159]. The observations were not recorded and not reviewed by a second investigator, which might have limited the reliability of the results.

Outlook Ongoing research will analyse the pharmacists' interviews and investigate their opinion on counselling. In a future similar observation study, we could ask patients' opinion on what they expect of counselling after having filled a prescription that has been observed. We could also develop instruments to assess the patients' needs and consequently tailor the counselling.

Conclusion

The observation of the dispensing process of prescribed medicines allowed to depict the community pharmacy practice from the customers' perspective (at the counter) and to identify factors influencing counselling provision at patient, prescription and pharmacy level. Significantly more counselling was provided by pharmacists, to customers with a first prescription, with a prescription requiring a pharmaceutical intervention, to carers who filled the prescription for a patient, to new customers, and to customers who did not refuse counselling. Counselling was not equally provided, indicating that pharmacy staff counsels at different degrees during PEs. A more transparent practice and patient-centered counselling is necessary to better meet the patients' needs on information. While pharmacists intervened frequently, only few additional activities and no further service (e.g. adherence support) were offered.

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Conflict of interest

The authors declare that they have no conflicts of interest.

Appendix

A3.1.1 Invitation letter for the study pharmacists
A3.1.2 Information document for the study pharmacists
A3.1.3 Checklist
A3.1.4 Characterisation page
A3.1.5 Data Dictionary for the characterisation page and the checklist
A3.1.6 The PharmDISC system (version 2.0, German)

C2 Dispensing of prescribed medicines in community pharmacies - Observations deviate from pharmacists' opinions

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Research report

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Background and Objectives

Counselling of patients on prescribed medicines is a key competency element to ensure a rational use of medicines. International good pharmacy practice guidelines [37] describe how pharmacists should counsel the patients about their medicines, offer additional activities where needed, and intervene at drug-related problems. In Switzerland, these services are reimbursed by a fee at the dispensing of prescribed medicines [50]. However, international literature shows that daily practice often differs from theory [126, 155, 160]. To our knowledge, the dispensing process of prescribed medicines including all activities from the prescription presentation to the medicines distribution has not been described in Swiss community pharmacies yet. This study aimed at illustrating the observed process of dispensing prescribed medicines in daily community pharmacy practice. This analysis focuses on pharmacists' opinions.

Setting and Method

Community pharmacies in Basel, Switzerland, were randomly invited for study participation. One master student in pharmacy performed non-participant observations during one day at each included community pharmacy (C1). At dispensing of prescribed medicines, patient data, content of counselling, and provision of additional activities (e.g. follow-up offer) were documented on a structured checklist with predefined themes. The pharmaceutical interventions were documented systematically with the PharmDISC system [85]. A 20-item semi-structured interview on the pharmacists' opinions on the counselling (triggers, facilitators and barriers), and on the documentation and transfer of pharmaceutical interventions was conducted at each community pharmacy with a pharmacist. We evaluated pharmacists' agreement with 4-point Likert scale (1=not true, 4=true).

Results

In March and April 2016, 18 of 49 invited community pharmacies participated in the study. They were mostly female (55.6%), manager of the pharmacy (n=9, 50%), deputy pharmacists (n=5, 27.8%), or owner (n=4, 22.2%). Their professional experience in community pharmacy ranged from 3 to 36 years. Seven of them had one specialization (Foederatio Pharmaceutica Helvetiae [FPH] title) and one pharmacist had two. A total of 556 encounters were analysed (first prescription: 269; refill prescription: 287).

Counselling on prescribed medicines

Counselling was provided to 367 (66.0%) of all customers (n=556 patients or carers) with an average of 2.9±3.1 themes per prescription encounter. A total of 148 customers refused counselling. The most counselled themes at first and refill prescription dispensing were: administration (first 476; refill 80), dose (191; 50), and use (153; 38). For the interviewed pharmacists (n=18), most important counselling themes to be discussed at first prescription dispensing were indication (n=11), administration (n=9), and anamnesis (n=8); for refill prescription dispensing: adherence (n=9), therapy benefits (n=9), and adverse effects (n=7) [Fig. 1].

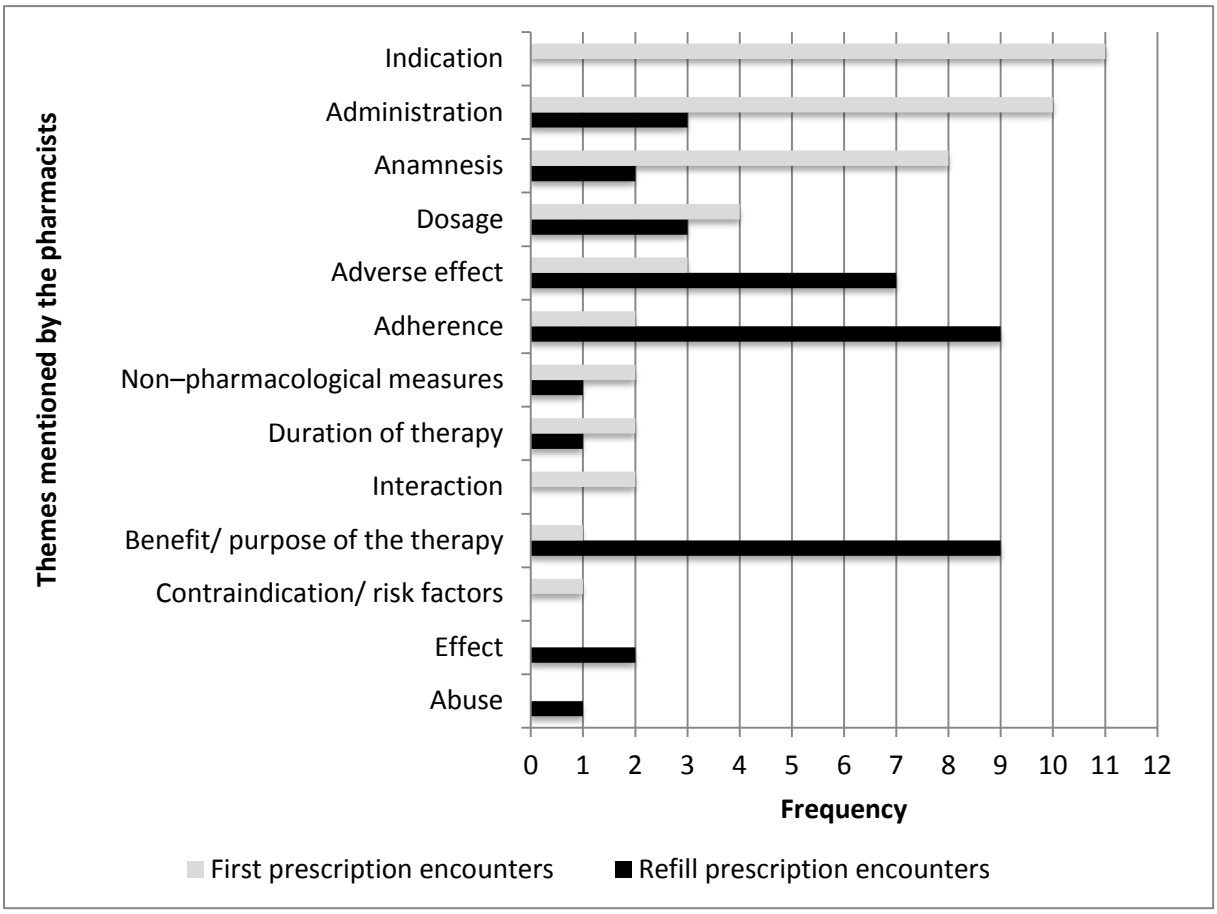

Fig. 1 The most important counselling themes for the pharmacists (n=18), during first (n=46 answers) and refill (n=37 answers) prescription encounters.

The counselling content of themes observed (Fig. 2, observation) and reported by the pharmacists (Fig. 3, interview) are illustrated and compared as follow:

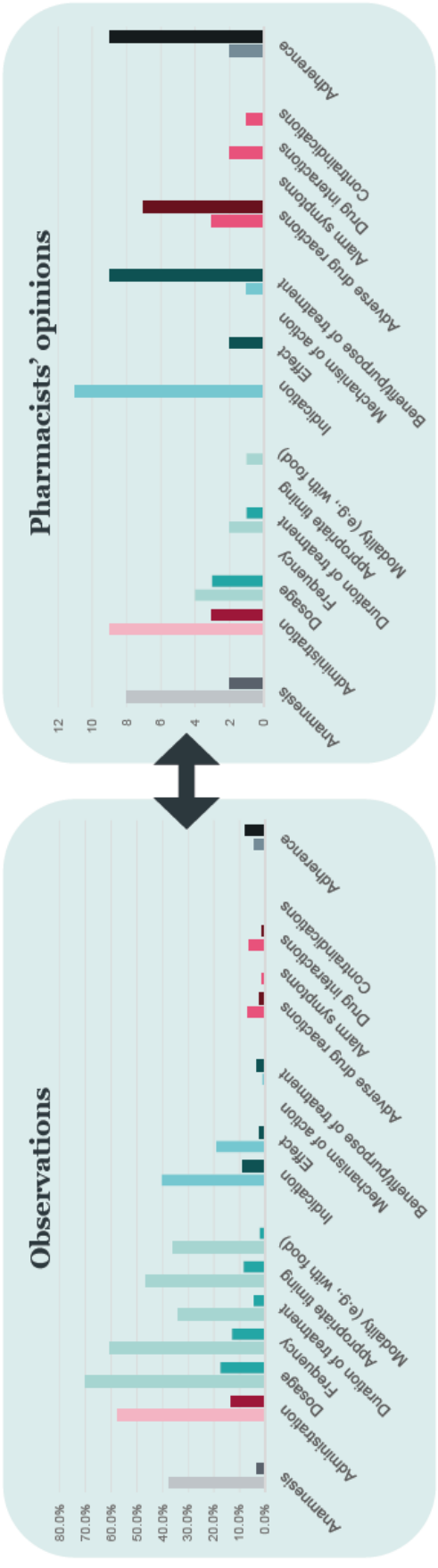

Figure 3 Counselling content by themes mentioned by pharmacists during the interview in absolute numbers (n=18). Bars for first prescriptions are in light colour, bars for refill prescriptions are in dark colour.

Figure 2 Counselling content by themes observed at 18 community pharmacies in [%] of encounters (n=269 for first, n=287 for refill prescriptions). Bars for first prescriptions are in light colour, bars for refill prescriptions are in dark colour.

Most pharmacists (n=13) felt that it was their obligation to ask questions about patients' health during the dispensing of prescription medicines and named trigger factors, but one third reported difficulties with asking questions. Pharmacists reported triggers, facilitators, and barriers for patient counselling on prescribed medicines (Table 1).

Table 1 Triggers, facilitators, and barriers for patient counselling that pharmacists (n=18) expressed

Triggers (n=45)	**n**
Patient's knowledge gap	8
Patient's motivation/interest	6
Drug-drug interaction	5
Polypharmacy, polymorbidity	4
Special patient population	4
Adverse drug reactions	3
First prescription	3
Adherence	3
Concerns of the patient	2
Special medicine	2
Others	5

Facilitators (n=34)	**n**
Interest of patient	11
Open-minded patient	4
Medical data available	4
Patient and provider speak same language/ suitable communication	4
Relationship	3
Patient understands necessity	2
Pharmacist's experience	2
Patient needs are clearly expressed	1
Privacy (e.g. in private room)	1
Pharmacist has enough time	1
Fully staffed	1

Barriers (n=35)	**n**
Counselling refusal by patient	13
Communication problems/language	7
Lack of time, stress	4
Medical data unavailable	3
Mental ability of the patient	2
Unclear indication and patients' need	1
Patient not present	1
Patients who are not aware of competency of pharmacy staff	1
Lack of knowledge (pharmacist)	1
Pharmacist incompetency	1
Difficult economic conditions	1

Documentation of pharmaceutical interventions

All 18 pharmacists confirmed that they documented their pharmaceutical interventions. Six pharmacists (33.3%) affirmed to always document them, seven often (38.9%), four sometimes (22.2%) and one rarely (5.6%). Most of the pharmacists (n=17, 94.4%) stated to electronically document them, nine (50.0%) to additionally write notes on the prescription and four pharmacists (22.2%) to have an additional system for documentation. Other documentation methods were used: a pharmacy noticed important changes on the medication list of the adherence aid and another pharmacy printed out all faxes and e–mails sent to the physician for collecting them in a folder. One pharmacy wrote in a "book

for pharmacists" all special events, mainly pharmaceutical interventions, so that the pharmacist overtaking the service can easily update him–/herself. Lastly, one pharmacy had an nonconformance document for each essential intervention, including the questions "What happened?", "When?", "How?", "Which decision was made?", and "Who does what until when?". Additionally, the document included a classification system (type of problem, category, and result) which had to be ticked. This document had to be filled out by hand and was collected in a folder. Some comments about the intervention were manually added in the electronic medical patient data.

Sixteen pharmacists found important and two quite important that the pharmaceutical interventions could be documented (mean user agreement 3.9 ± 0.3) (Fig. 4). Three agreed and thirteen quite agreed on the importance of the transfer of the performed interventions to other healthcare providers (3.1±0.7). Pharmacists suggested possible reasons for no transfer: minor relevance of some pharmaceutical interventions (e.g. substitution, n=15), overwork (e.g. too time-consuming, too much data, and difficult access to physician, n=9), no feedback of the physician (n=3) or unfriendly/negative feedback (n=2), unease (uncertainty, feeling of disturbance, n=2), and no patient wish (n=1).

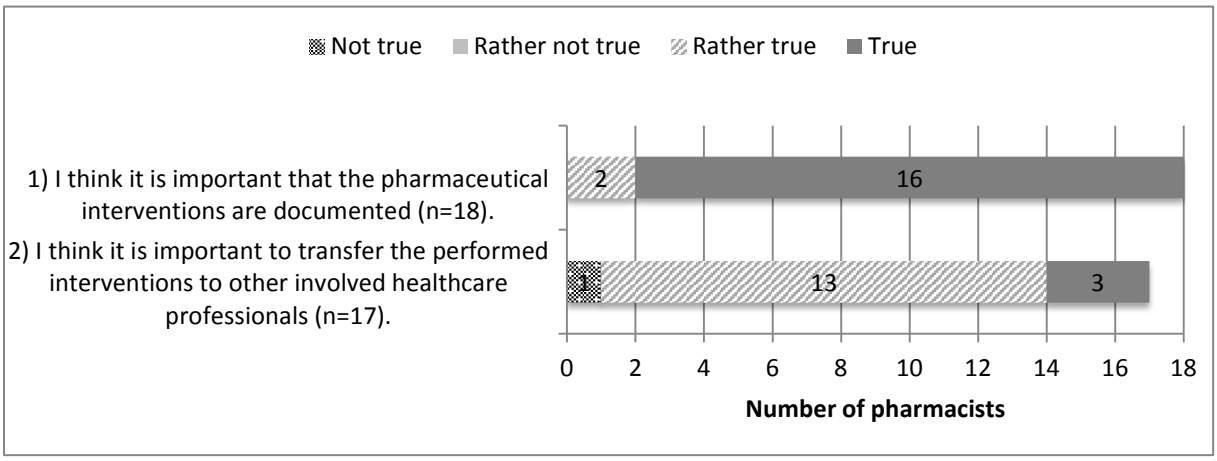

Fig. 4 Pharmacists' agreement on the importance of the documentation and the transfer of pharmaceutical interventions.

All 18 pharmacists reacted positively to the idea of having an intervention history (created from the data collected with a documentation system) for each patient (good n=9, great n=2, useful n=2, other positive comments n=5). Additionally, they expressed their overall opinion by making a comparison with the current situation (n=3) or by mentioning advantages of a consistent documentation of pharmaceutical interventions for each patient (n=3). Seven pharmacists added requests for the documentation system (with the option 'intervention history'); for example, the system should be simple, practicable and fast in use, and its use should be optional.

Figure 5 illustrates the new possibilities that the implementation of such documentation system would offer to the pharmacist's profession. However, two pharmacists warned that such system could be time-consuming by involving lots of computer work.

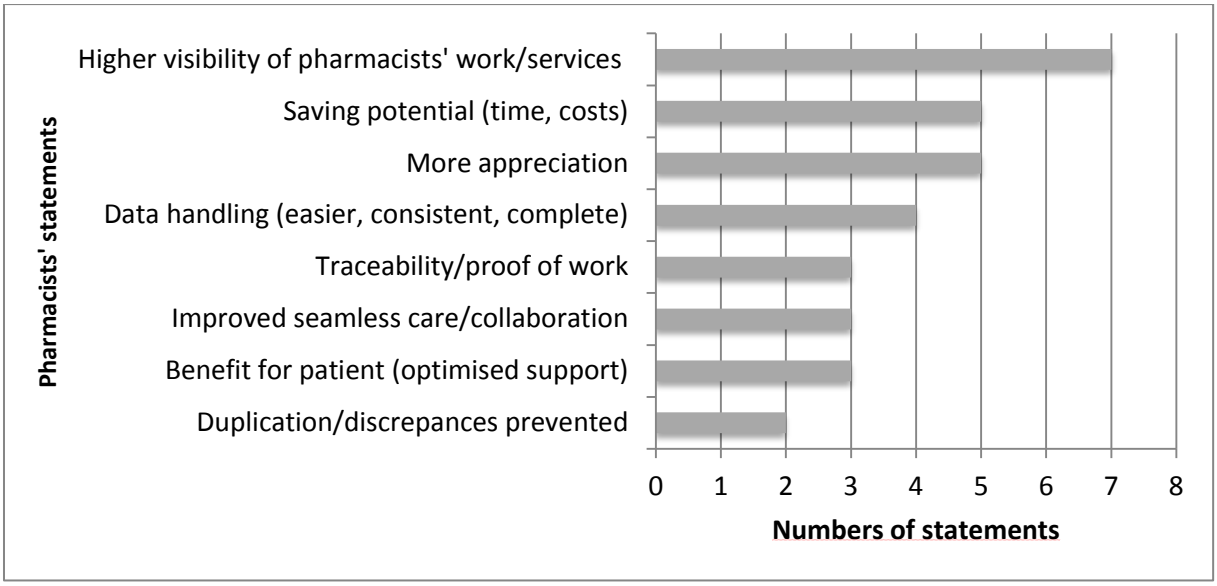

Fig. 5 Pharmacists' statements on new possibilities for the implementation of a documentation system for the pharmacists (n=32 statements).

The idea of a pop–up window, which appears automatically at the end of the prescription control and asks if an pharmaceutical intervention was performed, was accepted by nine of pharmacists (50.0%), while six (33.3%) found that it would disturb them. Eight pharmacists (44.4%) mentioned the risk that the pop–up window could be ignored over time.

Figure 6 illustrates the pharmacists' statements on facilitators for the implementation of a documentation system. Most pharmacists wished a short and practical training, online or on site, with case studies and simple instructions.

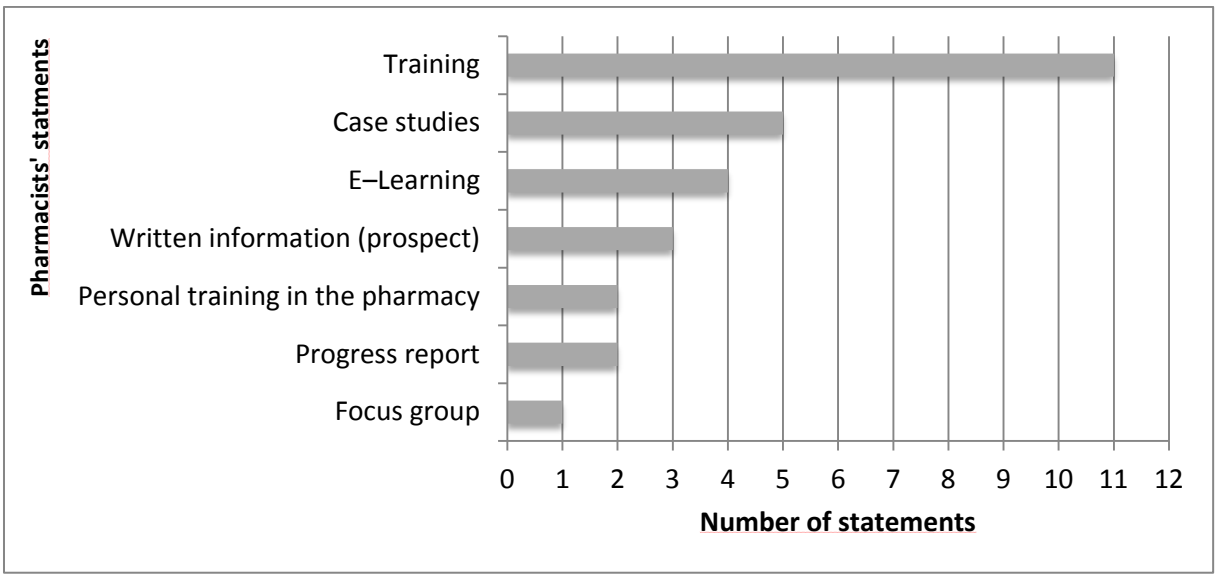

Fig. 6 Pharmacists' statements on facilitators for the implementation of a documentation system [n=28 statements]

Conclusions

A discrepancy in counselling content by observation compared to pharmacists' opinions was revealed. Observations showed a focus on product-centered themes (e.g. dose, administration), whereas pharmacists highlighted the importance of patient-centered content (e.g. benefit, adherence). This might indicate that pharmacists are aware but limited by barriers to practice according to good pharmacy practice guidelines.

The majority of the pharmacists recognised the importance of the documentation of the pharmaceutical interventions. The diverse documentation methods reported by the pharmacists in their own pharmacy showed that no standardised documentation is currently used. Pharmacists found important to transfer the performed pharmaceutical interventions to other healthcare providers, but some barriers (e.g. minor relevance of some pharmaceutical interventions, too time-consuming) could hinder it. A simple and fast in use computerised documentation system, with an additional intervention history option, could be a promising approach according to the positive reactions and the needs of the pharmacists. As stated by the pharmacists, its implementation should increase the appreciation and visibility of pharmacists' work, facilitate data handling by saving time and costs, ensure seamless care by improving collaboration among healthcare providers, and ultimately improve the therapy outcomes.

Appendix

A.3.2.1 Interview

GENERAL DISCUSSION AND CONCLUSIONS

The goal of this thesis was to create structured instruments for daily practice to improve the continuity of documentation and communication of pharmaceutical interventions during transitions of care. We approached this goal by developing and validating classification systems of pharmaceutical interventions for the hospital setting, the GSASA system, and for the community setting, the PharmDISC system, and evaluating their feasibility in practice (Fig. 1). We also depicted pharmacists' activities in real-life daily practice through the documentation of pharmaceutical interventions and the observation of patient counselling on prescribed medicines at dispensing.

The initial detected **need for documentation** was substantiated by the use of the classification systems in practice and/or research by hospital and community pharmacists, and the pharmacist-reported motivation to document pharmaceutical interventions in daily practice all along the projects. Thanks to an addition of a comment section to the classification systems, our classification systems became consequently structured documentation systems. Thus, by creating structured instruments, this thesis contributed to the **improvement of the documentation** of pharmaceutical interventions in practice and research.

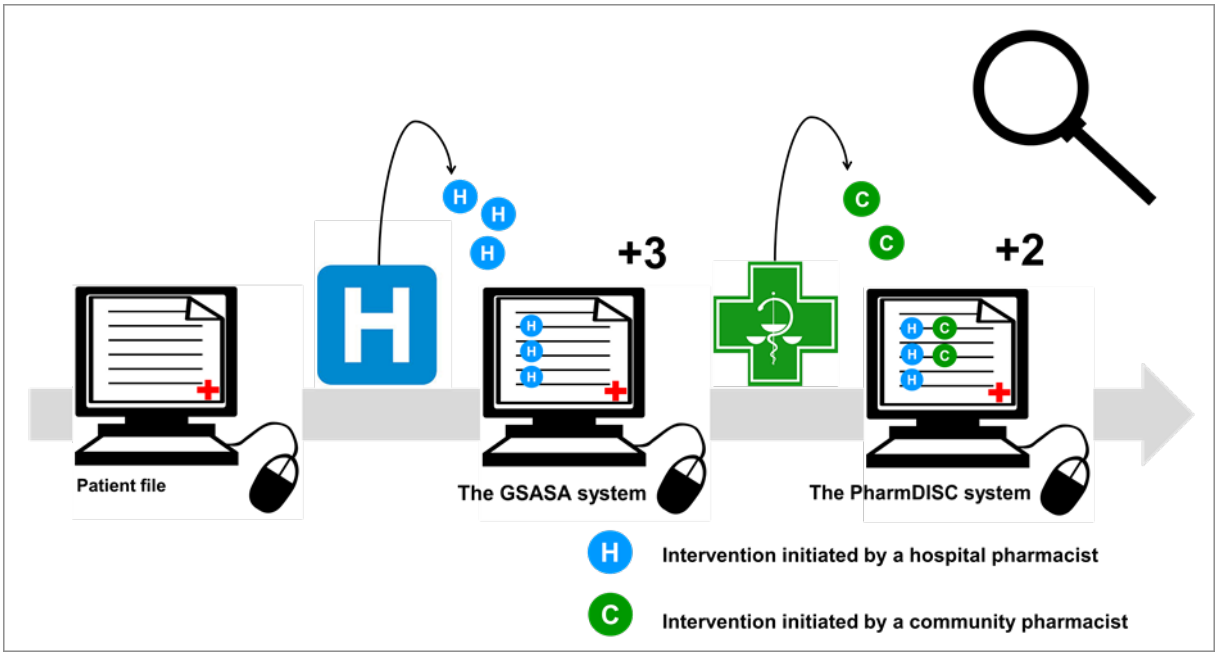

Fig. 1 Continuity of documentation: looking at the patient pathway during hospital stay, three pharmaceutical interventions could be documented with the GSASA system; and after discharge, two interventions initiated by a community pharmacist with the PharmDISC system, using the similarly structured and compatible classification. The documentation of these pharmaceutical interventions and the observation of patient counselling at dispensing enabled to depict pharmacists' activities in the routine practice.

The GSASA system

In **Project A**, we developed together with the GSASA working group in clinical pharmacy an intervention oriented classification system for hospital setting, the GSASA system. We validated the GSASA system (**A1**), evaluated its implementation in practice (**A2**), and developed a new seamless concept of classification of pharmaceutical interventions in patient care (**A3**).

The GSASA system was developed based on the PCNE system V6.2 [65] and the SFPC system [66] and is composed of five main categories (i.e. problem, type of problem, cause of intervention, intervention, and outcome of intervention) [81]. The GSASA system appeared to be valid and easy to use in daily clinical practice. The system is validated in terms of appropriateness, interpretability, validity, acceptability, feasibility, and reliability. Study **A1** showed that most of the 115 pharmaceutical interventions (n=93, 80.9 %) could be documented with the GSASA system and a similar ratio of 81.7% (n=94) with the PCNE system V6.2 [65], our benchmark. Comparable interrater reliability and acceptability for the GSASA and PCNE systems were also found. The comparative evaluation of the two systems revealed differences with respect to usability. Indeed, the category 'intervention' of the GSASA system allowed a more complete classification of the cases than the PCNE system. This reveals that our system respected its original approach, which focused on recording the interventions. The GSASA system is currently used in practice and in research. The current status and a selection of works is presented below.

Since the GSASA introduced the classification system to standardise the documentation of pharmaceutical interventions, the GSASA system has been implemented in daily practice. Twelve Swiss hospitals are using it to record all pharmaceutical interventions during ward rounds or any other activities/requests (**A2**) [82]. This substantiates that there was a real need for documentation of pharmaceutical interventions and indicates that the pharmacists are convinced of the beneficial use of the GSASA classification in the pharmacy practice. The obtained data on pharmacists' activities is used for epidemiological studies and described in the hospital annual report. This enabled demonstration of the performance/impact of clinical pharmacy services, which as a matter of fact facilitated political and economic discussions to obtain, for example, new job vacancies for clinical pharmacists. Moreover, the GSASA system as Microsoft Word or Excel file and the descriptive manual are available on the GSASA website in three languages (French, German, and Italian) [161]. The descriptive manual assists in categorisation and hereby will increase the quality of data due to an appropriate use of the standardised classification system. Some hospitals completed the Excel file by adding, for example, a section for comments (unstructured notes), the ward specialisation, and the pharmacist's initials.

On the research side, a recent randomised controlled study used the GSASA system to classify the addressed DRPs and describe the pharmacists' interventions during medication reviews on medicines use in patients on polypharmacy (Polymedication-check, PMC) in Swiss community pharmacies [44]. The authors adapted the system to the study setting: by dividing the subcategory 'insufficient knowledge of the patient' of the category 'cause' into three subcategories focusing on patients' information needs about a) safe and effective use of his medicines, b) potential adverse drug reactions, and c) lifestyle, nutrition, or empowerment in general; moreover the subcategory 'more cost-effective therapy available' was added to the category 'cause' as the generic substitution might be likely to be triggered throughout a PMC. In an ongoing study in a Swiss hospital, systematic medication reviews were performed with inpatients to detect potential and manifest DRPs. They were classified and evaluated by hospital pharmacists with the GSASA system in combination with the German version of the CLinical Economic and Organisational (CLEO) instrument [162] to validate a trigger tool for pharmacists' interventions (DART) [45].

These applications show that the GSASA system is usable in different settings and for various situations. However, in order to use it in the community setting, the GSASA system had to be slightly adapted. This confirms our seamless concept that the classification of pharmaceutical interventions should allow high flexibility in documenting pharmaceutical interventions (**A3**). According to the complexity of the case, the available information, the type of medication review, and the need for follow-up, different levels of classification may be indicated. This innovative classification system should be suitable for both, community and hospital pharmacy practices to facilitate continuity of care. Therefore, the basic structure of the GSASA classification system, currently used in hospitals, was adopted as far as possible to develop a similar classification system for the community pharmacies, the PharmDISC system.

The PharmDISC system

Project B succeeded in a two-phase development process of the PharmDISC system which followed a translational approach by adapting the existing hospital-specific system to the requirements of community pharmacies. The development process was split into two parts and four stages: Part 1 covered the development and piloting stages (**B1**), while Part 2 covered the evaluation and implementation stages (**B2**).

In Part 1 (**B1**), the PharmDISC system (version 1.0) reached higher interrater reliability (κ=0.61) than the GSASA system (κ=0.53) [81], revealing that the modifications made to the GSASA system were

suitable for the community pharmacy setting. All K-coefficients of the classification categories were above the threshold of K=0.40, indicating that the results were widely independent of the observers and that the categories were mutually exclusive. The study showed that the majority of the 725 pharmaceutical interventions (n=686, 94.6%) were completely documented with the PharmDISC system which demonstrated its clarity and completeness. To our knowledge, this is the first development of a classification system that combines a quantitative and a qualitative approach in a mixed methods study. Both, the observational study and interrater reliability study provided the quantitative baseline, which was used in a qualitative phase to gain the pharmacists' opinions using a focus group. The focus group participants confirmed the need for a classification system which is compatible with the electronic patient file by pointing out the importance of traceability of pharmaceutical interventions. Pharmacists wished to distinguish the type of intervention depending on the complexity. This could be solved by separating technical and clinical pharmaceutical interventions. Technical pharmaceutical interventions (e.g. generic substitution) are routine and non-complex pharmaceutical interventions that require little time expenditure as opposed to clinical pharmaceutical interventions (e.g. dose adjustment). The pharmacists were highly motivated to document pharmaceutical interventions, as it provides a tangible proof of their work, improves the communication within the team and with other healthcare professionals, and maintains quality management. Points for the optimisation of the PharmDISC system (e.g. addition of the category 'communication') were discussed and resulted in a new version.

In Part 2 (**B2**), the validation study showed that the PharmDISC system was suitable to document pharmaceutical interventions in community pharmacies, with 82.9% (n=430) of pharmaceutical interventions (n=535) completely classified in all categories. With the PharmDISC system version 1.1, we could demonstrate favourable interrater reliability for all but one classification categories (average K=0.66), which was on average higher than previously obtained with version 1.0 (average K=0.61). This improvement was likely due to refinements in the updated version as well as the introduction of the descriptive manual that may have facilitated the classification of pharmaceutical interventions.

Although all validation results of the PharmDISC system fulfilled the requirement for an acceptable classification system [68], its implementation into daily routine of a community pharmacy remains a challenge for information technology, as several different pharmacy software programs co-exist in Switzerland. In practice, the PharmDISC system has not been implemented in pharmacy software yet. However, an implementation is discussed as a standard for the Swiss electronic patient file, which is part of the "eHealth 2020" project of the federal health authorities. However, we expect the PharmDISC system to be is viable for future implementation for several reasons:

- In contrast to the classification of DRPs, which require an interpretation by the practitioner, the PharmDISC system focuses on the documentation of actual pharmaceutical interventions allowing for an objective assessment.
- The PharmDISC system offers a flexible and comprehensive classification system for pharmaceutical interventions of varying complexity that, consequently, is able to capture both prescription-focused as well as patient-centered pharmaceutical interventions.
- The descriptive manual, rated as helpful and relevant, provides clear definitions of pharmaceutical interventions which should aid in uniformly classifying pharmaceutical interventions, another requirement for classification systems [61].
- The pharmacists noted that with increasing familiarity with the PharmDISC system over the course of the study, the faster and more comprehensive their classification of pharmaceutical interventions became.
- Little time was necessary for the pharmacists to get accustomed with the PharmDISC system. This correlated with the pharmacists' positive opinions on the use of the PharmDISC system. Furthermore, most pharmacists were willing to use the system, but only once integrated into the pharmacy software. This underlined the need for a computerised classification system.
- The online training was highly appreciated by the pharmacists. It is therefore important to offer online training to future users of the PharmDISC system.
- The documentation of pharmaceutical interventions may raise the awareness for DRPs and subsequently increase the intervention rate and patient safety. It has been reported that documentation of pharmaceutical interventions makes pharmacists more attentive regarding the patients' drug-related needs and enhances the development of counseling skills and pharmaceutical care [53].

On the research side, the PharmDISC system is currently used in several unpublished studies in Switzerland. A recent Swiss study aimed at assessing the impact of a medication review focusing on anticoagulation therapy in ambulatory anticoagulated patients; and for that purpose applied the PharmDISC system to classify the interventions performed by the pharmacists [163]. As a seamless care example, a future Swiss prospective randomised controlled trial will apply the PharmDISC system in both hospital and community settings to document the pharmaceutical interventions performed at dispensing of hospital discharge prescriptions of the surgery and internal medicine wards. The aim is to demonstrate that the pharmaceutical interventions in community pharmacies can be reduced following a prior optimisation of the discharge prescriptions in hospital, and as a consequence the workload of the community pharmacists decreases. A first explorative trial of this future study aimed at illustrating this workload; a community pharmacist already recorded, during medication

reconciliation of hospital discharge prescriptions, pharmaceutical interventions with the PharmDISC system. Internationally, an ongoing research project (SIMENON study) of the University of Leuven in collaboration with the Universities of Ghent and Brussel and the Belgian National Pharmacists' Association on the medication use review in community pharmacies intended to use a Dutch version of the PharmDISC system.

All these current projects/applications show that the PharmDISC system, used in different settings and situations, has already become a well-accepted classification system in research, thus an implementation of it in practice is highly promising. In comparision, the PCNE system launched its seventh version V7.0 in 2016, referring to its importance in research. In order to be in line with current practice, the PCNE system V7.0 underwent corresponding modifications. Indeed, a review on the application of worldwide classification systems reported that three-quarters of the 268 published studies (n=202) using classification systems adapted an already existing one (46%, n=123) or developed one of their own (29.5%, n=79), while 25% (n=67) used an unmodified one [59]. The most used classification system unmodified was that of Cipolle et al [164], while the most frequently modified was that of Strand et al [55]. Of 21 published studies, the PCNE system was used unmodified in 9 studies, while 12 studies applied it in a modified version.

Depicting real-life daily practice

The subanalysis of the documented pharmaceutical interventions (data from Study A2) demonstrated that community pharmacists applied a medicines optimisation approach for a broad range of pharmaceutical interventions which was facilitated by direct patient-pharmacist interaction (**A3**). The pharmaceutical interventions, were mostly accepted by the involved person and implemented in practice. Individual assessment of each pharmaceutical intervention, the pharmacist's professional expertise, and the collaboration between the patient, caregiver or physician were needed to fully address the patients' needs. This ensured a safe and appropriate use of medicines - all while controlling treatment costs. Almost a quarter of the pharmaceutical interventions were related to patients who reported problems with their prescribed medicines at the time of dispensing. Our study findings revealed that patient-reported problems with prescribed medicines can frequently be addressed by community pharmacists [75]. As one of the last healthcare professionals before patients take their medicines, pharmacists provide a relevant contribution in improving treatment outcomes by intervening in DRPs, particularly during the dispensing of prescribed medicines [37, 75].

Pharmacists play also an important role in patient counselling on medicines by supporting the patients to make the best use of medicines. Moreover, patient counselling has been shown to be effective in identifying DRPs [75]. Therefore, in **Project C**, in order to investigate this role, patient counselling was depicted in respect to the non-participation observation method. The observation study allowed to describe the observed dispensing process of prescribed medicines at the counter in Swiss community pharmacies (**C1**). Counselling was given to 66.0% (n=367) of all 556 customers receiving prescribed medicines and moderate to good practice of counselling was observed. This indicates that the pharmacy staff assumed in certain cases the responsibility to ensure that the patient received sufficient oral and written information on prescribed medicines to make the best use of them [37]. Although a quarter of customers refused counselling, one-third of the customers, nevertheless, did not received any counselling. Our study design could not assess what happened before the observed prescription encounter and which information was already exchanged during prior prescription encounters. However, this study illustrated how the patient received the counselling at the counter; we observed that pharmacists were only involved by direct patient contact in a quarter of all prescription encounters. Pharmacists' activities such as drug interaction-check and investigation of the medication history that have been done in the back office are neither visible nor communicated to the customer. Pharmacy staff should be more transparent about their activities through openness and better communication with the consumer in daily practice.

Counselling was not equally provided, indicating that pharmacy staff use different degrees of counselling during prescription encounters. If extended counselling at each first and refill PE is not possible in daily practice, pharmacy staff should target counselling for specific situations. The study findings revealed factors influencing counselling provision at patient, prescription and pharmacy level. These indicators could help in prioritising prescriptions needing in-depth counselling. Significantly more counselling was provided by pharmacists, to customers with a first prescription, with a prescription requiring a pharmaceutical intervention, to carers who filled the prescription for a patient, to new customers, and to customers who did not refuse counselling. Furthermore, pharmacists intervened in 25.9 % of all prescription encounters, thus contributing to the safe, appropriate, and cost-effective use of drugs, while only few additional activities were offered. However, remunerated cognitive pharmaceutical services (e.g. 'Polymedication check', 'Adherence fee') were introduced in Switzerland since 2010 [50], but during the observation, none of these services were performed.

The interviews with the pharmacists of the observation study (**C2**) revealed a discrepancy in counselling content by observation compared to pharmacists' opinions was revealed. Observations showed a focus on product-centered themes (e.g. dose, administration), whereas pharmacists highlighted the importance of patient-centered content (e.g. benefit, adherence). This might indicate that pharmacists are aware but limited by barriers to practice according to good pharmacy practice guidelines.

The results of the interviews additionally showed that pharmacists occasionally documented their pharmaceutical interventions, however almost always not in a standardised way. Pharmacists found important to transfer the performed pharmaceutical interventions to other healthcare providers, but some barriers (e.g. too time-consuming, overwork) could hinder it. Therefore, a simple and fast in use computerised documentation system, with an additional intervention history option, could be a promising approach according to the positive reactions and the needs of the pharmacists. As stated by the pharmacists, its implementation should increase the appreciation and visibility of pharmacists' work, facilitate data handling by saving time and costs, facilitate seamless care by improving collaboration among healthcare providers, and ultimately improve the therapy outcomes.

Strengths and limitations

The main strength of **Project A** and **Project B** is the application of diverse methods at each development stage of the classification systems, which provides in-depth and complementary information, and can compensate for inherent weaknesses in single study designs [97, 98]. The PharmDISC system was developed combining a quantitative and a qualitative approach in a mixed methods study. Different methods for the validation of the GSASA and PharmDISC systems were used, according to the validation criteria proposed by Fitzpatrick [64]. Moreover, as the validation was performed in two regions of Switzerland with different languages and cultural backgrounds, we expect the PharmDISC system to be suitable also for other countries. The same can be assumed for the GSASA system which is implemented in twelve hospitals all over Switzerland.

A limitation presents the inclusion of highly motivated and qualified pharmacists into the studies. As the validation and reliability of the GSASA system were based on a small number of pharmacists, a selection bias cannot be excluded (**A1**). Many raters were involved in the different stages in the development process, and consequently, we cannot ensure the generalisability. The participants of the focus group were a limited number of highly motivated and qualified pharmacists. These findings highlight the factors which positively influenced the documentation of pharmaceutical interventions, yet might have reduced statements on possible opposing factors (**B1**). We also invited highly motivated and qualified pharmacists to participate in Study **B2**. In order to be able to generalise our findings, the PharmDISC system should be tested in a future study without pre-selected community pharmacies.

As a self-reported data method, pharmaceutical interventions were documented with the classification form, short description, prescription copy, and medication history. Although, the documented data was tested on consistency and plausibility, self-reported data also has limitations. In Study **B2**, we were not able to ensure that the collection of prescriptions was done consecutively, and there might have been a selection bias.

In contrast, in **Project C**, our approach to describe the observed process of prescribed medicines dispensing at the counter was non-participant observation. This allowed to describe customers' behavior and practice from real daily life [157], thus avoiding the biases of self-report methods [147]. However, the main limitation of the observation was the presence of an observer which could positively influence the counselling performance of the pharmacy staff by triggering them to be more aware of their way of approaching customers (the Hawthorne effect) [158]. Simulated client methods such as mystery shopping could minimise observation bias, but present limitations of their own. The

extracted information corresponds to a small part (snapshot) of healthcare practice only and is therefore hard to generalise to other health situations [159].

Finally, the classification and documentation of DRPs and interventions are a very up-to-date topic, entailing a fast update of the literature. Our findings were compared with international publications until November 2016.

Conclusions

This thesis adds some findings to the topic field of classification and documentation of pharmaceutical interventions. The following conclusions can be drawn:

The GSASA system

- The GSASA classification system appeared to be reliable and promising for the documentation of pharmaceutical interventions in daily practice (practical and less time-consuming). Its validation was successful in terms of appropriateness, interpretability, validity, acceptability, feasibility, and reliability (**A1**).
- After 18 months of introduction (2013), the GSASA classification system is already widely accepted in Swiss hospitals, suggesting to be suitable also to daily life settings. Most pharmaceutical interventions can be classified with adequate time effort and overall users' satisfaction is good. The extent to which the system is used and the good acceptance within a short time after implementation are promising results to use it as basis for a further development (**A2**).
- The GSASA classification system was tested in primary care and proved to be suitable also to classify interventions of medication reviews performed by community pharmacists in primary care; however, further refinements were necessary to improve the precision of the system. Thus, the development of one classification system suitable for both, primary and secondary care, flexible for addressing different levels of complexity, and easily integrable in daily practice and in electronic patient file was recognised as a promising approach (**A3**).

The PharmDISC system

- In a focus group interview, pharmacists recognised the importance of the documentation of pharmaceutical interventions and were convinced that this may allow traceability, facilitate communication within the team and other healthcare professionals, and eventually would increase quality of care (**B1**).
- Substantial interrater reliability and high rating of acceptability and feasibility indicates that the new PharmDISC system is a valid system for the documentation of pharmaceutical interventions in daily practice of community pharmacies. The pharmacists were satisfied with the system and considered it helpful, easy to use, and practical for daily work. They appraised the fact that by using an intervention oriented classification system, their awareness of DRPs and concurrently the intervention rate increased (**B2**).

- The developed descriptive manual of the PharmDISC system and the online training were helpful elements for an accurate use of the PharmDISC system and are promising utilities to enhance its implementation (**B2**).

Depicting real-life daily practice

- The high number of pharmaceutical interventions following DRPs and patient-reported problems highlights the importance of a direct patient-pharmacist interaction when dispensing prescribed medicines (**B3**).
- The observation of the dispensing process of prescribed medicines allowed to depict the community pharmacy practice from the customers' perspective (at the counter). However, counselling was not equally provided, indicating that prescription encounters need different degrees of counselling. A more transparent practice and patient-centered counselling is necessary to better meet the patients' needs on information. While pharmacists intervened frequently, only few additional activities and no further services were offered (**C1**).
- Factors influencing counselling provision were identified at patient, prescription and pharmacy level. Significantly more counselling was provided by pharmacists, to customers with a first prescription, to customers with a prescription requiring a pharmaceutical intervention, to carers who filled the prescription for a patient, to new customers, and to customers who did not refuse counselling (**C1**).
- A discrepancy in counselling content by observation compared to pharmacists' opinions was revealed. Observations show a focus on product-centered themes (e.g. drug administration, dose), whereas pharmacists' interviews highlight the importance of patient-centered themes (e.g. benefit, adherence). This might indicate that pharmacists are aware but hindered by barriers to practice according to good pharmacy practice guidelines (**C2**).
- Pharmacists recognised the importance of the documentation of pharmaceutical interventions and their transfer to others healthcare providers, but reported also possible reasons of non-transfer (e.g. minor relevant of pharmaceutical interventions, overwork) (**C2**).
- A simple and fast in use computerised documentation system, with an additional intervention history option, could be a promising approach according to the positive reactions and the needs of the pharmacists. As stated by the pharmacists, its implementation should increase the appreciation and visibility of pharmacists' work, facilitate data handling by saving time and costs, ensure seamless care by improving collaboration among healthcare providers, and ultimately improve the therapy outcomes (**C2**).

Outlook

In this thesis, we developed two valid classification systems of pharmaceutical interventions for hospitals, the GSASA system, and for the community setting, the PharmDISC system. A paper-based form of the systems was used in the research projects. To assure and maintain the sustainability of the systems in practice, a computerised version should be developed together with pharmacy software suppliers, and notably be continuously improved through research. Indeed, the integration of the classification system in pharmacy software can facilitate the provision of pharmaceutical care and support seamless care at transitions of care [51]. Once the pharmaceutical interventions are documented in their representative setting, the information exchange should be assured. The link between the GSASA and the PharmDISC systems allowing the transfer of pharmaceutical interventions has not been established to date, thus remaining a challenge of information technology [Fig. 2, red arrow].

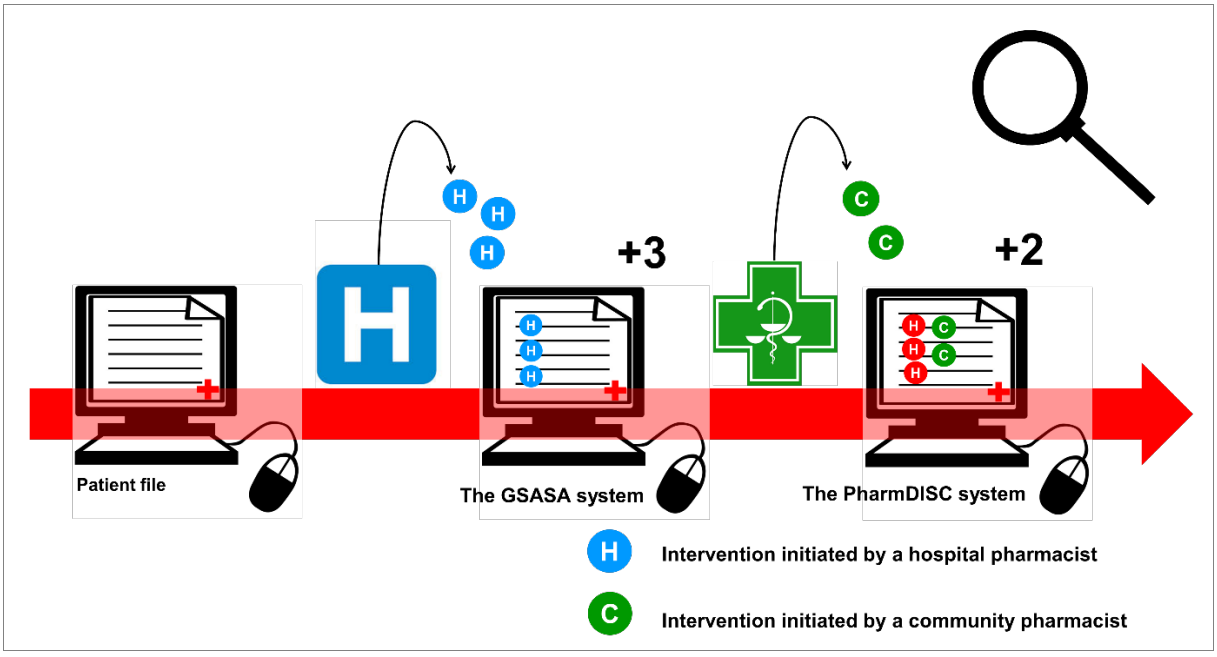

Fig. 2 Continuity of documentation: looking at the patient pathway during hospital stay, the five pharmaceutical interventions could be documented in their respective setting, but could not be exchanged between hospital and community setting yet.

To accomplish this task of linking, a handover can be a helpful document to ensure continuity of care, communication between healthcare professionals, safe transfer of information and patient safety, and transfer of responsibilities (follow-up, e.g. medication review) [108, 109]. It should contain all key information, such as medication modification, patient conditions, and care issues, that healthcare professionals should have access to when a patient arrives in their healthcare setting [109]. A Belgian

study has shown that its developed discharge medication plan was defined as valuable for the continuity of care by the community pharmacists and that they requested additional information such as medication modifications [110]. As both contain the information 'medication modification', the next step in the development process could be to connect the GSASA system with the PharmDISC system by exchanging the information regarding pharmaceutical interventions. This information could be extracted from the respective classification systems and combined in a handover document.

According to the conclusions and the experiences of this thesis, the recommendation for future research are as follows:

The GSASA system

- Re-evaluation of the implementation of the GSASA system including users' satisfaction, and collection of all documented pharmaceutical interventions from the hospitals using the GSASA system. Since the descriptive manual is available for the users, the quality of data should be increased thanks to appropriate utilisation of the standardised classification system.
- Adaptation of the version of the GSASA system to the current practice and setting by
    - further refinements to improve the precision of the system (e.g. addition of subcategories, clarification of existing subcategories)
- Integration of the GSASA system into patient file of the hospital software
- Creation of an electronic national database in which all the pharmacists could key in their pharmaceutical interventions

The PharmDISC system

- Implementation of the PharmDISC system in community pharmacies:
    - Development of a catalogue of case studies. In combination with the descriptive manual and the online training, this could be helpful material for the correct application of the PharmDISC system and facilitate its implementation.
    - Collaboration with IT specialists to integrate the PharmDISC system (ePharmDISC) in pharmacy software.
        - Development of an electronic quick classification with a variety of prefilled classification forms, based on frequent pharmaceutical interventions. This could save time and improve the quality of documentation.
        - Creation of an intervention history option by extracting the documented pharmaceutical interventions from the patient file
    - Validation of the ePharmDISC system in a feasibility study

- Modification of the PharmDISC system specific to particular settings/situations and current practice.

Depicting real-life daily practice

- Investigation of the patients' opinions on counselling in community pharmacies and patients' information needs about prescribed medicine in order to ameliorate the pharmacy practice.
- Acquisition of more knowledge about barriers and facilitators for patient-centered counselling.
- Development of instruments to assess the patients' needs and consequently to tailor accordingly the counselling.

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APPENDIX

Index

A1.1 Questionnaire Mapping clinical Pharmacy in Swiss Practice, incl. evaluation of the implementation of the GSASA system

Mapping Clinical Pharmacy Practice in Switzerland 2013

ATTENTION: The introductory text will not show up in paged forms.
For this case use an info field as first form field.

Teil 1 - Erhebung der Stammdaten des Spitals

Mit dieser Umfrage soll einerseits der heutige Stand der klinisch-pharmazeutischen Tätigkeiten innerhalb der Schweizer Spitäler erfasst werden. Weiter soll das Hilfsmittel zur Dokumentation von klinisch-pharmazeutischen Interventionen der GSASA erstmalig national ausgewertet werden. Wir möchten uns an dieser Stelle herzlich für Ihre Angaben bedanken.

Bitte füllen Sie die Umfrage auch dann aus, wenn Sie zum heutigen Stand keine klinisch-pharmazeutischen Aktivitäten ausweisen und/oder das GSASA-Dokumentations-Tool nicht nutzen.

WICHTIG: Wir setzen voraus, dass diese Umfrage von der verantwortlichen Person für den Fachbereich 'Klinische Pharmazie' ausgefüllt wird. Sollte keine entsprechende Person nominiert sein, bitten wir darum, dass die Leitung der Spitalapotheke die Fragen beantwortet. Das Ausfüllen des Fragebogens nimmt im Mittel 20 Minuten in Anspruch.

Für Fragen steht Ihnen Markus Messerli gerne zur Verfügung [Office 061 267 15 29, Email markus.messerli@unibas.ch].

Bitte speichern Sie sämtliche Bereiche nach dem Ausfüllen der Fragen ab und stellen Sie uns den Fragebogen am Ende mit 'Senden' zu (Button oben rechts). So stellen Sie sicher, dass Ihre Angaben ausgewertet werden können.

1. Name der Instutition ⓘ

2. Ort ⓘ

3. Postleitzahl ⓘ (1000 ... 9999)

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4. Art der Einrichtung ⓘ

- ○ Universitätsspital
- ○ Kantonsspital
- ○ Regionalspital mit Notfallstation
- ○ Regionalspital ohne Notfallstation
- ○ Privatspital
- ○ Rehabilitationsklinik/-zentrum
- ○ Psychiatrische Klinik
- ○ Spitalverbund / -netzwerk*
- ○ Andere Klinikform:

*** falls als Spitalnetzwerk/ -verbund organisiert...**

... beschreiben Sie bitte dessen Struktur und Umfang. Verwenden Sie dazu wenn immer möglich die Kategorien aus Frage 4. Beziehen Sie sich bitte im Weiteren Verlauf des Fragebogens auf die Einrichtung(en), welche von Ihrer Apothekeneinheit betreut wird. Sollten Sie mehrere Häuser mit mehreren Einheiten betreuen, so ist für jede Einrichtung ein Fragebogen auszufüllen.

5. Struktur und Umfang des Spitalnetzwerk/-verbund:

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6. Anzahl Betten: ⓘ

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7. Bildet Ihre Instutition Assistenzärzte aus (=Ausbildungskrankenhaus)? ⓘ ○ Ja ○ Nein

8. Anzahl Vollzeitstellen 'Apotheker/innen' als Zahl:

Zum Beispiel:
1 Apothekerin 100% + 1 Apotheker 80% = 180 Stellenprozente = 1.8 Vollzeitstellen

9. Wie viele Apotheker/innen werden mit diesen Stellenprozenten beschäftigt?

10. Anzahl Vollzeitstellen 'Pharma-AssistentInnen' als Zahl:

11. Wie viele Pharma-AssitentInnen werden mit diesen Stellenprozenten beschäftigt?

12. Wie viele der beschäftigten Apotheker/innen führen den Fachtitel 'FPH Spitalpharmazie'?

13. Wie viele der beschäftigten Apotheker/innen führen das Zertifikat 'FPH Klinische Pharmazie'?

14. Wie viele der beschäftigten Apotheker/innen führen sowohl den Fachtitel 'FPH Spitalpharmazie', als auch das Zertifikat 'Klinische Pharmazie'?

15. Werden Ausbildungsplätze für den Fachtitel 'FPH Spitalpharmazie' angeboten? ○ Ja ○ Nein

16. Falls 'JA': Wie viele?

17. Werden Ausbildungsplätze für das Zertifikat 'FPH Klinische Pharmazie' angeboten? ○ Ja ○ Nein

18. Falls 'JA': Wie viele?

19. Wie ist die pharmazeutischen Kompetenz innerhalb des Spitalbetriebs vernetzt?

	Ja - leitende Funktion	Ja - teilnehmende Funktion	Nein - keine Vertretung	Auf Anfrage	Nicht vorhanden
Spitalleitung	○	○	○	○	○
Arzneimittelkommission	○	○	○	○	○
Aus- und Weiterbildungskommission	○	○	○	○	○
Hygienekommission	○	○	○	○	○
Antimicrobial Stewardship	○	○	○	○	○
CIRS-Kommission	○	○	○	○	○
Qualitätskommission	○	○	○	○	○
Ernährungskommission	○	○	○	○	○
Palliativ Care	○	○	○	○	○
Patientenschulung (z.B. Ernährung / Diabetes)	○	○	○	○	○

20. Anderes:

21. Bietet die Apotheke regelmässig (min. 1x / Jahr) interne Weiterbildungskurse für PFLEGENDE an? ○ Ja ○ Nein

22. Bietet die Apotheke regelmässig (min. 1x / Jahr) interne Weiterbildungskurse für die ÄRZTESCHAFT an? ○ Ja ○ Nein

23. Welche der folgenden Dokumente unterliegen in Erstellung und Pflege der pharmazeutischen Kompetenz?

	Ja	Nein	Nicht vorhanden	k.A.
Sortimentsliste InHouse	○	○	○	○
Inkompatibilität von i.v.-Lösungen	○	○	○	○
Mörserbarkeit / Suspendierbarkeit von Medikamenten	○	○	○	○
Berechnungstabellen für individuelle Dosierungen	○	○	○	○
Verordnungshilfen für TPN	○	○	○	○
Verordnungshilfen für Onkologie	○	○	○	○
Unterlagen zur Abgabe an Patienten	○	○	○	○

24. Wie werden folgende Patientendaten elektronisch administriert?

	keine elektronische Erfassung angedacht	elektronische Erfassung in Planung	teilweise elektronische Erfassung	vollständige elektronische Erfassung	weiss nicht
Patientenanamnese mit ICD-10	○	○	○	○	○
Patientenanamnese ohne ICD-10	○	○	○	○	○
Vitalparameter	○	○	○	○	○
Verordung der Medikamente	○	○	○	○	○
Abgabe der Medikamente	○	○	○	○	○
Verlaufsbericht Ärzte	○	○	○	○	○
Verlaufsbericht Pflege	○	○	○	○	○
Verlaufsbericht Konsil (z.B. Empfehlung KlinPharm)	○	○	○	○	○
Laborresultate	○	○	○	○	○

25. Sind der Apotheke die elektronisch erfassten Patientendaten zugänglich?

○ Ja - Zugang vollständig gewährleistet

○ Nein - Zugang nicht gewährleistet

○ Teilweise. Zugänglich sind:

Seitenumbruch --- **Teil 2 - Dienstleistungen der Klinischen Pharmazie**

26. Werden in Ihrem Betrieb klinisch-pharmazeutische Dienstleistungen angeboten?

○ Ja ○ Nein, aber in Planung ○ Nein

Die Befragung hat die von der GSASA formulierte Definition für 'Klinische Pharmazie' als Basis:

‚Die klinische Pharmazie ist jener Teilbereich der Pharmazie, der die Entwicklung und Förderung einer angemessenen, sicheren und ökonomischen Anwendung von Arzneimitteln zum Ziel hat.

Im Spital versteht man unter „klinischer Pharmazie" die patientenorientierten pharmazeutischen Tätigkeiten auf den Pflegeabteilungen in interdisziplinärer Zusammenarbeit mit den anderen Fachpersonen.' (V.1, 11/2011)

Falls JA -> Bitte ALLE der folgenden Fragen beantworten. Danke!

Falls NEIN -> Bitte diese Seite unten speichern und mit Bereich 3 fortfahren. Danke!

27. Wie viele der Apotheken-Stellenprozente stehen für den Bereich 'Klinische Pharmazie' zur Verfügung?

28. Wie sind die Dienstleistungangebote des Bereichs 'Klinische Pharmazie' organisiert?

- Ohne Präsenz zur Patientenstation
- Teilweise mit Präsenz zur Patientenstation
- >50% der Arbeitszeit erfolgt auf der Patientenstation

29. Seit wann ist der Bereich 'Klinische Pharmazie' etabliert (Jahr als Zahl, z.B. '2002')?

30. Werden Pharma-Assistentinnen in den Bereich 'Klinische Pharmazie' miteinbezogen? Ja Nein

31. Falls 'JA': Was sind dabei ihre Aufgaben?

Wie häufig bieten Sie folgende Leistungen an (bezogen auf die letzten 12 Monate)?

Wir möchten die Dienstleistungsbereiche der Übersicht halber in drei Kategorien mit jeweils unterschiedlichem Fokus aufteilen. Erläuterung / Abgrenzungen zu den verschiedenen Dienstleistungen sind mittels Zahlenreferenz weiter unten einsehbar.

32. Patientenorientierte Dienstleistungen

	täglich	wöchentlich	monatlich	3-4x pro Jahr	1-2x pro Jahr	nie
Visite auf Station mit Mappex						
Visite auf Station mit Arzt & Mappex						
Visite auf Station mit Arzt am Patientenbett						
Patientenschulung während dem Aufenthalt						
Patientenschulung beim Austritt						

33. Behandlungsorientierte Dienstleistungen

	täglich	wöchentlich	monatlich	3-4x pro Jahr	1-2x pro Jahr	nie
Anamnese der Eintrittsmedikation						
Empfehlungen zu TDM-Verordnungen						
Empfehlungen zu TPN-Verordnungen						
Empfehlungen zu Verordnungen von Risikomedikamenten [1]						

Empfehlungen zu Verordnungen von Antibiotika	○	○	○	○	○	○
Empfehlungen zur Austrittsverordnung	○	○	○	○	○	○

34. Prozessorientierte Dienstleistungen

	täglich	wöchentlich	monatlich	3-4x pro Jahr	1-2x pro Jahr	nie
Beantworten von internen Anfragen	○	○	○	○	○	○
Beantworten von externen Anfragen	○	○	○	○	○	○
UAW-Meldung an Pharmacovigilanz-Zentrum	○	○	○	○	○	○
Erstellung von Therapieplan für Austrittsverordnung z.H. des Patienten	○	○	○	○	○	○
Bereitstellen der Medikamente mit Tagesdispenser [stationär]	○	○	○	○	○	○
Bereitstellen der Medikamente mit Tagesdispenser [ambulant]	○	○	○	○	○	○

[1] hier liegt der Fokus auf Wirkstoffen mit enger therapeutischer Breite und/oder kritischem Interaktionspotential. Ein Risikomedikament wäre demnach zum Beispiel Methotrexat.

35. Weitere Dienstleistungen, welche nicht aufgeführt sind:

36. Welche Fachbereiche werden klinisch-pharmazeutisch bedient?

	Regelmässig / nach Plan	Bei Bedarf / Anfrage	Keine Zusammenarbeit	Kein Fachbereich in unserem Betrieb
Intensiv Medizin	○	○	○	○
Innere Medizin	○	○	○	○
Dermatologie	○	○	○	○
Orthopädie	○	○	○	○
Chirurgie	○	○	○	○
Geriatrie	○	○	○	○
Rehabilitiation	○	○	○	○
Onkologie	○	○	○	○
Pädiatrie	○	○	○	○
Gynäkologie	○	○	○	○
Psychiatrie	○	○	○	○
Ambulante Patienten	○	○	○	○

37. Können Sie kurz schildern, wie die Zusammenarbeit in einem oder mehreren Bereichen zustande gekommen ist?

38. Bieten Sie eine Hotline für externe klinisch-pharmazeutische Anfragen von MEDIZINALPERSONEN an?

○ Ja ○ Nein

39. Bieten Sie eine Hotline für externe klinisch-pharmazeutische Anfragen von PATIENTEN an?

○ Ja ○ Nein

40. Bemerkungen zur Erfassung der klinisch-pharmazeutischen Dienstleistungen

Seitenumbruch --- **Teil 3 - Akzeptanz und Rahmenbedingungen in der klinischen Pharmazie**

41. Bitte nehmen Sie zu folgenden Aussagen Stellung:

	Stimme überhaupt nicht zu	Stimme eher nicht zu	Stimme eher zu	Stimme voll und ganz zu	Keine Äusserung
Bezogen auf die letzten fünf Jahre hat die Akzeptanz innerhalb der Ärzteschaft -was den Fachbereich 'Klinische Pharmazie' anbelangt- zugenommen.	○	○	○	○	○
Ärzte schätzen unsere Empfehlungen und setzen diese um.	○	○	○	○	○
Ich werde über die Umsetzung unserer Empfehlungen informiert.	○	○	○	○	○
Das FPH Zertifikat 'Klinische Pharmazie' sollte zu einem 'Master' bzw. 'Fachtitel FPH' aufgewertet werden.	○	○	○	○	○
Das Weiterbildungsangebot der GSASA im Bereich 'Klinische Pharmazie' ist ausreichend.	○	○	○	○	○
Mein Betrieb stellt genügend personelle Ressourcen für den Fachbereich 'Klinische Pharmazie' zur Verfügung.	○	○	○	○	○
Wir würden in unserem Betrieb gerne mehr klinische Pharmazie anbieten	○	○	○	○	○

42. Werden in Ihrem Betrieb Forschungsprojekte mit klinisch-pharmazeutischen Hintergrund bearbeitet? ○ Ja ○ Nein

43. Falls 'JA': Können Sie in Stichworten umschreiben, worin der Fokus liegt?

Seitenumbruch --- **Teil 4 - 'Dokumentation klinisch-pharmazeutischer Aktivitäten'**

44. Wie dokumentieren Sie ihre klinisch-pharmazeutischen Tätigkeiten hauptsächlich?

- ○ Keine strukturierte Dokumentation
- ○ Internes Dokumentationssystem (eigene Datenbank)
- ○ GSASA-Dokumentation, papierbasiert
- ○ GSASA-Dokumentation, elektronisch
- ○ ABDA Datenbank

45. Weshalb haben Sie sich für dieses Tool entschieden? (Mehrfachantworten möglich)

- ☐ Das Tool beinhaltet alle Kategorien, die ich benötige
- ☐ Die Kategorien sind klar differenzierbar
- ☐ Der Zeitaufwand ist gering
- ☐ Spitalinterne Gründe
- ☐ Das Tool ist einfach im Alltag zu benützen
- ☐ Andere Gründe: [ ]

46. Weshalb dokumentieren Sie Ihre klinisch-pharmazeutischen Aktivitäten? (Mehrfachantworten möglich)

- ☐ Wird von der Leitung verlangt
- ☐ Zur Qualitätsicherung
- ☐ Als Grundlage zur Entwicklung von Dienstleistungen
- ☐ Um die Nutzen der Interventionen sichtbar zu machen
- ☐ Aus ökonomischen Gründen
- ☐ Etwas anderes: [ ]

47. Wie vollständig dokumentieren Sie?

○ Mehr als 60 % der aufgetretenen Fälle ○ Zwischen 30 und 60 % der aufgetretenen Fälle ○ Unter 30 % der aufgetretenen Fälle

○ Nur ausgewählte Fälle (nur Überdosierungen, Interaktionen, etc): [ ]

48. Wie oft wird das Tool genutzt?

[mindestens 1 mal täglich ▾]

49. Falls Sie das GSASA-Tool nicht verwenden, weshalb?

[ ]

Information:

Falls Sie das GSASA-Tool nicht benutzen, ist hier der Fragebogen für Sie beendet. Wir bitten Sie am Ende des Fragebogens Ihre Angaben zu hinterlassen und den Bogen abzuschicken. Die Angaben werden in jedem Fall vertraulich behandelt. Sie dienen uns als Möglichkeit für allfällige Rückfragen. Vielen Dank!

50. Zufriedenheit zum GSASA-Tool. Bitte nehmen Sie zu folgenden Aussagen Stellung:

	gar nicht einverstanden	nicht einverstanden	neutral	einverstanden	völlig einverstanden	keine Äusserung
1) Das Klassifizierungssystem ist vollständig und beinhaltet alle DRPs, welche ich identifiziert hatte.	○	○	○	○	○	○
2) Das Klassifizierungssystem ist im Alltag einfach zu gebrauchen.	○	○	○	○	○	○
3) Im Allgemeinen bin ich zufrieden mit diesem Klassifizierungssystem.	○	○	○	○	○	○
4) Der Zeitaufwand zur Interventionsklassifzierung ist angemessen.	○	○	○	○	○	○

51. Ich habe keine Probleme, in den entsprechenden Kategorien meinen Fall zu erfassen.

	gar nicht einverstanden	nicht einverstanden	neutral	einverstanden	völlig einverstanden	keine Äusserung
Erfasstes Problem	○	○	○	○	○	○
Problemtyp (potentiell-manifest)	○	○	○	○	○	○
Grund der Empfehlung	○	○	○	○	○	○
Empfehlung/ Intervention	○	○	○	○	○	○
Resultate der Empfehlung	○	○	○	○	○	○

52. Welche Probleme konnten häufig nicht erfasst werden?

53. Wieviel Zeit benötigen Sie für die Eingabe eines Falles im System?

○ weniger als 1 Minute ○ 1 bis 2 Minuten ○ 2 bis 5 Minuten ○ mehr als 5 Minuten

Optimierung des GSASA-Tools

Um das von Ihnen verwendete GSASA-Tool zu verbessern, bitten wie Sie, folgende Fragen zu beantworten. Vielen Dank!

54. Welche Verbesserungen wünschen Sie sich?

	Stimme zu	Stimme nicht zu	Weder noch	Keine Äusserung
Allgemein eine Schulung zur Verwendung des Tools	○	○	○	○
Hinzufügen von Kategorien [1]	○	○	○	○
Klarere Differenzierung von Kategorien	○	○	○	○
Hinzufügen des ATC-Codes zur erweiterten Auswertung	○	○	○	○

Erläuterung der Begriffe

[1] Hinzufügen von Kategorien: Treten bei Ihnen Fälle auf, bei denen Sie für den Fall nicht die passende Kategorie in den Klassen (erfasstes Problem, Grund der Empfehlung..) finden?

55. Andere Verbesserungsvorschläge:

Kontaktdaten

Bitte geben Sie Ihre Kontaktdaten an. Diese werden vertraulich behandelt und dienen nur zu Rückfragen bei allfälligen Unklarheiten. Vielen Dank!

Wir möchten national die erfassten Daten des GSASA-Tools analysieren. Dabei sollen die wichtigsten Probleme erkannt, analysiert und Lösungsvorschläge zur Verhinderung dieser erstellt werden. Zusätzlich soll der Nutzen Ihrer täglichen Arbeit gezielt hervorgehoben werden. Deshalb würden wir uns freuen, wenn Sie uns Ihre Daten im excel-Format zur Verfügung stellen würden. Bitte schicken Sie diese per Mail an: amanda.gaufroid@stud.unibas.ch. Besten Dank!

56. GSASA-Tooldaten

○ Ich stelle meine Daten zur Verfügung. ○ Ich möchte meine Daten nicht freigeben.

57. Kontaktperson für Rückfragen:

58. E-Mail:

A2.1.1 Study protocol for Ethics committee

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Studienprotokoll von klinischen ‚Investigator-initiated' Studien

Projekt innerhalb einer Masterarbeit der Pharmazeutischen Wissenschaften

vom Januar bis Dezember 2014

Titel des Gesuchs:	Arzneimittelbezogene Probleme in öffentlichen Apotheken: Entwicklung eines Klassifikationssystems
Protokoll-No.:	-
Gesuchsteller:	Prof. Kurt E. Hersberger, Leiter Pharmaceutical Care Research Group PCRG, Universität Basel (kurt.hersberger@unibas.ch)
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Gesuchversion/Datum:	Version 1 / 16.12.2013

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.....

Basel, 13. Dezember 2013

Prof. Kurt E. Hersberger

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2 Für Arzneimittelstudien: Hintergrundinformationen

2.1 Bezeichnung und Indikation des/der Prüfpräparate(s), falls abweichend von der Zulassung

Nicht zutreffend.

2.2 Begründung der Dosierung, des Dosierungsschemas, falls abweichend von der Zulassung, und der Behandlungsdauer

Nicht zutreffend.

3 Zielsetzungen und Zweck

3.1 Hintergrund, Begründung und Ziel der Studie

Viele Studien zeigten, dass arzneimittelbezogene Probleme sehr häufig im ambulanten Bereich und im Spital auftreten. In beiden Einrichtungen gibt es Hinweise, dass durch Apotheker/in eingeleitete Interventionen das Auftreten von arzneimittelbezogenen Probleme verringern kann[1,2,3,4].

Gerade bei Erstverordnungen ist es von grosser Wichtigkeit, dass die Patienten richtig instruiert werden und dass das richtige Medikament in der richtigen Dosierung zum richtigen Zeitpunkt während der richtigen Dauer angewendet wird und dass dabei keine Probleme auftreten und insgesamt die Arzneimitteltherapie nicht abgebrochen oder falsch durchgeführt wird. Der Empfang eines neu verordneten Medikamentes ist eine außergewöhnliche Situation für einen Patienten, der möglicherweise kurz zuvor mit einer neuen Diagnose konfrontiert oder mindestens über die Notwendigkeit einer neuen Medikation informiert wurde. Das Risiko für arzneimittelbezogene Probleme kann in dieser Situation erhöht sein[5,6].

Ein Klassifizierungssystem hilft arzneimittelbezogene Probleme und pharmazeutische Interventionen zu charakterisieren und zu quantifizieren, um einen Datenpool für epidemiologische Studien zu generieren. Die Verwendung eines Klassifikationssystems ermöglicht eine gewisse Kontinuität der Versorgung[2]. Mehrere Klassifikationssysteme für arzneimittelbezogene Probleme wurden in der Literatur vorgeschlagen. Die meisten Instrumente wie PCNE[7], APS-Doc[8], DOCUMENT[9] und PI-Doc[10] erwiesen sich als zu zeitaufwendig in der Praxis.

Der Schweizerische Verein der Amts- und Spitalapotheker (GSASA) hat 2011 ein neues Klassifikationssystem für pharmazeutische Interventionen als Standardwerkzeug in Schweizer Spitälern entwickelt und validiert. Dieses Instrument enthält fünf Hauptkategorien: Problem, Problemtyp (manifest/potentiell), Grund der Intervention, Intervention, Ergebnis der Intervention. Die Resultate einer vorangehenden Studie zeigten, dass zwölf Schweizer Spitäler, welche Aktivitäten in klinischer Pharmazie anbieten, dieses Klassifikationssystem regelmässig brauchen. Dies erlaubt im Alltag eine schnelle und einfache Erfassung der pharmazeutischen Interventionen[11]. Da das GSASA Klassifikationssystem eher für die Spital-Einrichtung gedacht ist, braucht es eine für die öffentlichen Apotheken angepasste Version. Als Grundlage für die Anpassung der Klassifikation und die Entwicklung von geeigneten Dokumentationshilfen dient eine

frühere Studie, wo die Klassifizierung mit dem PCNE Klassifikationssystem durchgeführt wurde[7].
Validierte, strukturierte und standardisierte Klassifikationssysteme für pharmazeutische Interventionen zur einfachen Anwendung mit geringem Zeitaufwand in der täglichen ambulanten Praxis fehlen. Die Grobstruktur der heute in den Spitälern bereits genutzten GSASA-Klassifikation (siehe Anhang) sollte weitestgehend übernommen werden. Die Entwicklung und Validierung einer derartigen Klassifikation mit zugehörigen Dokumentationshilfen ist Ziel des Dissertationsprojektes von K. Maes.
Ziel der ersten Studie in diesem Projekt ist in einer prospektiven Beobachtungstudie in öffentlichen Apotheken arzneimittelbezogene Probleme zu erfassen, welche während der Ausführung von Erstverordnungen beobachtet werden, sowie die resultierenden pharmazeutischen Interventionen mittels eines modifizierten GSASA-Klassifikationssystems zu klassifizieren.

3.2 Fragestellung, Studienpopulation

Diese Studie soll als Teilstudie des gesamten Projekts laufen. Als ersten Schritt soll das bestehende GSASA Klassifikationssystem für den Einsatz in öffentlichen Apotheken angepasst werden (Entwicklung eines Klassifikationssystems). Eine Machbarkeitsstudie soll aufzeigen, ob die Apotheker/innen in der Lage sind, mittels dieses Instrumentes arzneimittelbezogene Probleme und die resultierenden Interventionen im Apothekenalltag zu klassifizieren. (Die Validierung des Klassifikationssystems ist nicht Inhalt dieser Masterarbeit, sondern erfolgt später als Folgestudie).

Weitere Fragestellungen:
- Welche arzneimittelbezogenen Probleme treten während der Ausführung von ärztlichen Rezepten in der öffentliche Apotheke auf?
- Welche pharmazeutischen Interventionen initiieren die Apotheker/innen um arzneimittelbezogene Probleme zu identifizieren, zu verhindern und zu lösen?

Die Population besteht aus den Patienten und Patientinnen über 18 Jahre, die in ihren Apotheken ein ärztliches Rezept mit mindestens einer Erstverordnung einlösen.

3.3 Hypothese

- ✓ Die arzneimittelbezogenen Probleme und die resultierenden pharmazeutischen Interventionen können im Apothekenalltag mittels eines angepassten GSASA Klassifikationssystems erfasst werden.

4 Studiendesign

4.1 Hauptzielparameter, und sekundäre Zielparameter (Wirksamkeits- und/oder Sicherheitsparameter)

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Hauptzielparameter:

1) Anwendbarkeit der Klassifikation und der zugehörigen Dokumentationshilfen im Apothekenalltag.

2) Hinweise auf die Optimierung der Klassifikation (z.B. Subkategorien vereinen, anpassen oder neu einführen).

Sekundäre Zielparameter

1) Benötigte Zeit für das Ausfüllen des Klassifikationsformulars.

2) Zufriedenheit der Benutzer

4.2 Studiendesign, tabellarische Übersicht der Untersuchungen mit Zeitraster (Flowchart), und Studienablauf, Studiendauer pro Patient, Abbruchkriterien, Bedingungen für Entblindung

Eine prospektive Beobachtungsstudie in öffentlichen Apotheken, die für angehende Apotheker/innen (5.Jahr Pharmaziestudium) eine Assistenzstelle anbieten. Für die Datenerhebung in öffentlichen Apotheken wird das Design der früheren Studie übernommen (siehe Anhang)[7].

4.3 Massnahmen zur Bias-Minimierung (Randomisierung, Verblindung)

Keine Randomisierung. Die zu beurteilenden Rezepte werden konsekutiv ausgewählt.

5 Auswahl von Versuchspersonen

5.1 Rekrutierung

Alle Studierenden (Pharmaziestudenten im 5.Jahr) sammeln konsekutiv während ihrer Tätigkeit in ihrer Ausbildungsapotheke je 5 Rezepte aus dem ambulanten Bereich sowie 5 Spitalaustrittsrezepte von Patientinnen und Patienten, welche mindestens ein Präparat neu verordnet erhalten.

5.2 Einschlusskriterien

- Erwachsene Personen (mindestens 18 Jahre alt)
- Mindestens zwei verordnete Medikamente auf Rezept
- Erstverordnung (gilt für neues Präparat, neue galenische Form, neue Dosierung, aber nicht neue Packungsgrösse)
- Spitalaustrittrezepte: die Patienten müssen mindestens 1 Nacht im Spital verbracht haben.

5.3 Ausschlusskriterien

- Rezept mit Kontrazeptiva

6 Bewertung der Wirksamkeit

6.1 Wirksamkeitsparameter: Messmethoden und Zeitpunkte

Nicht anwendbar.

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Hauptzielparameter:

1) Anwendbarkeit der Klassifikation und der zugehörigen Dokumentationshilfen im Apothekenalltag.

2) Hinweise auf die Optimierung der Klassifikation (z.B. Subkategorien vereinen, anpassen oder neu einführen).

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5.3 Ausschlusskriterien

- Rezept mit Kontrazeptiva

6 Bewertung der Wirksamkeit

6.1 Wirksamkeitsparameter: Messmethoden und Zeitpunkte

Nicht anwendbar.

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7 Bewertung der Sicherheit

7.1 Sicherheitsparameter: Messmethoden und Zeitpunkte

Nicht anwendbar.

7.2 Sicherstellung der Nachbeobachtung von Versuchspersonen nach unerwünschten Ereignissen

Nicht anwendbar.

8 Statistik

8.1 Definition des primären Endpunktes und der sekundären Endpunkte

Nicht zutreffend.

8.2 Geplante Anzahl Versuchspersonen mit nachvollziehbarer Begründung (ev. Poweranalyse)

Achtzig Studierende sammeln je 10 Rezepte; geplant ist, eine Anzahl von 800 Rezepten auszuwerten.

8.3 Beschreibung der vorgesehenen statistischen Methoden und der geplanten Zwischenauswertungen

Deskriptive Beschreibung der Population, der Rezepte, und Natur von arzneimittelbezogenen Problemen und deren resultierende pharmazeutische Interventionen.

8.4 Geplantes Signifikanzniveau

Nicht zutreffend.

8.5 Umgang mit fehlenden Daten sowie mit Daten bei vorzeitigem Studienabbruch von Teilnehmern

Nicht zutreffend.

8.6 Definition der Auswertungsgruppen (Intention To Treat, Per Protocol, etc.)

Nicht zutreffend.

9 Studienspezifische Vorsichtsmassnahmen und Pflichten

9.1 Studienspezifische Vorsichtsmassnahmen sind zu beschreiben

Nicht zutreffend.

9.2 Falls notwendig: Abschlussuntersuchung bei vorzeitigem Rücktritt aus der Studie

Nicht zutreffend.

10. Pflichten des Prüfers

10.1 Bestätigung, dass die Studie gemäss Protokoll, GCP, und den geltenden gesetzlichen Bestimmungen durchgeführt wird

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Der Prüfer wird vom Studienkoordinator an der Universität geschult und verpflichtet sich, sich bei der Klassifikation an die strukturellen und inhaltlichen Vorgaben des Prüfplans zu halten. Die Studienapotheker verpflichten sich entsprechend der üblichen Praxis, alle relevanten medizinischen oder pharmazeutischen Probleme, welche sie während der Klassifikation neu erkennen, an den behandelnden Arzt weiterzuleiten.
Die gesammelten Formulare und Kopien der zugehörigen Rezepte werden vor der Analyse anonymisiert indem Nachnamen und Adressen der Patienten entfernt werden.

10.2 Berichterstattung von schwerwiegenden unerwünschten Ereignissen, (Protokoll-) Änderungen, Zwischen- und Abschlussberichten an Swissmedic (für Heilmittel-Versuche) und Ethikkommission(en)
Ein Schlussbericht wird in Form des Abstracts der Masterarbeit an die Ethikkommission zugestellt.

10.3 Stellungnahme zur Deckung von Schäden (z.B. Versicherung, kostenlose medizinische Betreuung)
Nicht zutreffend.

11 Ethische Überlegungen

11.1 Bewertung des Risiko-Nutzen Verhältnisses
Bei der Studie wird auschliesslich die gängige Praxis (usual care) abgebildet. Es finden keine Interventionen auf Patienten-Ebene statt, welche durch die Studie initiiert werden.
11.2 Beschreibung, warum besonders schützenswerte Versuchspersonen eingeschlossen werden
Nicht zutreffend.
11.3 Andere ethische Aspekte, z.B. Placeboabgabe
Nicht zutreffend.

12. Qualitätskontrolle und Qualitätssicherung: Beschreibung der Massnahmen

12.1 Gewährleistung des direkten Zugangs zu den Originaldaten, Erlauben von Audits, und Inspektionen durch die Behörden, und Ethikkommissionen, Durchführung des Monitorings
Der direkte Zugang zu Originaldaten, Audits, Monitoring und Inspektionen sind gewährleistet.

12.2 Umgang mit Daten und Proben (Datenschutz), Archivierung (Ort, Dauer) und Vernichtung
Die anonymisierten Formulare und anonymisierten Kopien der zugehörigen Rezepte werden gesammelt. Die anonymisierten Formulare werden mit der Erfassungssoftware für Formulare und Dokumente TeleForm® version 10.2 von Cardiff Software Inc., Vista, USA, verarbeitet. Um mögliche Fehler zu vermeiden, werden alle numerischen und schriftlichen Anerkennungen visuell auf Datenblättern und auf dem Bildschirm überprüft. Die Daten werden in das SPSS Programm

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(Statistical Package of the Social Sciences) automatisch übertragen und analysiert. Zugang zu allen Computern ist mit einem persönlichen Code geschützt. Am Schluss der Masterarbeit werden alle Daten in einen zentralen Passwort geschützten Ordner auf einem Computer der PCRG transferiert. Daten auf dem Studenten-Laptop werden gelöscht. Papierunterlagen werden in der PCRG während 10 Jahren archiviert, in einem abschliessbaren Büro unter geeigneten Bedingungen (Raumtemperatur, oberhalb des Bodens, entfernt von Wasserleitungen). Elektronische Daten werden auf einem zentralen Server der Universität gespeichert, mit Zugang nur von berechtigten Personen (Mitarbeiter der Pharmaceutical Care Research Group). Updates und Unterhalt sind durch die Universität Basel gewährleistet. Die Masterarbeit wird keine persönlichen Daten, sondern nur demographische Beschreibungen enthalten.

Prüfer und weitere Mitarbeiter haben eine Geheimhaltungserklärung unterschrieben. Diese wird von allen Personen und zu allen Zeiten eingehalten, auch nach Abschluss der Masterarbeit. Verletzung der Geheimhaltungspflicht wird gem. Art 321bis StGB in Verbindung mit Art. 321 StGB bestraft.

12.3 Direkt in den Case Report Forms einzutragende Daten (nicht in Krankenakten vermerkt) beschreiben

Das entdeckte arzneimittelbezogene Problem, die dazu gehörige Ursache und pharmazeutische Intervention (Das Case Report Form entspricht in dieser Studie dem Klassifikationsformular, welches in dieser Rahmen zu entwickeln ist).

Anhang

- GSASA Pharmazeutischer Interventionsbogen
- Kopie von der Publikation: Eichenberger PM, Lampert ML, Kahmann IV, van Mil JW, Hersberger KE. Classification of drug-related problems with new prescriptions using a modified PCNE classification system. Pharm World Sci 2010;32:362-72.

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A2.1.2 Study information sheet for the master pharmacy students

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Assistenzjahr 2013/14: **Aufgabe „Klassifizierung von pharmazeutischen Interventionen"**

Hintergrund und Ziel: Die Studierenden der Universität Basel sollen im Rahmen des Assistenzjahres eine Aufgabe lösen, die sich mit arzneimittelbezogenen Problemen und den Aktivitäten der Pharmazeuten befasst. Es geht darum, mit Hilfe einer für die Offizin standardisierte Klassifizierung, Probleme zu erfassen, welche nach Erstverordnungen, sowohl nach einem Spitalaufenthalt als auch im ambulanten Bereich auftreten.

Aufgabe: Alle Studierenden sammeln je 5 Rezepte aus dem ambulanten Bereich sowie 5 Spitalaustrittsrezepte von Patientinnen oder Patienten mit mindestens 1 Nacht im Spital. Falls nach 2 Wochen keine Spitalrezepte vorhanden sind, können 10 ambulante Rezepte gesammelt werden.

Die Patienten bzw. Rezepte müssen folgende Kriterien aufweisen:
- Erwachsene Personen (mindestens 18 Jahre alt)
- Spitalaustritt: Die Patienten müssen mindestens 1 Nacht im Spital verbracht haben
- Mindestens zwei verordnete Medikamente davon:
  Mindestens 1 Erstverordnungen (Präparat, galenische Form, Dosierung; ≠Packungsgrösse!)
- keine „Pillenrezepte"

Ablauf: Die Rezepte werden zuerst wie gewohnt nach den Richtlinien der Apotheke ausgeführt (Rezeptvalidierung). Die Rezepte müssen nicht zwingend durch die Studierenden ausgeführt werden, aber die Klassifizierung sollte mit dem/r involvierten Apotheker/in durchgeführt werden. Es wird **konsekutiv** jedes Rezept mit einer Intervention, welches die oben beschriebenen Kriterien erfüllt, anonymisiert kopiert. Nach der Ausführung des Rezeptes wird das Case Report Formular (CRF) und den Interventionsbogen „Klassifizierung von pharmazeutischen Interventionen" am selben Tag ausgefüllt. Auf dem CRF, bitte, den Fall kurz beschreiben. Die 5 ambulanten Rezepte und die 5 Spitalaustrittsrezepte können gemischt bearbeitet werden.

Testat: Jede Studentin und jeder Student muss 10 CRF und mindestens 10 Interventionsbogen ausfüllen (1 Bogen pro Intervention, 1 Kreuz pro Kategorie).

Zeitplan

31. Januar 2014	Information und Verteilung der Aufgabe und Dokumente
Spätenstens 31. März	Abgabetermin der Dokumenten sowie der kopierten, anonymisierten Rezepte in Couvert an die obige Adresse.

Bei Fragen oder Unklarheiten: Karen Maes (**karen.maes@unibas.ch**)

Checkliste

Durchführung Aufgabe	Ja	Nein
• 10 Rezepte mit Intervention gesammelt, validiert und klassifiziert	☐	☐
• Wenn möglich 5 Spitalaustrittsrezepte und 5 ambulante Rezepte **konsekutiv** gesammelt	☐	☐
• Zu jedem CRF das **passende anonymisierte** Rezept kopiert und nummeriert	☐	☐
	☐	☐
• Zu jedem Rezept kurze Fallbeschreibung auf CRF	☐	☐
• **Pro Interventionsbogen nur 1 Intervention** klassifiziert (1 Kreuz pro Kategorie)	☐	☐
• Dokumente nicht gefaltet	☐	☐
• Studie-Studenten ID auf jeder CRF aufgetragen	☐	☐
• Dossier vollständig in das Couvert gelegt und abgeschickt	☐	☐
• Online Validierungsfragebogen (Flexiform) ausgefüllt und abgeschickt		

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A2.1.3 Case Report Form PharmDISC Part 1

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Klassifizierung von pharmazeutischen Interventionen (AJ 2013/14):
Case Report Form (CRF)

Studenten ID der Studie: _____

Einschlusskriterien von Rezept bzw. Patient/in	Ja	Nein
• Erwachsene Personen ≥ 18 Jahre alt	☐	☐
• Mindestens zwei verordnete Medikamente pro Rezept davon:	☐	☐
Mindestens 1 Erstverordnung (Präparat, galenische Form, Dosierung)	☐	☐
• Keine „Pillenrezepte“	☐	☐
• Bei Spitalaustritt: Patient/in mindestens 1 Nacht im Spital verbracht	☐	☐
Angabe von Rezept bzw. Patient/in	Ja	Nein
• **Rezeptnummer:** _____ Datum der Rezeptausführung: ___/___/_____		
• Initialen (Vorname Nachname): _____ Jahrgang (z.B. 1987) : _____		
• Geschlecht: ☐ m ☐ w		
• Rezept ☐ Spitalaustritt ☐ ambulant		
• Rezept ☐ gedruckt ☐ handgeschrieben		
• Rezeptkopie nummeriert, anonymisiert und an CRF geheftet	☐	☐
Angabe zu der Intervention	Ja	Nein
• Kontakt mit dem Arzt	☐	☐
• Rezept geändert	☐	☐
• Anzahl Interventionen pro Rezept: _____		

CRF Klassifizierung AJ 13/14

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Kurze Fallbeschreibung

Hintergrund	
Grund der Intervention	
Intervention	
Resultat der Intervention	

A2.1.4 Two model pharmaceutical interventions, adapted from Ganso et al. for the training with the online voting (Movo.ch)

Case 1

- Ms. K., 77 years old, 165cm, 66kg, is treated in the accident surgery due to a lower leg fracture.
- The patient has got postoperatively a bad Creatinin-Clearance.
- Because of her condition after a myocardial infarct, she receives like prestationary Aldactone® 50mg Drageés 2-0-0.
- You notice that Aldactone® is contraindicated at bad kidney function. You recommend to pause with the Aldactone® to the physician.
- The physician agrees, however he will go on with 25mg.

Case 2:

- Ms. A, 81 years, 167cm, 59kg, enters the pharmacy.
- Because of her depression she gets Cipralex® (Escitalopram) 20mg tablets 0-0-1.
- Since a while she complains about sleeping problems.
- You ask Ms. A why the drug is prescribed in the evening.
- No plausible reason is found for the vespertine intake.
- Therefore you propose a morning intake.
- Ms. A agrees.

A2.1.5 Three model pharmaceutical interventions, adapted from Ganso et al

Case 12:

- Mr. E suffers from a herniated disk.
- Because of his strong aches he gets Oxycontin® (Oxycondon) 20mg controlled-release tablets 1-0-1. Mr. E gets strict bed rest for 6 weeks.
- You fear an obstipation. Therefore you propose a laxative to the physician.
- The physician agrees.

Case 14:

- Mr. K, 61 years, 175cm, 74kg, is treated in the general surgery because of his esophagus carcinoma.
- Furthermore he is suffering from Coronary Heart Disease and receives per stomach tube Corvaton® (Molsidomin) 2mg tablets ½-0-0.
- During this therapy he sustains repeated angina pectoris attacks.
- You propose to the physician to increase the dosage to Corvaton® 4mg tablets 1-0-1. The current blood pressure is stable.
- The physician agrees.

Case 21:

- Ms. L, 61 years, 167cm, 64kg, enters the pharmacy with her permanent prescription. Ms. L suffers from Hypertonia.
- For that the patient gets for a long time Reniten® (Enalapril) 10mg tablets 1-0-0 as well as Esidrex® (Hydrochlorothiazid) 25mg tablets 1-0-0. Her blood pressure is in the normal range.
- The patient moans about the huge daily intake of tablets.
- You propose to change to the combination remedy Co-Reniten® to reduce the amount of tablets to be taken.
- The patient agrees.

A2.2.1 Invitation letter for the participation in the study

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Basel, den 23.01.2015

Klassifikation von pharmazeutischen Interventionen in der Offizin:
Einladung für die Teilnahme an einer Querschnittstudie

Liebe Kolleginnen und Kollegen

Mit diesem Schreiben, möchten wir Sie herzlich einladen bei einer Querschnittstudie mitzumachen zum Thema Klassifikation bzw. Dokumentation von pharmazeutischen Interventionen in der öffentlichen Apotheke. Ziel der Studie ist, ein praktisches und im Alltag anwendbares Instrument zu entwickeln. Und dafür brauchen wir Sie!

Wieso Sie?

Wir zählen Sie zu den engagierten Offizinapotheker/innen mit viel Berufserfahrung. Sie haben ein Interesse an diesem Thema und für Sie ist die Dokumentation ein wichtiges Thema. Deswegen sind Sie unverzichtbar für unsere Studie!

Warum machen wir diese Forschung?

- Erhöhung der Visibilität der Leistungen der Apotheke
- Verbesserung der Patientensicherheit
- Reduzierung der Diskrepanzen im Medikationsmanagement
- Förderung der Vermittlung von Informationen (seamless care)

Was ist ein Klassifikationssystem?

Ein einfaches und strukturiertes Erfassungsdokument um Apothekern zu helfen, Interventionen zu quantifizieren und um Aktivitäten der Apotheker zu beschreiben. Dies dient auch zur Datensammlung für epidemiologische Studien. Unser Klassifikationssystem wurde bereits in vorangehenden Studien getestet, teilweise validiert und verfeinert.

Was ist eine Querschnittstudie?

Eine Querschnittstudie ist eine Beobachtungsstudie bei welcher Daten einer Gruppe zu einem bestimmten Zeitpunkt gesammelt werden. Mit Hilfe dieser Methode kann eine Art „Momentaufnahme" dieser Gruppe dokumentiert werden.

Wie läuft es ab?

Die teilnehmenden Apotheken bestimmen eine/n verantwortliche/n Apotheker/in, welche/r gesamthaft 30 Interventionen dokumentiert. Die Interventionen werden an 5 Tagen innerhalb der Studienperiode (März bis Anfang April 2015) dokumentiert. Die Tage sind frei wählbar, sie sollen im Voraus bestimmt und der Studienleitung mitgeteilt werden. Der Arbeitsaufwand für die Studie wird pro Studientag maximal eine Stunde betragen. Leider fehlt ein Sponsor für diese Studie, aber wir werden Ihnen gerne nach Abschluss ein kleines Präsent überreichen.

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1) Studienvorbereitung: Die Teilnehmer nehmen an einer ca. 30 min Online-Schulung teil, in der die Anwendung des Klassifikationssystem erklärt wird. Die Schulung umfasst ein Video mit Beispielen und einen Fragebogen. Um Ihren Aufwand möglichst gering zu halten, kann die Schulung selbständig durchgeführt und beliebig wiederholt werden.
2) Durchführung der Studie: Die Apotheker dokumentieren und klassifizieren mit Hilfe des Klassifikationssystems mind. 30 Rezepte, bei welchen sie pharmazeutische Interventionen zur Lösung eines arzneimittelbezogenen Problems ausführen. Um bei allfälligen Schwierigkeiten zu helfen, bieten wir zu Beginn der Studienperiode ein virtuelles Treffen (Webinar) mit den Teilnehmern an, in welchem Fragen beantwortet werden.
3) Bewertung des Klassifikationssystems: Ihre Meinung ist uns wichtig! Deshalb wird es am Ende der Studie einen Fragebogen geben, wo Sie uns Ihre Meinung mitteilen können.
4) Analyse: Die von Ihnen erfassten Daten werden im Rahmen einer Masterarbeit ausgewertet und das ganze Projekt ist Bestandteil einer Dissertation.
5) Kollaboration mit Policlinique médicale universitaire (Lausanne): die Studie wird gleichzeitig in der Romandie stattfinden.

Was wollen wir damit erreichen? (Ziele)

- Validierung des Klassifikationssystems in öffentlichen Apotheken (external validity)
- Definition von Barrieren / begünstigenden Faktoren zur Einführung des Klassifikationssystems in den Apothekenalltag.

Wir würden uns sehr freuen wenn Sie an unserer Studie teilnehmen würden und hoffen auf eine spannende und produktive Zusammenarbeit. Wir bitten Sie um eine kurze Rückmeldung per Fax oder E-Mail mit dem Anmeldeformular (siehe unten).

Als Motto gilt:

"Wenn etwas nicht dokumentiert ist, ist es nie passiert!
Eine Dokumentation ist ein Beweis für unsere Arbeit!"

Mit herzlichen Grüssen,

Karen Maes
Dipl. pharm, Doktorandin

Dr. Markus Lampert
Projektleiter

Prof. Dr. Kurt Hersberger
Leiter PCRG

A2.2.2 Study protocol for the participating pharmacists

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Pharm-DISC Studie: Klassifizierung von pharmazeutischen Interventionen

Studienprotokoll und Gebrauchsanweisung

Herzlich Willkommen und vielen Dank für die Teilnahme an unserer Pharm-DISC Studie!
„DISC" steht für Documentation of Interventions in Seamless Care.

Warum machen wir diese Forschung?

- Erhöhung der Sichtbarkeit der Leistungen der Apotheke durch Quantifizierung der Interventionen
- Verbesserung der Patientensicherheit durch Förderung der Vermittlung von Informationen (seamless care) und Reduzierung der Diskrepanzen im Medikationsmanagement

Was wollen wir damit erreichen? (Ziele)

- Validierung des Klassifikationssystems Pharm-DISC in öffentlichen Apotheken. Mit dieser Studie, möchten wir den Inhalt des Instruments prüfen, ob es wirklich misst was man messen möchte (=Validierung), deswegen haben wir für die Studie eine Version auf Papier gewählt; später sollte die Klassifikation in die Computersysteme integriert sein.
- Erfassung von Barrieren / begünstigenden Faktoren zur Einführung des Klassifikationssystems in den Apothekenalltag

Was ist ein Klassifikationssystem?

Ein einfaches und strukturiertes Erfassungsdokument um Apothekern zu helfen, Interventionen zu quantifizieren und um Aktivitäten der Apotheker zu beschreiben. Dies dient auch zur Datensammlung für epidemiologische Studien. Unser Klassifikationssystem Pharm-DISC wurde bereits in vorangehenden Studien getestet, teilweise validiert und verfeinert.

Unser Forschungsfrage

Ist das Klassifikationssystem Pharm-DISC ein geeignetes Instrument um die Aktivitäten der ApothekerInnen zu dokumentieren?

Wie läuft die Studie ab?

Die teilnehmenden Apotheken bestimmen eine/n verantwortliche/n Apotheker/in, welche/r gesamthaft **30 Interventionen** dokumentiert. Die Interventionen werden an **5 Tagen** innerhalb der Studienperiode (**2.März bis 4. April 2015**) dokumentiert. Die Tage sind frei wählbar, sie sollen im Voraus bestimmt und der Studienleitung mitgeteilt werden. Der Arbeitsaufwand für die Studie wird pro Studientag maximal eine Stunde betragen. Leider fehlt ein Sponsor für diese Studie, aber wir werden Ihnen gerne nach Abschluss ein kleines Präsent überreichen.

Studienvorbereitung:

Die Teilnehmer nehmen an einer ca. 15 min Online-Schulung teil, in der die Anwendung des Klassifikationssystems erklärt wird. Die Schulung umfasst ein Video mit Studienvorstellung, ein Video mit einem Fallbeispiel sowie 3 Fälle, die Sie selbständig als Übung ausführen (Diese Unteralgen werden Sie mit dem Studienmaterial per Post erhalten) Diese Fallbeispiele dienen dazu, Sie mit dem

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Instrument vertraut zu machen und es wird uns erlauben, die Übereinstimmung der Nutzer zu beurteilen. Wir bitten Sie, das Dokument mit den 3 Fällen vor dem Studienbeginn auszufüllen und uns zurückzuschicken.

Um Ihren Aufwand möglichst gering zu halten, kann die Schulung selbständig durchgeführt und beliebig wiederholt werden. Die Schulung und alle Informationen befinden sich unter http://tinyurl.com/pharmDISC-Deutsch .

Zusätzlich, damit die Klassifizierung der pharmazeutischen Interventionen möglichst homogen ausfällt, wurde ein Dokument ‚Deskriptives Manual' mit Interpretationsspielregeln zu den einzelnen Rubriken erarbeitet und auf die Website hochgeladen.

Durchführung der Studie:

Die Apotheker dokumentieren und klassifizieren mit Hilfe des Klassifikationssystems Pharm-DISC mind. 30 Rezepte, bei welchen sie pharmazeutische Interventionen zur Lösung eines arzneimittelbezogenen Problems ausführen.

1. Definition von 5 Studientagen und kommunizieren Sie uns Ihre Wahl via E-Mail.
2. Während des Studientages führen Sie die Rezepte wie gewohnt nach den Richtlinien der Apotheke aus (Rezeptvalidierung). Zu jedem Rezept, welches eine Intervention zur Folge hat, wird nach der Ausführung des Rezeptes das Case Report Formular (CRF) und der Interventionsbogen Pharm-DISC noch am selben Tag ausgefüllt. Auf dem CRF, bitten wir Sie, den Fall kurz zu beschreiben. Zudem soll das Rezept anonymisiert kopiert und eine Übersicht der Bezüge von drei Monaten ausgedruckt werden. (Um bei allfälligen Schwierigkeiten zu helfen, bieten wir zu Beginn der Studienperiode ein virtuelles Treffen (Webinar) mit den Teilnehmern an, in welchem Fragen zu diesem Ablauf beantwortet werden.)

3.Einzuschickendes Dossier:

- 1 CRF (Case Report Form) zu jedem Rezept mit Interventionen, mit:
  - 1 kopiertes und anonymisiertes Rezept (Keine Arzt- und Patientenamen)
  - 3-monatige Übersicht der Bezüge (anonymisiert)
  - 1 kurze Fallbeschreibung
  - 1 oder mehrere Pharm-DISC Interventionsbogen
- Bitte, schicken Sie das vollständige Dossier (30 CRF) an die vorgegebene Adresse mittels Rückantwortcouverts.
- Couvert sollte bis spätestens **10.04.2015** eintreffen

Wichtige Anmerkungen - Spielregeln

- 1 CRF pro Rezept
- 1 Intervention pro Pharm-DISC Interventionsbogen. Wenn ein Rezept oder ein arzneimittelbezogenes Problem mehrere Interventionen erfordern, bitte mehrere Interventionsbogen benützen.

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Fax +41 (0)61 267 14 28
www.pharmacare.unibas.ch

- Alle Kategorien des Pharm-DISC Interventionsbogen sollen ausgefüllt werden. Nur 1 Kreuz pro Kategorie, ausser für Kategorie E „Kommunikation: involvierte Personen", wo eine Mehrfachauswahl möglich ist.
- Die Klassifizierung muss am gleichen Tag wie die Intervention stattfinden, um möglichst die Realität der Praxis abzubilden.

Bewertung des Klassifikationssystems Pharm-DISC

Ihre Meinung ist uns wichtig! Deshalb wird es am Ende der Studie einen Fragebogen geben, wo Sie uns Ihre Meinung mitteilen können. Sie werden am Ende der Studie per Email einen Link bekommen, der zum Fragenbogen Zugang gibt.

Datenanalyse

Die von Ihnen erfassten Daten werden im Rahmen einer Masterarbeit ausgewertet und das ganze Projekt ist Bestandteil einer Dissertation. Wir werden Sie über die Resultate informieren.

Kollaboration mit Policlinique médicale universitaire (Lausanne):

Die Studie wird gleichzeitig in der Romandie stattfinden, um der Studie eine nationale Dimension zu geben.

Um Ihnen bei der Studien-Durchführung zu helfen, befindet sich im Anhang eine persönliche Checkliste.

Wir freuen uns sehr auf eine spannende und produktive Zusammenarbeit! Wir schätzen Ihr Engagement in der Forschung der Universität Basel sehr.

Bei allfälligen Fragen, stehen wir gerne zur Verfügung.

Mit herzlichen Grüssen,

Ihr Pharm-DISC Team

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Checkliste

Durchführung der Studie	Gemacht!
• Schulung online besucht	☐
• Deskriptives Manual gelesen	☐
• Das Dokument mit den 3 Fällen vor Beginn der Studie ausgefüllt und zurückgeschickt	☐
• 30 Rezepte mit Intervention gesammelt, validiert und klassifiziert	☐
• Zu jedem CRF, das **passende anonymisierte** Rezept kopiert und nummeriert	☐
• Zu jedem CRF, 3-monatige Übersicht der Bezüge (anonymisiert)	☐
• Zu jedem Rezept kurze Fallbeschreibung auf CRF	☐
• **Pro Pharm-DISC Interventionsbogen nur 1 Intervention** klassifiziert	☐
• Dokumente nicht gefaltet	☐
• ApothekerIn ID auf jedem CRF und Interventionsbogen eingetragen	☐
• Dossier vollständig in das Couvert gelegt und abgeschickt	☐
• Online Validierungsfragebogen (Flexiform) ausgefüllt und abgeschickt	☐

A2.2.3 Three model pharmaceutical interventions, adapted from Ganso et al

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Pharm-DISC Studie: Klassifizierung von 3 pharmazeutischen Interventionen

Wir bitten Sie, die 3 Fälle vor dem Studienbeginn selbständig zu klassifizieren (Teil der Schulung) und uns das ausgefüllte Dokument mittels Rückantwortcouverts zurückzuschicken.

StudienapothekerIn ID: _____

Fall 1

Hintergrund	Frau L., 61 Jahre, 167cm, 64kg, kommt mit ihrem Dauerrezept in die Apotheke. Frau L. leidet an Hypertonie. Für diese erhält die Patientin seit längerem Reniten® (Enalapril) 10mg Tabletten 1-0-0 sowie Esidrex® (Hydrochlorothiazid) 25mg Tabletten 1-0-0. Ihre Blutdruckwerte liegen im Normbereich.
Grund der Intervention	Die Patientin beklagt sich, weil sie so viele Tablette einnehmen muss.
Intervention & Involvierte Person/en	Sie schlagen vor, auf das Kombipräparat Co-Reniten® zu wechseln, um die Tablettenanzahl zu reduzieren
Resultat der Intervention	Die Patientin ist damit einverstanden.

Fall 2

Hintergrund	Herr K., 61 Jahre, 175cm, 74kg, wird zur Resektion eines Ösophagus-Karzinoms auf der Allgemeinchirurgie behandelt. Des Weiteren hat der Patient eine KHK und erhält per Magensonde Corvaton® (Molsidomin) 2mg Tabletten ½-0-0.
Grund der Intervention	Unter dieser Therapie hat der Patient wiederholt Angina-Pectoris-Anfälle.
Intervention & Involvierte Person/en	Sie schlagen daher dem Arzt eine Dosiserhöhung auf Corvaton® 4mg Tabletten 1-0-1 vor. Der aktuelle Blutdruck spricht nicht gegen eine Dosiserhöhung von Corvaton®.
Resultat der Intervention	Der Arzt ist damit einverstanden.

Fall 3

Hintergrund	Herr E., 39 Jahre, 186cm, 81kg, erlitt einen Bandscheibenvorfall. Wegen seinen starken Schmerzen bekommt er Oxycontin® (Oxycodon) 20mg Retardtabletten 1-0-1. Der Patient hat für 6 Wochen strenge Bettruhe.
Grund der Intervention	Sie befürchten eine Obstipation.
Intervention & Involvierte Person/en	Sie schlagen dem Arzt eine zusätzliche Gabe eines Laxans vor.
Resultat der Intervention	Der Arzt willigt ein.

Interrater reliability Pharm-DISC 2015

A2.2.4 Case Report Form PharmDISC Part 2

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Pharm-DISC Studie: Klassifizierung von pharmazeutischen Interventionen
Case Report Form (CRF)

Studienapotheker/in ID (Apo ID): _____

Angabe zum Rezept bzw. Patient/in	Ja	Nein
• Rezeptnummer (RpNr) ☐☐		
• Datum der Rezeptausführung ___/___/____		
• Initialen (Vorname Nachname) ☐☐		
• Jahrgang ☐☐☐☐		
• Geschlecht ☐ m ☐ w		
• Patient/in ist Stammkunde (Patientendossier in der Apotheke vorhanden)	☐	☐
• Rezept ☐ Spitalaustritt ☐ ambulant		
• Rezept ☐ gedruckt ☐ handgeschrieben		
• Rezeptkopie nummeriert, anonymisiert und an CRF geheftet	☐	
• Übersicht der Bezüge für 3 Monate (History) anonymisiert und ausgedruckt	☐	

Angabe zu der Intervention	Ja	Nein
• Kontakt mit dem Arzt	☐	☐
• Rezept geändert	☐	☐
• Anzahl Intervention/en auf diesem Rezept: _____		

CRF Pharm-DISC Studie 2015

UNI BASEL

Kurze Fallbeschreibung

Hintergrund	
Grund der Intervention	
Intervention und involvierte Personen	
Resultat der Intervention	

Wenn Schwierigkeiten bei der Klassifikation der Intervention auftraten, bitte kommentieren Sie diese (Zweifel bei der Auswahl der Subkategorien, Vorschlag neue Subkategorie, usw.):

A2.2.5 Online training: slides to the video presenting the study

Pharm-DISC: Klassifikationssystem für pharmazeutische Interventionen

- **Für was ist das Tool?**
  - Um Apothekern zu helfen, Interventionen und DRPs zu erfassen und zu quantifizieren.
  - Um Aktivitäten der Apotheker zu beschreiben → Sichtbarkeit
  - Zur Datensammlung → Pool für epidemiologische Studien
- **Wann wird es gebraucht?**
  - Wenn ein DRP detektiert wird und eine Intervention folgt
  - Bei Problemerkennung während der Medikamentenabgabe, Medikationsanalyse, medication reconciliation, Visite, usw.
- **Wie brauchen wir es?**
  - 1 Intervention →1 Pharm-DISC Interventionsbogen

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Online Schulung

Pharm-DISC Studie 2015

Klassifizierung von pharmazeutischen Interventionen

Pharmaceutical Care Research Group
Klingelbergstrasse 50
CH-4056 Basel

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Fallbeispiel

Hintergrund	Frau K.S, 85 Jahre (1930), 165cm, 66kg, war wegen einer Verstauchung des linken Fusses beim Hausarzt in Behandlung. Wegen ihrer Schmerzen, soll sie laut Verordnung, Dafalgan® 1g Filmtabletten 1-1-1-1 erhalten.
Grund der Intervention	Dafalgan® ist im hohen Alter überdosiert.
Intervention & involvierte Person/en	Empfehlung für den Arzt, die Dosis von Dafalgan® 1g auf 1-1-1-0 zu reduzieren.
Resultat der Intervention	Der Arzt stimmt grundsätzlich zu, will aber trotzdem mit 4 g täglich weiterfahren, er limitiert aber auf maximal 5 Tage.

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Die Klassifikation

6 Kategorien, 51 Subkategorien

- **Problem:** Risiko durch Behandlung
- **Problemtyp:** potentiell, präventive Massnahme
- **Grund der Intervention** Keine Dosisanpassung im hohen Alter
- **Intervention:** Dosisanpassung
- **Kommunikation:** Arzt
- **Resultat der Intervention:** Teilweise akzeptiert

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Pharm-DISC: Klassifizierung von pharmazeutischen Interventionen

A Problem (1 Wahl)
- ☐ 1. Effektivität der Behandlung
- ☐ 2. Nicht behandelte Indikation
- ☒ 3. Risiko durch Behandlung
- ☐ 4. Behandlungskosten
- ☐ 5. Unzufriedenheit / Problem des Patienten

B Problemtyp (1 Wahl)
- ☐ 1. Manifest, reaktiv
- ☒ 2. Potentiell, präventiv

C Grund der Intervention (1 Wahl)

1. Wahl der Behandlung
- ☐ 1. Keine Übereinstimmung mit Richtlinien, nur suboptimale Behandlung möglich
- ☐ 2. Kontraindikation
- ☐ 3. Interaktion
- ☐ 4. Medikament nicht indiziert
- ☐ 5. Duplikation
- ☐ 6. Unerwünschte Wirkung
- ☐ 7. Fehlende Informationen betreffend Patienten

2. Wahl der galenischen Form
- ☐ 1. Ungeeignete/r Verabreichungsform/ -weg

3. Wahl der Dosis
- ☐ 1. Unterdosierung
- ☐ 2. Überdosierung
- ☐ 3. Unzweckmässiges Monitoring
- ☒ 4. Keine Dosisanpassung (z.B. Nieren, Leber, Alter)

4. Anwendung des Medikamentes
- ☐ 1. Ungeeigneter Zeitpunkt / Frequenz
- ☐ 2. Ungeeignete Anwendungsweise
- ☐ 3. Unangemessene Dauer der Behandlung

5. Patient
- ☐ 1. Ungenügende Compliance
- ☐ 2. Ungenügendes Wissen
- ☐ 3. Bedenken / Sorgen wegen Behandlung
- ☐ 4. Finanzielle Belastung

6. Logistik
- ☐ 1. Verordnetes Medikament nicht verfügbar
- ☐ 2. Fehler im Medikationsprozess

7. Verschreibungsqualität
- ☐ 1. Unvollständige / unklare Verordnung
- ☐ 2. Unleserliche Verordnung
- ☐ 3. Fehlende Verordnung notwendiger Hilfsmittel
- ☐ 4. Formaler / regulatorischer Grund

Technisch

D Intervention (1 Wahl)
- ☐ 1. Substitution / Austausch
- ☒ 2. Dosisanpassung
- ☐ 3. Anpassung Packungsgrösse /-anzahl
- ☐ 4. Optimierung Verabreichungsmodalitäten/-weg
- ☐ 5. Abbruch der Behandlung / keine Abgabe
- ☐ 6. Beginn neue Behandlung / Fortsetzung
- ☐ 7. Vertiefte Beratung des Patienten
- ☐ 8. Instruktion der Anwendung (Schulung)
- ☐ 9. Abgabe Compliance-Hilfe inkl. Beratung
- ☐ 10. Klärung/Vervollständigung Informationen
- ☐ 11. Weiterleitung von Informationen
- ☐ 12. Veranlassung Therapie Monitoring

E Kommunikation: Involvierte Personen (Mehrfachauswahl möglich)
- ☐ 1. nur Apotheker
- ☒ 2. Arzt
- ☐ 3. Pflege/ Spitex
- ☐ 4. Patient/ Angehörige

F Resultat der Intervention (1 Wahl)
- ☐ 1. Akzeptiert und umgesetzt
- ☒ 2. Teilweise akzeptiert oder akzeptiert ohne Umsetzung
- ☐ 3. Nicht akzeptiert
- ☐ 4. Verlauf unbekannt
- ☐ 5. Nicht anwendbar

Was ist eine pharmazeutische **Intervention**?

In der Patientenbetreuung verstehen wir unter einer pharmazeutischen Intervention eine Empfehlung des Apothekers als Antwort auf ein arzneimittelbezogenes Problem eines einzelnen Patienten im Medikationsprozess

Eine **Intervention** hat immer einen **Grund** und involviert eventuell **Drittpersonen**, um zu einem **Resultat** (Lösung) zu kommen.

Das entdeckte arzneimittelbezogene **Problem** kann **manifest** (→ Reaktive, korrigierende Intervention) oder **potentiell** (→ präventive Intervention) sein.

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Was ist eine Intervention während der **Rezeptvalidierung**?

D Intervention (1 Wahl)

- □ 1. Substitution / Austausch
- □ 2. Dosisanpassung
- □ 3. Anpassung Packungsgrösse /-anzahl
- □ 4. Optimierung Verabreichungsmodalitäten/-weg
- □ 5. Abbruch der Behandlung / keine Abgabe
- □ 6. Beginn neue Behandlung / Fortsetzung
- □ 7. Vertiefte Beratung des Patienten
- □ 8. Instruktion der Anwendung (Schulung)
- □ 9. Abgabe Compliance-Hilfe inkl. Beratung
- □ 10. Klärung/Vervollständigung Informationen
- □ 11. Weiterleitung von Informationen
- □ 12. Veranlassung Therapie Monitoring

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Was gehört zur **Rezeptvalidierung?**

- **Konsultation von Fachliteratur**
- **Konsultation von Kollegen**
- **Konsultation des Patientendossier**
- **Erste Instruktion bei der Anwendung von Fertigspritze, Inhalationsgerät (Asthmasprays), usw. → Beratungsbedarf**
- **Etikettierung**

→ KEINE INTERVENTIONEN

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Überblick des Projektes

PHARM disc

- **Validierung und Implementierung des Klassifikationssystems im Spital** ✓
- **Entwicklung und 1. Validierung des Pharm-DISC Klassifikationssystems mit Studenten in öffentlichen Apotheken (MA 2014)** ✓
- **Fokusgruppen-Diskussion (2.12.2014)** ✓
  - Meinungen von Experten
  - Verfeinerung Pharm-DISC

- **Pharm-DISC Studie mit OffizinapothekerIn (Januar-Juni 2015)**

→ **Hier brauchen wir Ihre Hilfe !**

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Ziel der Studie

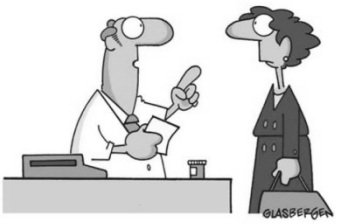
- **Validierung des Klassifikationssystems Pharm-DISC in öffentlichen Apotheken**
- **Definition von Barrieren und begünstigenden Faktoren zur erfolgreichen Einführung des Klassifikationssystems in den Apothekenalltag**

Studie Durchführung

- **Schulung**
  - Video Studienvorstellung
  - Video Fallbeispiel
  - Dokumente zum Runterladen
    - PHARM-DISC Interventionsbogen
    - Deskriptives Manual
    - Studienprotokoll
  - Selbständige Klassifizierung von 3 Fällen
    - mit Studienmaterial
    - **vor** dem Studienbeginn auszufüllen
    - uns zurückzuschicken mittels Rückantwortcouverts

Spielregeln

- Studienperiode: **2.März bis 4. April 2015**
- Während **5 Tagen** innerhalb der Studienperiode,
- **30 Rezepte** in der Apotheke sammeln und Interventionen mit dem Pharm-DISC Interventionsbogen klassifizieren
- Intervention **am gleichen Tag** klassifizieren, CRF und Interventionsbogen ausfüllen
- **Nur 1 Intervention pro Interventionsbogen**
- 1 Kreuz pro Kategorie ausser Kategorie E 'Kommunikation: involvierte Personen'



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Studienmaterial
Case Report Form CRF

Pharm-DISC Studie: Klassifizierung von pharmazeutischen Interventionen
Case Report Form (CRF)

ID bekommen Sie mit dem Studienmaterial

Studienapotheker/in ID (Apo ID): 321

Angabe zum Rezept bzw. Patient/in	Ja	Nein
• Rezeptnummer (RpNr) 01		
• Datum der Rezeptausführung 17/2/2015		
• Initialen (Vorname Nachname) KS		
• Jahrgang 1930		
• Geschlecht ☐ m ☒ w		
• Patient/in ist Stammkunde (Patientendossier in der Apotheke vorhanden)	☒	☐
• Rezept ☐ Spitalaustritt ☒ ambulant		
• Rezept ☐ gedruckt ☒ handgeschrieben		
• Rezeptkopie nummeriert, anonymisiert und an CRF geheftet	☒	
• Übersicht der Bezüge für 3 Monate (History) anonymisiert und ausgedruckt	☒	
Angabe zu der Intervention	**Ja**	**Nein**
• Kontakt mit dem Arzt	☒	☐
• Rezept geändert	☐	☒
• Anzahl Intervention/en auf diesem Rezept: 1		

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CRF: Kurze Fallbeschreibung

Kurze Fallbeschreibung

Hintergrund	Frau K.S, 85 Jahre (1930), 165cm, 66kg, war wegen einer Verstauchung des linken Fusses beim Hausarzt in Behandlung. Wegen ihrer Schmerzen, soll sie laut Verordnung, Dafalgan® 1g Filmtabletten 1-1-1-1 erhalten.
Grund der Intervention	Dafalgan® ist im hohen Alter überdosiert
Intervention und Involvierte Person/en	Empfehlung für den Arzt, die Dosis von Dafalgan® 1g auf 1-1-1-0 zu reduzieren.
Resultat der Intervention	Der Arzt stimmt grundsätzlich zu, will aber trotzdem mit 4 g täglich weiterfahren, er limitiert aber auf maximal 5 Tage.

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CRF: Falls Schwierigkeiten in der Klassifikation...

Wenn Schwierigkeiten bei der Klassifikation der Intervention auftraten, bitte kommentieren Sie diese (Zweifeln in der Auswahl Subkategorien, Vorschlag neuer Subkategorie, usw.):

Bei der Klassifizierung 'Grund der Intervention', habe ich zwischen 'Überdosierung' und 'Keine Dosisanpassung (z.B Nieren, Leber, Alter) gezweifelt.

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Pharm-DISC: Klassifizierung von pharmazeutischen Interventionen

A Problem (1 Wahl)
- ☐ 1. Effektivität der Behandlung
- ☐ 2. Nicht behandelte Indikation
- X 3. Risiko durch Behandlung
- ☐ 4. Behandlungskosten
- ☐ 5. Unzufriedenheit / Problem des Patienten

B Problemtyp (1 Wahl)
- ☐ 1. Manifest, reaktiv
- X 2. Potentiell, präventiv

C Grund der Intervention (1 Wahl)

1. Wahl der Behandlung
- ☐ 1. Keine Übereinstimmung mit Richtlinien, nur suboptimale Behandlung möglich
- ☐ 2. Kontraindikation
- ☐ 3. Interaktion
- ☐ 4. Medikament nicht indiziert
- ☐ 5. Duplikation
- ☐ 6. Unerwünschte Wirkung
- ☐ 7. Fehlende Informationen betreffend Patienten

2. Wahl der galenischen Form
- ☐ 1. Ungeeignete/r Verabreichungsform/ -weg

3. Wahl der Dosis
- ☐ 1. Unterdosierung
- ☐ 2. Überdosierung
- ☐ 3. Unzweckmässiges Monitoring
- X 4. Keine Dosisanpassung (z.B. Nieren, Leber, Alter)

4. Anwendung des Medikamentes
- ☐ 1. Ungeeigneter Zeitpunkt / Frequenz
- ☐ 2. Ungeeignete Anwendungsweise
- ☐ 3. Unangemessene Dauer der Behandlung

5. Patient
- ☐ 1. Ungenügende Compliance
- ☐ 2. Ungenügendes Wissen
- ☐ 3. Bedenken / Sorgen wegen Behandlung
- ☐ 4. Finanzielle Belastung

6. Logistik
- ☐ 1. Verordnetes Medikament nicht verfügbar
- ☐ 2. Fehler im Medikationsprozess

7. Verschreibungsqualität
- ☐ 1. Unvollständige / unklare Verordnung
- ☐ 2. Unleserliche Verordnung
- ☐ 3. Fehlende Verordnung notwendiger Hilfsmittel
- ☐ 4. Formaler / regulatorischer Grund

Technisch

D Intervention (1 Wahl)
- ☐ 1. Substitution / Austausch
- X 2. Dosisanpassung
- ☐ 3. Anpassung Packungsgrösse /-anzahl
- ☐ 4. Optimierung Verabreichungsmodalitäten/-weg
- ☐ 5. Abbruch der Behandlung / keine Abgabe
- ☐ 6. Beginn neue Behandlung / Fortsetzung
- ☐ 7. Vertiefte Beratung des Patienten
- ☐ 8. Instruktion der Anwendung (Schulung)
- ☐ 9. Abgabe Compliance-Hilfe inkl. Beratung
- ☐ 10. Klärung/Vervollständigung Informationen
- ☐ 11. Weiterleitung von Informationen
- ☐ 12. Veranlassung Therapie Monitoring

E Kommunikation: Involvierte Personen (Mehrfachauswahl möglich)
- ☐ 1. nur Apotheker
- X 2. Arzt
- ☐ 3. Pflege/ Spitex
- ☐ 4. Patient/ Angehörige

F Resultat der Intervention (1 Wahl)
- ☐ 1. Akzeptiert und umgesetzt
- X 2. Teilweise akzeptiert oder akzeptiert ohne Umsetzung
- ☐ 3. Nicht akzeptiert
- ☐ 4. Verlauf unbekannt
- ☐ 5. Nicht anwendbar

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Dossier

- 1 CRF enthält
  - 1 kopiertes und anonymisiertes Rezept (Keine Arzt- und Patientenamen)
  - 1 kurze Fallbeschreibung
  - 1 oder mehrere Pharm-DISC Interventionsbogen
  - 3-monatige Übersicht der Bezüge
- Bitte, schicken Sie das vollständige Dossier (30 CRF) an die vorgegebene Adresse.
- Couvert spätestens bis **10.04.2015** eingetroffen
- Online Evaluationsfragenbogen (Flexiform) ausfüllen: Email in April

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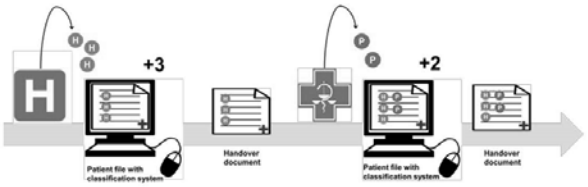
Vielen Dank & Keep in mind

Wenn etwas nicht dokumentiert ist, ist es nie passiert!

Eine Dokumentation ist ein Beweis für unsere Arbeit!



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Vielen Dank !

Das Pharm-DISC Team:

PCRG
Universität Basel

- Prof. Dr. Kurt Hersberger
- Dr. Markus Lampert
- Karen Maes, MSc Pharm
- Helene Studer, BSc Pharm

Pharmacie de la Policlinique médicale universitaire

- Prof. Olivier Bugnon
- Dr. Jérôme Berger
- Nour, BSc Pharm

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A2.2.6 Example used in the role play video of the online training

Kurze Fallbeschreibung

Hintergrund	Frau A, 25 Jahre, kommt mit einem Rezept für Cipralex® 20mg Filmtabletten, eine Tablette täglich, in die Apotheke. Frau A nimmt die Tablette jeweils vor dem Schlafen gehen. Sie beklagt sich über Schlafstörungen, seitdem sie das Medikament einnimmt.
Grund der Intervention	Ungeeigneter Zeitpunkt der Einnahme.
Intervention und involvierte Personen	Die Einnahme von Cipralex® sollte auf den Morgen verschoben werden. Involvierte Personen: Patientin und Apotheker
Resultat der Intervention	Die Patientin hat den Vorschlag akzeptiert und wird von nun an die Tablette morgens einnehmen.

Wenn Schwierigkeiten bei der Klassifikation der Intervention auftraten, bitte kommentieren Sie diese (Zweifel bei der Auswahl der Subkategorien, Vorschlag neue Subkategorie, usw.):

A2.2.7 Print screen of the online platform for the participating pharmacists

A3.1.1 Invitation letter for the study pharmacists

UNIVERSITÄT BASEL

DEPARTMENT OF PHARMACEUTICAL SCIENCES

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Pharmaceutical Care Research Group PCRG
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www.pharmacare.unibas.ch

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Doktorandin, Apothekerin

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Basel, den 28.01.2016

Basler Apothekenbeobachtungsstudie BABS 2016

Liebe Kolleginnen und Kollegen

Die Basler Apothekenbeobachtungsstudie (BABS) wurde seit 1995 bereits sieben Mal in verschiedenen Apotheken der Region durchgeführt. Die bisherigen Studien erhoben Daten zu Rezept, Patientenwunsch, Varia und Kundenberatung im Allgemeinen, sowie speziell im Bereich der Analgetika.
Bei der aktuellen Beobachtungsstudie konzentrieren wir uns auf die Abgabe von verschriebenen Medikamenten. Während der Studie werden die Rezeptbezüge und dabei auftretende arzneimittelbezogene Probleme dokumentiert. Das Ziel ist es, mehr Informationen zum Prozess der Medikamentenabgabe auf Rezept in öffentlichen Apotheken zu erhalten.
Für die Durchführung dieser Studie sind wir auf Ihre Hilfe angewiesen! Es würde uns freuen, wenn Sie uns erlauben würden, in Ihrer Apotheke Daten zu erheben.

Die Studie wird in diesem Jahr von Jasmine Ruppanner, Masterstudentin an der Universität Basel, durchgeführt. Ihre Anwesenheit wird sich auf das Beobachten und das Protokollieren der Rezeptbezüge und auf ein kurzes Gespräch mit Ihnen beschränken.
Die Beobachtung soll an einem Tag im März 2016 stattfinden. Abgesehen vom kurzen Interview (max. 15 Minuten) wird für Sie und das Team kein weiterer Arbeitsaufwand anfallen. Der normale Tagesablauf wird nicht gestört und die Patienten werden nicht angesprochen oder in anderer Weise einbezogen. Die Dokumentationen werden anonymisiert erfolgen und es können keine Rückschlüsse auf die teilnehmenden Apotheken und Patienten gezogen werden.

Bei Interesse bitten wir Sie, das Anmeldeformular auszufüllen und uns schnellstmöglich, aber spätestens bis am 09.02.2016 per Mail oder Fax zuzusenden. Nach erfolgter Anmeldung werden wir telefonisch Kontakt mit Ihnen aufnehmen, um allfällige Fragen zu klären und das definitive Studiendatum festzulegen. Zudem werden Sie ein Informationsblatt mit weiteren Details zu der Studie erhalten.
Herzlichen Dank bereits im Voraus für Ihre Unterstützung!

Mit freundlichen Grüssen

Karen Maes
Dipl. pharm, Doktorandin

Dr. Markus Lampert
Projektleiter

Prof. Dr. Kurt Hersberger
Leiter PCRG

A3.1.2 Information document for the study pharmacists

UNIVERSITÄT BASEL

DEPARTMENT OF PHARMACEUTICAL SCIENCES

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Wie läuft der Beobachtungstag ab?

Am vereinbarten Termin wird die Masterstudentin Jasmine Ruppanner (ggf. mit Unterstützung) den Arbeitstag in der Apotheke verbringen. Die erfasste Zeitspanne soll so lange wie möglich sein und eine Dauer von 7.5 h nicht unterschreiten.

Zu Beginn des Beobachtungstages ist eine kurze Vorbesprechung (ca. 10 Minuten) mit dem Apothekenteam geplant, um sich kennenzulernen, den Ablauf der Studie kurz zu erklären und allfällige Fragen zu klären.

Während des Tages wird sich die Masterstudentin als Beobachterin im Hintergrund aufhalten und den ablaufenden Prozess bei Rezeptbezügen protokollieren. Sie wird nicht in das Gespräch eingreifen oder den Tagesablauf auf andere Weise stören. Die Patienten werden nicht über die Tatsache informiert, dass das Gespräch beobachtet wird. Sie werden nicht angesprochen oder in anderer Weise einbezogen.

Damit eine spätere Validierung der Daten möglich ist, werden zu allen protokollierten Gesprächen die dazugehörigen Rezepte kopiert und ein Auszug der repetierbaren Medikamente erstellt. Dabei wird die Masterstudentin auf Unterstützung Ihres Teams angewiesen sein. Die Dokumentationen werden anonymisiert erfolgen und vertraulich behandelt. Es können keine Rückschlüsse auf die teilnehmenden Apotheken und Patienten gezogen werden.

Am Ende des Arbeitstages wird zudem ein kurzes strukturiertes Interview (max. 15 Minuten) mit dem/ der verantwortlichen Apotheker/in durchgeführt. Die Aufzeichnungen dazu erfolgen handschriftlich.

Leider stehen für diese Studie keine Sponsoren zur Verfügung. Für Sie und Ihr Team wird aber abgesehen vom Interview kein zusätzlicher Arbeitsaufwand anfallen.

Datenanalyse

Die Daten werden im Rahmen einer Masterarbeit ausgewertet. Wir werden Sie gerne über die Resultate der Studie informieren.

Wir möchten uns nochmals für Ihre Teilnahme an der Studie bedanken und freuen uns auf eine spannende und produktive Zusammenarbeit! Wir schätzen Ihr Engagement in der Forschung der Universität Basel sehr.

Bei allfälligen Fragen stehen wir Ihnen gerne zur Verfügung.

Mit herzlichen Grüssen,
Ihr BABS Team

2

A3.1.3 Checklist

BABS 2016 **Apo- Code:** 1 ☐☐☐ **Beobachtung:** 2 ☐☐☐☐ **Zeit:** 3 ☐☐:☐☐ – ☐☐:☐☐

Bedienung:

4 Code(s) _____

Rezept

5.1 ☐ Erstbezug 5.2 ☐ Wiederholung

6 ☐ Vorbezug 7 ☐ Abgabe ohne Rp

8 # Abgegebene Medikamente: _____

9 ☐ Abgabeverweigerung: _____

Arzt

10 ☐ Kontaktaufnahme 11 ☐ Überweisung

Intervention

12 ☐ Ja -> PharmDISC 13 # R. geändert: ____

Situation

14 ☐ Unterbrechung 15 ☐ Wartende Kunden

16 ☐ Laut 17 ☐ Kein Sichtkontakt

18 ☐ Sprache 19 ☐ Komm. Problem

Kommunikation

20 ☐ Positiv 21 ☐ Emotional

22 ☐ Negativ 23 ☐ Sozial

Beratung

27 ☐ Beratungsangebot
28 ☐ Beratung in sep. Raum
29 # Medis beraten: _____

30 ☐ Beratung abgelehnt
31 ☐ Medikament bekannt

32 ☐ Patient erfragt Beratung
33 ☐ Patient erklärt (x)

	F	E	
34	☐	☐	**Anamnese:** Medis
35	☐	☐	Erkrankung
36	☐	☐	Allergien
37	☐	☐	SS/ ST
38	☐	☐	Familiär
39	☐	☐	Lifestyle
40	☐	☐	klin. Parameter
41	☐	☐	**Dosierung**
42	☐	☐	**Anwendung**: Wie
43	☐	☐	Dauer
44	☐	☐	Instruktion
45	☐	☐	**Einnahme:** Intervall
46	☐	☐	Dauer
47	☐	☐	Zeitpunkt
48	☐	☐	Modalität
49	☐	☐	**schriftl. Info:**Etikette
50	☐	☐	Flyer/Brosch.
51	☐	☐	Plan
52	☐	☐	Unterlagen

Patient

24.1 ☐ Männlich 25.1 ☐ Stammkunde 26.1 ☐ Anwesend

24.2 ☐ Weiblich 25.2 ☐ Neukunde 26.2 ☐ Angehörige/r

Beratung - Fortsetzung

	F	E	
53	☐	☐	Indikation
54	☐	☐	Wirkung (grob)
55	☐	☐	Wirkmechanismus
56	☐	☐	Nutzen/ Therapieziel
57	☐	☐	UAW
58	☐	☐	Red flags
59	☐	☐	Interaktion
60	☐	☐	KI
61	☐	☐	Vergessene Einnahme
62	☐	☐	Unterdosierung
63	☐	☐	Überdosierung
64	☐	☐	Lagerung
65	☐	☐	Info an Gesundheitsp.
66	☐	☐	Adhärenz
67	☐	☐	Selbst/- Monitoring

68 ☐ Follow up/Betreuung Apo

69 ☐ „Haben Sie Fragen?“

Zusatzleistungen

70 # OTC Wunsch :_____
71 # OTC Zusatzverkauf :_____

72 # Zusatzverkauf nicht-med.:____
73 # Andere Dienstleistung:_____

74 ☐ Nicht- med. Beratung

75 **Offenes Bemerkungsfeld**

76 **Alter Patient**

Geburtsjahr: ☐☐☐☐ -> Alter: ☐☐☐ Jahre

Rezept:

77.1 ☐ Spitalaustritt 77.2 ☐ Ambulant

78.1 ☐ Handgeschrieben 78.2 ☐ Gedruckt 78.3 ☐ Gemischt

Medikamente auf Rezept:

79 Anzahl : ☐☐

80 **Vorhandene Dokumente:**

☐ Rezeptkopie

☐ Auszug repetierbarer Medikamente

☐ PharmDISC Interventionsbogen (Anzahl: ☐☐)

Universität Basel

Departement
Pharmazeutische Wissenschaften

Protokollblatt Masterarbeit Jasmine Ruppanner

A3.1.4 Characterisation page

Universität Basel
Departement Pharmazeutische Wissenschaften

DEPARTMENT OF PHARMACEUTICAL SCIENCES

Basler Apothekenbeobachtungsstudie (BABS) 2016

Characterization Page

Angaben zur Apotheke:

1 Apotheken-Code: ☐☐☐

2 Ort: ☐ Stadtbezirk ☐ Landbezirk

3 Lage: ☐ Zentrumslage ☐ Periphere Lage
☐ Einkaufszentrum

Nächstgelegenes Spital: ☐☐☐.☐ km

4 Apothekentyp: ☐ Unabhängig ☐ Gruppierung ☐ Kette

5 Spezialisierung: ☐ Vorhanden ☐ Nicht vorhanden

Welche? _____

6 Software: ☐ ProPharma ☐ Golden Gate ☐ _____

7 OTC- Erfassung: ☐ Routinemässig ☐ Gelegentlich ☐ Nein

8 Anzahl Kassen (total): ☐☐ 9 Anzahl Kassen (gebraucht): ☐☐

10 Anzahl Theken (total): ☐☐ 11 Anzahl Theken (gebraucht): ☐☐

Angaben zum Beobachtungstag:

12 Wochentag: ☐ Mo ☐ Di ☐ Mi ☐ Do ☐ Fr ☐ Sa

13 Öffnungszeiten: ☐☐:☐☐ - ☐☐:☐☐ / ☐☐:☐☐ - ☐☐:☐☐

14 Erfasste Zeit: _____

15 Beobachterin(nen): ☐ Jasmine (J) ☐ Tamara (T)

16 Anzahl Rezepte in Apo/ Tag: ☐☐☐ 17 Anzahl beobachtete Rezepte/ Tag: ☐☐☐

18 Anzahl Rezepte/ Tag (total): ☐☐☐

19 Anzahl Barverkäufe/ Tag: ☐☐☐ 20 Anzahl Verkäufe/ Tag (total): ☐☐☐

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21 **Mitarbeiter/innen:**

	Beruf	FPH	Position	Arbeitserfah-rung (Jahre)	Arbeitszeit am Studientag
M01					
M02					
M03					
M04					
M05					
M06					
M07					
M08 M09					
M10					
M11					
M12					

Totale Anzahl Mitarbeitende am Studientag:

22 Apotheker/in: ☐☐.☐

23 Pharma-Assistent/in: ☐☐.☐

24 Drogist/in: ☐☐.☐

25 Apotheker/in in Ausbildung: ☐☐.☐

26 Lehrling: ☐☐.☐

27 Total ☐☐.☐

A3.1.5 Data Dictionary for the characterisation page and the checklist

Universität Basel

Departement
Pharmazeutische Wissenschaften

DEPARTMENT OF PHARMACEUTICAL SCIENCES

Basler Apothekenbeobachtungsstudie (BABS) 2016
Data-Dictionary

1.) Characterization Page

Pro teilnehmende Apotheke wird die Characterization Page einmal ausgefüllt. Die Daten werden soweit möglich zu Beginn des Studientages eingetragen und am Ende des Studientages ergänzt.

1 Apotheken-Code
Zur Gewährleistung der Anonymität wird jeder Apotheke ein Code zugewiesen. Die Zuweisung des Codes geschieht anhand der randomisierten Liste. Diejenige teilnehmende Apotheke, die auf der Liste zu oberste steht und dementsprechend die kleinste randomisierte Zahl aufweist, erhält den Code A01. Die nächste darunterliegende teilnehmende Apotheke erhält den Code A02 etc. (A steht für Apotheke)

2 Ort
Die Studie wird ausschliesslich im Kanton Basel- Stadt (BS) durchgeführt. Dieser ist in einen Stadt- (Basel) und Landbezirk (Gemeinden Kleinhüningen, Riehen und Bettingen) aufgeteilt. Das Auswahlkästchen des entsprechenden Bezirks wird angekreuzt.

3 Lage
Die Lage der Apotheke wird mittels Kategorien angegeben. Es wird unterschieden zwischen Apotheken mit peripherer Lage (Quartier, Aussenquartier, Nebenstrasse), Zentrumslage (City, Passantenlage, Bahnhof, Ladenpassage) und Apotheken im Einkaufszentrum. Das entsprechende Auswahlkästchen wird angekreuzt.
Zudem wird erfasst, in welchem Radius sich das nächstgelegene Spital befindet. Die Kilometerangabe wird auf eine Kommastelle gerundet angegeben. Z. B. wenn sich das nächste Spital in 1.24 km Luftlinie von der Studienapotheke A entfernt befindet, wird „1.2 km" notiert.

4 Apothekentyp
Es wird erfasst, ob es sich um eine selbständige Apotheke handelt oder ob sie einer Kette/ Gruppierung angehört.

5 Spezialisierung
Falls die Apotheke eine Spezialisierung aufweist (z.B. Medinform Atemwegsapotheke, Hautapotheke, Kinderapotheke), wird das Kästchen „Ja" angekreuzt und die Spezialisierung notiert. Falls nicht, wird „Nein" angekreuzt.

6 Software
Die Software, welche in der Apotheke installiert ist, wird erfasst, z.B. ProPharma oder Golden Gate. Falls eine andere Software in Gebrauch ist, wird das dritte Kästchen angekreuzt und der Name der Software ergänzt.

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7 OTC-Erfassung
Es wird erfasst, ob und wie oft OTC-Verkäufe bei Stammkunden im Patientendossier dokumentiert werden. Ist es jedem Mitarbeiter selber überlassen, die OTC Produkte nach eigenem Ermessen zu dokumentieren, ist „gelegentlich" die richtige Wahl. Werden dagegen nur die verschriebenen Medikamente im Patientendossier erfasst, wird „Nein" angekreuzt.

8 Anzahl Kassen (total)
Die totale Anzahl an Kassen (resp. Computer–Monitore auf den Theken), die in der Apotheke vorhanden sind, wird erfasst.

9 Anzahl Kassen (gebraucht)
Die Anzahl an Kassen (resp. Computer–Monitore auf den Theken), die während der erfassten Zeit mindestens einmal gebraucht werden, wird notiert.

10 Anzahl Theken (total)
Die in der Apotheke vorhandenen alleinstehenden Inseln/ Theken mit Kassen werden erfasst.

11 Anzahl Theken (gebraucht)
Die Anzahl Theken, an denen während der erfassten Zeit mindestens ein Kunde bedient wird, werden gezählt und notiert.

12 Wochentag
Dies entspricht dem Wochentag, an dem die Beobachtungsstudie in der entsprechenden Apotheke durchgeführt wird.

13 Öffnungszeiten
Die offiziellen Öffnungszeiten am Studientag werden erfasst.

14 Erfasste Zeit
Dies entspricht der Zeitspanne, die von der Beobachterin tatsächlich erfasst wird.
Die erfasste Zeit kann von den Öffnungszeiten abweichen, insbesondere wenn die Apotheke durchgehende oder besonders lange Öffnungszeiten hat. Es handelt sich also um die Netto-Zeit abzüglich aller Pausen und nicht erfassten Zeitspannen aufgrund fehlender Anwesenheit am Morgen oder Abend.
Ein Beispiel: Die Beobachtung der Studienapotheke A startet um 8:00 und endet um 18:15. Dazwischen wird von der Beobachterin eine Pause am Morgen von 9:45-10:00, sowie eine Mittagspause von 12:15-13:15 gemacht. Als erfasste Zeit wird somit folgendes vermerkt: 8:00-9:45, 10:00-12:15, 13:15-18:15.

15 Beobachterin(nen)
Die am Studientag in der Apotheke anwesenden Beobachterinnen werden erfasst. Falls mehr als eine anwesend ist, müssen sie nicht zwingend gleich lang und zur selben Zeit anwesend sein.

16 Anzahl Rezepte in Apo/ Tag
Dies entspricht der totalen Anzahl an Kundenkontakten mit Rezeptbezügen, welche während der gesamten Öffnungszeit am Studientag in der Apotheke stattfanden. Diese Zahl wird durch das manuelle zählen aller Kunden erhalten, die in der Apotheke ein Rezept einlösen, sei das für sich selber oder eine(n) Angehörige(n).
Diese Angabe beinhaltet folglich auch die Rezeptbezüge, die nicht beobachtet und dokumentiert werden. Gemäss Definition „Kundenkontakt" werden ausgeführte Rezepte ohne Patientenkontakt in der Apotheke (Heim- und Hauslieferungen) ausgeschlossen.

17 Anzahl beobachtete Rezepte/ Tag
Die Anzahl an beobachteten und dokumentierten Kundenkontakten mit Rezeptbezügen, d.h. die Anzahl ausgefüllter Protokollblätter, wird am Ende des Studientages gezählt und notiert.

18 Anzahl Rezepte/ Tag (total)
Die totale Anzahl an Rezepten, die während des gesamten Studientages ausgeführt werden, wird notiert.
Die Zahl wird durch das Statistikprogramm der Apothekensoftware generiert. Diese Zahl wird am Ende des Tages erfasst, d. h. bei Ladenschluss. Falls dieser Zeitpunkt nicht mit dem Ende der erfassten Zeit übereinstimmt, wird das Apothekenteam gebeten, diese Zahl per Mail nachzureichen.

19 Anzahl Barverkäufe/ Tag
Dies entspricht der totalen Anzahl an Barverkäufen während der gesamten Öffnungszeit am Studientag.
Die Zahl wird durch das Statistikprogramm der Apothekensoftware generiert. Diese Zahl wird am Ende des Tages erfasst, d. h. bei Ladenschluss. Falls dieser Zeitpunkt nicht mit dem Ende der erfassten Zeit übereinstimmt, wird das Apothekenteam gebeten, diese Zahl per Mail nachzureichen.

20 Anzahl Verkäufe/Tag (total)
Die totale Anzahl an Verkäufen, die während der gesamten Öffnungszeit am Studientag getätigt werden, wird erfasst.
Die Zahl wird durch das Statistikprogramm der Apothekensoftware generiert. Diese Zahl wird am Ende des Tages erfasst, d. h. bei Ladenschluss. Falls dieser Zeitpunkt nicht mit dem Ende der erfassten Zeit übereinstimmt, wird das Apothekenteam gebeten, diese Zahl per Mail nachzureichen.

21 Mitarbeiter/ innen
Alle Mitarbeiter/innen der Apotheke, die während dem Studientag anwesend sind und **mindestens einmal während einer Beobachtungsperiode im Kundenkontakt stehen**, werden erfasst und durchnummeriert. Dazu gehören Apotheker/ innen, Pharma- Assistent/ innen, Drogist/ innen, Lehrlinge (des Berufes der/ des Pharma- Assistenten/in) und Apotheker/ innen in Ausbildung. Reinigungskräfte und Praktikanten, die eine rein beobachtende Funktion ausüben, werden nicht mitgezählt.
Für jede Person wird eine separate Zeile in der Tabelle ausgefüllt. Die Reihenfolge und folglich die Zuweisung des Codes (M für Mitarbeiter und 2 Ziffern) erfolgt zufällig. Der erste Mitarbeiter, der am Studientag in eine Beobachtungsperiode eingeschlossen wird, erhält den Code M01. Die Person, die als zweites beobachtet wird, erhält den Code M02 etc. Der Beobachterin muss aber bewusst sein, welcher Person welcher Code zugewiesen wurde, da dieser auf dem Protokollblatt verwendet wird.

Beruf
Die Berufsbezeichnung wird notiert. Es wird unterschieden zwischen Apotheker, Pharma- Assistent, Drogist, Lehrling (des Berufes des Pharma- Assistenten) und Apotheker in Ausbildung.

FPH/ Position
Bei Apothekern wird zudem erfasst, ob sie einen FPH-Titel besitzen. Der entsprechende Titel wird notiert, z.B. Offizin, Klinische Pharmazie oder Impfung.
Bei „Position" wird vermerkt, ob es sich bei der jeweiligen Person um den Besitzer oder Verwalter handelt. Falls zutreffend wird „Besitzer", „Verwalter" oder „angestellter Apotheker" notiert.

Arbeitserfahrung
Die Arbeitserfahrung der Person wird aufgeschrieben. Dabei handelt es sich um die Anzahl Jahre, welche die entsprechende Person aktiv in einer Apotheke gearbeitet hat (inkl. Ausbildung). Babypausen und Auszeiten (z.B. für längere Reisen) werden nicht mitgezählt. Das Arbeitspensum hat keinen

Einfluss auf die Bestimmung der Arbeitserfahrung. Arbeitet z.B. Mitarbeiter A seit 3 Jahren nur 80% und Mitarbeiter B seit 3 Jahren 100% und beide haben eine 3-jährige Lehre in der Apotheke absolviert, wird bei beiden 6 Jahre notiert.
Für die Personen in Ausbildung wird einfach die Anzahl Ausbildungsjahre in der Apotheke (abgeschlossene und angeschnittene) notiert. Ist z.B. ein Lehrling im 2. Lehrjahr, wird „2 Jahre" notiert. Bei Pharmaziestudenten im Assistenzjahr wird „1 Jahr" notiert.
Die hier erhobenen Daten beruhen auf Eigenangaben der Mitarbeiter oder Fremdnennung durch die verantwortliche Person der Apotheke. Die Angaben können daher auf Schätzungen beruhen.

Arbeitszeit am Studientag
Bei der Arbeitszeit am Studientag wird zwischen Ganztagesarbeit und Halbtagesarbeit unterschieden. Ganztagesarbeit (≥ 8 Stunden Arbeitszeit am Studientag, unabhängig vom Startzeitpunkt und der Verteilung dieser Stunden über den Tag) wird mit einer 1 und Halbtagesarbeit (< 8 Stunden Arbeitszeit am Studientag) mit 0.5 codiert.

Totale Anzahl Mitarbeitende am Studientag (22-27)
Ergänzend wird die Summe **aller anwesenden** Mitarbeiter notiert. Dies beinhaltet somit auch diejenigen Personen, welche am Studientag nie während einer Beobachtungsperiode im Kundenkontakt standen und denen somit kein Mitarbeiter-Code zugewiesen wurde. Von jeder Berufskategorie wird die Summe separat, sowie ein Gesamttotal aller Mitarbeiter berechnet. Die Summen werden ungerundet notiert.

Ein Beispiel zur Illustration: Während des ganzen Tages sind ein Apotheker, zwei Pharma- Assistentinnen und ein Pharmaziestudent im Assistenzjahr in der Studienapotheke A anwesend und führen aktiv Patientengespräche durch. Zudem ist ein Praktikant vor Ort, der nur beobachtet. Am Morgen ist ein zusätzlicher Apotheker anwesend und am Nachmittag eine Pharma- Assistentin, die auch im Kundenkontakt stehen. Die korrekten Summen sind:

Apotheker/in:	1.5 (1 Ganztagesarbeiter + 1 Halbtagesarbeiter)
Pharma-Assistent/in:	2.5 (2 Ganztagesarbeiter + 1 Halbtagesarbeiter)
Drogist/in:	0
Apotheker/in in Ausbildung:	1 (1 Ganztagesarbeiter)
Lehrling:	0
Total:	5 (4 Ganztagesarbeiter + 2 Halbtagesarbeiter = 5)

2.) BABS – Protokollblatt

Pro erfasster Beobachtungsperiode wird ein separates Protokollblatt („Checkliste") ausgefüllt. Alle beobachteten Prozessschritte und Handlungen während einer Beobachtungsperiode werden von der Beobachterin auf demselben Protokollblatt festgehalten. **Eine Beobachtungsperiode beginnt mit der Begrüssung des Patienten und endet mit dem Abschliessen der Patientenberatung.** Ein Spezialfall ist die Situation, falls der Patient verschriebene Medikamente sowohl für sich als auch für eine andere Person bezieht. Falls die Bezüge und demnach die Beratungen klar getrennt voneinander stattfinden, d.h. der Rezeptbezug für die eine Person abgeschlossen ist, bevor der zweite angesprochen wird, werden die Beobachtungen auf zwei separaten Protokollblättern erfasst. Falls aber beide gemeinsam angesprochen und ausgeführt werden, erfolgen die Dokumentationen auf einem Protokollblatt. Mit unterschiedlichen Farben soll versucht werden, die Handlungen zu den eigenen Medikamenten und denen der nicht anwesenden Person zu unterscheiden. Zudem wird ein Kommentar dazu im offenen Bemerkungsfeld (Nr. 75) gemacht.

Resultierende Interventionen werden zusätzlich mit dem PharmDISC Interventionsbogen dokumentiert. In der englischen Definition von „patient care" werden pharmazeutische Interventionen definiert *„as a recommendation initiated by a pharmacist in response to a drug-related problem in an individual patient occurring in any phase of the medication process."*(1) Pharmaceutical Care Network Europe definiert ein arzneimittelbezogenes Problem (drug related problem) folgendermassen: *„an event or circumstance involving drug therapy that actually or potentially interferes with desired health outcomes.(2)*
Für jede Intervention wird ein separater Interventionsbogen ausgefüllt. **Pro Beobachtungsperiode** wird somit immer nur **ein Protokollblatt**, aber je nach Bedarf **eine unterschiedliche Anzahl an Interventionsbogen** ausgefüllt.
Zu allen protokollierten Gesprächen werden die dazugehörigen Rezepte kopiert und ein Auszug der repetierbaren Medikamente erstellt. Die Dokumentationen erfolgen anonym und werden vertraulich behandelt.

Nach Möglichkeit werden alle Rezeptbezüge dokumentiert. Es werden aber nie mehrere Rezeptbezüge (von der gleichen Beobachterin) zur selben Zeit erfasst. Überlappungen sind nicht zulässig. Erst wenn die Beobachtungsperiode eines Patienten beendet ist, kann eine Neue gestartet werden.

Abholungen von bestellten verschriebenen Medikamenten werden nicht zu den abgegebenen verschriebenen Medikamenten oder zum Zusatzverkauf dazugezählt. D.h. eine reine Abholung von bestellten verschriebenen Medikamenten wird nicht erfasst. Falls die Abholung im Rahmen eines weiteren Rezeptbezuges stattfindet, wird das neue Rezept normal beobachtet und dokumentiert, die bestellten abgeholten Medikamente werden jedoch nicht erfasst. Dass der Rezeptbezug im Rahmen einer Abholung stattfindet, wird im offenen Bemerkungsfeld (Nr.75) vermerkt.
Im Gegensatz dazu zählt ein verschriebenes Medikament, das während der Beobachtungsperiode nicht an Lager ist und bestellt werden muss, zu der Rubrik „# abgegebene Medikamente" (Nr. 8). Zusätzlich wird ein Vermerk im offenen Bemerkungsfeld (Nr.75) gemacht, dass Medikamente bestellt werden mussten und deren Anzahl notiert.
Falls das/ die Medikament/e auf dem Rezept nicht für die anwesende Person selber bestimmt ist/ sind, wird der Fall dennoch in die Studie eingeschlossen und dementsprechend vermerkt (Auswahlkasten: Patient -> Angehörige/r).
Nach Möglichkeit werden auch Kundengespräche in Fremdsprachen geführt erfasst werden. Die sprachlichen Barrieren können sowohl die Beratungstiefe, wie auch die Detailliertheit der Aufzeichnungen beeinflussen. Daher sollen bei allen Patientengesprächen, die in einer anderen Sprache als Deutsch stattfinden, die Richtlinien der Kästchen „Sprache" und „Komm. Probleme" beachtet werden (Nr. 18 und 19).

Administratives

Kategorie	Auswahlmöglichkeiten	Bemerkung
1 Apo- Code	Handschriftlich notieren (Buchstabe A und 2 Ziffern)	Der Code, welcher der Apotheke aus Anonymisierungsgründen zugewiesen wurde, wird notiert. Dieser ist mit dem Apotheken- Code auf der Characterization Page identisch. Details zur Generierung des Codes sind dort vermerkt.
2 Beobachtung	Handschriftlich notieren (1 Buchstabe und 3 Ziffern)	In jeder Studienapotheke werden die erfassten Beobachtungsperioden der Reihe nach durchnummeriert. Jede Beobachterin startet mit 01. Vor den zwei Ziffern wird der Anfangsbuchstabe des Vornamens der Beobachterin gesetzt. D.h. die erste Beobachtungsperiode durch Jasmine wird mit J01 vermerkt, die nächste mit J02 etc. Am darauffolgenden Beobachtungstag in einer anderen Apotheke wird wieder mit 01 begonnen.
3 Zeit	Handschriftlich notieren (4 Ziffern)	Die Tageszeit, zu welcher die Beobachtungsperiode beginnt und endet, wird auf die Minute genau angegeben.

Bedienung

Kategorie	Auswahlmöglichkeiten	Bemerkung
4 Code(s)	Handschriftlich notieren (Buchstabe M und 2 Ziffern)	Der Code, welche dem bedienenden Mitarbeiter zugewiesen wurde (siehe Richtlinien Characterizaton Page), wird erfasst. Es werden der Reihe nach alle Personen protokolliert, die bei dem Gespräch mitwirken. Als erster Code wird somit derjenige Mitarbeiter erfasst, der die Beobachtungsperiode startet. Wird ein Apotheker nur zur Kontrolle des Rezeptes beigezogen, wird sein Code nicht notiert, es sei denn, er interagiert mit dem Patienten.

Patient

Kategorie	Auswahlmöglichkeiten	Bemerkung
24 Geschlecht	• Männlich • Weiblich	Es wird zwischen männlich und weiblich unterschieden.
25 Patientendossier	• Stammkunde • Neukunde	Es wird unterschieden, ob von dem Patienten bei Rezeptbezug ein Patientendossier in der Apotheke vorhanden war (ankreuzen von „Stammkunde") oder ob der Rezeptbezug die Erstellung eines Patientendossiers initiiert hat („Neukunde" ankreuzen).
26 Zielperson	• Anwesend • Angehörige/ r	Löst der Patient ein Rezept für sich selber ein, wird „anwesend" ausgewählt. Ist das eingelöste Rezept jedoch für eine nicht anwesende Person bestimmt, wird „Angehörige/r" angekreuzt. Dabei ist es gleichgültig, ob die Personen wirklich miteinander verwandt oder z.B. nur Nachbarn/Pflege sind. Wie die Beziehung zueinander

		ist, wird (falls erfassbar) im Bemerkungsfeld (Nr.75) notiert. Falls die Bestimmung der Zielperson durch die Beobachtung nicht ersichtlich ist, wird beim Apothekenteam nachgefragt und falls dies auch nicht hilft, kein Kästchen angekreuzt.
76 Alter	Handschriftlich notieren: Geburtsjahr -> 2. Seite des Protokoll-blattes	Das Geburtsjahr wird vom Rezept abgelesen und notiert. Zudem wird das Alter berechnet. Bei Bestimmung des Alters wird von einem Geburtstag im Januar ausgegangen.

Rezept

Kategorie	Auswahlmöglichkeiten	Bemerkung
5-9 Rezeptart und Vorgehen	• Erstbezug • Wiederholung • Vorbezug • Abgabe ohne Rp • # Abgegebene Medikamente • Abgabeverweigerung	Es gibt eine obligatorische Unterscheidung zwischen einer Erstverordnung und einem wiederholten Bezug. Wichtig: Beratungsaspekte zu Erstverordnungen werden mit einem rotem Stift notiert und solche zu einer Wiederholung mit blau! Die Auswahlmöglichkeiten „Vorbezug“ und „Abgabe ohne Rp“ (bei Notfallsituationen!) sind optional bei Bedarf anzukreuzen. Auch das Kästchen „Abgabeverweigerung“ kann, falls zutreffend, zusätzlich angekreuzt werden. Der Grund für die Abgabeverweigerung wird daneben notiert. Bei „# abgegebene Medikamente“ wird die Anzahl unterschiedlicher verschriebener Medikamente notiert, die abgegeben (oder bestellt) werden. Falls von einem Medikament mehrere Packungen bezogen werden, zählt dies nur als eins. Abholungen von verschriebenen Medikamenten werden nicht mitgezählt.
77 Hintergrund	• Spitalaustritt • Ambulant -> 2. Seite des Protokoll-blattes	Es wird zwischen einem Rezept aufgrund eines Spitalaustrittes oder einem ambulanten Arztbesuch unterschieden.
78 Rezeptausstellung	• Handgeschrieben • Gedruckt • Gemischt -> 2. Seite des Protokoll-blattes	Bei einer Erstverordnung wird erfasst, ob das Rezept vollständig handschriftlich erstellt wurde oder gedruckt ist. Falls handschriftliche Ergänzungen oder Änderungen (z.B. Packungsgrösse) durch den Arzt auf dem ansonsten ausgedruckten Rezept vorhanden sind, wird das Kästchen „gemischt“ ausgewählt.
79 Medikament	Anzahl -> 2. Seite des Protokoll-blattes	Die Anzahl Medikamente auf dem Rezept, resp. der Etikette einer Repetition, werden gezählt und notiert.

Arzt

Kategorie	Auswahlmöglichkeiten	Bemerkung
10 Kontaktaufnahme		Wird angekreuzt, sofern per Fax oder Telefon mit dem Arzt Rücksprache gehalten wird. Der Grund für die Kontaktaufnahme wird im offenen Bemerkungsfeld (Nr.75) vermerkt.
11 Überweisung		Wird angekreuzt, falls der Patient die Aufforderung erhält, den Arzt aufzusuchen, sofern sich die Symptome nicht verbessern oder sogar verschlechtern. Falls der Patient sofort den Arzt aufsuchen soll, wird dies im offenen Bemerkungsfeld (Nr.75) vermerkt.

Intervention

Kategorie	Auswahlmöglichkeiten	Bemerkung
12 Ja -> PharmDISC		Dieses wird angekreuzt, falls mind. eine Intervention stattfindet. (siehe Definition von Intervention auf S.5) Ergänzend wird pro Intervention ein PharmDISC Interventionsbogen ausgefüllt.
13 # R. geändert		Die Anzahl an Rezepten, bei denen bei der Ausführung mindestens eine Änderung vorgenommen wurde, wird gezählt und notiert. (z.B. Änderung der Packungsgrösse, Substitution)

Situation

Kategorie	Auswahlmöglichkeiten	Bemerkung
14 Unterbrechung		Der Auswahlkasten wird angekreuzt, falls das Patientengespräch durch andere Personen, als die im Gespräch involvierten, unterbrochen wird. Falls das Beratungsgespräch einer Pharma-Assistentin beobachtet wird und dieses pausiert wird, da der Apotheker als beratende Person oder zur Kontrolle des Rezeptes hinzugezogen wird, so erfolgt kein Ankreuzen. Das Kästchen wird nur angekreuzt, falls das Gespräch durch eine externe Störung unterbrochen wird, die nichts mit dem eigenen Patientengespräch zu tun hat. Z.B. falls ein Beratungsgespräch des Apothekers beobachtet wird und eine Pharma-Assistentin dieses unterbricht, um ein Rezept für eine andere Person, als die in der Beobachtungsperiode eingeschlossene, kontrollieren zu lassen.
15 Wartende Kunden		Falls es mind. einen Kunden gibt, der während der Beobachtungsperiode in der Apotheke steht und (über 15 Sekunden) auf einen Gesprächspartner wartet, wird ein Kreuz gesetzt.
16-17 Hindernisse für Beobachterin	• Laut • Kein Sichtkontakt	Die Auswahl „laut“ beruht auf einer subjektiven Einschätzung der Beobachterin. Falls die Beobachterin aufgrund des Geräuschpegels Mühe

		hat, dem Gesprächsverlauf zu folgen, wird das Kästchen angekreuzt. Ob die Ursache für die Lautstärke bei einem parallel ablaufenden Patientengespräch oder Abläufen im Hintergrund liegt, ist für die Auswahl gleichgültig. Falls die Beobachterin das Gespräch nicht vollständig beobachten kann, also nur hört, wird das Kästchen „kein Sichtkontakt" angekreuzt
18-19 Gespräch	• Sprache • Komm. Probleme	Falls die verwendete Sprache des Gesprächs von Deutsch abweicht oder eine Kombination aus Deutsch und einer anderen Sprache ist, wird das Kästchen „Sprache" angekreuzt und die Sprache(n) im offenen Bemerkungsfeld (Nr.75) vermerkt. Die Auswahl „Komm. Probleme" wird angekreuzt, falls eine ins Gespräch involvierte Person Mühe hat, sich mit der anderen zu verständigen. Die Sprache spielt dabei keine Rolle. Beratet der Apothekenmitarbeiter z.B. auf Deutsch und der Patient zeigt Schwierigkeiten dem Gespräch zu folgen, wird das Kästchen angekreuzt.
20-23 Kommunikation	• Positiv • Emotional • Negativ • Sozial	Hierbei wird die Kommunikationsweise des Apothekenmitarbeiters etwas genauer untersucht. Als „Positiv" gelten lachen, scherzhafte Bemerkungen, Zustimmungen, Bestätigungen der Patientenaussage (z.B. „Ja, das ist richtig.") und Komplimente an den Patienten. Als „Emotional" gelten Aspekte der Empathie (z.B. „Ich verstehe Ihre Bedenken."), Anteilnahme am Geschehen und sich zu sorgen (z.B. „Ich habe gehört, dass schwere Nebenwirkungen auftreten können."). Auch ermutigende und optimistische Aussagen (z.B. „Es wird nun besser werden.") und Bemerkungen, die auf eine partnerschaftliche Beziehung hindeuten (z.B. „Falls Sie noch irgendetwas brauchen sollten, dürfen Sie sich gerne wieder melden.") gehören dazu. Zu „Negativ" zählen Kritik (z.B. „Ich bin der Meinung, dass Ärzte heutzutage viel zu schnell Antidepressiva verschreiben.") und Ablehnung/ Unzufriedenheit (z.B. „Ich denke nicht, dass dies eine gute Idee ist.") Als „Sozial" gelten persönliche Anmerkungen, d.h. Bemerkungen, die über das gewöhnliche „Guten Tag" und „Auf Wiedersehen" hinausgehen. Ein Beispiel ist der Satz: „Wie fühlen Sie sich?". Auch Bemerkungen am Ende des Gespräches, wie z.B. „Ich wünsche Ihnen einen schönen Tag.", zählen dazu. Angaben gemäss Chong W. W. et al. (3)

Beratung

Die Erfassungen zu den Beratungsaspekten (Nr.34-69) werden mittels **Strichliste** durchgeführt. D.h. für jedes Medikament, bei dem einer der Beratungsaspekte angesprochen/erfragt wird, wird beim entsprechenden Kästchen ein Strich gesetzt. Die oralen Antikoagulantien (OAKs) bilden eine Ausnahme. Alle Angaben zu diesen Medikamenten werden mit einem Stern (*) gekennzeichnet.
Falls aber eine Frage zu mehreren Medikamenten gleichzeitig gestellt wird, z.B. „Kennen Sie die Anwendung der Medikamente bereits?" wird das Kästchen angekreuzt. Durch das **Kreuz** wird signalisiert, dass bei der Frage alle Medikamente gemeinsam angesprochen wurden. Dies unterscheidet sich vom Strichlisten-System, bei dem ein Strich ein angesprochenes Medikament wiederspiegelt.
Des Weiteren muss beachtet werden, dass es eine Farbunterscheidung bei der Dokumentation der Beratungen zu Erstbezügen und Wiederholungen gibt. Erstverordnungen werden mit roter Farbe und Wiederholungen mit blauer gekennzeichnet.
Es werden nur die Aspekte erfasst, die im Gespräch mit dem Patienten erwähnt werden. Besprechen die Mitarbeiter untereinander etwas, ohne dass der Patient mithören kann, wird dies nicht in die Wertung miteinbezogen.

Bei der Rubrik Beratung gibt es für jede Kategorie, resp. Unterkategorie (Auswahlmöglichkeit) zwei Kästchen zur Auswahl: F (für Frage) und E (für Erklärung). Diese Punkte beziehen sich auf das Handeln des Apothekenmitarbeiters. Stellt er dem Patienten eine Frage, wird beim entsprechenden Thema das Kästchen „F" ausgewählt. Gibt der Apothekenmitarbeiter anschliessend eine Erklärung dazu, wird zudem das Kästchen „E" ausgewählt. Falls der Apothekenmitarbeiter von sich aus erzählt, ohne den Patienten vorher etwas zu fragen, wird nur das zutreffende „E"-Kästchen ausgewählt.
Aber Achtung: Bestätigt der Apotheken- Mitarbeiter nur, was der Patient schon von sich aus erzählt hat und wiederholt davon nochmals das Wichtigste, wird kein Strich bei „E" gemacht. Nur wenn der Apotheker neue Informationen gibt, wird das Kästchen ausgewählt.
Es ist auch möglich, dass nur bei „F" ein Strich gezeichnet wird. Z.B. wenn der Patient auf die Frage des Apothekers mit „ja, ist schon bekannt" antwortet und daher keine Erläuterung gegeben wird oder wenn die Ausführung wegen einer Unterbrechung vergessen geht.

Gibt es bei den verschiedenen Kategorien mehrere Unterkategorien (Auswahlmöglichkeiten), so ist immer eine Mehrfachauswahl möglich, resp. jeder Punkt muss einzeln bewertet werden. Z. B. wird bei der Anamnese einzeln angeschaut, ob Begleitmedikation, Allergien, eine bestehende Schwangerschaft etc. durch eine Frage abgeklärt oder/und durch Wissenserläuterung des Apothekenmitarbeiters angesprochen wird.
Pro Unterkategorie kann somit eines, beide oder keines der Kästchen („F" und „E") ausgewählt werden.

Ob und wie der Patient in das Gespräch involviert ist, wird separat erfasst. Siehe dazu die Richtlinien von Nr. 32 und 33.

Achtung: Beim Ausfüllen der Beratungsaspekte muss das Auftreten einer Intervention immer im Kopf behalten werden, denn eine vertiefte Beratung z.B. zu Interaktionen oder einem anderen arzneimittelbezogenen Problem kann zu einer Intervention führen. Sobald ein Problem erkannt und eine aktive Reaktion vom Apothekenmitarbeiter dazu beobachtet wird, muss „Intervention –Ja" (Nr. 12) angekreuzt und ein PharmDISC Interventionsbogen ausgefüllt werden.

 Masterarbeit Jasmine Rupanner 10

Kategorie	Auswahlmöglichkeiten	Bemerkung
27-29 Beratung	• Beratungsangebot • Beratung in sep. Raum • # Medis beraten	Beratungsangebot wird angekreuzt, wenn die Frage „Kennen Sie dieses Medikament bereits?“ gestellt wird, resp. Abwandlungen davon, wie z.B. „Ist das Medikament schon bekannt?“. Das Kästchen wird somit nur angekreuzt, wenn eine allgemeine Frage vom Apothekenmitarbeiter gestellt wird, bei der kein konkreter Punkt der Beratungsaspekte (Nr.34-69) erwähnt wird. Sobald dies der Fall ist (z.B. „Kennen Sie die Anwendung des Medikamentes?“), wird das entsprechende Kästchen bei den Beratungsaspekten (hier z.B. „Anwendung-Wie“ bei F) angekreuzt, das Kästchen Beratungsangebot dafür nicht. Als Beratungsangebot zählt aber auch die Frage: „Haben Sie noch Fragen“ (Nr.69) Falls sich das Gespräch in einen separaten Beratungsraum verschiebt, wird dieses Kästchen angekreuzt. Sofern möglich, d.h. falls vom Patienten und Apothekenmitarbeiter erlaubt, folgt die Beobachterin und führt die Beobachtung fort. Ansonsten wird die Beobachtungsperiode an dieser Stelle abgebrochen und im offenen Bemerkungsfeld (Nr.75) ein Vermerk dazu gemacht. Zusätzlich werden alle Medikamente (mittels einer Strichliste) gezählt, zu denen mindestens ein Aspekt der Beratung angesprochen wird: „# Medis beratet“.
30-31 Patient abweisend	• Beratung abgelehnt • Medikament bekannt	Jegliche abweisende Haltung des Patienten dem Beratungsangebot gegenüber wird durchs Ankreuzen von „Beratung abgelehnt“ protokolliert. Z.B. die Äusserung, dass keine Zeit vorhanden sei. Falls der Patient eine Frage nach Bekanntheit z.B. („Ist die Anwendung des Medikamentes bekannt?“) mit „Ja“ beantwortet, wird zusätzlich „Medikament bekannt“ angekreuzt. Auch eine Unterbrechung der Ausführungen des Mitarbeiters zum Medikament mit dem Hinweis, dass dies schon bekannt sei, wird mit „Medikament bekannt“ gewertet.
32-33 Patient aktiv	• Patient erfragt Beratung • Patient erklärt	Wenn der Patient von sich aus eine Beratung vom Apothekenmitarbeiter erfragt, wird das Auswahlkästchen angekreuzt und die erfragten Themen (Nr.34-69) unterstrichen. Wenn der Patient dagegen etwas erklärt, sei das von sich aus ohne Aufforderung des Apothekenmitarbeiters oder als Antwort auf eine Frage, wird das Kästchen „Patient erklärt“ angekreuzt und hinter die entsprechenden Themen (Nr.34-69) ein Kreuz gesetzt. Sollte es vorkommen, dass bei mehreren Medika-

		menten die selbe Situation stattfindet, wird das Vorgehen dementsprechend wiederholt. Z.B. falls der Patient zu zwei neu verordneten Medikamenten die Nebenwirkungen beim Apothekenmitarbeiter erfragt, wird UAW zweimal unterstrichen. Als Erinnerungshilfe für die Beobachterin ist das Vorgehen auf dem Protokollblatt vermerkt: „erfragt" ist unterstrichen und hinter Nr. 33 ist ein Kreuz gezeichnet.
34-40 Anamnese	• Medis • Erkrankung • Allergien • SS/ ST • Familiär • Lifestyle • klin. Parameter	Bei der Anamnese werden verschiedene Themen unterschieden. Zu „Medis" zählen Medikamente der bisherigen Therapie, resp. zusätzliche nicht verschriebene Medikamente („Nehmen Sie noch zusätzliche Medikamente ein?") Zu „Erkrankung" zählen Begleiterkrankungen und Neudiagnosen. Zudem wird erfasst, ob eine vorhandene (Medikamenten-) Allergie oder eine bestehende Schwangerschaft (SS)/ Stillzeit (ST) abgeklärt wird. „Familiär" wird ausgewählt, wenn ähnliche Erkrankungen von Familienmitgliedern thematisiert werden. Des Weiteren gibt es die Auswahlmöglichkeiten „Lifestyle" (Rauchen, Sport, Ernährung, etc.) und „klin. Parameter" (Körpergewicht, Blutdruck oder andere Laborwerte).
41 Dosierung		Falls die Dosierung angesprochen wird, gibt es einen Strich.
42-44 Anwendung	• Wie • Dauer • Instruktion	Es wird zwischen generellen Anwendungsanweisungen (Wie einnehmen? Wo anwenden? Vor Gebrauch gut schütteln -> „ Wie") und der Behandlungsdauer (v.a. bei semisoliden Arzneimitteln, z.B. 30 min einwirken lassen -> „Dauer") unterschieden. Das Kästchen Instruktion wird ausgewählt, falls technische Instruktionen zur Anwendung, z.B. eines Inhalators, gegeben werden und die korrekte Anwendung vorgeführt, resp. gemeinsam geübt wird.
45-48 Einnahme	• Intervall • Dauer • Zeitpunkt • Modalität	Es wird zwischen dem Intervall (täglich, 2x täglich, alle 12h, bei Bedarf etc.) und der Therapiedauer (während 2 Wochen, bis Ende Monat etc.) unterschieden. Zur Einnahmedauer zählt auch die Erwähnung der Haltbarkeit von abgegebenen Medikamenten. Wird die Tageszeit angesprochen, zu der das Medikament eingenommen werden soll (morgens, am Mittag etc.), wird das Kästchen „Zeitpunkt" ausgewählt. Werden zusätzliche Aspekte angesprochen, die beim Timing der Medikamenteneinnahme beachtet werden müssen, z. B. zusätzliche Medikamente oder Mahlzeiten („mind. eine Stunde vor dem

		Essen einnehmen"), so wird das Kästchen „Modalität" mittels Strich versehen. Beim Erwähnen, dass der Einnahmezeitpunkt anderer Medikamente beim Timing dieser Einnahme beachtet werden muss, wird zudem „Interaktion" (Nr.59) weiter unten auf dem Protokollblatt ausgewählt und die dort erwähnten Richtlinien beachtet.
49-52 Schriftliche Info	• Etikette • Flyer/ Brosch. • Plan • Unterlagen	Falls eine Abgabe von schriftlicher Information zum Medikament, der Krankheit oder Handhabung von Hilfsmitteln erfolgt, wird ein Strich in das Kästchen gemacht. Es wird unterschieden zwischen einer Etikette auf der Medikamentenpackung, einem Flyer oder Broschüre, einem Einnahmezeitplan und notwendigen Dokumentationsunterlagen zu den Medikamenten wie z.B. ein Dokumentationsbuch fürs Selbst-Monitoring oder ein Patientenausweis bei Antikoagulatien. Falls ein Angebot für die Abgabe schriftlicher Information gemacht wird, wird „F" ausgewählt. Beim Punkt „Unterlagen" wird bereits ein Strich gesetzt, wenn abgeklärt wird, ob der Patient diese Unterlagen besitzt. Bei der Abgabe von schriftlichen Informationen wird „E" ausgewählt.
53 Indikation 54-56 Wirkung	• Wirkung (Grob) • Wirkmechanismus • Nutzen/ Therapieziel	Wird erklärt, wegen welcher Erkrankung/Diagnose das Medikament eingesetzt wird, gibt es einen Strich. Falls der Effekt beschrieben wird, gibt es bei „grob" einen Strich. (z.B. bei Antikoagulantien: „Das Medikament wirkt blutverdünnend.") Wird der Wirkmechanismus genauer erklärt, wird auch diese Auswahl ausgewählt. (z.B. bei Antikoagulantien: „Dadurch wird die Fibrinbildung im Blut gehemmt.") Davon abgegrenzt wird die Erwähnung des Nutzens des Medikamentes (z.B. bei Antikoagulantien: „Es verhindert die Thrombenbildung."). Fragt der Apothekenmitarbeiter nach, ob das Medikament bis anhin bei der Behandlung geholfen hat, zählt dies ebenfalls zu „Nutzen/ Therapieziel".
57 UAW		Werden Informationen zu potentiellen Nebenwirkungen gegeben oder nachgefragt, ob das Medikament bis anhin gut vertragen wurde, zählt dies zu „UAW".
58 Red flags		Wird ausgewählt, falls Warnsymptome angesprochen werden, bei deren Auftreten der Patient sofort handeln muss, z.B. den Arzt aufsuchen soll. Bei Erwähnung des Arztes wird zudem das Kästchen Nr.11 „Überweisung" ausgewählt.
59 Interaktion		Falls ein Interaktionspotential mit Medikamenten angesprochen wird, welches potentiell zu Symptomen führen kann, wird das Kästchen mit einem Strich versehen.

	Falls der Patient bereits Medikamente mit Interaktionspotential gleichzeitig einnimmt und manifeste Symptome abgeklärt werden, zählt dies ebenfalls dazu. Falls der Apothekenmitarbeiter die Interaktion nicht nur erwähnt, sondern aktiv dazu beratet und den Patienten schult, zählt dies als Intervention und folglich wird Nr.12 angekreuzt und ein PharmDISC Interventionsbogen ausgefüllt.
60 KI	Wird ausgewählt, falls Kontraindikationen thematisiert werden.
61-63 Einnahmefehler • Vergessene Einnahme • Unterdosierung • Überdosierung	Falls das Vorgehen bei allfällig auftretenden Einnahmefehlern Thema im Gespräch ist, wird das entsprechende Kästchen mit einem Strich versehen: Wie muss/ soll gehandelt werden bei einer vergessenen Einnahme, einer Über- oder Unterdosierung.
64 Lagerung	Falls Anweisungen zur korrekten Lagerung der Medikamente gegeben werden (z.B. im Kühlschrank lagern), wird das Kästchen ausgewählt.
65 Info an Gesundheitsp.	Ein Strich wird gesetzt, falls thematisiert wird, dass es bei gewissen Medikamenten (z.B. Antikoagulantien) wichtig ist, weitere Gesundheitspartner (z.B. Arzt, Zahnarzt) über deren Einnahme zu informieren.
66 Adhärenz	Falls während dem Gespräch Themen der Therapietreue angesprochen werden, wird dieses Kästchen ausgewählt. Es muss sich um ein explizites Adhärenz- Gespräch handeln.
67 Selbst-/ Monitoring	Selbst-Monitoring wird ausgewählt, falls die Durchführung/ Technik des Selbst-Monitoring erklärt wird und Termine der Durchführung angesprochen werden. Dies beinhaltet auch eine Anleitung zur richtigen Interpretation der gemessenen Parameter. Das Kästchen wird auch ausgewählt, wenn alternativ das Monitoring in der Apotheke oder beim Arzt erklärt wird. Es kann im Rahmen eines Gesprächs zu Adhärenz erwähnt werden, dann wird es zusätzlich zu Nr. 66 ausgewählt. Falls es aber unabhängig von diesem Kontext, also nicht in einem expliziten Gespräch zu Adhärenz angesprochen wird, wird nur „Selbst-/Monitoring“ Nr. 67 ausgewählt.
68 Follow up/ Betreuung Apo	Dieses Kästchen wird ausgewählt, falls der Apothekenmitarbeiter ein konkretes Angebot zur Reevaluation bei bestehen bleiben der Symptome/ Situation macht. z.B. „Falls sich die Symptome innerhalb einer Woche nicht verbessern, melden Sie sich wieder bei uns.“ Auch generelle Kontrolltermine in der Apotheke sind eingeschlossen, z.B. „Kommen Sie nächste Woche zur Nachkontrolle nochmals vorbei.“ Es zählen jedoch nur Termine in

		der eigenen Apotheke. Wird der Patient bei einem verbleiben der Symptome auf den Arzt verwiesen, gilt dies nicht als „Follow up", sondern als „Überweisung" (Nr. 11).
69 Informationsbedarf	• „Haben Sie Fragen?"	Ein Strich wird gesetzt, falls abgeklärt wird, ob noch Fragen/ Unklarheiten beim Patienten bestehen. Zusätzlich wird das Kästchen Beratungsangebot (Nr.27) angekreuzt.
70-71 OTC Verkauf	• OTC Wunsch • OTC Zusatzverkauf	Bei diesen beiden erfolgt die Erfassung auch mittels Strichliste. Zu OTC-Wunsch zählen OTC- Verkäufe, die auf dem direkten Wunsch des Patienten beruhen. Zu Zusatzverkauf zählen dagegen alldiejenigen OTC-Verkäufe, die durch die Beratung und den Vorschlag des Apothekenmitarbeiters ausgelöst werden.
70-74 Zusätzliche Dienstleistung	• # Zusatzverkauf nicht-med. • # Andere Dienstleistungen • Nicht-med. Beratung	Auftreten und Art von zusätzlichen Dienstleistungen wird erfasst. Die Anzahl an Zusatzverkäufen nicht-medikamentöser Art, z.B. Shampoos, Taschentücher, Pflaster etc. wird mittels Strichliste direkt auf dem Protokollblatt erfasst. Zu „andere Dienstleistungen" zählen z.B. Blutdruckmessungen und netcare. Die Anzahl dieser Dienstleistungen wird gezählt (Strichliste). Um welche Dienstleistung es sich genau handelt, wird im offenen Bemerkungsfeld (Nr.75) vermerkt. Zu nicht-med. Beratung zählen z.B. Beratung des Lifestyles, aber auch allgemeine Tipps, wie „Waschen Sie sich vor der Einnahme die Hände". Hier gibt es nur einen Ja/Nein-Entscheid mittels ankreuzen, falls beratet wird.

Sonstiges

Kategorie	Auswahlmöglichkeiten	Bemerkung
75 Kommentare	Offenes Bemerkungsfeld	Alle relevanten zusätzlichen Informationen werden hier vermerkt, die ungenügend durch die obigen Auswahlmöglichkeiten erfasst werden. Falls der Kommentar zu einem vorhandenen Auswahlkästchen gehört, wird die entsprechende Nummer notiert.
89 Vorhandene Unterlagen	• Rezeptkopie • Auszug repetierbarer Medikamente • PharmDISC Interventionsbogen	Sobald die genannten Unterlagen erstellt und dem Protokollblatt beigefügt wurden, wird das entsprechende Kästchen angekreuzt. Beim Interventionsbogen wird zudem vermerkt, wie viele pro Beobachtungsperiode ausgefüllt wurden (pro Intervention ein Interventionsbogen). Falls keine Interventionen stattfanden, wird die Anzahl 0 notiert. Anmerkung: Auf allen zusätzlichen Dokumenten

		wird der entsprechende Apotheken- und Beobachtungs-Code notiert.

Anmerkung zur Handhabung am Studientag:
Die Vollständigkeit der Unterlagen wird mithilfe von drei Klarsichtfolienmäppchen überblickt:

- **Rot:** Es fehlen noch Unterlagen wie Rezeptkopie oder Auszug der repetierbaren Medikamente. Zusätzlich können die Punkte von „Gelb" zutreffen.
- **Gelb:** Es fehlen noch handschriftliche Notizen, z.B. das Alter des Patienten und/oder es sind noch nicht alle Angaben anonymisiert worden.
- **Grün:** Das Dossier ist vollständig, inkl. aller Dokumente, handschriftlichen Ergänzungen und ist komplett anonymisiert. Das Dossier wurde mittels Bostitch zusammengeheftet.

Referenzen:

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2. Pharmaceutical Care Network Europe. Definition drug-related problem. http://www.pcne.org/working-groups/2/drug-related-problems. Accessed 2 Feb 2016.
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A3.1.6 The PharmDISC system (version 2.0, German)

PharmDISC : Dokumentation von pharmazeutischen Interventionen	
A Problem (1 Wahl) □ 1. Effektivität der Behandlung □ 2. Nicht behandelte Indikation □ 3. Risiko durch Behandlung □ 4. Behandlungskosten □ 5. Unzufriedenheit / Problem des Patienten □ 6. Technisches / formales Problem	**B Problemtyp (1 Wahl)** □ 1. Manifest, reaktiv □ 2. Potentiell, präventiv
C Grund der Intervention (1 Wahl) **1. Wahl der Behandlung** □ 1. Keine Übereinstimmung mit Richtlinien, nur suboptimale Behandlung möglich □ 2. Kontraindikation □ 3. Interaktion □ 4. Medikament nicht indiziert □ 5. Duplikation □ 6. Unerwünschte Wirkung □ 7. Fehlende Informationen betreffend Patienten **2. Wahl der galenischen Form** □ 1. Ungeeignete/r Verabreichungsform/ -weg **3. Wahl der Dosis** □ 1. Unterdosierung □ 2. Überdosierung □ 3. Unzweckmässiges Monitoring □ 4. Keine Dosisanpassung (z.B. Nieren, Leber, Alter)	**4. Anwendung des Medikamentes** □ 1. Ungeeigneter Zeitpunkt / Frequenz □ 2. Ungeeignete Anwendungsweise □ 3. Unangemessene Dauer der Behandlung **5. Patient** □ 1. Ungenügende Compliance □ 2. Ungenügendes Wissen □ 3. Bedenken / Sorgen wegen Behandlung □ 4. Finanzielle Belastung (Pat./Gesundheitswesen) **6. Logistik** □ 1. Verordnetes Medikament nicht verfügbar □ 2. Fehler im Medikationsprozess **7. Verschreibungsqualität** □ 1. Unvollständige / unklare Verordnung □ 2. Unleserliche Verordnung □ 3. Fehlende Verordnung notwendiger Hilfsmittel □ 4. Formaler / regulatorischer Grund Technisch
D Intervention (1 Wahl) □ 1. Substitution / Austausch □ 2. Dosisanpassung □ 3. Anpassung Packungsgrösse /-anzahl □ 4. Optimierung Verabreichungsmodalitäten/-weg □ 5. Abbruch der Behandlung / keine Abgabe □ 6. Beginn neue Behandlung / Fortsetzung	□ 7. Vertiefte Beratung des Patienten □ 8. Instruktion der Anwendung (Schulung) □ 9. Abgabe Compliance-Hilfe inkl. Beratung □ 10. Klärung/Vervollständigung Informationen □ 11. Weiterleitung von Informationen □ 12. Veranlassung Therapie Monitoring
E Kommunikation: Involvierte Personen ausser Apotheker (Mehrfachauswahl möglich)	
□ 1. Keine □ 2. Arzt	□ 3. Pflege / Spitex □ 4. Patient / Angehörige
F Resultat der Intervention (1 Wahl) □ 1. Akzeptiert und umgesetzt □ 2. Teilweise akzeptiert oder akzeptiert ohne Umsetzung	□ 3. Nicht akzeptiert □ 4. Verlauf unbekannt □ 5. Nicht anwendbar
Kurze Fallbeschreibung/ Bemerkungen	

A3.2.1 Interview

Universität Basel

Departement
Pharmazeutische Wissenschaften

DEPARTMENT OF PHARMACEUTICAL SCIENCES

Apotheken-Interview BABS 2016

Apo-Code: ☐☐☐ Mitarbeiter-Code: ☐☐☐

Während dem Interview werde ich Ihnen einige Fragen zu den zwei Themen Beratung rezeptpflichtiger Medikamente und Dokumentation von Interventionen stellen. Das Interview ist dementsprechend in zwei Teile gegliedert. Das Ziel ist es, Ihre persönliche Meinung zu erfassen. Daher gibt es keine richtigen oder falschen Antworten. Es sind Fragen, bei denen Sie frei erzählen/ aufzählen können, was für Sie persönlich am zutreffendsten erscheint. Ich möchte Sie bitten, dass Sie sich jeweils genug Zeit nehmen, um die für Sie zutreffende Antwort zu finden. Das Interview wird ungefähr 15 Minuten dauern.

Teil 1: Beratung von verschriebenen Medikamenten

Unter Beratung verstehen wir den Vorgang, bei dem personenbezogene und fachkundige Anweisungen gegeben und/oder Unterstützung angeboten wird.

1.) Was ist für Sie die Kunst der Beratung?

_____

_____

2.) Bei einem **Erstbezug**: Welche Themen sprechen Sie im Beratungsgespräch konkret an? Zählen Sie bitte die **für Sie** wichtigsten Themen auf.

2.1 ☐ Dosierung	2.2 ☐ Anwendung	2.3 ☐ Wirkung
2.4 ☐ Therapiedauer	2.5 ☐ Behandlungsdauer	2.6 ☐ Einnahmezeitpunkt
2.7 ☐ Interaktionen	2.8 ☐ UAW	2.9 ☐ KI/ RF
2.10 ☐ Anamnese	2.11 ☐ Adhärenz	2.12 ☐ Lagerung
2.13 ☐ Indikation	2.14 ☐ Nutzen/ Therapieziel	
2.15 ☐ Anderes:_____		

3.) Und bei einer **Repetition**: Welche Themen sprechen Sie im Beratungsgespräch konkret an? Zählen Sie bitte die **für Sie** wichtigsten Themen auf.

3.1 ☐ Dosierung	3.2 ☐ Anwendung	3.3 ☐ Wirkung
3.4 ☐ Therapiedauer	3.5 ☐ Behandlungsdauer	3.6 ☐ Einnahmezeitpunkt
3.7 ☐ Interaktionen	3.8 ☐ UAW	3.9 ☐ KI/ RF
3.10 ☐ Anamnese	3.11 ☐ Adhärenz	3.12 ☐ Lagerung
3.13 ☐ Indikation	3.14 ☐ Nutzen/ Therapieziel	
3.15 ☐ Anderes:_____		

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4.) Welches sind Ihrer Meinung nach die wichtigsten Faktoren, die eine umfassende Beratung **auslösen**?

Patient

4.1 ☐ Alter 4.2 ☐ Motivation/Interesse 4.3 ☐ Wissenslücken
4.4 ☐ Neukunde 4.5 ☐ Adhärenz 4.6 ☐ Fähigkeiten/ Fertigkeiten
4.7 ☐ Stammkunde 4.8 ☐ Spez. Krankheitsbild z.B. Demenz:_____
4.9 ☐ Spez. Patientenpopulation z.B. Kinder, Personen mit Sehschwäche:_____

Behandlung

4.10 ☐ Polymedikation 4.11 ☐ Zusätzlich OTC 4.12 ☐ Spez. Medikament:_____

Prozess/ Situation

4.13 ☐ Erstbezug 4.14 ☐ Repetition 4.15 ☐ Spitalaustrittsrezept
4.16 ☐ Beratungsraum 4.17 ☐ Genügend Zeit 4.18 ☐ Änderung im Therapieplan
4.19 ☐ Anderes:_____

5.) Welches sind Ihrer Meinung nach die wichtigsten Faktoren, die eine umfassende Beratung **erschweren**?

Patient

5.1 ☐ Ablehnung 5.2 ☐ Spez. Krankheitsbild, z.B. Demenz

Berater

5.3 ☐ Müdigkeit 5.4 ☐ Mangelnde Erfahrung

Prozess/ Situation

5.5 ☐ Team knapp 5.6 ☐ Wartende Kunden 5.7 ☐ Zeitmangel
5.8 ☐ Fehlende Privatsphäre 5.9 ☐ Fehlende Vergütung 5.10 ☐ Fehlendes Patientendossier
5.11 ☐ Fehlende Checkliste, Demonstrationsmaterial etc. vorhanden
5.12 ☐ Anderes:_____

6.) Welches sind Ihrer Meinung nach die wichtigsten Faktoren, die eine umfassende Beratung **erleichtern**?

Patient

6.1 ☐ Interesse (stellt Fragen) 6.2 ☐ Spez. Krankheitsbild, z.B. Demenz

Berater

6.3 ☐ Motivation 6.4 ☐ Erfahrung

Prozess/ Situation

6.5 ☐ vollständiges Team 6.6 ☐ Keine wartende Kunden 6.7 ☐ Genügend Zeit
6.8 ☐ Privatsphäre 6.9 ☐ Vergütung 6.10 ☐ Patientendossier
6.11 ☐ Checkliste, Demonstrationsmaterial etc. vorhanden
6.12 ☐ Anderes:_____

7.) Was ist Ihre persönliche Einstellung dazu, dem Patienten während der Rezeptausführung Fragen zu seinem Gesundheitszustand zu stellen?

_____

_____

8.) Welche Verhaltensweisen sind aus Ihrer Sicht für eine erfolgreiche Kommunikation mit dem Patienten ausschlaggebend?

8.1 ☐ Kunde integrieren	8.2 ☐ Fragen stellen	8.3 ☐ Zeit nehmen
8.4 ☐ Beziehung	8.5 ☐ Interesse zeigen	8.6 ☐ Augenkontakt
8.7 ☐ Zuhören	8.8 ☐ Offenheit	8.9 ☐ Empathie(auf Kunden eingeh.)
8.10 ☐ Anderes:_____		

9.) Haben Sie noch Bemerkungen/ Suggestionen zum Thema Beratung?

_____

_____

2. Teil: Dokumentation von Interventionen

Nun kommen wir zum zweiten Teil des Interviews, der sich um die Dokumentation von Interventionen dreht. Unter Interventionen verstehen wir jede aktive Reaktion auf ein entdecktes arzneimittelbezogenes Problem. Das Spektrum ist breit und reicht von vertiefter Patientenschulung und Substitutionen bis hin zur Dosisanpassung. In einer Studie aus Norwegen wurde eine Tendenz festgestellt, dass nicht alle Interventionen dokumentiert werden.

10.) Dokumentieren Sie Ihre Interventionen bei der Rezeptvalidierung?

10.1 ☐ Ja 10.2 ☐ Nein

11.) Falls ja, wie oft?

11.1 ☐ Selten 11.2 ☐ Manchmal 11.3 ☐ Oft 11.4 ☐ Immer

12.) Wie dokumentieren Sie die Interventionen?

_____

_____

13.) Ich lese Ihnen nun einen Satz vor. Sagen Sie mir bitte danach, wie zutreffend diese Aussage für Sie ist.
„Ich halte es für wichtig, dass die Interventionen der Apotheke dokumentiert werden können."

13.1 ☐ Trifft nicht zu 13.2 ☐ Trifft eher nicht zu
13.3 ☐ Trifft eher zu 13.4 ☐ Trifft zu

14.) Ich lese Ihnen nun einen Satz vor. Sagen Sie mir bitte danach, wie zutreffend diese Aussage für Sie ist.
„Ich halte es für wichtig, die durchgeführten Interventionen an involvierte Gesundheitspersonen, wie dem verschreibenden Arzt, weiterzuleiten."

14.1 ☐ Trifft nicht zu 14.2 ☐ Trifft eher nicht zu
14.3 ☐ Trifft eher zu 14.4 ☐ Trifft zu

15.) Was sind für Sie mögliche Gründe, dass Interventionen nicht weiterkommuniziert werden?

15.1 ☐ Zu aufwendig 15.2 ☐ Keine Rückmeldung 15.3 ☐ Kein einheitliches Dok.system
15.4 ☐ Fehlende Relevanz
15.5 ☐ Anderes:_____

 Masterarbeit Jasmine Ruppanner 4

Im Rahmen der Dissertation von Karen Maes, Mitarbeiterin der Pharmaceutical Care Research Group der Universität Basel, wird ein Instrument für die Dokumentation von Interventionen in Offizinapotheken entwickelt. Das Ziel ist es, dieses System in die Apothekensoftware zu integrieren. Ihre Meinung zu folgenden Fragen würde bei dessen Umsetzung helfen.

16.) Was halten Sie von einer Interventionshistory für jeden Patienten?

_____

_____

17.) Welche neuen Möglichkeiten würden sich dadurch Ihrer Meinung nach für den Beruf des Apothekers eröffnen?

_____

_____

18.) Was halten Sie von der Idee eines Pop-up Fensters, das nach jedem Abschluss einer Rezeptausführung automatisch auftaucht und nachfragt, ob eine Intervention stattgefunden hat?

_____

_____

19.) Wenn das Dokumentationssystem implementiert wird, was wäre für Sie hilfreich, um den Anwendungseinstieg zu erleichtern?

_____

_____

20.) Haben Sie Bemerkungen/ Suggestionen zum Thema Dokumentation von Interventionen?

_____

_____

CURRICULUM VITAE AND PUBLICATION LIST

On request