Development and testing of practicable strategies for professional pharmacy services, with medication adherence as an illustrative example

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An investment in knowledge pays the best interest

Benjamin Franklin

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LIST OF ABBREVIATIONS

ABC Taxonomy	Ascertaining Barriers to Compliance Taxonomy
ATC	Anatomical Therapeutic Chemical Classification System
BM-LQ	Das Tool zur Erfassung der Belastung durch die Medikation und der Lebensqualität
CDC	Centers for Disease Control and Prevention
CDM	Chronic Disease Management
CFIR	Consolidated Framework for Implementation Research
CMA	Continuous Multiple interval measures of medication Availability
COM-B	Capability, Opportunity, and Motivation-Behavior
CSA	Continous Single interval measure of medication Availability
DBI	Drug Burden Index
DOAC	Direct Oral Anticoagulants
DOT	Directly Observed Therapy
DRP	Drug Related Problems
ECHO	Economic, Clinical, and Humanistic Outcomes
EHD	Electronic Healthcare Data
EKNZ	Ethics Committee of Northwest and Central Switzerland
EMERGE Guidelines	ESPACOMP Medication Adherence Reporting Guideline
EPIS Framework	Exploration, Adaptation Decision/Preparation, Active Implementation, Sustainment Framework
EPOC	Cochrane Collaboration's Effective Practice and Organization of Care
ESC	European Society of Cardiology
ESPACOMP	International Society for Medication Adherence Working Group
FIP	International Pharmaceutical Federation
FISpH	Framework for the Implementation of Services in Pharmacy
FOCUS-PDCA	Find, Organize, Clarify, Understand, Select - Plan, Do, Check, Act
fokus°PDCA	find, organize, clarify (klären), understand, select ° Plan, Do, Check, Act
GIF	Generic Implementation Framework
GP	General Practitioner
GSASA	Swiss Association of Public Health Administration and Hospital Pharmacists
HC	Health Care
HCP	Health Care Professional

HRQoL	Health Related Quality of Life
I-CVI	Content Validity Index
IHS	Indian Health Service
IS	Implementation Science
ISO9001	International Organization for Standardization 9001
ISPOR	International Society of Pharmacoeconomics and Outcomes Research
MFI	Model For Improvement
MPR	Medication Possession Ratio
MRB	Medication-Related Burden
MRB-QoL	Medication-Related Burden Quality of Life Tool
MRC	Medical Research Council
MRCI	Medication Regimen Complexity Index
MTM	Medication Therapy Management
NHS	National Health Service
OTC	Over The Counter
PARIHS	Promoting Action on Research Implementation in Health Services
PCNE	Pharmaceutical Care Network Europe
PDC	Proportion of Days Covered
PDCA	Plan, Do, Check, Act
PDSA	Plan, Do, Study, Act
PharmDISC	Pharmacists' Documentation of Intervention in Seamless Care
PLEM	Patients' Lived Experience with Medicines
PRECEDE-PROCEED Framework	Predisposing, Reinforcing and Enabling Constructs in Educational/Environmental Diagnosis and Evaluation and the Policy, Regulatory and Organizational Constructs in Educational and Environmental Development Framework
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-analyses
QI	Quality Improvement
RADAR	Results, Approach, Deploy, Assess, Refine
RCT	Randomized Controlled Trials
RE-AIM	Reach, Effectiveness, Adoption, Implementation, Maintenance-Framework
S-CVA/Ave	Average Content Validity Index
SDCA-PDCA	Standardize, Do, Check, Act – Plan, Do, Check, Act
SMART	Specific, Measurable, Attainable, Relevant, and Time-bound
StaRI	Standards for Reporting Implementation Studies

STP-approach	Segmentation, Targeting, Positioning - approach
ΔT	Delta T
TDF	Theoretical Domains Framework
TDM	Therapy Drug Monitoring
TEOS	Timelines, Events, Objectives, Sources
TMF	Theories, Models, and Frameworks
WHO	World Health Organization

CONTENTS

SUMMARY

Introduction

To fulfill the newly defined role of a primary care provider, pharmacists must define and implement professional pharmacy services that are aimed at improving patients' health outcomes. One area in which the whole pharmacy team can provide valuable support to the patient is medication adherence. Depending on the source consulted, 25-50% of patients do not take their medication as agreed upon. Despite some promising medication adherence services that have already been implemented, few are sustained. The final step of scaling up an intervention from a few motivated patients in a controlled trial setting to a routinely provided service often fails. In general, implementation success is defined by three determinants: the service, the setting, and the process. However, in recent years, most research in pharmacy practice has been consistently focused on developing and evaluating new services rather than on the mechanism for successful implementation of existing services. Successful implementation and delivery of services for pharmacy teams depend on changing multiple behaviors and working processes. In addition, the pharmacy teams' experience in implementing new services is limited. Therefore, a focus should be on the successful implementation and delivery of professional pharmacy services. We hypothesize that the pharmacy team should be provided with a toolkit of practical strategies for each step during these processes that is, when taking medication adherence as an illustrative example, from screening for nonadherent patients to follow-up after the intervention. This thesis focuses on developing and testing practicable strategies for screening nonadherent patients, and implementing professional pharmacy services.

Goal

The goal of this thesis was the development and testing of practicable strategies for professional pharmacy services, with medication adherence as an illustrative example.

- **Project A** was developed to refine the groundwork for medication adherence screening in community pharmacies.
- **Project B** was developed to use implementation concepts in order to establish professional pharmacy services in community pharmacies.

Project A

Project A focused on collecting and assessing patient data on medication adherence.

Project A1 aimed at deriving a new adherence estimate from dispensing data of patients of direct oral anticoagulants (DOAC). The new estimate ΔT represents the difference between the calculated and effective refill day. With ΔT we characterized 2204 refill events from 116 DOAC patients with 19 refills. The medication possession ratio was high (0.975 ± 0.129) and showed a positive correlation with mean ΔT. Refills occurred on average 17.8 ± 27.9 days “too early”, with a mean of 75.8 ± 20.2% refills being “on time”. Four refill behavior patterns were identified, including constant gaps within or at the end of the observation period, which were critical.

Project A2 aimed at investigating medication adherence thresholds in relation to clinical outcomes. We conducted a systematic literature search. Six articles were included that assessed clinical outcomes linked to adherence rates in 7 chronic disease states. Five studies defined adherence thresholds between 46 and 92%. One study confirmed the 80% threshold as valid to distinguish adherent from nonadherent patients.

Project A3 aimed at translating the Medication-Related Burden Quality of Life tool (MRB-QoL) into German and assessing its practicality in primary health care. The MRB-QoL allows for measuring the burden of medication on patients' psychological, social, physical, and financial well-being. The translation and adaptation for primary health care resulted in a final 17-item German tool. For stakeholders, its practicality is in primary patient care as a screening tool for the general practitioner who initiate targeted interventions in collaboration with nurses and pharmacists.

The aim of **Project A4** was to develop and test a framework that allows pharmacy teams to define and apply a strategy to address medication adherence in community pharmacies. A framework based on the principles of social marketing was developed. It consisted of 3 items: the target patient ("Who"), the target plan ("How"), and the target goal ("How many"). Pharmacy teams tested the framework by developing strategies based on the three items and applying them during one pilot day. The pharmacy teams generated strategies that consisted of 18 different target patients and 20 different target plans. A total of 325 encounters were observed, of which 208 patients (64%) corresponded to the predefined target patients. Medication adherence was addressed with 73 patients (22.5%), and adherence counseling was performed with 50 patients (15%). The framework was accepted by the pharmacy teams who judged it feasible and adaptable to their needs.

Project A5 was a subanalysis of Project A4. Patients who were counseled about adherence (n = 50) were compared with patients who were not counseled about adherence (n = 275). The encounters with adherence counseling were on average 1.6 minutes longer (7.5 ± 5.2 min vs. 5.9 ± 4.8, $p = 0.002$). The number of counseling topics (excluding medication adherence counseling) was on average two per encounter and did not differ between both groups (2.04 ± 2.04 vs. 1.93 ± 1.93, $p = 0.762$). On average, 1.4 ± 0.6 topics of medication adherence were thematized during adherence counseling, mainly addressing patient-related issues (e.g., positive reinforcement, therapy/disease understanding, and motivation)

Findings of Project A

- A new absolute adherence estimate ΔT was developed that characterizes every refill event and highlights the dynamic of the refill behavior of DOAC patients.
- The 80% threshold in adherence calculation was questioned as a general standard for determining patients' medication adherence.
- The MRB-QoL tool was translated in German and adapted to a short version so that in the future, the patient's medication-related burden can be measured in the primary care setting.
- The proposed 3-item framework represents a simple tool that enables pharmacy teams to develop a strategy for addressing medication adherence in community pharmacies.
- Community pharmacy teams are able to counsel on a broad spectrum of patient-related issues when addressing medication adherence. Addressing medication adherence during patient counseling is not time-consuming and does not affect other counseling activities.

Project B

In **Project B,** implementation concepts were used to establish a new professional pharmacy service in community pharmacies with a focus on implementation strategies and outcomes.

Project B1 aimed at developing an implementation strategy for professional pharmacy services in community pharmacies that is based on the PDCA cycle. The developed implementation strategy named fokus°PDCA was designed to be used repetitively throughout the implementation process. First evaluations of the strategy resulted in good scores for usability, comprehensibility, acceptability, feasibility, and appropriateness.

The aim of **Project B2** was to evaluate the implementation of a new professional pharmacy service named TopCompliance with the use of the implementation outcomes defined by Proctor et al. During the 6-month pilot study, the five included pharmacies had on average 3.3 ± 2 active users of the service. At the implementation start, the agreement between pharmacy team members (n = 28) was high for appropriateness (75%) and adoption (92.3%), and discordand for acceptability (50%). After one month (n = 25), the agreement dropped remarkably (appropriateness: 36.5%, adoption: 53.8%, and acceptability: 3.8%). Feasibility was evaluated with 2.8±0.2 on a 4 point Likert scale. After the observation period of 6 months, 4 out of 5 pharmacies were still using the service (penetration: 80%), and two pharmacies planned to continue working with TopCompliance (sustainability: 40%).

Findings of Project B

- An implementation strategy for professional pharmacy services was successfully developed, piloted, and evaluated.

- Proctor et al.'s implementation outcomes were successfully adapted and tested for professional pharmacy services. They are practicable to evaluate the implementation process of professional pharmacy services repeatedly.

Conclusion

In the past, pharmaceutical care research has focused mainly on developing and evaluating professional services. The implementation gap (i.e., the poor implementation of these services) has only been acknowledged in the last decade by adapting implementation concepts in the pharmacy setting. To our knowledge, this thesis is one of the first that places a particular focus on the process and the deliverers of professional pharmacy services, i.e., the pharmacy teams:

- by providing the pharmacy team with screening tools for nonadherent patients,
- by applying implementation science concepts with a focus on strategies and outcomes to the pharmacy setting,
- by applying new methods and theories such as social marketing theory or process models to increase the participation of stakeholders in pharmaceutical care research.

Outlook

In the future, the pharmacy teams should have a toolbox of viable methods and strategies to identify nonadherent patients and provide professional pharmacy services to the patient. To realize the full potential of this work, the individual findings and strategies should be linked to the improvement of the process of pharmaceutical care in the area of medication adherence, and the provision of professional pharmacy services to the patient. The findings from Project A should be used to identify potential patients in need of medication adherence intervention. The findings from Project B should be used to implement professional pharmacy services. To link Project A and B and close the process loop of pharmaceutical care, the next step should be to develop tools that allow the pharmacy teams to tailor interventions to the patient. In addition, future projects should pursue the vision of providing pharmacy teams with a toolbox of strategies for screening nonadherent patients and implementing services by developing new strategies and evaluating the existing strategies.

GENERAL INTRODUCTION

The shifting role of the community pharmacist in health care

Since the separation between pharmacy and medicine by the Medical Order of Salerno in 1232, the pharmacist has been a researcher, innovator of new medicines/formulations, and trader rolled into one for almost 600 years.[1] The establishment of the study of pharmacy at universities in the 19th century marked a first remarkable shift in the role definition of the pharmacist. Most scientific activities were increasingly carried out in universities, whereas the pharmacist focused on the production and distribution of medicines. The rapid development of the pharmaceutical industry at the beginning of the 20th century redefined the role for a second time. The daily tasks shifted from mainly producing medication to increasingly medication-centered services, including testing the quality and identity of medication and providing advice around medication.[2] Fast forward to the 21 century, and the third shift seems to have happened, from a provider of medication-centered services to patient-centered services. In 2011, the declaration of "Good Pharmacy Practice"—published by the International Pharmaceutical Federation (FIP) in collaboration with the World Health Organization (WHO) defined four main roles in which society expects the pharmacist to be involved:[3]

1. Prepare, obtain, store, secure, distribute, administer, dispense and dispose of medical products.
2. Provide effective medication therapy management.
3. Maintain and improve professional performance.
4. Contribute to improve effectiveness of the healthcare system and public health.

After nearly 800 years of separation between the pharmacist and the general practitioner (GP), the two professions' defined roles and tasks seem to be converging once again in primary health care. The pharmacist should contribute to the care of patients, which was first envisioned by Helper and Strand in 1990, introducing the concept of pharmaceutical care.[4]

> *"Pharmaceutical Care is the pharmacist's contribution to the care of individuals in order to optimize medicines use and improve health outcomes."[5]*

Pharmaceutical care should be seen as an addition to the existing roles of pharmacists by addressing the medication needs of patients. The key features of this patient-centered care approach are [6]:

1. Collaboration with other healthcare professionals.
2. Prevention, identification and solution of drug-related problems.
3. Optimization of medicine use to improve patient outcomes and quality of life.

The pharmaceutical care process can be divided into five recurring steps (see Figure 1).[7, 8]

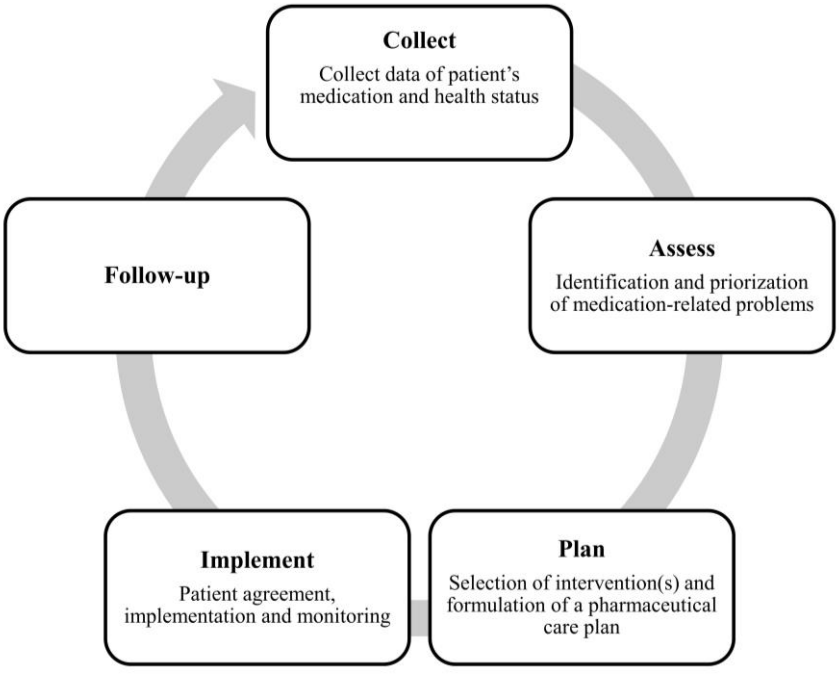


Figure 1 Pharmaceutical care process with five steps adapted from [7, 8]

From a medicines' specialist to a future primary care provider?

Despite the newly created environment with the expanded competencies of pharmacists in patient care and increased patient-based education of pharmacy students[9], the proportion of pharmacists' provision of primary care is still low.[10] Community pharmacists spent nearly half of their time on semiprofessional activities (i.e., activities that can be delegated to pharmacy technicians) and nonprofessional activities.[11] The next 10-15 years should mark the change of the community pharmacist to the role of a primary care provider, measuring outcomes, and managing populations' health.[6] To fulfill the newly defined role, the pharmacist has to introduce and implement changes with new patient-related processes that require the delivery of health interventions in the form of patient-centered services.

> Health intervention "*is an act performed for, with or on behalf of a person or population whose purpose is to assess, improve, maintain, promote or modify health, functioning or health conditions."[12]*

Defining pharmacists' services

There are multiple definitions of patient-centered services and ongoing discussions about how to characterize and classify them. The commonly used terms for patient-centered services delivered in pharmacies to improve patient outcomes are: "professional pharmacy services"[13], "cognitive pharmacy service"[14], or "pharmacist-led cognitive service"[15]. Since there is currently no official majority-supported definition and nomenclature, this work uses the following definition for convenience:

> Professional pharmacy service is defined as *"an action or set of actions undertaken in or organised by a pharmacy, delivered by a pharmacist or other health practitioner, who applies their specialised health knowledge personally or via an intermediary, with a patient/client, population or other health professional, to optimize the process of care, with the aim to improve health outcomes and the value of healthcare."[13]*

Professional pharmacy services should optimize the care process by implementing changes that benefit the patient and can be part of the solution against underprovision in primary healthcare due to the shortage of GPs and the aging of the population.[16] Effective chronic disease management (CDM) services are promising, especially in long-term care. The goals of CDM are to increase functional status, minimize distressing symptoms, prolong life through secondary prevention, and improve quality of life.[17] As a

medication expert, the community pharmacist could be part of an effective CDM by reducing drug-related adverse events and promoting better patient intake behavior.[18] This thesis has a particular interest in developing framework conditions for pharmacists to implement professional pharmacy services with an emphasis on improving patients' intake behavior i.e., medication adherence.

Medication Adherence

Defining medication adherence

In recent decades, an increased focus on improving medication therapy effectiveness and patient outcomes has been directed at inconsistent and non-users of medicines.[19] Initial studies by Haynes and Sackett in the 1960s first documented the irregular use of antihypertensive medicines.[20] The term "compliance" was introduced in 1975:

> Compliance *"is the extent to which a person's behavior (in terms of taking medication, following diets, or executing lifestyle changes) coincides with medical or health advice."[21]*

Thirty years later, the term "adherence" was established and refers more to the concept of shared decision making in which the therapy plan is discussed with the patient, the patient's values are explored, and the healthcare professional assumes a collaborative role in relation to the patient's goals and decisions.[22]

> Adherence *"is the extent to which a person's behaviour – taking medication, following a diet, and/or executing lifestyle changes – corresponds with agreed recommendations from a health care provider."[23]*

Taxonomy of medication adherence

The taxonomy for medication adherence defines three phases: initiation, implementation, and discontinuation.[24] The medication adherence process starts with the initiation of a therapy defined by the patient's first intake of a prescribed medication. The process continues with the implementation, which is defined as "*the extent to which a patient's intake behavior corresponds to the prescribed dosing regimen, from initiation until the last dose is taken."* The last phase is the discontinuation, defined as the time point when the patient stops the intake. The length of time between initiation and discontinuation defines persistence.[24] Nonadherence to medication is an umbrella term incorporating several situations where the medication is not taken as prescribed: late or non-initiation of the prescribed treatment, sub-optimal implementation i.e., irregular use of the medication, or early discontinuation of the treatment.[24] Therefore, not separating the medication adherence phases is a common source of measurement error and confusion in medication adherence studies.[25]

Measuring medication adherence

An appropriate quantification of the patient's intake behavior should be a cornerstone of medication adherence sciences.[24] The underlying problem is that the actual intake behavior can only be determined with intrusive methods such as directly observed therapy (DOT)[26] or newly developed technology such as digital pills with ingestible electronics.[27] These extensive methods raise ethical concerns about affecting patients' autonomy and represent an unpleasant form of surveillance. In addition, these methods are not widely used.[28] Several more practicable estimates for the intake behavior i.e., adherence parameters, have been developed for scientific and clinical settings (see Table 1). The adherence parameters are grounded in various measurement methods taken from different data sources.[29]

Table 1 Medication adherence measurement methods with corresponding advantages and disadvantages, adapted from Anghel et al.[30]

Measurement method	Advantages	Disadvantages	Parameter measured
Direct			
Therapy drug monitoring (TDM), measurement of drug/metabolite levels in the blood	Accurate Objective, proving the ingestion of the medication	Costly Invasive Inter-individual differences Only for a selection of substances	The concentration of the medication/metabolite
DOT, direct observed therapy	Accurate Objective, proving the ingestion of the medication	Costly Resource binding	The taking of the medication
Indirect			
Pill counts	Simple Inexpensive	Evidence of the medication being dispensed but no evidence that the medication is being ingested	The number of doses missed
Electronic databases	Easy to use Inexpensive Non-invasive, patients not aware that they are being monitored Specific to identify nonadherent patients	Evidence of the medication being dispensed but no evidence that the medication is being ingested	The maximum possession of medication as proxy for doses taken, most often Continuous Multiple interval measures of Medication Availability (CMA) such as Medication possession ratio (MPR) or Proportion of days covered (PDC)
Self-report tools (questionnaires, diaries, visual analog scales)	Easy to use Inexpensive	Overestimates medication adherence Subject is influenced by recall or reporting bias	A value that is interpreted in regards to a pre-established cut-off point
Electronic monitoring systems	Objective Additional information on the dynamics of medication adherence The most accurate methods	Expensive Primarily used in clinical trials The patient is aware of the evaluation No evidence that the medication is being ingested (except for ingestible electronics)	The time stamps allow a analysis of the doses taken and omitted, and the intervals between doses

Most parameters have in common that the use of the medicine is related to the estimated use over a certain time and is usually reported as an adherence rate (i.e., percentage). In some cases, adherence is also reported as a dichotomous variable (adherent/nonadherent) or classified into levels of adherence (low/medium/high level).[30] Most adherence parameters do not have a unit, resulting in different adherence rates that can be reported for the same patient depending on the method selected.[31] It even goes further, with different values being obtained with the same method and the same parameter when a different operationalization of the same measure was chosen.[32-34]

In literature, many authors have emphasized the problems that result from bad reporting, heterogeneity, and low accuracy of medication adherence measures.[35-37] Several literature reviews have derived recommendations for adherence measurement[29, 38-40] by reviewing different methods[41] or comparing different data sources. Still, there is no gold standard for adherence measurement methods.[29] The most appropriate measurement method depends on the underlying question of the researchers. Therefore, comparability will always be challenging to achieve.[42] To improve transparency, reproducibility, and facilitate comparisons of medication adherence studies, the International Society for Medication Adherence Working Group (ESPACOMP) has developed a framework that establishes the operational definitions of medication adherence based on the variables: Timelines, Events, Objectives, and Sources (TEOS)[42] (see Figure 2).

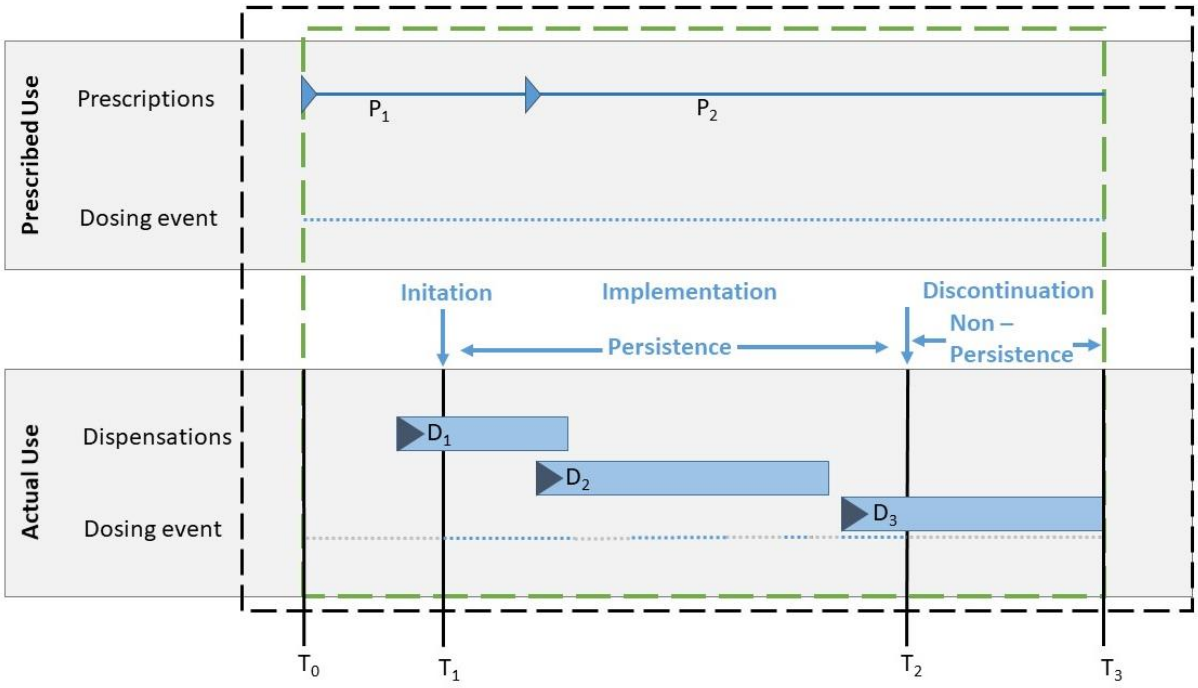


Figure 2 ABC-taxonomy of medication adherence [24] in blue; Dashed rectangles: Follow-up window (black) and observation window (green); P_1 First prescription, P_2 Second prescription, D_1 First dispensation, D_2 Second dispensation (First Refill), D_3 Third dispensation (Second Refill), T_0 First recommended dosing event, T_1 First actual dosing event, T_2 Last actual dosing event, T_3 Last recommended dosing event; adapted from Dima et al.[42]

Defining nonadherence

"Half of the patients are adherent to chronic medicines" is one of the most often cited statements in adherence research and originates from the WHO medication adherence report.[23] The report cites the study by Sackett and colleagues of 1975[43], one of the first randomized trials aiming to improve medication adherence in steelworkers with hypertension. Half of the 250 men recruited in this study had not taken at least 80% of their medicines. Despite the importance of these findings as a foundation pillar for establishing medication adherence research, this single study is not sufficient to establish 50% as the universal average level for medication adherence across populations, medications, disease states, and time.[44] A newer comprehensive review and meta-analysis suggest that the average adherence is higher, around 75%, across different diseases, medications, populations, and time.[45] Nevertheless, there can be significant differences in adherence between different medicines.[45, 46] Medication-related factors can play a decisive role, such

as a complex intake regimen, the way of application, or even the application technique such as e.g., an inhalation.[47] Also, the importance of medication adherence differs depending on individual patients' medicines or disease state, but a threshold for an unacceptable adherence level (i.e., nonadherence) is rarely defined. The Merriam-Webster Dictionary simply defines nonadherence as a "lack of adherence."[48] Most often, 80% is used as a universal threshold for distinguishing adherent from nonadherent patients.[44] The 80% threshold originates from the same study by Sackett with steelworkers from 1975.[43] There is an indubitable association between a high adherence level greater than 80% and improved outcomes.[49, 50] However, the 80% threshold is often chosen by researchers without clinical rationale and no prior exploration of the dose-response relationships of the used medicines.[51-53] Only recently, higher and lower thresholds have been proposed that better define clinically useful adherence cut-off points for specific populations, diseases, and medicines.[54-56] Despite the unclear definition of nonadherence, a consensus exists regarding the need for increased action to understand and improve nonadherence, and to prevent consequences such as emergency room visits, hospitalizations, and higher healthcare costs.[57-59]

Understanding the root causes of nonadherence

Medication adherence is a complex, constantly changing behavior that is influenced by over 771 factors.[60] These factors can have either positive, negative, or neutral effects on intake behavior.[60] According to the WHO, they are organized into the five dimensions of nonadherence: patient-related factors, social/economic factors, health system/health care team factors, condition-related factors, and therapy-related factors.[23] The reasons for nonadherence can depend on a single factor (e.g., fear of side effects) or can include a variety of factors that can be interdependent and/or influence each other. For example, unemployment (socioeconomic factor) influences the daily routine (patient-related factor) and can lead to low self-esteem (patient-related factor). Additionally, it has to be considered that nonadherence can be intentional[61], meaning an *"active decision on the part of patients to forego (discontinue, skip or alter) prescribed therapy."*[62] Some factors are modifiable, such as therapy-related factors (e.g., simplifying the medication regimen), and some are non-modifiable (e.g., ethnicity or cognitive impairment).[63] Frameworks such as the Theoretical Domains Framework (TDF) have been developed that simplify the multitude of behavioral problems that have been associated with medicine intake. With the TDF, researchers and practitioners have guidance in designing adherence interventions.[64]

The patient's perspective on medicine intake

A key component when considering the reasons for nonadherence is incorporating the patient's perspective and experience with the recommended treatment.[65, 66] The patient's experience can be described as the sum of all events involving medication treatment that a patient encounters in their lifetime.[67] This also includes negative experiences with medicine, which may have an impact on the psychological, social, physical, and financial well-being of an individual and can be defined as the medication-related burden (MRB; see Figure 3).[68] Health care professionals (HCPs) need to acknowledge that medication intake can be a burdensome experience for the patient and offer support to prevent nonadherence.[69]

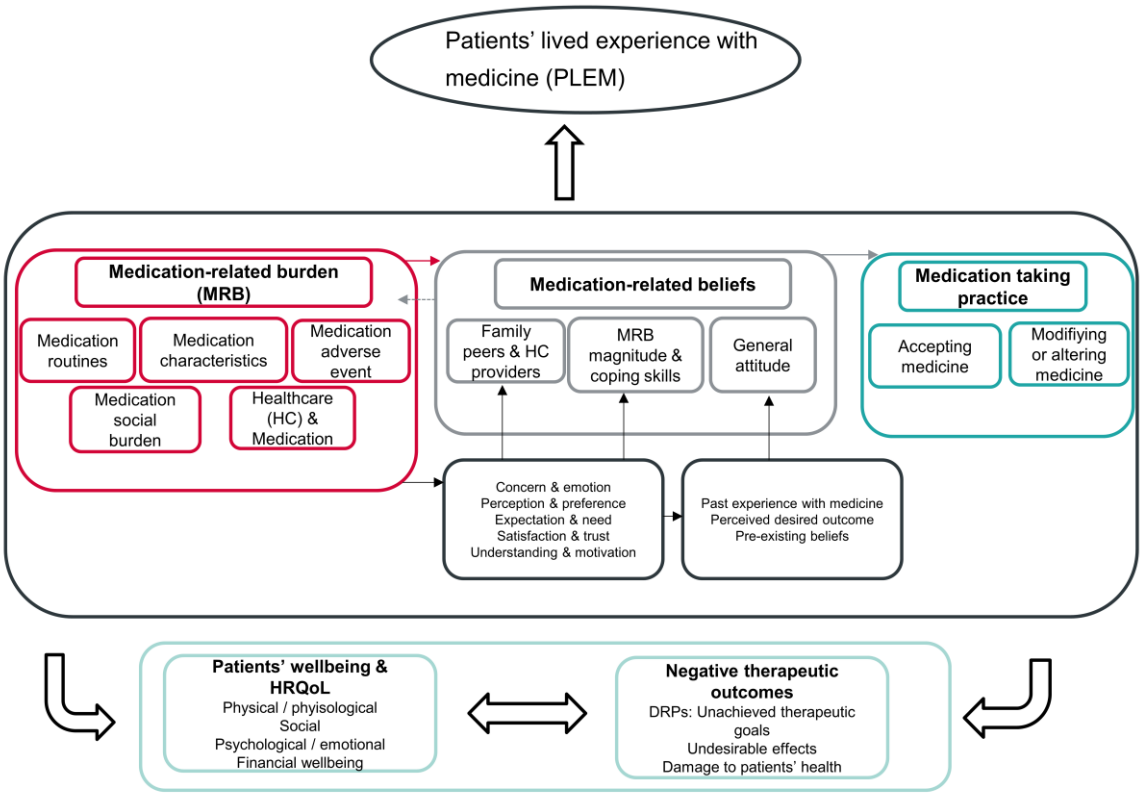


Figure 3 Conceptual model of patients' lived experience with medicines (PLEM) adapted from Mohammed et al.[69]; DRPs = drug-related problems, HC = Healthcare, HRQoL = health-related quality of life, MRB = medication-related burden

Improving medication adherence: Interventions

There is no universal key intervention that can improve the intake behavior of all patients. The multitude of developed interventions is as diverse and even as complex as the reasons why patients do not take their medicines as prescribed.[37] For some time, efforts have been made to improve the design of interventional studies. Thus, the International Society of Pharmacoeconomics and Outcomes Research (ISPOR) has developed guidelines for better reporting of adherence research studies[70, 71] and the EMERGE Guidelines (ESPACOMP Medication Adherence Reporting Guideline)[72] have been recently published to harmonize adherence results. Despite inconsistent evidence, there is agreement that multi-faceted interventions are more effective than interventions that try to solve a single aspect of nonadherence.[73, 74] According to a Cochrane review by Cross et al., interventions with mixed educational and behavioral interventions may improve medication adherence in older adults who are prescribed multiple medicines.[75] Nevertheless, no matter which approach has been chosen, no intervention had a large impact on medication adherence and

clinical outcomes.[37] In addition, it seems that the effect of initially promising interventions is only temporary.[75] A potential major factor for the small effect of interventions might be that most interventions are not strictly applied to nonadherent patients.[37] In 190 randomized controlled studies, only 6 (3%) of the studies included participants based on their level of adherence.[76] There is growing evidence suggesting that interventions can only be effective when they are tailored to the patient's needs.[77, 78] If intervention is “the key”, it should be precisely matched to the determinants for nonadherence; in other words, “the lock” of the patient, to “unlock” a better adherence behavior (see Table 2).[63] Therefore, Allemann et al. have advocated that adherence studies should select nonadherent patients, systematically measure individual factors at baseline, and select tailored interventions based on the (most important) modifiable factors in the study population.[76] Finally, the interventions should target current modifiable patient’s determinants and be tailored to the unmodifiable determinants.[63]

Table 2 Examples of matched medication adherence interventions and patient's determinants according to the 11 Theoretical Domains Framework (TDF) categories, adapted from Allemann et al.[63]

Domain	Interventions (Examples)	Determinants (Examples)
Knowledge	Adequate labeling	Knowledge about therapy and devices
Skills	Swallowing training	Physical difficulties
Social/professional role and identity	Contract	Relationship patient/healthcare professional
Beliefs about capabilities	Patient empowerment	Beliefs about self
Beliefs about consequences	Discuss: Beliefs, barriers, ambivalence to treatment, medication adherence	Beliefs about treatment
Intentions	Rewards (material, monetary)	Motivation
Memory, attention, and decision processes	Reminders (e.g., mailing, appointment)	Forgetfulness
Environmental context and resources	Tailor treatment to daily habits	Intrusiveness
Social influences	(Culturally modified) family intervention	Social/family support
Emotion	Psychological therapy	Psychological problems
Behavioral regulation	Point-of-care testing	Monitoring of treatment

Pharmacy-based medication adherence interventions

Pharmacy-based medication interventions already exist that can improve medication adherence.[79] Some are endorsed by governmental health organizations such as the Centers for Disease Control and Prevention (CDC)[80] or the National Health Service (NHS)[81]. The report "*Use of medicines by the elderly: The role of pharmacy promoting adherence"* by the International Pharmaceutical Federation (FIP) has defined five types of interventions that are already effective and implemented in community pharmacies[82]:

1. New medicine services, comprising education and counseling of patients by pharmacists when new medicines are dispensed, with follow-up face-to-face and telephone counseling sessions over the subsequent weeks.
2. Review, education, and counseling of patients and carers by pharmacists when continuing medicines are dispensed, with continuing reinforcement when the delivery of a dose requires a specific maneuver, particularly, for example, the use of inhaled medicines.
3. The provision of dose administration aids that facilitate taking the correct dose at the correct time.
4. Systems for reminding patients to take their medicines as prescribed.
5. Simplification of medication regimens by managing polypharmacy and reducing the frequency of dosing.

Despite the increasing provision of professional pharmacy services, there are great regional differences in implementing such services worldwide. In a European survey about professional pharmacy services, nearly half of the country representatives indicated low levels of service implementation.[10]

Implementing a professional pharmacy service

From a promising pharmacy-based medication adherence intervention to a professional pharmacy service

According to the new Medical Research Council (MRC) guidance, the development of complex interventions generally consists of four steps: 1) development, 2) feasibility/piloting, 3) evaluation, 4) implementation. In most scientific studies, the focus is on steps 1-3.[83] The final step is a comprehensive implementation in practice, and is often not carried out. Passing from an intervention with a few motivated patients to a routinely provided service often fails.[84] The reasons for implementation failure vary: First, some interventions may not be suitable in the community pharmacy setting because of the high amount of work and the time-consuming nature of the intervention.[85, 86] Second, the implementation depends on changing multiple behaviors and working processes in a pharmacy team. Third, during the introduction of the professional pharmacy service, various barriers such as poor communication with patients, insufficient interprofessional collaboration, or insufficient motivation can result in low service promotion.[87] In the past, the process of introducing a new service has been mainly addressed through the process of diffusion and dissemination.

> Diffusion *"is the passive, untargeted, unplanned, and uncontrolled spread of new interventions."[88, 89]*

> Dissemination *"is the active approach of spreading evidence-based interventions to the target audience via determined channels using planned strategies."[88, 89]*

It is now known that diffusion and dissemination are not sufficient to ensure that innovations are effectively integrated into the routine.[90] To ensure the long-term sustainability of new professional pharmacy services, more active approaches are needed that apply tailored and evidence-based methods based on implementation theory and research.

Implementation theory and research

Implementation can be described as *"the process of putting to use or integrating evidence-based intervention within a setting."[91]* In this context, implementation research focuses on assessing the most effective methods for implementing interventions sustainably.

> Implementation research *"is the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice, and, hence, to improve the quality and effectiveness of health services."[92]*

Implementation research produces knowledge used in the form of implementation theory and tools to support the implementation (see Figure 4). This includes identifying implementation factors, the most impactful implementation strategies, and mechanisms for sustaining and expanding effective services.[93]

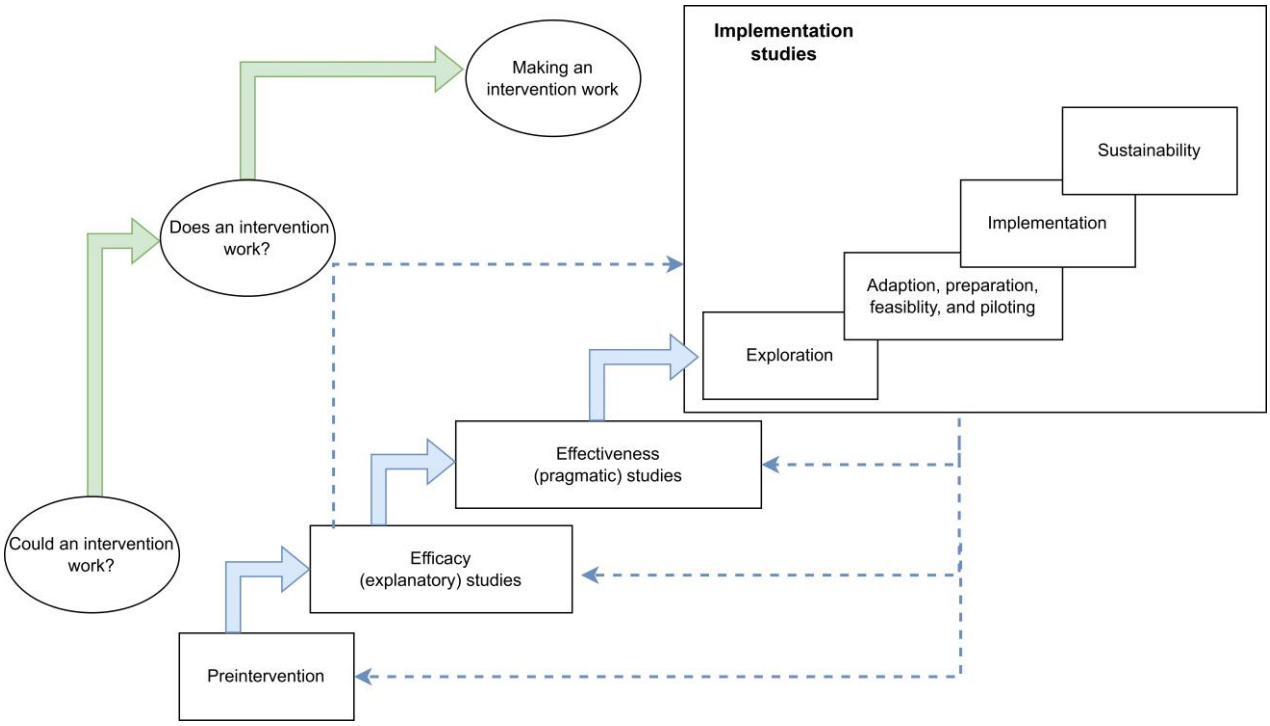


Figure 4 Role of implementation studies in the process from development to sustainability of an intervention, according to the Standards for Reporting Implementation Studies (StaRI).[94]

To gain insights into the mechanisms and factors that catalyze a successful implementation process, increasingly theoretical approaches are used by applying theories, models, and frameworks. Theories, models, and frameworks (TMFs) are essential to universalize implementation efforts and research findings, but the selection criteria for choosing a TMF are rarely described in papers.[95] Although theories are *"a set of analytical principles or statements designed to structure our observation, understanding, and explanation of the world"*[96], models involve a conscious simplification of a phenomenon or an aspect of a phenomenon.[97] Examples of applied theories and models are the "Theory of Diffusion"[98] or the "Model for change" by Grohl and Wensing.[99] In health care, frameworks are often used that *"are a graphical or narrative representation of the key factors, concepts, or variables to explain the implementation phenomenon*."[100] There are over 60 frameworks used in health care [101-104], including evidence-based examples such as the Promoting Action on Research Implementation in Health Services (PARIHS)[105, 106], the Consolidated Framework for Implementation Research (CFIR)[107], and the RE-AIM Framework (Reach, Effectiveness, Adoption, Implementation, Maintenance-Framework).[108] Despite their different theoretical background, theories, models, and frameworks are generally used with three goals:

1. Describing and/or guiding the process of translating research into practice,
2. Understanding and/or explaining what influences implementation outcomes,
3. Evaluating the implementation.

The TMFs can be categorized into five approaches (see Table 3).[109]

Table 3 Five theoretical categories of approaches used in implementation science, adapted from Nilsen.[109]

Category	Description	Examples
Process models	aim to describe and/or guide the process of translating research into practice, specifies steps (stages, phases) including the implementation and use of research. An action model is a type of process model that provides practical guidance in the planning and execution of implementation endeavors and/or implementation strategies to facilitate implementation	Model for change by Grohl and Wensing[99]
Determinant frameworks	specify types (also known as classes or domains) of determinants and individual determinants, which act as barriers and facilitators (independent variables) that influence implementation outcomes (dependent variables). Some frameworks also specify relationships between some types of determinants. The overarching aim is to understand and/or explain influences on implementation outcomes, e.g., predicting outcomes or interpreting outcomes retrospectively	PARIHS[105, 106], CFIR[107], FISpH[110]
Classic theories	originated from fields external to implementation science, e.g., psychology, sociology, and organizational theory, can be applied to provide understanding and/or explanation of aspects of implementation	Theory of Diffusion[98]
Implementation theories	developed by implementation researchers (from scratch or by adapting existing theories and concepts) to provide understanding and/or explanation of aspects of implementation	COM-B[111]
Evaluation frameworks	specify aspects of implementation that could be evaluated to determine implementation success	RE-AIM[108], Outcomes by Proctor et al.[112]

Implementation science and professional pharmacy services

Pharmacy researchers have used the concept of implementation science for implementing professional pharmacy services.[93, 113, 114] Implementation concepts will increasingly gain importance as one of the main drivers for transforming pharmacy practice.[93] Primarily, frameworks such as the CFIR have already been used for documenting barriers and facilitators of professional pharmacies services.[115] Further, they have been adapted for community pharmacy, resulting in a Framework for the Implementation of Services in Pharmacy (FISpH).[110]

The difference between implementation science (IS) and quality improvement (QI)

Although pharmacies are rarely exposed to the theories, models, and frameworks of implementation science (IS), quality improvement (QI) concepts are increasingly applied in daily routine in pharmacies with a quality management system such as ISO 9001.[116] IS and QI both share the ultimate goal of improving patient health outcomes.

> Quality improvement is defined as *"the combined and unceasing efforts of everyone – healthcare professionals, patients, and their families, researchers, payers, planners, and educators – to make the changes that will lead to better patient outcomes (health), better system performance (care) and better professional development (learning)."[117]*

The main differences between IS and QI are the triggers, the extent of efforts invested by the stakeholder, and the timeframe.[90] QI is generally initiated to address a specific issue at the local level, and results in testing change in rapid iterative feedback cycles.[118] The most prominent quality improvement method is the PDCA cycle, also called the Deming cycle, which has origins in the lectures of William Edwards Deming's in Japan in 1950.[119] The PDCA cycle is used for problem-solving, and includes the steps: 1) P for plan (definition of a problem and a hypothesis about possible causes and solutions), 2) D for do (implementing change), 3) C for check (evaluating the results), and 4) A for action (back to plan if the results are unsatisfactory or standardization if the results are satisfactory; see Figure 5). The PDCA cycle focuses on preventing the recurrence of errors by setting standards and continuously applying iterative, sequential cycles.[120]

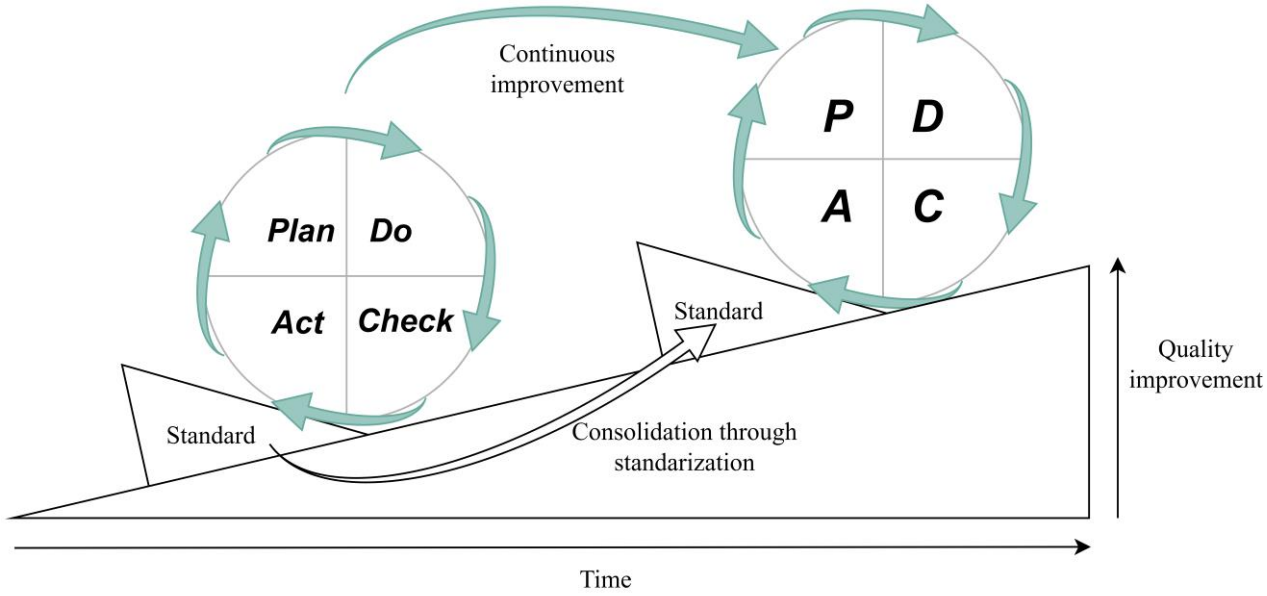


Figure 5 The Deming cycle, also called the PDCA cycle, for quality improvement described by the four steps: Plan, Do, Check and Act.[121]

The successful application of quality improvement measures can later be extended to an entire health care institution and eventually generalized to findings for the entire health care system (bottom-up approach). In comparison, the starting point in implementation science is often an evidence-based intervention or practice, and the adaptation and implementation into a health care system is explored.[84] Thereby, theoretical or conceptual models and validated measures during a more extended period, including a preparation and observation phase, are used (top-down approach). Nevertheless, there is considerable overlap between IS and QI, particularly because QI methods are often used as a strategy for implementing innovations into practice.[122]

Implementation process

Implementing innovation is a complex process that can be described as a *non-linear, recursive, reiterative progression of implementation*.[110] For simplification and illustrative purposes, implementation researchers break down the process into individual stages with process models or action models (see Table 3).[109] The number of process stages varies depending on the process model. In some derivations, the stages are further divided into activities. The situation is even more complicated by the fact that a process step can have different names in different process models.

Some examples of process stages of process models are:

- Orientation, Insight, Acceptance, Change, Maintenance (Model for Change by Grohl and Wensing)[99]
- Exploration, Adaptation Decision/Preparation, Active implementation, Sustainment (EPIS Framework)[123]
- Exploration/Adaptation, Program Installation, Initial Implementation, Full Operation, Innovation, Sustainability[124]

For the implementation of professional services in pharmacies, six stages can be defined according to Moullin et al.[110] (see Figure 6):

1. Development or Discovery: Development of the service by the pharmacy or pharmacy group and/or discovery of externally developed services.
2. Exploration: Assessment of whether the service fits into the pharmacy, as well as what benefits does the service bring to the pharmacy.
3. Preparation: Preparing the delivery of the service.
4. Testing: Trialing the service, operating for a defined period or with limited numbers.
5. Operation: Full rollout of the service.
6. Sustainability: Ongoing service provision, maintenance of supportive conditions, and persistence of service outcomes.

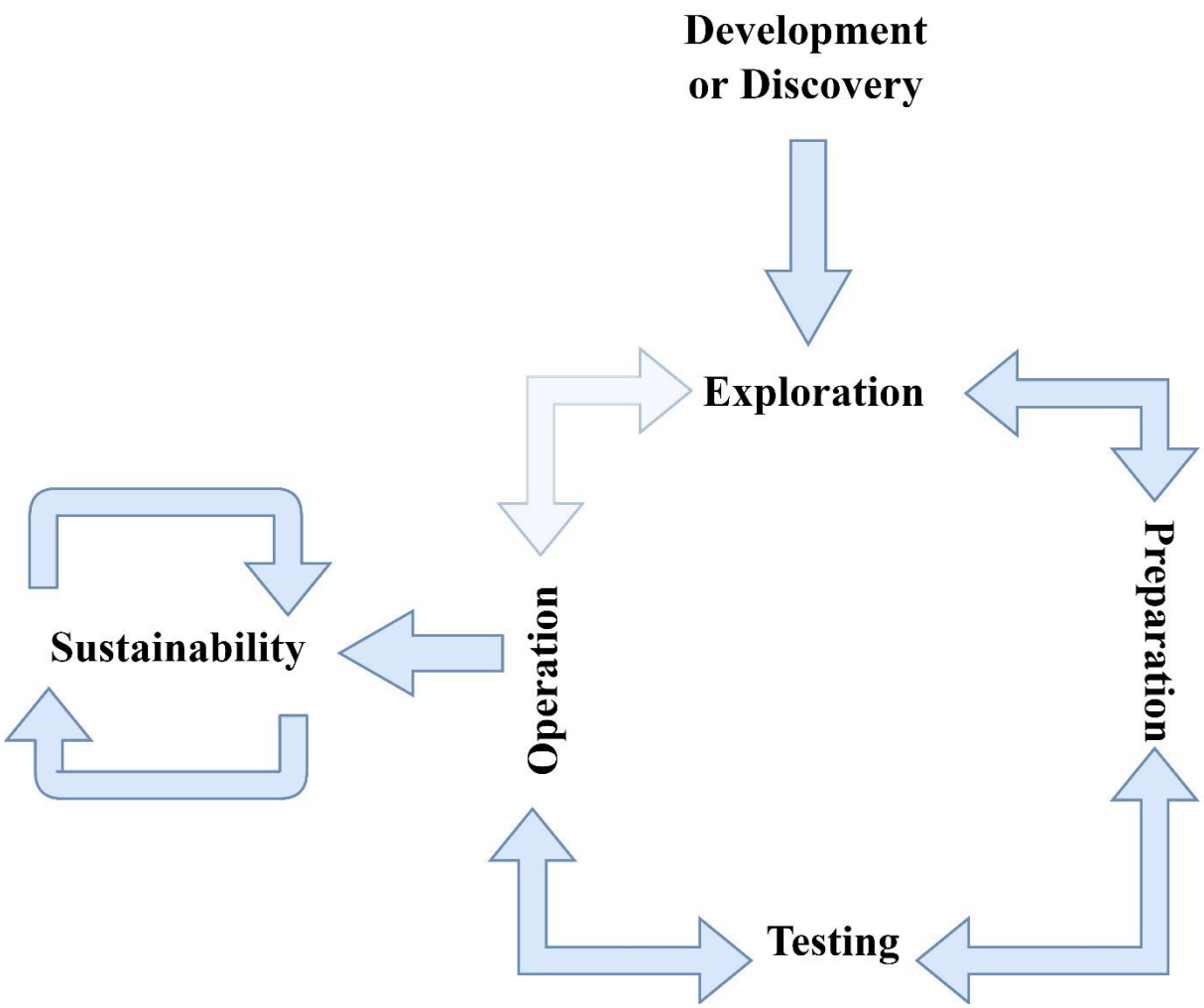


Figure 6 The six stages according to the Framework for the implementation of services in pharmacy (FISpH) that define the implementation process in pharmacies, adapted from[110]

Implementation factors: the key for understanding the implementation process

Implementation factors are variables that may affect the implementation process.[125] The factors can act as facilitators (i.e., positive moderator) or barriers (i.e., negative moderator) during the implementation process of professional pharmacy services.[126] Some of these factors are universal and may influence the implementation of any professional pharmacy service, whereas others are specific to the service, the target group, or the setting.[127] The factors can also influence different levels (i.e., domains) of the implementation process and outcomes, and can influence each other.[128] For the implementation of professional pharmacy services, the factors can be grouped into five domains: Service-related factors (e.g., complexity, patient recruitment), pharmacy staff-related factors (e.g., motivation), pharmacy-related factors (e.g., workplace, teamwork, workflow), local environment-related factors (e.g., patient demographics, interprofessional collaboration), and system-related factors (e.g., policy, legislation, economic climate; see Figure 7).[126]

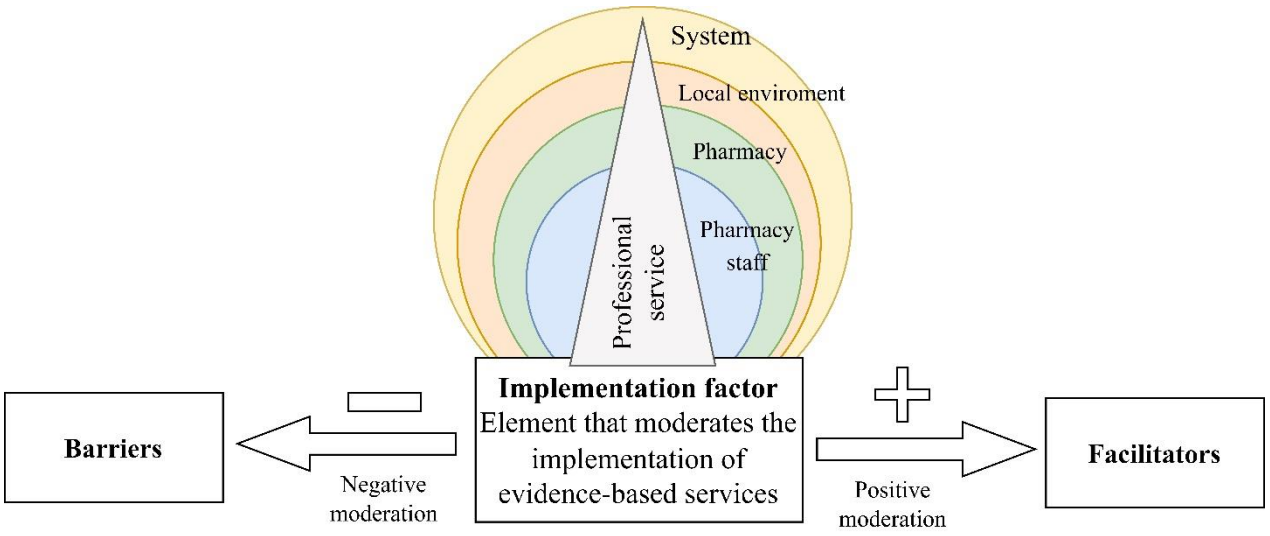


Figure 7 Implementation factors, barriers, and facilitators, adapted from[126]

Implementation strategies: improving the implementation process

To improve the implementation process, strategies should be used as facilitators or to overcome implementation barriers.[129]

> Implementation strategies are "*methods or techniques used to enhance the adoption, implementation, and sustainability of a clinical program or practice."[122]*

Implementation strategies operate at different levels (i.e., micro to macro-level) and are applied at different times (i.e., development to sustainability phase of the intervention) with different complexities. The definition and categorization pose a great challenge as most strategies may influence diverse processes during the implementation.[90] Powell et al. differentiated between discrete strategies (i.e., educational meetings), multi-faceted strategies (i.e., the combination of two or more discrete strategies such as developing academic partnerships and conducting educational meetings), and blended strategies (multiple discrete strategies that are combined as strategy package). Furthermore, a review and expert consensus approach was used to create a consolidated compilation of 73 discrete strategies grouped in nine clusters (see Table 4).[122]

Table 4 Categories of 73 implementation strategies into nine cluster groups with an example and the corresponding definition, adapted from Powell et al. and Waltz et al.[122, 130]

Cluster group[130]	Example of a strategy[122]	Definition of the strategy[122]
Use evaluative and iterative strategies	Conduct small cyclical tests of change	Implement changes in a cyclical fashion using small tests of change before taking changes system-wide. Tests of change benefit from systematic measurement and results of the tests of change are studied for insights into how to do better.
Provide interactive assistance	Provide local technical assistance	Develop and use a system to deliver technical assistance focused on implementation issues using local personnel.
Adapt and tailor to context	Tailor strategies	Tailor the implementation strategies to address barriers and leverage facilitators that were identified through earlier data collection.
Develop stakeholder interrelationships	Develop academic partnerships	Partner with a university or academic unit for shared training and bringing research skills to an implementation project.
Train and educate stakeholders	Conduct educational meetings	Hold meetings targeted toward different stakeholder groups to teach them about the clinical innovation.
Support clinicians	Remind clinicians	Develop reminder systems designed to help clinicians to recall information and/or prompt them to use the clinical innovation.
Engage consumers	Involve patients/consumers and family members	Engage or include patients/consumers and families in the implementation effort.
Utilize financial strategies	Alter patient/consumer fees	Create fee structures where patients/consumers pay less for preferred treatments and more for less-preferred treatments.
Change infrastructure	Change physical structure and equipment	Evaluate current configurations and adapt, as needed, the physical structure and/or equipment to best accommodate the targeted innovation.

Many of these strategies are already used in community pharmacies, but the selection is highly individual. In a sample of 21 Australian pharmacies implementing various professional pharmacy services, 51 out of the 73 strategies were used, but generally, only one or two pharmacies utilized the same strategy.[110] Alongside with the low uptake of implementation strategies, their effectiveness is modest.[131] Moreover, there are still ambiguities regarding the choice of the appropriate implementation strategy for a particular context or innovation[132] because of missing reliable evidence.[133] Several factors limit the understanding of how, when, where, and why implementation strategies are effective. The main contributing factor is the lack of documentation. In most implementation studies, the implementation strategies are not named, defined, nor specified.[134] The missing specification of strategies limits their generalizability for science and practice, and hinders the ability to determine if multi-faceted strategies are more effective than single-component strategies[135] or which components of multi-faceted and blended implementation strategies are the main contributor to a successful implementation.[136] Consequently, efforts have been made in the last few years to develop guidelines for transparent and accurate reporting of implementation studies, such as the Standards for Reporting Implementation Studies (StaRI) initiative that encourages researchers to report both the implementation strategy and the effectiveness of the intervention.[94] Besides naming and defining the strategy, the strategy should also be clearly specified by the following seven variables according to Proctor et al.: the actor, the action, target of the action, temporality, dose, implementation outcome, and justification (see Table 5).[134]

Table 5 Variables needed to specify the implementation strategy according to the recommendations by Proctor et al.[134]

Variable	Requirements
The actor	Identify who enacts the strategy (e.g., administrators, payers, providers, patients/ consumers, advocates, etc.)
The action	Use active verb statements to specify the specific actions, steps, or processes that need to be enacted
Action target	Specify targets according to conceptual models of implementation; identify the unit of analysis for measuring implementation outcomes
Temporality	Specify when the strategy is used
Dose	Specify dosage of the implementation strategy
Implementation outcome affected	Identify and measure the implementation outcome(s) likely to be affected by each strategy
Justification	Provide empirical, theoretical, or pragmatic justification for the choice of implementation strategies

Evaluating the implementation: defining implementation outcomes

It is essential to define outcomes for documenting the success of the implementation actions and evaluating their complex effect during the implementation process. Implementation outcomes should be specific additional measures besides clinical and economic outcomes, and evaluate the implementation of evidence-based interventions. They are increasingly applied in effectiveness studies for interventions with effectiveness-implementation hybrid designs.[137-139] Depending on the body of evidence for the intervention, three types of studies are proposed[140]:

1. Type I: Testing effects of a clinical intervention on relevant outcomes while observing and gathering information on implementation,
2. Type II: Dual testing of clinical and implementation interventions/strategies,
3. Type III: Testing effects of an implementation strategy while observing and gathering information on the clinical intervention's impact on relevant outcomes.

In literature, a diverse range of implementation outcomes have been proposed[112], such as the RE-AIM framework[108] or the PRECEDE-PROCEED framework.[141] However, and most prominently, eight distinct implementation outcomes are used: acceptability, appropriateness, feasibility, adoption, fidelity, implementation cost, penetration, and sustainability (see Table 6).[112, 142] In the context of the implementation of professional pharmacy services, it seems that implementation outcomes are rarely or not defined at all.[110] Few studies have assessed the implementation success with existing frameworks such as the RE-AIM framework[143, 144] or with new models that were specifically developed for evaluating implementation programs and professional pharmacy services.[104] However, implementation success is mostly still defined by the impact of the service on the clinical, economic and humanistic outcome while using RCT designs.[145]

Table 6 Implementation outcomes with corresponding definitions, according to Proctor et al.[112]

Implementation outcome	Definition
Acceptability	is the perception among implementation stakeholders that a given treatment, service, practice, or innovation is agreeable, palatable, or satisfactory
Adoption	is defined as the intention, initial decision, or action to try or employ an innovation or evidence-based practice
Appropriateness	is the perceived fit, relevance, or compatibility of the evidence-based practice for a given practice setting provider, or consumer; and/or perceived fit of the innovation to address a particular issue or problem
Feasibility	is the extent to which a new treatment or an innovation can be successfully used or carried out within a given agency or setting
Fidelity	is defined as the degree to which an intervention was implemented as it was prescribed in the original protocol or as it was intended by the program developers
Implementation cost	is defined as the financial impact of an implementation effort
Penetration	is defined as the integration of practice within a service setting and its subsystems
Sustainability	is the extent to which an evidence-based intervention can deliver its intended benefits over an extended period of time after external support

Rationale and Approach

To fulfill the newly defined role of a primary care provider, the pharmacist has to introduce and implement professional pharmacy services in areas such as medication adherence to ultimately improve patients' health outcomes. Despite some already promising implemented services, only a few are implemented sustainably.[10] Furthermore, the pharmacist is still mainly engaged in dispensing medicines and nonprofessional activities.[11] The reasons for the implementation failure of new professional pharmacy services are manifold, while implementation success can be simplistically determined by: what is implemented (the innovation), where it is implemented (implementation setting), and how it is implemented (the implementation process).[146] In recent years, the focus has mainly been on the "what" by developing and evaluating new services. It appears that the complex setting of community pharmacies ("where") and the implementation process itself ("how") were not the focus of the innovators of new services. We argue that a focus should be laid on the setting and the process in order to support the pharmacy teams who ultimately deliver professional pharmacy services. We hypothesize that the pharmaceutical care process steps should be followed in order to successfully deliver professional pharmacy services, especially for services focused on medication adherence (see Figure 8). The pharmacist needs a toolkit of practical strategies to follow the process steps. This thesis focuses on developing and testing practicable implementation strategies for three steps with medication adherence as illustrative example: First, this thesis focuses on the steps "collecting" and "assessing" patient data on medication adherence. We see these two elements as fundamental screening requirements for patients in need of professional pharmacy services. Second, this thesis focuses on the step "implementing". We argue that a structured and planned implementation of services in pharmacy is a fundamental prerequisite for successful service delivery.

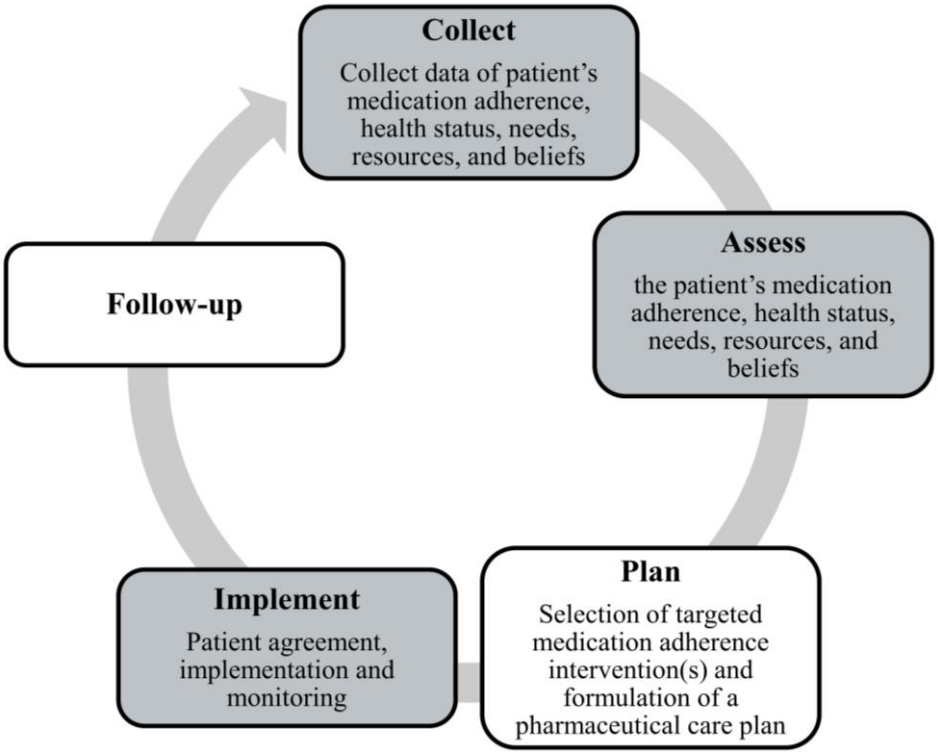


Figure 8 Model for the pharmaceutical care process with activities adapted from[7, 8] for the delivery of professional pharmacy services around medication adherence. A focus in the thesis was placed on the steps "collect" , "assess" and "implement" (gray color).

The goal of this thesis was the development and testing of practicable strategies for professional pharmacy services, with medication adherence as an illustrative example (see Figure 9).

- **Project A** was developed to refine the groundwork for medication adherence screening in community pharmacies
- **Project B** was developed to use implementation concepts in order to establish professional pharmacy services in community pharmacies

THESIS OVERVIEW

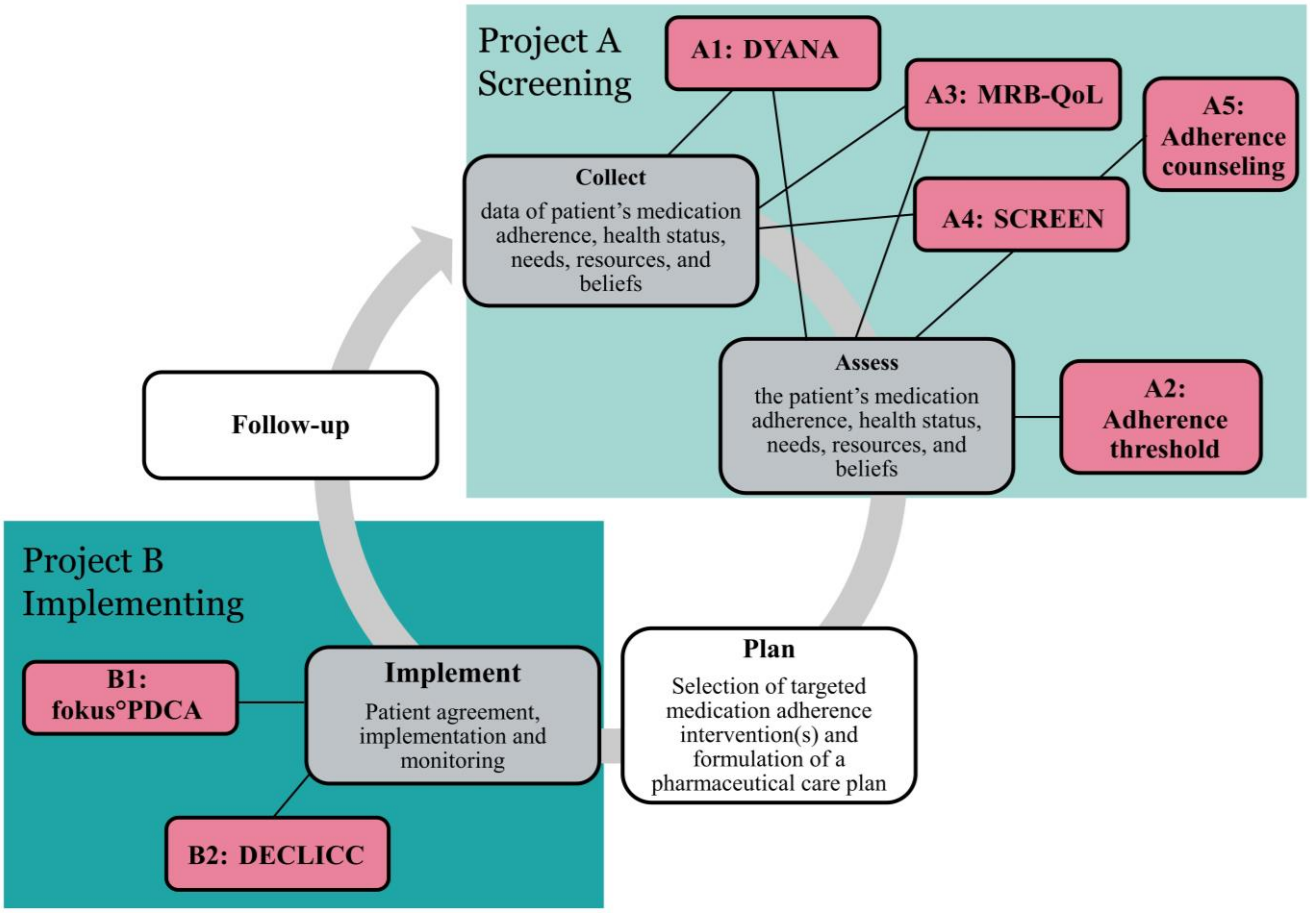


Figure 9 Overview of the seven projects developed in this thesis within the pharmaceutical care process delivering professional pharmacy services focusing on medication adherence

Table 7 Overview of projects, including the project description, title, and aim.

Project A

Goal: To refine the groundwork for medication adherence screening in community pharmacies

Project description	Title and Aim
A1- Project "DYANA" Developing a new adherence calculation method from pharmacy refill data	**Title:** Delta T, a useful indicator for pharmacy dispensing data to monitor medication adherence **Aim:** To derive a new absolute adherence estimate from dispensing data
A2- Project "Adherence threshold" Defining medication adherence thresholds depending on clinical outcomes	**Title:** A systematic review of medication adherence thresholds dependent of clinical outcomes **Aim:** To investigate medication adherence thresholds in relation to clinical outcomes
A3- Project "MRB-QoL" Assessing the medication related-burden of patients with a new tool	**Title:** Developing the German version of the MRB-QoL and defining its field of use, an instrument for measuring the burden of medicine on functioning and well-being in the primary care setting **Aim:** To translate the MRB-QoL tool into German, and assess its field of use in primary health care.

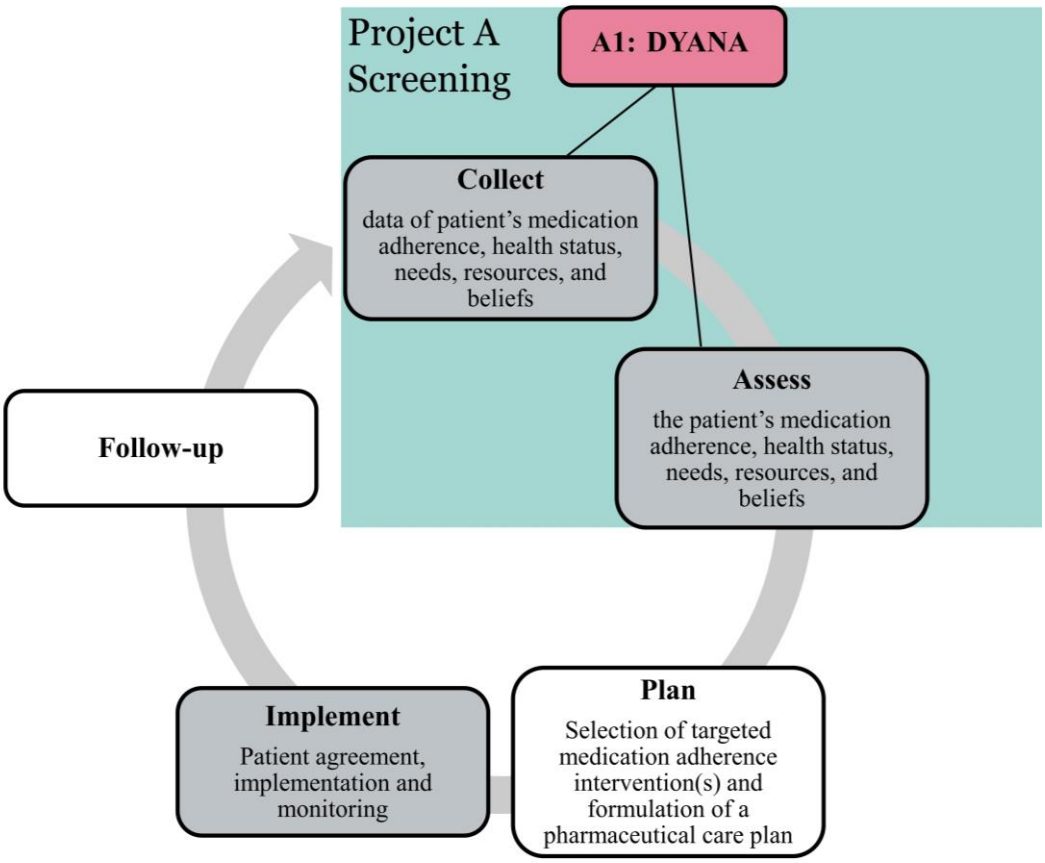
A4- Project "SCREEN" Proposing a framework for a strategy addressing medication adherence in community pharmacies	**Title:** Development and testing of a framework for defining a strategy to address medication adherence during patient encounters in community pharmacies **Aim:** To develop and test a framework that allows pharmacy teams to define and apply a strategy to address medication adherence in community pharmacies
A5- Project "Adherence counseling" Analyzing patient encounters with pharmacy teams with a focus on medication adherence	**Title:** Characteristics of medication adherence counseling encounters in community pharmacies **Aim:** To characterize the adherence counseling encounters in community pharmacies and compare the encounters with and those without addressed medication adherence

Project B **Goal:** To use implementation concepts to establish professional pharmacy services in community pharmacies	
Project description	**Title and Aim**
B1- Project "fokus°PDCA" Developing an implementation strategy for professional pharmacy services	**Title:** Development and piloting of an implementation strategy for professional pharmacy services: introducing the fokus°PDCA **Aim:** To develop an implementation strategy for professional pharmacy services in community pharmacies based on the PDCA cycle
B2- Project "DECLICC" Documenting the implementation of a professional pharmacy service	**Title:** How to prospectively document the implementation outcomes of a professional pharmacy service? - A case study **Aim:** To evaluate the adequacy of the implementation outcomes defined by Proctor et al. when a pharmacy team implements a new professional pharmacy service named TopCompliance

PROJECT A

Refining the groundwork for medication adherence screening in community pharmacies

A1- DYANA: Developing a new adherence calculation method from pharmacy refill data



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Article

Delta T, a Useful Indicator for Pharmacy Dispensing Data to Monitor Medication Adherence

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Abstract: Introduction: Calculating patients' medication availability from dispensing or refill data is a common method to estimate adherence. The most often used measures, such as the medication possession ratio (MPR), average medication supplies over an arbitrary period. Averaging masks the variability of refill behavior over time. Goal: To derive a new absolute adherence estimate from dispensing data. Method: Dispensing histories of patients with 19 refills of direct oral anticoagulants (DOAC) between 1 January 2008 and 31 December 2017 were extracted from 39 community pharmacies in Switzerland. The difference between the calculated and effective refill day (ΔT) was determined for each refill event. We graphed ΔT and its dichotomized version (dΔT) against the MPR, calculated mean ΔT and mean dΔT per refill, and applied cluster analysis. Results: We characterized 2204 refill events from 116 DOAC patients. MPR was high (0.975 ± 0.129) and showed a positive correlation with mean ΔT. Refills occurred on average 17.8 ± 27.9 days "too early", with a mean of 75.8 ± 20.2 refills being "on time". Four refill behavior patterns were identified including constant gaps within or at the end of the observation period, which were critical. Conclusion: We introduce a new absolute adherence estimate ΔT that characterizes every refill event and shows that the refill behavior of DOAC patients is dynamic.

Keywords: medication adherence; compliance; pharmacy claims; measures; cluster analysis

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1. Introduction

Electronic healthcare data (EHD) represent a non-intrusive, low-cost data source for the retrospective estimation of medication adherence in large populations [1,2] and can be used prospectively for adherence management [3,4]. Prescribing, dispensing, or claims data allow calculation of a patient's medication availability over a defined observation period. Different calculation methods exist, which mostly differ regarding one of three characteristics: the distribution of the medication adherence variable (continuous or dichotomous), the number of refill intervals (single or multiple), and the consideration of gaps [5]. The most used measures are continuous multiple interval measures of medication availability (CMA), such as the medication possession ratio (MPR) or the proportion of days covered (PDC). They represent the proportion of days' supply during the observation period [6]. For any calculation method, a record of each medication event and the duration of the supply (elaborated from the refill data) are mandatory [7]. Based on these variables, the numerator can be operationalized either as the sum of all day's supplies (MPR) or as the days covered with supply (PDC), and the denominator is the length of the observation period. The calculated rates are usually interpreted by setting a threshold to distinguish adherent from nonadherent patients [8–10]. The most often used threshold is 0.8 [11], while 0.95 is often applied for medicines requiring strict adherence such as direct oral anticoagulants (DOAC) [12]. The CMA is a single number with several limitations. The main limitation is the strong dependence on the defined observation window that delineates

the included medication events. As a consequence, different medication adherence rates may be obtained with the same patient data and may misclassify a patient as a non-adherer. Second, CMAs are aggregate measures, and the prediction of patients' refill behavior from CMAs is undifferentiated. As an example, CMAs cannot differentiate between a patient with a low implementation rate, and a patient with a high implementation rate who has discontinued their therapy, mainly because most EHD do not allow identifying precisely the time point of discontinuation [13]. Further, an aggregate estimate obscures the variability of refills over time i.e., the dynamic of medication adherence. Such inaccuracy deviates from consensus-based guidelines' advice on best practice in defining medication adherence (ABC-Taxonomy) [14,15] or reporting of empirical studies (EMERGE-guidelines) [16]. According to these new recommendations, medication adherence research should specify the medication adherence phases under scrutiny, that is, initiation, implementation, or discontinuation. Some new approaches have been recently developed on how to display the temporal refill patterns, in other words how to characterize a continuous single interval measure of medication availability (CSA). One variation involves calculating the PDC over two refill intervals (so-called time-varying PDC [17]). Another approach is to use shorter and potentially overlapping observation windows (so-called sliding windows) to obtain more precise statements about the patient's refill behavior [18]. To our knowledge, no study has analyzed the absolute relationship between single refill events from a patient population to characterize patient behavior, and the potential of this method has not yet been assessed. We hypothesize that opposite to MPR, the characterization of every single refill event allows depicting a patient's refill behavior over time. The usefulness of this new approach consists in delineating the dynamic of medication adherence. Our goal was to derive a new absolute adherence estimate from dispensing data.

2. Methods

2.1. Development of the New Estimate Delta T (ΔT)

We used the nomenclature for CSA and CMA proposed by Steiner et al. [5], the ABC-Taxonomy [15], the TEOS Framework [19], and the standardized elements according to Arnet [20] to develop the new estimate (see Appendix A). We specified that the new estimate describes every refill event (R_n) during the implementation phase of pharmacotherapy and defined implementation as consecutive dispenses with no gap of more than 182 days (=6 months). We assumed that every dispensing record includes exact single event dates and further variables so that the number of days' supply (A_n) and the refill interval (B_n) can be calculated [7]. Two dispensing events at least are needed. The new estimate Delta T (ΔT) is calculated at each refill event (R_n) as the difference between the number of days of medicine previously supplied (A_n) and the number of days in the corresponding refill interval (B_n). Positive values and zero ($\Delta T \geq 0$) indicate the number of days the patient has a sufficient supply at the refill event Rn, and negative values ($\Delta T < 0$) indicate days without supply or "gaps" before the next refill event (see Figure 1). We defined a dichotomized form of ΔT (dΔT) with 1 for "on time" refill events ($\Delta T \geq 0$; the patient obtained a refill before running out of supply) and 0 for "too late" refill events ($\Delta T < 0$; the patient had not enough supply to cover the period until the next refill). In the case of oversupply, the number of days' supply is carried over to the next number of days' supply ($A_n + 1$), thus assuming patients will terminate the oversupply before using the new supply. This approach should prevent the underestimation of medication adherence at the patient level over time [21,22].

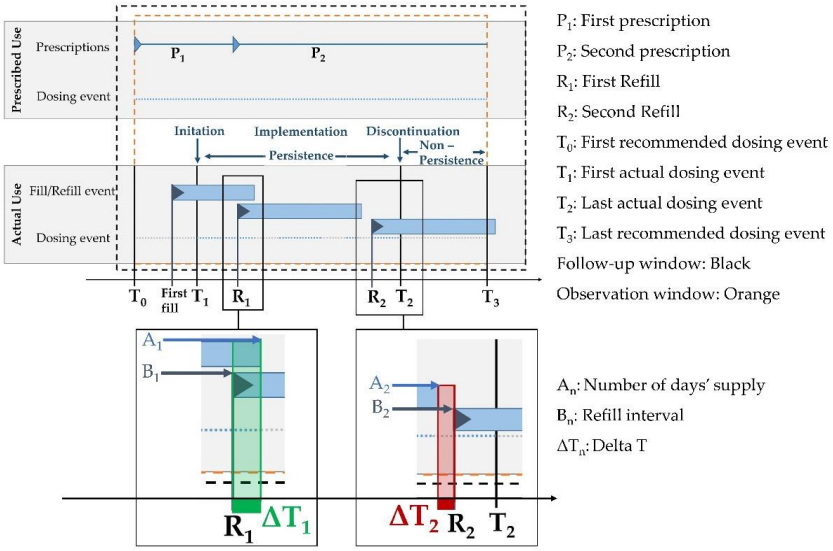

Figure 1. Visualization of a refill history of a fictitious patient with the phases of medication adherence according to the ABC taxonomy [11] (Adapted from Frontiers, 2018), the defined timelines and events according to the TEOS framework adapted from [15], and the characterization of the refill events with ΔT. Dots represent the dosing history with dosing event (blue) and without dosing event (grey). The backline of the triangles indicates the refill events and must not correspond to the dosing events (T0-T3). Blue bars represent the duration of the supply.

2.2. *Data Source*

We selected real-life dispensing data from TopPharm pharmacies in Switzerland. From the 130 independent pharmacies of the group, 39 (30%) agreed to participate in the study. We selected the direct oral anticoagulants (DOAC; ATC Codes: B01AF01, B01AF03, B01AF02, B01AE07) for their non-forgiving property that requires strict medication adherence. We extracted dispensing histories of patients with at least two dispenses (that is, one fill and one refill) between 1 January 2008 and 31 December 2017 (10 years coverage). For every case, we obtained patient characteristics: year of birth, gender, zip code, number of further medicines (=unique ATC Codes in the first 12 months after the first dispensing event of any DOAC in the follow-up period), and dispensing characteristics (date of the medication event, ATC code, the strength of the medicine supplied, quantity dispensed, prescribed daily dosage). We assumed that the higher the number of refills, the more likely it is that medication possession and consequently MPR will be high. Simultaneously, we expect variations in refill behavior that are sufficiently marked to be detected. Therefore, we selected all patients from pharmacy databases with at least 20 consecutive dispenses of DOAC. This should guarantee a theoretical refill period greater than 1.5 years, extrapolated from a package of 30 tablets that lasts for one month. Approval for the data export and extraction was obtained from the Ethics Committee of Northwestern Switzerland (EKNZ Nr. 2018-01490, 11 September 2018).

2.3. *Analytical Procedure and Statistical Analysis*

We calculated ΔT and dichotomized ΔT (dΔT) for each refill. The MPR was calculated for each patient according to Vollmer et al. [23] and the values were dichotomized following the common 80% threshold [11]. As recommended to fully understand the structure of the estimates [9], we characterized and graphed the distribution of the MPR, average ΔT, and average dΔT for each patient; and characterized the population by the descriptive statistics

of the mean value, standard deviation, the median, interquartile range (IQR), maximum (max ΔT) and minimum values (min ΔT). We graphed mean ΔT and mean dΔT against the corresponding MPR value of each patient to investigate how the average refill time corresponds to the medication availability, and computed Spearman's rank correlation to assess the relationship between MPR and ΔT. We plotted ΔT over the 19 refills for three illustrative patients to visualize the dynamic of different refill behaviors. The three illustrative patients showed a "perfect" MPR of 1; an MPR of 0.95 [12] and an MPR below 0.8 [11]. For each patient, median ΔT (IQR), mean ΔT ± standard deviation, max ΔT, min ΔT, the corresponding range (=max ΔT–min ΔT), dΔT [%], and the sum of days without supply (=sum of negative ΔT) were calculated. To see an overall trend in the refill behavior with increasing refill number in the population, we calculated mean ΔT per refill over all patients, the percentage of patients per refill who were "on time" ($\Delta T \geq 0$), and computed Spearman's rank correlation between ΔT and increasing refill number. To visualize the dynamics of different refill behaviors in the population, we plotted heat maps of ΔT and dΔT. We applied cluster analysis to classify patients into different refill behavior patterns. For this purpose, we used hierarchical cluster analysis with the dichotomized Euclidian method and the linkage method furthest distance neighbor measure. The data were analyzed with the Statistical Package for the Social Sciences (SPSS; Version 25.0 IBM Corporation, Armonk, NY, USA), or Microsoft Excel (Microsoft Office Home and Student 2016, Microsoft Corporation, Redmond WA, USA), or Tableau Desktop Professional Edition Version (2019.3.0, Tableau Software, Seattle, WA, USA). Heat maps were generated with Tableau Desktop Professional Edition Version (2019.3.0, Tableau Software, Seattle, WA, USA).

3. Results

3.1. Study Population

A total of 2919 pharmacy dispensing histories of patients were extracted of whom 116 (4%) patients had at least 20 consecutive dispenses (19 refills) of DOAC, corresponding to a total of 2204 refill events. At the first DOAC dispense, patients were on average 72.01 ± 10.91 years old with 54.2% women and were additionally obtaining a mean of 15 ± 7.84 different medicines during the next 12 months. The period for refilling 19 times the DOAC was on average 3.15 ± 1.28 years (range: 0.74 to 5.39 years). The mean supply duration was 59.7 ± 25.6 days (range: 14.7 to 98.0 days). The most often dispensed DOAC were rivaroxaban (69.3%) followed by dabigatran (15.7%) and apixaban (15%). A switch between DOAC was rare (16.1%) and was mostly from rivaroxaban to apixaban (54.5%).

3.2. Mean Delta T and Dichotomized Delta T

Overall, refills occurred on average 17.8 ± 27.9 days "too early" (see Figure 2A). The patients were on average 14 out of 19 times "on time" to refill their DOAC (mean dΔT: 75.8 ± 20.2%, see Figure 2B). A positive mean ΔT indicating DOAC oversupply was observed for 95 patients (81.1%).

3.3. Comparison with the Medication Possession Ratio

Mean MPR for DOAC was high with 0.975±0.129 and 104 (89.7%) patients with a MPR above 0.8 (see Figure 2C). There was a positive correlation between the two variables MPR and mean ΔT ($r(114) = 0.778$, $p = 0.001$, see Figure 2D).

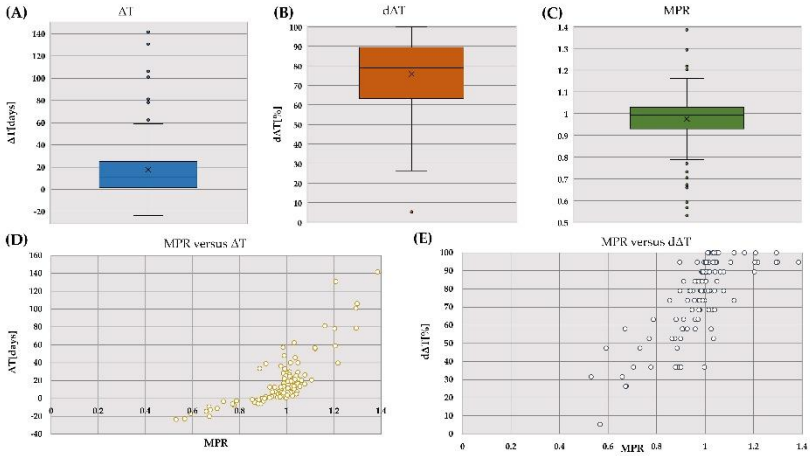

Figure 2. Upper panel: (**A**) distribution of ΔT around the mean of 17.8 ± 27.9; (**B**), distribution of dΔT around the mean of 75.8 ± 20.2%; (**C**) distribution of MPR around the mean of 0.975 ± 0.129 lower panel: (**D**) ΔT graphed against the corresponding MPR; (**E**) mean dΔT graphed against the corresponding MPR. MPR, medication possession ratio; ΔT, mean ΔT; dΔT, mean dichotomized ΔT. Refer to text for details.

3.4. Individual Refill Pattern of Three Illustrative Patients

Large fluctuations of ΔT over the 19 refills were observed for the three illustrative patients (see Figure 3) including refills that were "too late" (between 3 refills for the patient with an MPR of 1 and 7 refills for the patient with MPR of 0.78). The number of gaps in supply, that is, a negative ΔT, ranged from 12 (for the patient with MPR of 1) to 84 days (for the patient with an MPR of 0.78; see Table 1) with a different temporal pattern. The patient with an MPR of 0.78 presented gaps at the beginning and the end (refill number 6, 18), the patient with an MPR of 0.95 in the middle (refill number 10, 11), and the patient with an MPR of 1 at the end (refill number 15, 17) of the refill period.

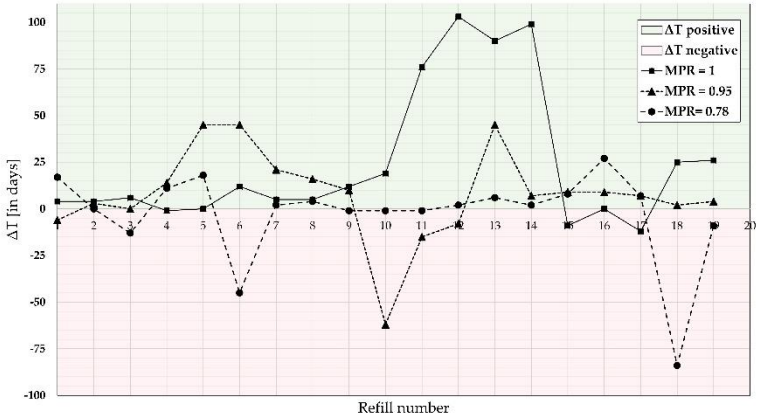

Figure 3. Unique refill patterns with ΔT from three illustrative patients with MPR of 1 (square), of 0.95 (triangle), and of 0.78 (dots) over the period of 19 refills. The green area above the x-axis indicates positive ΔT that is, refilling too early and oversupply; the red area below the x-axis indicates negative ΔT that is, refilling too late and gaps in DOAC supply.

Table 1. Values of ΔT for the three illustrative patients.

Patient	Median ΔT (IQR) [In Days]	Mean ΔT ± SD [In Days]	Max ΔT [In Days]	Min ΔT [In Days]	Range (=Max ΔT–Min ΔT) [In Days]	dΔT [%]	Sum of Days without Supply (=Sum of Negative ΔT) [In Days]
MPR = 1	6 (26)	24.4 ± 36.5.3	103	−12	115	84.2	22
MPR = 0.95	7 (16)	7.7 ± 23.4	45	−62	107	78.9	91
MPR = 0.78	2 (9)	−2.6 ± 23.9	27	−84	111	63.2	154

3.5. Refill Trend in the Population

There was a positive correlation between the refill number and mean ΔT (r (114) = 0.950, $p = 0.001$, see Figure 4). The values increased from one refill to the next by approximately 20% with an increase by 27.2 days from the first to the last dispense (mean ΔT_1: 4.9 days vs. mean ΔT_{19}: 32.1 days). The average percentage of patients that were "on time" fluctuated from refill to refill between 69.8% (ΔT_{11}) and 83.6% (ΔT_4) with no observed trend over time.

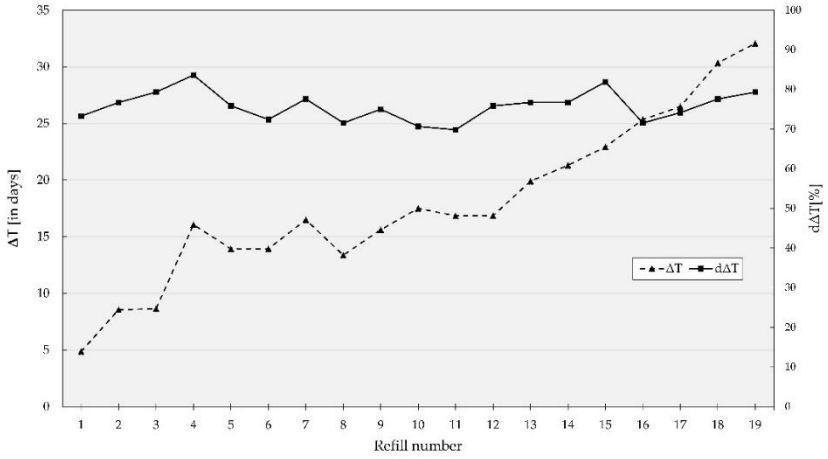

Figure 4. Scatter plots of ΔT (triangle) and dΔT (square) against the refill number over the period of 19 refills; *y*-axis in days (**left**) and percent (**right**).

3.6. Refill Groups within the Population

The 2204 individual DOAC refill events were visualized in heat maps that replicated all single ΔT (19 refills from 116 patients) with the color code green for refill events "on time" ($\Delta T \geq 0$) and red for refill events "too late" ($\Delta T < 0$). The picture obtained was standardized with a color gradient between −150 days (red) and +150 days (green, see Figure 5A). When values were dichotomized (dΔT), then the dominance of the green color appeared (see Figure 5B). When the cluster analysis was applied to dΔT, four different patterns were differentiated (see Figure 5C and Table 2). We characterized the largest group ($n = 71$; 61.2%) as patients who consistently refilled "on time", followed by erratic pattern ($n = 29$; 25.0%), gaps in the middle or at the end of the refill period (both with $n = 8$; 6.9%).

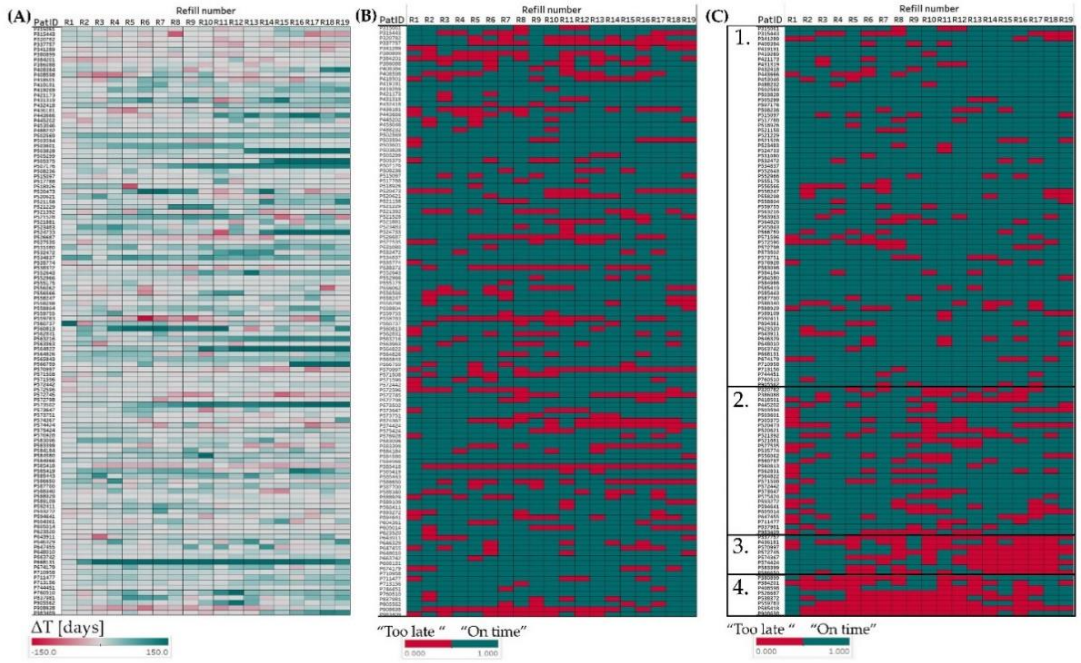

Figure 5. Heat maps replicating all 2204 ΔT (19 refills × 116 patients) per refill number with green color indicating refill events "on time" ($\Delta T \geq 0$) and red color indicating events "too late" ($\Delta T < 0$); (**A**) with a color gradient from +150 days (green) to −150 days (red); (**B**) after dichotomization into green ("on time") and red ("too late"); and (**C**) after clustering into the 4 refill groups: (1) refills are mostly "on time", (2) erratic refills, (3) gaps at the end of the refill period, and (4) gaps in the middle of the refill period.

Table 2. Characteristics of the four refill groups after clustering of the 2204 ΔT values obtained from 19 refills from 116 patients.

Cluster Number	Characterization of the Clusters	Number of Patients (%)	Mean Age ± SD [In Years]	Percentage of Women [%]	ΔT ± SD [In Days]	dΔT ± SD [%]	MPR ± SD
1	Refills "on time"	71 (61.2)	70.8 ± 10.3	54.9	25.4 ± 27.7	87.3 ± 10.2	1.01 ± 0.09
2	Erratic refills	29 (25.0)	75.1 ± 12.3	54.7	19.0 ± 29.7	72.1 ± 13.3	0.99 ± 0.10
3	Gaps at the end of refill period	8 (6.9)	70.1 ± 13.7	37.5%	−6.6 ± 7.8	39.5 ± 8.9	0.79 ± 0.13
4	Gaps in the middle of refill period	8 (6.9)	71.1 ± 12.3	62.5%	−12.0 ± 8.9	34.9 ± 15.1	0.75 ± 0.13

4. Discussion

In our data set comprising 116 patients with 19 refill events over up to 5.4 years, we were able to calculate ΔT for 2204 refill events for DOAC and showed trends of refill behavior that enabled us to define four different groups of refill patterns. In this highly selective sample with high MPR values and a small scatter, ΔT permitted a more differentiated characterizing of the refill behavior of patients compared to the MPR.

4.1. Estimating the Refill Behavior with Mean ΔT

The mean ΔT per patient showed a positive relationship with the medication possession ratio. However, a high MPR did not necessarily coincide with good refill behavior. As an example, up to 14 different ΔT mean values could be assigned to a "perfect" MPR of 1 (range 0.995–1.005, see Figure 2D). Therefore, ΔT can add valuable information to estimate medication adherence or can even be used as a more precise alternative to the MPR. Further, mean ΔT has the unit "days" and represents a more comprehensible value for researchers, health professionals, or policymakers for deciding what is an appropriate level of medication adherence compared to common CMAs. The 80% threshold to distinguish adherent from non-adherent patients [24–26] is mostly without clinical rationale [5,24,26] and with no precise picture of the exact patient refill behavior. The illustrative patient with an MPR of 95% had a median ΔT of 7 days and is considered as adherent according to the 80% threshold. However, patients also had gaps of −62 days during the 19 refills. In the case of non-forgiving medicines such as the DOAC where non-adherence can have fatal consequences [27], a potential 62-day gap of medication without supply can be risky at any time during the refill interval. Therefore, we question the 80% medication possession as a universally accepted threshold for good adherence [11] and suggest defining the allowable gap (that is, the negative ΔT) for a specific medicine according to a clinical rationale.

4.2. Documenting the Changing Refill Behavior with ΔT

Our DOAC population had a high MPR and a positive mean ΔT, but patients were still on average 5 out of 19 times too late for their refill in the pharmacy. This provided the first indication that refill behavior was not steady over time. The trend pattern of our DOAC population was an increased oversupply of about 20% per refill (calculated with ΔT), but a constant percentage of patients obtained their medication "on time" (calculated with the dichotomized form dΔT). This suggests that some DOAC patients have steadily accumulated oversupply and boosted the absolute ΔT at every refill. Even if no risky trend was observed in our population, "oversupplying" can be a critical refill behavior and has been associated with higher hospitalization rates [28,29] and increased health care costs [30]. The cluster analysis confirmed that the dominant patient group in our population were patients who refilled consistently on time or too early indicating sufficient possession of medicines. However, the cluster analysis showed that 16 patients nevertheless had gaps in their therapy. These patients present a different refill behavior that is best represented by longer breaks with no refills inserted between stable phases of sufficient supply. Different interventions are needed for these patients compared to the majority of balanced "oversuppliers". In addition, they will be potentially missed when only applying the MPR to selected non-adherers. We chose a hierarchical cluster analysis that allowed us to show the differentiated refill behavior. Among the potentially suitable methods for forming groups, we decided to apply the cluster analysis on dΔT. By choosing the dichotomized variable, the constant oversupplies were erased, and the focus was set on patients "at clinical risk", that is, with undersupply. Our method was able to detect 16 patients whose deviant refill behavior was dramatic and who required to be actively approached in the pharmacy. For predicting the refill behavior, group-based trajectory models could be applied to ΔT to differentiate patients into different trajectory groups. This method has been used for simulated medication adherence data [18] and real-life data [31,32]. Nevertheless, and independently of the clustering methods used, all these methods are equally useful to decide on the behavioral support the patient would need [18].

4.3. Potential Applications for ΔT in Research

With dispensing data, different values can be calculated to map the refill behavior of a population as a proxy for medication adherence. They are needed either for the description of population data or intervention studies. In the latter, the medication adherence estimate is usually compared before and after the intervention [33]. Hence, defining the beginning and the end of these observation periods is of paramount importance because the inclusion of

medication events at the edge crucially influences the calculated CMA values (such as MPR and PDC) [8–10]. This source of variability is not evident with ΔT. In population studies, ΔT delivers the average refill behavior, the refill trend, or the classification into different refill groups. These estimates enable a deeper insight into the refill behavior of a patient compared to MPR. Finally, for medication synchronization and reminder programs, ΔT could be considered rather than CMAs [34] because the effect of the intervention is measured more directly by answering the question: Do patients with reminders come earlier to the pharmacy? In contrast, CMAs answer indirectly the question: Does a reminder influence the medication availability? Therefore, ΔT can depict in-depth the refill behavior of a population and can evaluate directly whether an intervention can influence refill behavior.

4.4. Potential Applications for ΔT in Practice

Automated real-time measurements of medication adherence exist already in pharmacy software, such as the Australian Med Screen Compliance program. These programs help community pharmacies to improve and sustain medication adherence. The system alerts the pharmacist when the MPR is below 70% and suggests an educational-based intervention [35]. Our ΔT represents a suitable calculation base for automatized medication adherence calculation systems. Because the nature of medication adherence is dynamic [36], automated calculations with ΔT are potentially more suitable to screen for non-adherent patients than the MPR, as ΔT can preset the current refill behavior of the patient. In addition, the number of theoretically remaining tablets at the refill event can be easily calculated from ΔT. This corresponds to the principle of the "pill count" adherence measurement method, which is a frequently used measurement in clinical trials [37] but not in practice [38]. Therefore, the "pill count" based on ΔT could be used to adjust the days' supply instead of asking for feedback such as: "How many tablets have you still at home?". Depending on the answer, a medication adherence consultation could be offered. In addition, the presented visualization of ΔT as heat map, with the intuitive traffic light scheme color code using green for refills "on time" and red for refills "too late", could enable rapid detection of patients in need of a targeted intervention. In focus groups conducted by Fénélon-Dimanche et al. asking for the expectations of an electronic medication adherence tool based on prescription refills, the pharmacists wanted a table displaying medication adherence with a color code representing adherence level [39]. Compared to their proposed annual MPR and quarterly MPR, ΔT provides a more sophisticated mapping of patient behavior. Additionally, ΔT can be used as a quality or performance measure between pharmacies or health care plans by identifying "best practice" at a health care system level. Thus, ΔT could represent a pharmacy adherence measure that is comparable to the Pharmacy Quality Alliance measures that use the PDC [3,4].

4.5. Strength and Limitations

Our study has several strengths. First, ΔT is an absolute value with the unit "days" and is solely defined by the days' supply and the refill interval. This represents a major advantage compared to established possession estimates such as the MPR or PDC that are usually reported without units as rate or percentage [8–10]. As an example, different values are obtained for a patient with the same alleged CMA because of different calculation methods [8–10], which makes comparability of studies almost impossible [19]. Second, we defined and derived ΔT from the nomenclature for CSA and CMA proposed by Steiner et al. [5], the ABC-Taxonomy [15], and the TEOS Framework [19]. With this transparent definition, we hope that researchers will not create variations of ΔT that will hinder standardization and high-quality systematic reviews in medication adherence research [40,41]. Third, we used real life data for the development of ΔT. Thus, we demonstrated that our calculations not only work in theory, but also in practice. A trend could be detected, as well as four different refill behavior groups. Fourth, the cluster analysis were applied for patients with 19 refills. This corresponds to a mean observation period of approximately three years, which supports the strength of our calculation. This study also has several

limitations. First, our calculation with ΔT was focused on a single medication. Thus, the suitability of ΔT in polypharmacy remains to be shown. Variations of the MPR or PDC are already developed and used for polypharmacy [22,42,43]. Second, the mean supply duration varied between patients. This is linked to the commercially available package sizes and is an unmodifiable factor. Nevertheless, trends can be estimated. Third, the patient sample was highly selective. As expected, patients with 20 dispenses showed persistence in their therapy resulting in high medication possession rates. The largest cluster group included 71 patients who refilled their DOAC on time or too early and stockpiled with increasing refill numbers. Nevertheless, the advantage of ΔT is that even in this highly selective patient sample, patients with suboptimal refill behavior could be detected. To determine the true potential of ΔT as a useful indicator for pharmacy dispensing data, the next step should be to apply ΔT in a less selective population with a lower medication possession rate and fewer refills. Fourth, due to the selected population, the sample was small with only 116 patients. In general, CMAs are used in large EHD, which have 10 to 1000 times more patients [21,36,44]. However, it is common to use either simulation samples or small data sets when developing medication adherence measures [18,43]. Fifth, clinical data for the involved patients were sparse so that any association between the index and a clinical outcome was impossible to draw.

5. Conclusions

We introduced Delta T, a new absolute medication adherence measure that can characterize every refill event of a patient. Its potential applications are manifold. In practice, Delta T may support targeted, evidence-based interventions for medication adherence. In research, Delta T represents a more specific estimate compared to MPR. In our population of DOAC patients, the percentage of patients who refilled "on time" remained steady while the absolute ΔT increased, indicating few constant over-suppliers inflating ΔT. Still, it was possible with ΔT to show the dynamism in refill behavior and filter out the few patients in need of targeted medication adherence interventions. Further studies need to demonstrate the association of the new index Delta T with a clinical outcome that would require a follow-up after a targeted intervention.

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Institutional Review Board Statement: The study was conducted according to the guidelines of the Declaration of Helsinki and approved by the Ethics Committee of Northwestern Switzerland (EKNZ Nr. 2018-1490, 11 September 2018).

Informed Consent Statement: Patient consent was waived as all patients agreed that their anonymized data could be passed on to third-party providers for research purposes.

Data Availability Statement: The data presented in this study are available upon request from the corresponding author.

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Conflicts of Interest: The authors declare no conflict of interest. ProPharma Systems AG and AARDEX Group had no role in the design of the study; in the collection, analyses, or interpretation of data; in the writing of the manuscript, and in the decision to publish the results.

Appendix A. Elements for Calculating ΔT

Element	Definition	Standard and Calculation
Medication event [19]	Prescribing or dispensing record of a given medication with a given strength.	M
Refill event	Prescribing or dispensing record of a given medication with the exclusion of the first medication event	R = M−1
Start and endpoints of the observation period [20]	The period starts at t_0 and ends at t_n or t_a	t_0 = date of first medication event t_n = date of last refill t_a = arbitrary date
Observation period [20]	Number of days in the entire period	$t_n - t_0$ or $t_a - t_0$
Quantity dispensed [20]	Number of dispensed medication units (e.g., tablets, pills, etc.)	$[quant\_disp]_n$
Prescribed daily dosage (PDD) [20]	Amounts of units to be consumed per day according to the dosing instructions	PDD_n = number of units per dose x number of doses per day
Number of days' supply (A_n) with oversupply	Number of days medication available with oversupply	$([quant\_disp]_n / PDD_n) + C_{n-1}$
Refill interval (B_n) [20]	Number of days between two dispensations	$t_n - t_{n-1}$
Delta T (ΔT)	Difference between number of days' supply and refill interval	$\Delta T_n = A_n - B_n$
dDelta T (dΔT)	Dichotomized Delta T	$d\Delta T_n = A_n - B_n$ If $\Delta T_n \geq 0 = 1$ If $\Delta T_n < 0 = 0$
Oversupply (C_n) [20]	Number of days' supply accumulated from previous dispensing (stockpile)	If ΔT > 0
Gap (D_n) [20]	Number of days without medication supply	If ΔT < 0
Medication adherence measures for comparison: Medication possession ratio (MPR) [23]	CMA1 = number of days dispensed, excluding the last refill/first to last dispensing	$(\sum A_{n-1})/(t_n - t_0)$

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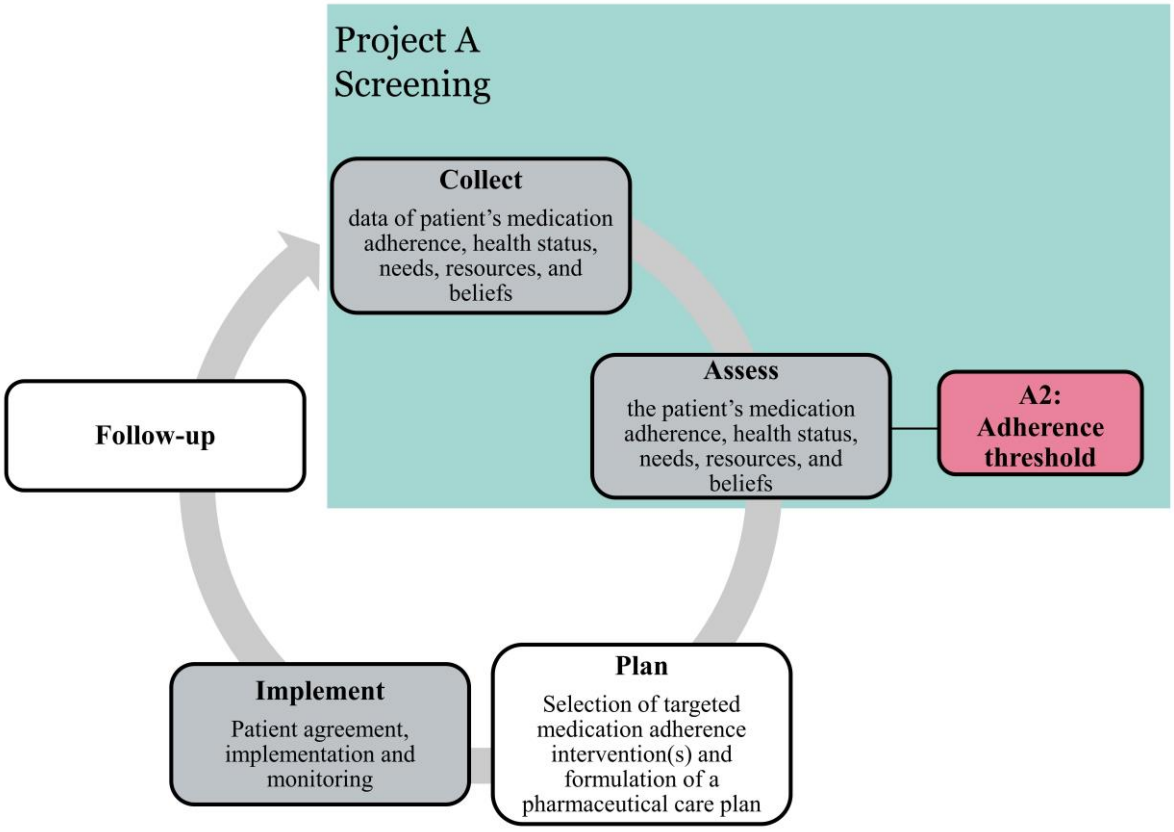
A2- Adherence threshold: Defining medication adherence thresholds depending on clinical outcomes



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SYSTEMATIC REVIEW
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A Systematic Review of Medication Adherence Thresholds Dependent of Clinical Outcomes

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Background: In pharmacotherapy, the achievement of a target clinical outcome requires a certain level of medication intake or adherence. Based on Haynes's early empirical definition of sufficient adherence to antihypertensive medications as taking ≥80% of medication, many researchers used this threshold to distinguish adherent from non-adherent patients. However, we propose that different diseases, medications and patient's characteristics influence the cut-off point of the adherence rate above which the clinical outcome is satisfactory (thereafter medication adherence threshold). Moreover, the assessment of adherence and clinical outcomes may differ greatly and should be taken into consideration. To our knowledge, very few studies have defined adherence rates linked to clinical outcomes. We aimed at investigating medication adherence thresholds in relation to clinical outcomes.

Method: We searched for studies that determined the relationship between adherence rates and clinical outcomes in the databases PubMed, Embase® and Web of Science™ until December 2017, limited to English-language. Our outcome measure was any threshold value of adherence. The inclusion criteria of the retrieved studies were (1) any measurement of medication adherence, (2) any assessment of clinical outcomes, and (3) any method to define medication adherence thresholds in relation to clinical outcomes. We excluded articles considered as a tutorial. Two authors (PB and IA) independently screened titles and abstracts for relevance, reviewed full-texts, and extracted items. The results of the included studies are presented qualitatively.

Result: We analyzed 6 articles that assessed clinical outcomes linked to adherence rates in 7 chronic disease states. Medication adherence was measured with Medication Possession Ratio (MPR, $n = 3$), Proportion of Days Covered (PDC, $n = 1$), both ($n = 1$), or Medication Event Monitoring System (MEMS). Clinical outcomes were event free episodes, hospitalization, cortisone use, reported symptoms and reduction of lipid levels. To find the relationship between the targeted clinical outcome and adherence rates, three studies applied logistic regression and three used survival analysis. Five studies defined adherence thresholds between 46 and 92%. One study confirmed the 80% threshold as valid to distinguish adherent from non-adherent patients.

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Conclusion: The analyzed studies were highly heterogeneous, predominantly concerning methods of calculating adherence. We could not compare studies quantitatively, mostly because adherence rates could not be standardized. Therefore, we cannot reject or confirm the validity of the historical 80% threshold. Nevertheless, the 80% threshold was clearly questioned as a general standard.

Keywords: medication adherence (MeSH), patient compliance, threshold, systematic (literature) review, clinical outcome, adherence measurement methods, adherence metric, adherence methodologies

INTRODUCTION

With pharmacotherapy, the achievement of the targeted clinical outcome (e.g., control of high blood pressure or HIV viral load suppression) requires a certain level of medication intake or adherence (Maggiolo et al., 2007; Jung et al., 2013). Adherence to medication is defined as "the extent to which a patient's behavior matches the agreed recommendations from a healthcare provider"(Sabaté, 2003). Individual patient's adherence is usually reported as percentage of the actual medication taken over a defined period of time (i.e., adherence rate) and varies from 0% to over 100% in literature (DiMatteo, 2004; Briesacher et al., 2008; Fischer et al., 2010; Nieuwlaat et al., 2014; Huurne et al., 2015). By using a threshold, patients can be dichotomized in persons who take their medications as prescribed (i.e., adherers) and those who deviate from the recommendations in any way (i.e., non-adherers). Based on Haynes's early empirical definition of sufficient adherence to antihypertensive medications as taking ≥80% of medication (Haynes et al., 1980), many researchers used this threshold to distinguish adherent from non-adherent patients (Caro et al., 2004; Doro et al., 2005; Hansen et al., 2010). In Haynes's study, the 80% threshold was supported by a regression analysis indicating that diastolic blood-pressure only fell systematically above this level of adherence. Unsurprisingly, in most other studies the 80% threshold has been used with no clinical rationale (Steiner and Prochazka, 1997; Doro et al., 2005; Hansen et al., 2010). The misconception of using 80% as universal threshold for good adherence is one remaining myth in 40 years of adherence science (Gellad et al., 2017). We propose that the disease, medication and patient's characteristics influence the cut-off point of the adherence rate above which the clinical outcome is satisfactory (thereafter medication adherence threshold). Moreover, the assessment of adherence and clinical outcomes may differ greatly and should be taken into consideration. Some recent theoretical approaches exist to determine adherence thresholds with computer models such as using simulated pharmacodynamic and pharmacokinetic parameters of statins to simulate the adherence rate needed to reach a LDL-C value below 70 mg/dL (Stauffer et al., 2017). However, to our knowledge, very few studies have defined adherence thresholds according to clinical outcomes. We aimed at defining medication adherence thresholds in relation to clinical outcomes.

METHODS

We searched for studies that determined medication adherence thresholds in relation to clinical outcomes. We conducted a systematic literature search according to the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) Guidelines (Moher et al., 2009).

Eligibility Criteria

To be included, a study had to describe (1) any measurement of medication adherence, (2) any assessment of clinical outcomes, and (3) any method to define medication adherence thresholds in relation to clinical outcomes. Citations of the type book chapter, conference proceedings, and dissertations were excluded. We excluded articles considered as a tutorial. We deliberately avoided to restrict our search to a target population, disease, or medication because of the universality of adherence behavior.

Search Strategy and Information Sources

We developed our strategy utilizing the terms "adherence" and synonyms, and "threshold" and synonyms in the title of publications. The databases PubMed, Embase® and Web of Science™ were searched covering the time period from inception to 31st December 2017, limiting to English-language publications. The search strategy for each database is shown in **Supplementary Material.**

Study Selection

After we removed all duplications, the retrieved citations were screened based on the title and abstract, then on the full text. Two investigators assessed eligibility (PB, IA). Any disparity was resolved by consensus. All work was performed in Endnote™ (Clarivate Analytics, Version X8).

Data Collecting Process

Data extraction was performed by one investigator (PB) and a second investigator (IA) checked the worktable for completeness and accuracy. Disagreements were resolved by consensus.

Data Items

We collected the following variables in the included studies: disease; medication class or medication; population; medication

adherence measurement; clinical outcomes; study design; method for threshold determination.

Summary Measure

Measures of interest were: mean medication adherence rate with standard deviation; medication adherence threshold value; probability to reach the targeted clinical outcome with the medication adherence threshold (expressed as odds ratio or hazard ratio); percentage of patients below the threshold.

RESULT

Study Selection

The systematic literature search yielded 194 records. After removal of duplicates, 119 unique citations were screened based on title and abstract. We excluded 107 articles that were not in the field of medicine ($n = 51$), investigated medical lab testing ($n = 52$), or were discussing adherence interventions ($n = 4$). Of the remaining twelve articles that were assessed for eligibility in full text, 6 articles were excluded [conference abstracts ($n = 3$), focusing on economic outcome ($n = 1$), discussing a theoretical approach ($n = 2$)]. Six articles met all set eligibility criteria and were included in our qualitative synthesis (see **Figure 1**).

Study Characteristics

The 6 identified studies were published between 2009 (Karve et al., 2009; Wu et al., 2009) and 2017 (Govani et al., 2017) and were all conducted in the USA (Karve et al., 2009; Wu et al., 2009; Oleen-Burkey et al., 2011; Watanabe et al., 2013; Lo-Ciganic et al., 2015; Govani et al., 2017). Data originated from insurance services covering patients throughout the USA (Oleen-Burkey et al., 2011; Govani et al., 2017), from a Medicaid program of a state (Karve et al., 2009; Lo-Ciganic et al., 2015), the Department of Veterans affairs (Watanabe et al., 2013) or cardiology clinics in Central Kentucky (Wu et al., 2009). Average age of patients ranged from 41 (Govani et al., 2017) to 68.4 years (Karve et al., 2009), the percentage of females 4.6 (Watanabe et al., 2013) to 81.29% (Oleen-Burkey et al., 2011). The study population ranged from 135 (Wu et al., 2009) to 37,912 patients (Karve et al., 2009). Fives studies (Wu et al., 2009; Oleen-Burkey et al., 2011; Watanabe et al., 2013; Lo-Ciganic et al., 2015; Govani et al., 2017) were focusing on a single chronic disease, while one (Karve et al., 2009) included patients with one out of five chronic disease states (schizophrenia, diabetes, hypertension, hyperlipidemia, and congestive heart failure). Medication adherence was calculated to a single medication in five studies (Karve et al., 2009; Wu et al., 2009; Oleen-Burkey et al., 2011; Watanabe et al., 2013; Govani et al., 2017), or to all hypoglycemic agents in one study (Lo-Ciganic et al., 2015). Two studies (Oleen-Burkey et al., 2011; Watanabe et al., 2013) focused on new medication users, and four studies (Karve et al., 2009; Wu et al., 2009; Lo-Ciganic et al., 2015; Govani et al., 2017) included patients on the medication of interest without further explanations.

Study Design

Five studies were retrospective with pharmacy claims data (Karve et al., 2009; Oleen-Burkey et al., 2011; Watanabe et al., 2013; Lo-Ciganic et al., 2015; Govani et al., 2017), one study was designed as a prospective study using an electronic medication bottle (MEMS®) (Wu et al., 2009). The observation period ranged from 1 (Karve et al., 2009; Watanabe et al., 2013; Lo-Ciganic et al., 2015) to 4 years (Govani et al., 2017). Three studies observed adherence and clinical outcome simultaneously (Oleen-Burkey et al., 2011; Watanabe et al., 2013; Govani et al., 2017) while three studies assessed sequentially first adherence, followed by the targeted clinical outcome (Karve et al., 2009; Wu et al., 2009; Lo-Ciganic et al., 2015). The period during which medication adherence was measured ranged from 3 months (Wu et al., 2009) to 4 years (Govani et al., 2017). The occurrence of the targeted clinical outcome was assessed over 1 year (Karve et al., 2009; Watanabe et al., 2013; Lo-Ciganic et al., 2015) up to 4 years (Govani et al., 2017).

Medication Adherence Measures

Retrospective database studies measured adherence by calculating the Medication Possession Ratio (MPR; this measure assesses the proportion of time with adequate supply over a predefined observation period) (Oleen-Burkey et al., 2011; Watanabe et al., 2013; Govani et al., 2017), or the Proportion of Days Covered (PDC; this measure represents the proportion of days a patient has a medication available in a given period of time, mostly a calendar year) (Lo-Ciganic et al., 2015) or both (Karve et al., 2009). Different definitions and operationalization of the MPR and PDC were used (See **Table 1**). In the MEMS® study (Wu et al., 2009), adherence rates were defined as the percentage of prescribed doses taken (dose count) and percentage of days with correct number of doses taken (dose day). Adherence outliers were truncated at 100 (Karve et al., 2009; Lo-Ciganic et al., 2015), at 140% (Govani et al., 2017), or not (Wu et al., 2009; Oleen-Burkey et al., 2011; Watanabe et al., 2013).

Clinical Outcomes

Five studies used event free survival as clinical outcome (Karve et al., 2009; Wu et al., 2009; Oleen-Burkey et al., 2011; Lo-Ciganic et al., 2015; Govani et al., 2017) and one study used the reduction of lipid levels (Watanabe et al., 2013). Events were defined as mortality (Wu et al., 2009), hospitalization (Karve et al., 2009; Wu et al., 2009; Oleen-Burkey et al., 2011; Lo-Ciganic et al., 2015; Govani et al., 2017), cortisone use (Govani et al., 2017), cortisone prescription (Oleen-Burkey et al., 2011), and reported symptoms (Wu et al., 2009). Studies using hospitalization as clinical outcome were either including all-cause hospitalization (Oleen-Burkey et al., 2011; Lo-Ciganic et al., 2015; Govani et al., 2017), disease specific hospitalization (Wu et al., 2009) or both (Karve et al., 2009).

Threshold Determination

Two methods were applied to link the targeted clinical outcome and adherence rates: logistic regression [i.e., correlating the independent variable "adherence" with the dependent

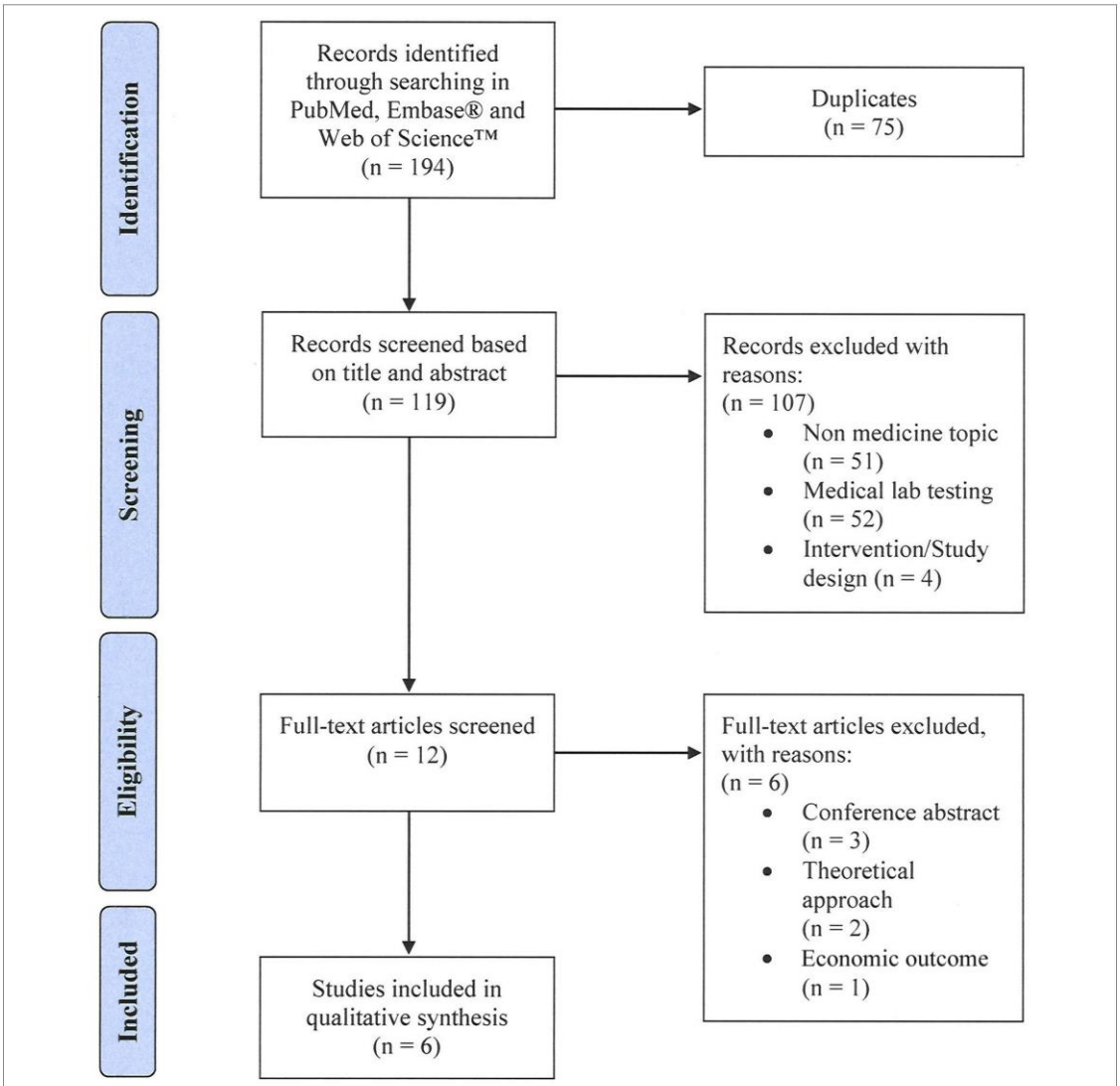

FIGURE 1 | Study flow diagram.

dichotomized variable "outcome" (Karve et al., 2009; Oleen-Burkey et al., 2011; Watanabe et al., 2013)] and survival analysis [i.e., comparing different adherence rate groups in regard to time to event rates (Wu et al., 2009; Lo-Ciganic et al., 2015; Govani et al., 2017)]. Studies using logistic regression determined the optimal threshold based on Receiver Operating Characteristic curve (i.e., a method that plots sensitivity/specificity values to a particular decision threshold) (Karve et al., 2009); or compared the odds ratio of different adherence rate groups for a relapse (Oleen-Burkey et al., 2011) or for achieving a therapeutic goal (Watanabe et al., 2013). For survival analysis, maximized log rank statistics generated two adherence groups that separated most significantly either by shifting the threshold and comparing the resulting dichotomized adherence groups (Wu et al., 2009) or using a macro (Contal and O'Quigley, 1999) that calculates log rank statistics for all possible thresholds (Govani et al., 2017) or a special approach developing a random survival forest model for predictor of hospitalization with adherence being one of fifteen predictors for hospitalization (Lo-Ciganic et al., 2015).

TABLE 1 | Characteristics of included studies.

Study [Ref] (year)	Disease	Medication class (specific medication)	Population: Data sources (State/Country)	Population: *n* = sample size	Population: Age ± s.d. [years]	Population: Female [%]	Study design: Inclusion period DD/MM/JJJJ	Study design: Order of observation: adherence ⟶ outcome - - ⟶	Adherence measure [verbatim]	Outcome measure	Threshold determination
Govani et al., 2017	Inflammatory bowel disease	Biologicals (Adalimumab: ADA Certolizumab: CZP)	Truven Health MarketScan Commercial Claims and Endcounters database (–/USA)	Overall *n* = 6'048 ADA *n* = 5'325 CZP *n* = 723	41.0 ± 15.0 41.3 ± 15.3 41.1 ± 13.8	54.0 53.8 57.8	01/01/2009–31/12/2013	4 years ⟶ 4 years - - ⟶	$MPR = \frac{[n] \text{ days of medication}}{[n] \text{ of days in the total refill intervals}}$ MPR capped at 1.4	Any disease flare defined as: hospitalization; or new corticosteroid use	**Survival analysis:** According the Log-Rank: Contal and O'Quigley Method
Karve et al., 2009	Schizophrenia Diabetes Hypertension Hyperlipidemia Congestive heart failure (CHF)	– – – – –	Medicaid administrative claims data (Arkansas/USA)	*n* = 3'396 *n* = 4'943 *n* = 16'398 *n* = 7'925 *n* = 5'251	42.9 ± 13.2 60.9 ± 15.9 59.6 ± 17.5 59.6 ± 14.0 68.4 ± 15.7	75.7 74.4 73.8 79.2 75.7	01/07/2000–31/12/2004	1 year : 1 year ⟶ : - - ⟶	$MPR = \frac{[n] \text{ of days supplied in the index year}}{[n] \text{ of days patient is ambulatory}}$ PDC = MPR capped at 1.0	Any-cause and disease-related hospitalization	**Regression analysis:** Logistic regression C-statistic based on ROC model
Lo-Ciganic et al., 2015	Diabetes type II	All oral hypoglycemic medications	Medicaid administrative claims data (Pennsylvania/USA)	n = 33'130	48.3 ± 10.0	66.5	01/07/2007–31/12/2009	1 year : 1 year ⟶ : - - ⟶	$PDC = \frac{[n] \text{ of days of medication supplied}}{[n] \text{ of days between first and last prescription+ accumulated [n] days of last prescription}}$ PDC truncated at 1.0	Time to first all-cause hospitalization	**Survival analysis:** Survival trees and random survival forests
Oleen-Burkey et al., 2011	Multiple sclerosis	Initial use Copaxone (Glatiramer acetate)	i3 Invision™ Data Mart (–/USA)	*n* = 839	45.17 ± 10.4	81.3	01/07/2006–01/04/2008	2 year ⟶ 2 year - - ⟶	$MPR = \frac{[n] \text{ of days supply glatiramer available}}{[n] \text{ of days in the post period}}$ All injection also in physicians office or hospital	Relapse defined as hospitalization/or corticosteroid prescription	**Regression analysis** Logistic regression
Watanabe et al., 2013	–	Statins	Department of Veteran Affairs (VA), (California, Nevada/USA)	*n* = 4'691	63.3 ± 10.9	4.6	30/11/2006–02/12/2007	1 year ⟶ 1 year - - ⟶	$MPR = \frac{[n] \text{ days' supply of medication dispensed}}{[n] \text{ of days based on the prescriptions}}$	25% or more reduction of lipid levels: non-high density lipoprotein (non-HDL) cholesterol; low density lipoprotein (LDL); cholesterol total cholesterol (TC)	**Regression analysis:** Multiple logistic regression Cochran-Armitage trend test

(Continued)

TABLE 1 | Continued

Study [Ref] (year)	Disease	Medication class (specific medication)	Population			Study design		Adherence measure [verbatim]	Outcome measure	Threshold determination
			Data sources (State/Country)	*n* = sample size	Age ± s.d. [years]	Female [%]	Inclusion period DD/MM/JJJJ	Order of observation: adherence ⟶ outcome ⟶		
Wu et al., 2009	Heart failure (HF)	Beta blocker/ACE-inhibitor Angiotensin receptor blocker/ Digoxin	Cardiology clinics (Central Kentucky/USA)	*n* = 135	61.0 ± 11.0	30.4	Not reported	3 months 3.5 years	Medication event monitoring system (MEMS®) dose count: percentage of prescribed doses taken dose days: percentage of days with correct number of doses taken	Event free survival; event defined as: symptoms of decompensated HF; or cardiac rehospitalization; or mortality	**Survival analysis:** Log-Rank Kaplan-Meier Cox-survival analysis; ROC model

Adherence Thresholds and Clinical Outcomes

Four studies reported mean adherence rates (Karve et al., 2009; Lo-Ciganic et al., 2015; Govani et al., 2017) between 61% in congestive heart failure (Karve et al., 2009) and 94% in patients with inflammatory bowel disease (Govani et al., 2017). Adherence rate thresholds linked to the targeted clinical outcome ranged from 63% for congestive heart failure (Karve et al., 2009) to 90% for statins (Watanabe et al., 2013). In the study with diabetes type II, threshold values were determined depending on other predictors of hospitalization (such as prior hospitalization, number of monthly prescriptions, insulin use), and ranged from 46 to 92% (Lo-Ciganic et al., 2015). In the retrieved studies, the relationships between the medication adherence thresholds and the clinical outcomes were expressed as odds ratio (Karve et al., 2009; Oleen-Burkey et al., 2011; Watanabe et al., 2013) or hazard ratio (Wu et al., 2009; Lo-Ciganic et al., 2015; Govani et al., 2017). For example, the hazard ratio for a flare was 0.75 for patients achieving an MPR of 0.86 (i.e., patients who reached a Medication Possession Ratio of 86% had a 25% lower risk to have a flare) (Govani et al., 2017). For all values, see **Table 2**.

DISCUSSION

To our knowledge, this is the first systematic review that aimed at defining medication adherence threshold in relationship to a targeted clinical outcome, and shed light on the historical 80% threshold. Six studies published in the past 9 years met our eligibility criteria and demonstrate the low interest in the question or the complexity of the task. Five studies critically questioned the commonly used 80% adherence threshold as being suboptimal. However, studies were highly heterogeneous predominately concerning study design, clinical outcomes, number of included patients and underlying diseases. Further, various methods exist for the assessment of medication adherence and for its calculation, according to the research setting. Therefore, we were unable to standardize the adherence rates of the different measures, and could not compare the included studies quantitatively. A general agreement to reject or confirm the historical 80% threshold cannot be given due to the low number and the high diversity of the included studies. However, we could summarize some findings to guide future research.

Medications Under Investigation

Three studies investigated one medication as surrogate for multiple treatments in the disease of interest (Karve et al., 2009; Wu et al., 2009; Watanabe et al., 2013). This was done with the rationale that a single medication suffices to detect the medication intake behaviors of a patient. However, medication adherence is known to be negatively influenced by a large number of medications or the complexity of treatment (Marcum and Gellad, 2012). In diseases with simple or limited drug regimens, such as hyperlipidemia or multiple sclerosis, it is possible to choose medications as a surrogate with similar properties out of a chemical subgroup [such as HMG-CoA reductase inhibitors

TABLE 2 | Summarized results of the included studies.

Study [Ref] (year)	Disease or medication class	Mean medication adherence rate ± standard deviation	Medication adherence rate threshold	Probability to reach the targeted clinical outcome with the medication adherence threshold (odds ratio [OR], hazard ratio [HR], and confidence interval [CI])	Percentage of patients below medication adherence threshold
Govani et al., 2017	Adalimumab	MPR 0.94 ± 0.13	**0.86**	Hazard Ratio (HR): 0.75 (95% CI 0.67–0.83) for a flare	24%
	Certolizumab	MPR 0.87 ± 0.14	**0.87**	HR: 0.59 (95% CI 0.46–0.76) for a flare	24%
Karve et al., 2009	Schizophrenia	MPR 0.738 ± 0.310	**0.76**	OR: 0.456 for disease related hospitalization	–
		PDC 0.724 ± 0.295	**0.76**	OR: 0.430 for disease related hospitalization	–
	Diabetes	MPR 0.763 ± 0.279	**0.85**	OR: 0.449 for disease related hospitalization	–
		PDC 0.751 ± 0.266	**0.85**	OR: 0.434 for disease related hospitalization	–
	Hypertension	MPR 0.712 ± 0.304	**0.82**	OR: 0.712 for disease related hospitalization	–
		PDC 0.702 ± 0.293	**0.82**	OR: 0.708 for disease related hospitalization	–
	Hyperlipidemia	MPR 0.731 ± 0.295	**0.81**	OR: 0.591 for disease related hospitalization	–
		PDC 0.722 ± 0.284	**0.81**	OR: 0.581 for disease related hospitalization	–
	Congestive heart failure	MPR 0.619 ± 0.304	**0.58**	OR: 0.856 for disease related hospitalization	–
		PDC 0.612 ± 0.295	**0.58**	OR: 0.855 for disease related hospitalization	–
Lo-Ciganic et al., 2015	Diabetes type II	0.65 ± 0.26	**0.46–0.94**	HR: 0.48-0.69 for all cause hospitalization according the patient health and medication complexity	–
Oleen-Burkey et al., 2011	Multiple sclerosis	–	**0.7**	OR: 0.547 (95% CI 0.362–0.826) for relapse	49.23%
Watanabe et al., 2013	Statins	–	**0.9**	OR: 12.90 (95% CI 9.60–17.35) for 25% reduction of non-HDL cholesterol	–
				OR: 11.29 (95% CI 8.61–14.80) for 25% reduction of LDL cholesterol	–
				OR: 9.11 (95% CI 6.62–12.53) for 25% reduction of total cholesterol	–
Wu et al., 2009	Heart failure	Dose count: 0.887 ± 0.156	**0.88**	HR: 2.2 for time to first event for the non-adherent group	44%
		Dose day: 0.808 ± 0.228	**0.88**	HR: 3.2 for time to first event for the non-adherent group	44%

(Watanabe et al., 2013)] or even special chemical substance [such as glatiramer acetate (Oleen-Burkey et al., 2011)]. In progressive diseases complex drug regimens are common. As for example, according to the European Society Cardiology (ESC) guidelines, treatments for congestive heart failure (Ponikowski et al., 2016) consist of up to four simultaneous medications with different mechanisms of action. Thus, selecting one single medication as a surrogate for a complex treatment needs clear ground, especially when adherence parameters will be extrapolated from a lead medication to the entire regimen. Therefore, we recommend to include all concerned medications when investigating the intake behaviors of a patient.

Clinical Outcome and Observation Period

Ideally, there are two types of outcome markers available for analysis, intermediary outcomes (surrogate measures such as blood pressure, lipids, glucose), and patient-important outcomes [e.g., death, stroke, myocardial infarction, hospitalization (Yordanov et al., 2018)]. The latter would require much larger and longer studies—but they would answer the key question of whether the adherence level makes a clinically important difference. Five studies (Karve et al., 2009; Oleen-Burkey et al., 2011; Watanabe et al., 2013; Lo-Ciganic et al., 2015; Govani et al., 2017) used hospitalization as outcome marker for a various diseases such as diabetes (Wu et al., 2009), congestive heart

failure (Wu et al., 2009), schizophrenia (Karve et al., 2009), and hyperlipidemia (Watanabe et al., 2013); and for various medications such as adalimumab (Govani et al., 2017) and galtiramer acetate (Oleen-Burkey et al., 2011). Surrogate markers were seldom described (Watanabe et al., 2013). However, the observation periods were mostly 1 year (Karve et al., 2009; Watanabe et al., 2013; Lo-Ciganic et al., 2015), which is short to observe hard endpoints such as hospitalization. Even if hospitalization is easy to document and allows dichotomization for statistical analysis, many cofactors influence the probability of hospitalization in a year such as number of monthly prescriptions, prior hospitalization and disease severity (Lo-Ciganic et al., 2015). As a comparison, the follow-up period of randomized controlled trials with statin therapy and patient important outcome measures (major coronary event, stroke, death) was at least 3 years (Cheung et al., 2004). Consequently, for smaller studies with short observation periods, fast reacting surrogate measures such as blood pressure seem more suitable endpoints to link adherence level with single medication. Thus, researchers should select a specific clinical endpoint and an observation period long enough to catch the full effect of medication adherence on the target clinical outcome.

Calculation of Medication Adherence

Even without a gold standard (Lam and Fresco, 2015), any mathematical method used to compute medication adherence needs to be clearly defined (Arnet et al., 2016). Many studies demonstrated that medication possession ratio (MPR) is highly influenced by the observation period (Kozma et al., 2013; Sperber et al., 2017) and oversupply (Martin et al., 2009). Thus, it is surprising that the four retrieved studies that used MPR (Karve et al., 2009; Oleen-Burkey et al., 2011; Watanabe et al., 2013; Govani et al., 2017) present four different formulas with poor specification. Consequently, each study is a standalone and direct comparison is impossible.

Further, according to a new adherence taxonomy (Vrijens et al., 2012), behaviors differ whether patients are initiating, implementing, or discontinuing their treatment. Calculating adherence rate from claims data delivers an aggregate estimate of a patient's medication possession. MPR and PDC are summary measures and cannot differentiate between implementation and discontinuation, mainly because pharmacy claims data do not allow to define precisely the time point of discontinuation. Currently, no method to calculate medication adherence from claims data seems adequate to deliver values for each phase of medication adherence. Researchers need to be aware of the prerequisites of the calculation measure they plan to use.

Dichotomizing Continuous Data

To determine medication adherence thresholds, the authors of the studies categorized the population in two groups that vary significantly. Dichotomizing is commonly used in medicine, because it makes data summarization more efficient and offers a simple risk classification in populations for clinicians. However, statisticians advise against dichotomizing continuous data such as medication adherence data, because a substantial loss of information can occur (Streiner, 2002; Royston et al., 2006). Further, replicates of thresholds are made impossible in subsequent studies. As a consequence, the continuous variable "medication adherence" should be described with a distribution plot to present the entire data. In the retrieved studies, only mean adherence value and standard deviation (as indicator of homogeneity) were given to describe the data (Karve et al., 2009; Wu et al., 2009; Lo-Ciganic et al., 2015; Govani et al., 2017). These two values are insufficient to describe the distribution of the data. A graphic such as a histogram of the medication adherence values could deliver additional and comprehensive information covering the distribution.

Adherence Threshold in Context of the Clinical Relevance

The novelty of the retrieved studies was not to try to distinguish adherent from non-adherent patients, but to express the clinical benefit obtained by patients reaching a certain level of engagement in their dosing regimens. Thus, categorizing patients in arbitrary groups such as "good" and "poor" adherer is misleading. On the contrary, to indicate the degree of execution of a treatment in form of a medication adherence threshold represents valuable and concrete information for clinicians. Surprisingly, only half of the studies (Wu et al., 2009; Oleen-Burkey et al., 2011; Govani et al., 2017) presented the percentage of the population below their medication adherence threshold. Thus, this information combined with the adherence distribution (mean value, standard deviation, graphic representation) should enable healthcare providers and policy makers to target patients with low adherence that would clearly clinically benefit reaching a certain level of adherence.

Limitations

We acknowledge some limitations. First, we may have missed articles that did not contain our search words in their title. However, it is likely that such articles have mentioned adherence threshold in a subsidiary content and then would not have filled our inclusion criteria. For example, a recently published study investigating the adherence to antihypertensive medications and the risk of cardiovascular disease among older adults did not define an unambiguous threshold (Yang et al., 2017). Second, the search was limited to English-language. Third, all included studies were performed in the US-population with inherent specificities such as the underrepresentation of women [US veterans with a percentage 4.6% women (Watanabe et al., 2013)], population with lower income patients [Medicaid enrollees (Karve et al., 2009; Lo-Ciganic et al., 2015)] or a small locally defined population (Wu et al., 2009). Consequently, our results cannot be generalized to other populations. Fourth, due to the diversity of studies, the quantitative comparison of adherence thresholds was not possible.

CONCLUSIONS

This study revealed a large research gap in determining medication adherence thresholds in relationship to clinical outcomes. The authors of the included studies must be

complimented for their attempt to question the historical 80% threshold. We were able to extract five recommendations for future research in this field:

1. Include all medications prescribed for a disease to estimate the medication intake behavior;
2. Select an observation period sufficiently long to detect the targeted clinical outcome; orientate to the length of the observation period used in high quality studies;
3. Define the adherence measurement; calculations have to be replicable;
4. Select statistical methods for the threshold determination carefully, in order to avoid loss of information;
5. Put the adherence threshold in context to clinical relevance.

Based on this new knowledge, further studies are needed to define adherence thresholds linked to the targeted clinical outcome in order to deliver high quality and comparable results to ultimately guide healthcare professionals.

AUTHOR CONTRIBUTIONS

PB designed the review protocol, carried out the literature search, extracted data from selected studies, and drafted the manuscript. IA participated in the literature search. RH, KH, and IA revised the manuscript critically for intellectual content. All authors read and approved the final manuscript.

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SUPPLEMENTARY MATERIAL

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fphar.2018.01290/full#supplementary-material

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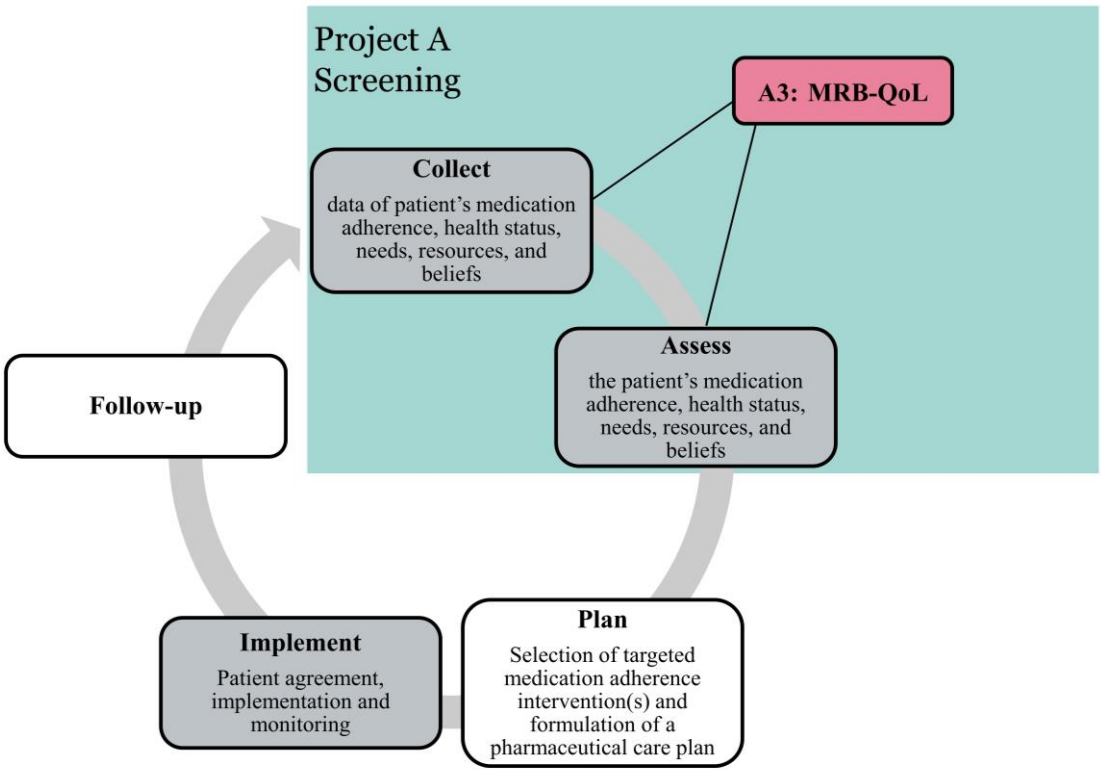
Conflict of Interest Statement: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

A3- MRB-QoL: Assessing the medication related-burden of patients with a new tool



Short report: Developing the German version of the MRB-QoL and defining its field of use, an instrument for measuring the burden of medicine on functioning and well-being in the primary care setting

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Abstract

Background: The quality of life and the well-being of individuals can be affected by a negative experience with medicines. The 31-item Medication-Related Burden Quality of Life (MRB-QoL) tool has been developed in English to measure the burden of medication on patients' psychological, social, physical, and financial well-being.

Aim: To translate the MRB-QoL tool into German, and assess its field of use in primary health care.

Method: The ten steps of the ISPOR "Principles of Good Practice for the Translation and Cultural Adaptation Process for Patient-Reported Outcomes Measures" were used to translate the MRB-QoL tool. The cognitive debriefing (step 7) was extended according to Valmi et al. to three rounds in the order 1) patients rated the items for clarity (clear/unclear); 2) experts rated the items for clarity (clear/unclear), and for relevance (4-point Likert scale from “not relevant” to “highly relevant”); 3) experts rated the revised items for relevance. We calculated inter-rater agreement for clarity and content validity index at the item level (I-CVI) for relevance; thresholds were set at 0.80 and 0.78, respectively. The tool’s field of use was assessed with primary care stakeholders: general practitioners (GP), community pharmacists, nurses, and patients. Four online semi-structured interviews were performed with 2-3 people of each stakeholder group. Process mapping was used in a swimlane diagram to visualize the setting, process flows, and responsibilities for the MRB-QoL tool for each stakeholder group.

Results: The translation process was performed with 15 patients and 15 experts. Clarity was not given for nine items (cognitive debriefing round 1) that were revised. One item was removed because of similarity with another item. Nine other items needed revision to improve clarity (cognitive debriefing round 2). Relevance was low for 13 items (cognitive debriefing round 3) that were removed, resulting in a final 17-item German tool. Two GPs, two pharmacists, two nurses, and three patients were interviewed for 35 ± 8 minutes on average. According to the stakeholders, patients at risk for medication-related burden should fill in the MRB-QoL tool at the GP’s surgery or in the home care setting. The result of the tool should be assessed by the GP that initiates and carry out targeted interventions that should be coordinated with nurses and pharmacists.

Conclusion: The MRB-QoL tool was successfully translated into German. Adaption yielded a shortened 17-item tool. Primary care stakeholders see its field of use in an interprofessional setting. In a next step, the German version of the MRB-QoL will be validated in this setting.

Introduction

An increasing proportion of people are taking more than five medicines, which is commonly defined as polypharmacy.[1] Polymedicated patients are known to have a higher risk for drug-related problems (DRP) that are defined as *"an event or circumstance involving drug treatment that actually or potentially interferes with the patient's experiencing an optimum outcome of medical care."[2]* The past negative experiences with medication can lead to a manifold of decisions by the patient, such as not taking the medication as prescribed, also known as nonadherence.[3] This includes that the patient is not starting a new therapy, not taking the medication regularly (i.e., low implementation), or abruptly stopping the therapy (i.e., early discontinuation).[4] Nonadherence to medication can have major clinical and financial consequences for the patient[5, 6], potentially creating a vicious cycle, adding more negative experiences with medication over time. Therefore, the awareness of health care professionals (HCPs) that the intake of medication can be a burdensome experience for the patient is essential.[7] This is particularly important as patients experiencing a burden related to their medication often report poor health-related quality of life.[7-9] There are already tools for HCPs to evaluate objectively the burden of medicines such as the Drug Burden Index (DBI)[10], or the Medication Regimen Complexity Index (MRCI).[11] They aim to improve treatment outcomes and prevent inappropriate polypharmacy.[12] Unfortunately, they miss measuring the individual medication-related burden (MRB), also defined as "*a negative experience with medicine, which may have an impact on the psychological, social, physical, and financial well-being of an individual*."[13]

In Australia, the Medication-Related Burden Quality of Life (MRB-QoL) tool was developed to measure the burden of medicine on functioning and well-being from the patient's perspective.[13] The tool was developed in three phases: Conceptualization by defining the construct and establishing the need for a new measure (Phase I), developing the instrument by generating and refining an item pool (Phase II), and evaluating the instrument by psychometric testing (Phase III).[7, 14, 15] The final tool is a 31-item questionnaire, with five subscales labeled as "Routine and Regimen Complexity" (11 items), "Psychological Burden" (six items), "Functional and Role Limitation" (seven items), "Therapeutic Relationship" (three items) and "Social Burden" (four items). To our knowledge, there is currently no validated tool that measures the medication-related burden on quality of life in the German language. This work aimed to translate the original English version of the MRB-QoL tool into German and assess its field of use in primary health care.

Methods

Translation

The translation process into German was conducted according to the ten steps of the ISPOR Principles of Good Practice for Translation and Cultural Adaption Process for Patient-Reported Outcome Measures.[16] Two German-native pharmacists (PB, OK) independently translated the original English version (source language) into German (target language). The two translations were compared and discussed by the two translators. Items with major grammatical discrepancies, were given to two other German-native pharmacists (FD, MH), who independently translated the concerned items. During a reconciliation meeting, the four translators resolved the discrepancies and created a first German version. The back-translation from German into English was done by an English-native professional translator (SR) unfamiliar with the original English tool. The differences between the original and the back translation versions in English were discussed during a consensus meeting (PB, OK, and SR) until an adapted German version was generated.

The cognitive debriefing (step 7) was adapted from Sousa et al.[17] and consisted of three rounds with patients (round 1) and experts (rounds 2 and 3). Online surveys with Google forms were created. For round 1, patients with German as mother tongue, having at least one chronic disease, and taking at least three medicines regularly[13] were recruited in the investigators' acquaintance and in the pharmacy they were working. The patients were asked to rate each item for clarity (clear/unclear). Patients who ticked an item "unclear" were required to elaborate on their rating and to suggest how to rewrite the items. Two investigators (PB, OK) revised the items that had an inter-rater agreement below 80% and followed the suggestions of the raters.[18] An expert panel was set up with German-native speaking HCPs from Switzerland, Germany, and Austria, and knowledgeable about the content areas of the construct of the tool. The experts were recruited in the acquaintance of the investigators and asked to rate the items. In round 2, the experts rated each item for clarity and content equivalence by judging its relevance (content-related validity) with a 4-point Likert scale (1 = not relevant; 2 = somewhat relevant; 3 = quite relevant; 4 = highly relevant). The content validity index was calculated at the item level (I-CVI; the proportion of experts giving items a relevance rating of 3 or 4) and the scale level (S-CVI/Ave; an average of the I-CVI for all items); and Fleiss kappa coefficient was calculated.[19] We interpreted the kappa values according to Landis and Koch < 0.00 as poor, 0.00 - .20 as slight, .21 to .40 as fair, .41 to .60 as moderate, 61 to 80 as substantial,

and 0.81 to 1.00 as almost perfect.[20] The minimum acceptable values were 0.78 for I-CVI [21], 0.90 for S-CVA/Ave.[22]. In round 3, the I-CVI determined in the previous round for each item was given in brackets and the experts again rated the content equivalence. After round 3, items with an I-CVI value of ≤ 0.78 were removed from the tool.

Interviews and Process mapping

The field of use of the German version of the MRB-QoL was determined by stakeholders in primary care that is, general practitioners (GPs), pharmacists, nurses, and patients. Four independent semi-structured interviews were conducted online via Zoom with at least two representatives per stakeholder group. Participants gave their agreement to the audio recording. The interview guide consisted of 15 pre-defined questions concerning the setting, process flows, and responsibilities when using the MRB-QoL tool in primary patient care. The discussion was guided by a moderator (OK, master student) and simultaneously processed by an investigator (PB, PhD student) with a swimlane diagram.[23-25] The four elements setting (Place), application of the tool (Do), evaluation of the results (Check), and next steps (Act) were mapped according to an adapted PDCA cycle (see Appendix A for the template).[26] The resulting process map for the MRB-Qol tool was then presented to the interviewees and discussed until consensus was reached. Finally, the two investigators (PB, OK) combined the four swimlane diagrams into one final process map.

Results

Translation and adaption

The translation process lasted 17 weeks between January and April 2021, and nine different German versions were created. Fifteen people belonging to the target patient group took part in round 1 of the cognitive debriefing. They were all Swiss residents and were on average 46 ± 16 years old. Nine out of 31 items had a comprehensibility rating of 80% or less and were revised. The revision consisted in adding an example to facilitate the understanding of one statement, replacing seven incomprehensible terms with more colloquial words, and removing one item. For the cognitive debriefing rounds 2 and 3, a total of 15 experts from Germany (9), Austria (2), and Switzerland (4) accepted to participate (see Table 1).

Table 1 Demographics of the expert group in the cognitive debriefing Round 2 and 3

		Round 2	Round 3
Demographics	Number of participants	15	12
	Female (%)	8 (53.3)	8 (66.7)
	Age [years ± sd]	46.3 ± 15.4	45.1 ± 10.8
	Working experience [years ± sd]	20.3 ± 15.2	19.2 ± 11.1
Country of origin	Switzerland (%)	4 (26.7)	3 (23.1)
	Germany (%)	9 (60)	8 (61.5)
	Austria (%)	2 (13.3)	1 (15.4)
Field of activity	Academia (%)	11 (73.3)	6 (50.0)
	Professional association (%)	3 (20)	3 (25)
	Community pharmacy (%)	5 (33.3)	6 (50.0)
	Nursing (%)	1 (6.7)	1 (8.3)

The agreement between experts was weak in round 2 (Fleiss kappa: $\kappa = 0.056$) but increased to a fair agreement ($\kappa = 0.329$) in round 3 of the cognitive debriefing. In the cognitive debriefing round 2, the expert group rated the comprehensibility for nine items and the relevance for 11 items as insufficient (see Table 2). A total of 13 items were rated as not relevant after the cognitive round 3. The items were removed from the tool, resulting in the final German version named: "*Das Tool zur Erfassung der Belastung durch die Medikation und der Lebensqualität (BM-LQ)"* (see Figure 1).

Table 2 Percentage of participants who rated the items to be comprehensible, and content validity index at the item level (I-CVI), with the decision to maintain (Yes) or discard (No) the corresponding item.

	Round 1	**Round 2**			**Round 3**	**Decision**
	Comprehensibility by patients [in %] N = 15	Comprehensibility by experts [in %] N = 15		Relevance by experts [I-CVI] N = 15	Relevance by experts [I-CVI] N = 12	Considered for the German version of the MRB-QoL
Item 1	53.3	80		0.867	1	**Yes**
Item 2	86.7	53.3		0.6	0.583	No
Item 3	66.7	40		0.6	0.833	**Yes**
Item 4	73.33	Deleted		Deleted	Deleted	No
Item 5	86.7	46.7		0.933	0.917	**Yes**
Item 6	80	100		1	1	**Yes**
Item 7	93.3	80		1	1	**Yes**
Item 8	80	93.3		0.933	1	**Yes**
Item 9	93.3	66.7		0.933	0.917	**Yes**
Item 10	93.3	86.7		0.8	0.5	No
Item 11	100	100		0.867	1	**Yes**
Item 12	100	93.3		0.867	0.833	**Yes**
Item 13	100	100		1	1	**Yes**
Item 14	93.3	93.3		1	1	**Yes**
Item 15	100	93.3		0.733	0.583	No
Item 16	73.3	100		1	1	**Yes**
Item 17	100	86.7		0.733	0.25	No
Item 18	66.7	100		0.933	1	**Yes**
Item 19	100	86.7		0.533	0.167	No
Item 20	100	73.3		0.867	0.667	No
Item 21	100	86.7		0.933	1	**Yes**
Item 22	100	93.3		0.867	0.917	**Yes**
Item 23	80	73.3		0.8	0.833	**Yes**
Item 24	100	86.7		0.867	0.916	**Yes**
Item 25	86.7	73.3		0.6	0.333	No
Item 26	73.3	86.7		0.667	0.333	No
Item 27	86.7	86.7		0.533	0.333	No
Item 28	100	100		0.867	0.583	No
Item 29	100	100		0.667	0.5	No
Item 30	80	86.7		0.667	0.583	No
Item 31	93.3	100		0.467	0.333	No
Average ±SD	88.8 ± 12.5	85.4 ± 15.7	**S-CVA/Ave**	0.804	0.730	

Figure 1 Final version of the German adaption of the MRB-QoL named: *"Das Tool zur Erfassung der Belastung durch die Medikation und der Lebensqualität (BM-LQ)"*

Patienten Nummer

Das Tool zur Erfassung der Belastung durch die Medikation und der Lebensqualität (BM-LQ)

Anleitung

Wir interessieren uns für die Auswirkungen von Medikamenten auf die Gesundheit und das Wohlbefinden. Da Sie selbst Medikamente anwenden, sind Sie die ideale Person um einschätzen zu können, wie die Medikamente Ihre Gesundheit und Ihr Wohlbefinden beeinflussen. Nachfolgend haben wir Aussagen aufgelistet, die anderen Personen in diesem Zusammenhang wichtig waren. Beantworten Sie jede Frage indem Sie das passende Kästchen ankreuzen.

Abschnitt A: Die folgenden Aussagen beziehen sich auf **die Belastung im Zusammenhang mit der medikamentösen Therapie und der Routine der Medikamenteneinnahme**. Betrachten Sie die letzten zwei Wochen und geben Sie an, wie sehr Sie jeder Aussage zustimmen oder nicht zustimmen.

		Stimme voll und ganz zu	Stimme zu	Stimme weder zu noch lehne ab	Stimme nicht zu	Stimme überhaupt nicht zu
1	Ich finde es schwierig, meine Medikamente zu organisieren (z. B. sortieren, bereitstellen)	☐	☐	☐	☐	☐
2	Es fällt mir schwer, die mit der Medikamenteneinnahme verbundenen Tätigkeiten zu bewältigen (z. B. Zubereitung, Routine)	☐	☐	☐	☐	☐
3	Das Einnehmen von Medikamenten beeinträchtigt meine körperlichen Aktivitäten	☐	☐	☐	☐	☐
4	Es fällt mir schwer, die Medikamenteneinnahme mit meinem Tagesablauf in Einklang zu bringen	☐	☐	☐	☐	☐
5	Meine derzeitige medikamentöse Therapie ist für mich schwierig zu handhaben (z. B. Injektionen, Tabletten, Augentropfen)	☐	☐	☐	☐	☐
6	Manchmal fällt es mir schwer zu verstehen, wie ich meine Medikamente anwenden soll	☐	☐	☐	☐	☐
7	Meine derzeitigen Medikamente haben eine für mich unangenehme Form zum Einnehmen (z. B. schwer zu schlucken, unangenehmer Geschmack/Geruch)	☐	☐	☐	☐	☐
8	Manchmal fällt es mir schwer die Verpackung meiner Medikamente zu öffnen (z. B. wegen kindersicheren Verschlüssen)	☐	☐	☐	☐	☐

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Patienten Nummer

Abschnitt B: Die folgenden Aussagen beziehen sich auf die Auswirkungen der Belastung durch die Medikation auf **das psychische Wohlbefinden**. Betrachten Sie die letzten zwei Wochen und geben Sie an, wie sehr Sie jeder Aussage zustimmen oder nicht zustimmen.

		Stimme voll und ganz zu	Stimme zu	Stimme weder zu noch lehne ab	Stimme nicht zu	Stimme überhaupt nicht zu
9	Es beschäftigt mich, dass ich dauerhaft Medikamente einnehmen muss	☐	☐	☐	☐	☐
10	Ich bin besorgt über die Anzahl der Medikamente die ich einnehme	☐	☐	☐	☐	☐
11	Ich mache mir Sorgen über die Langzeitfolgen von Medikamenten auf meine Gesundheit	☐	☐	☐	☐	☐
12	Ich bin besorgt, dass meine Medikamente sich gegenseitig beeinflussen könnten	☐	☐	☐	☐	☐

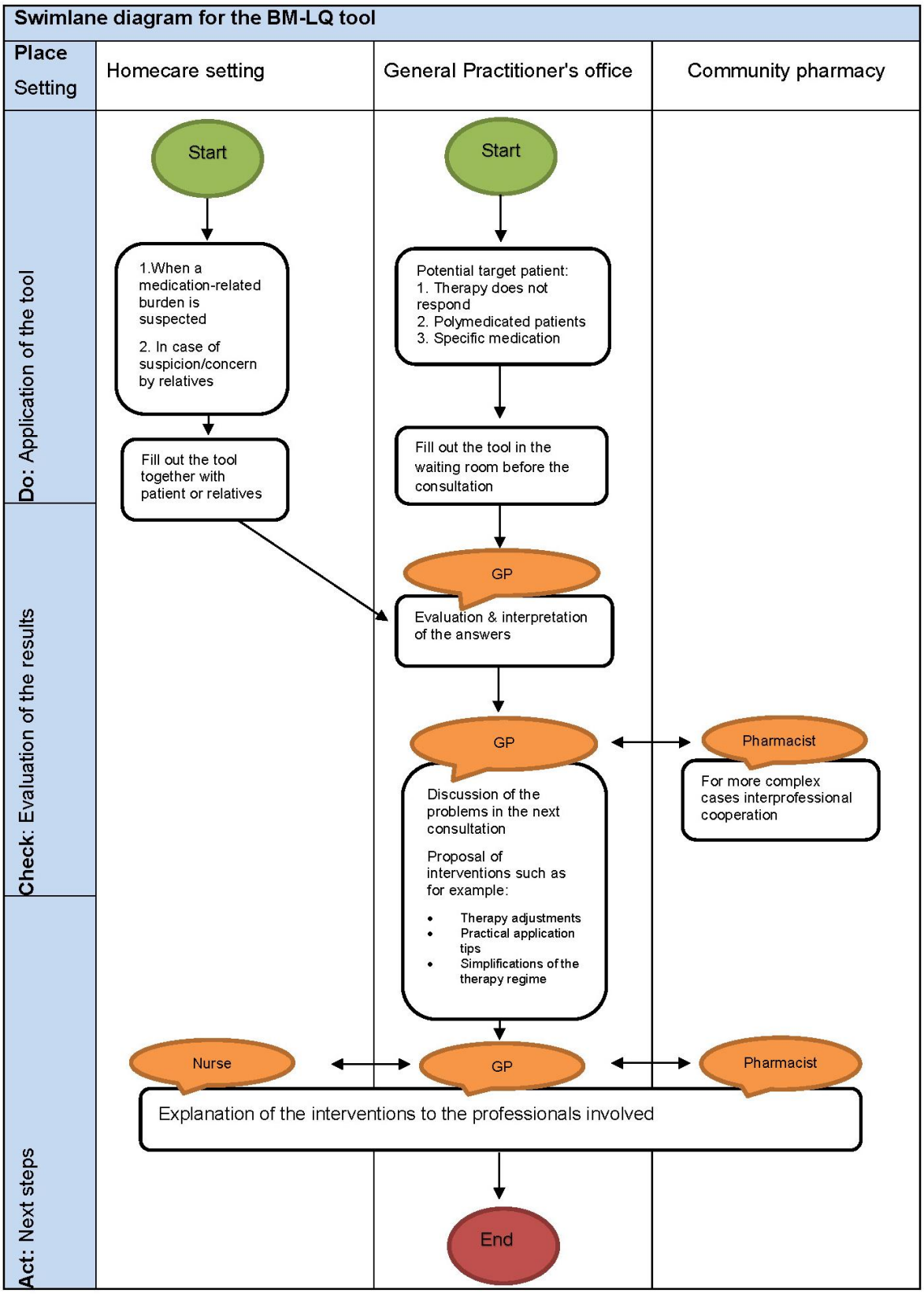
Abschnitt C: Die folgenden Aussagen beziehen sich auf die Auswirkungen der Belastung durch die Medikation auf **das körperliche Wohlbefinden**. Betrachten Sie die letzten zwei Wochen und geben Sie an, wie sehr Sie jeder Aussage zustimmen oder nicht zustimmen.

13	Manchmal beeinträchtigen meine Medikamente mein Sexualleben	☐	☐	☐	☐	☐
14	Ich schlafe oft schlecht wegen meiner Medikamente	☐	☐	☐	☐	☐
15	Aufgrund meiner Medikamente fühle ich mich zu müde, um körperliche Aktivitäten durchzuführen	☐	☐	☐	☐	☐
16	Aufgrund der Wirkung meiner Medikamente kann ich nicht so arbeiten wie gewohnt	☐	☐	☐	☐	☐
17	Bei einigen meiner Medikamente fühle ich mich aufgrund der Nebenwirkungen unwohl	☐	☐	☐	☐	☐

Interviews and Process mapping

Two GPs, two pharmacists, two nurses, and three patients were interviewed over three weeks in April 2021. The discussions were conducted in Swiss German and lasted 35 ± 8 minutes on average. The stakeholders delineated the four steps of the process and named different settings to apply the BM-LQ tool that were combined into an optimal process (see Figure 2): The GP's office and in-home care were the places where the patients should fill out the tool. Patients at risk for medication-related burden were those with polypharmacy, not responding to treatment, or with specific medicines. Patients at risk should either fill out the tool in the GP's office's waiting room or be assisted by a nurse and relatives in the home care setting. In the next step, the GP should evaluate the result of the tool and discuss it with the patient during the next consultation. In accordance with the patient, the GP should then initiate targeted interventions such as treatment adjustments or simplification. When initiating more complex interventions, an interprofessional collaboration between the physician and other health care professionals is advised. Finally, all involved HCPs should be informed about the interventions to contribute to an optimal outcome for the patient.

Figure 2 Visualization of the optimal process for the BM-LQ tool in a swimlane diagram, according to 4 steps following an adapted PDCA cycle (Place, Do, Check, Act).[26]



Discussion

We successfully translated and culturally adapted the MRB-QoL for German-speaking patients. The adaption resulted in a shortened 17-item tool, the BM-LQ. Key stakeholders in the primary care setting defined an optimal process for the BM-LQ, including an interprofessional collaboration when initiating targeted interventions.

Translation of the MRB-QoL tool

The translation steps were performed according to the ten steps of ISPOR. The cognitive debriefing (step 7) was expanded and modified according to Valmi D. Sousa et al. by including experts who evaluated the comprehensibility and relevance of the items. This additional step in two rounds led to the elimination of 14 items, including the two subsections "health care services" and "social well-being" of the MRB-QoL. Although the experts agreed that these two subsections were nonrelevant, they perceived very differently what constitutes the medication-related burden for patients. The interrater reliability showed weak agreement (κ=0.056), but increased to a slight agreement(κ=0.329). Therefore, the BM-LQ must be clearly distinguished from the original tool, which claims to assess medication-related burden and quality of life-related changes fully.[13] In contrast, the BM-LQ represents a shortened version of the original tool designed to screen patients with a medication-related burden in primary health care. Therefore, the next step should be to evaluate the tool for this purpose in the primary health care setting.

Process mapping

We used process mapping, precisely the swimlane method, to define the process of using the BM-LQ in primary health care. The method was developed for the industry, but it is particularly suitable for the healthcare sector due to its simplicity.[26] This method allows for visually arranging and structuring essential activities of processes of interest. In addition, it enables the assignment of responsibilities to the involved stakeholders.[27, 28] We defined the basic structural phases of the process using the PDCA cycle to define a clear process flow, including the responsibilities of the individual stakeholder within the process.[26] However, with only four process steps, the level of detail is low and is a general limitation of swimlane diagrams.[27] Still, the method has proven to be a feasible approach to define the process of the BM-LQ in daily practice. We conducted process mapping in the different stakeholder groups separately.

This helped to understand the different viewpoints on the newly introduced concept of medication-related burden. It would have been conceivable to conduct a focus group discussion with all stakeholders together. However, the opinions of dominant participants are often more strongly represented in focus groups.[29] Thus, one large focus group discussion would probably have resulted in only one process with the opinions of dominant individuals/professional groups, which would have most likely influenced the results. Still, the essential aspect named by all stakeholders during the process mapping was interprofessional cooperation. Therefore, a valuable next step might be to invite all stakeholders to discuss the final process map in a professional consensus meeting and delineate the further steps to implement the BM-LQ in the primary care setting.

Strengths and Limitations

The work's strengths lie in the structured methodological approach of the translation process following the ten steps of the ISPOR principle. This allows to minimize the risk of mistranslations or inserting misinterpretations of words. In addition, the cognitive debriefing with native-speaking patients and experts should guarantee the comprehensibility and relevance of the tool for the targeted users. Also, we introduce process mapping as a feasible and straightforward working tool in the interprofessional environment in primary health care. We also acknowledge some limitations. First, all patients involved in the cognitive debriefing were from Switzerland. This could have been prevented with an equal distribution of the participants among the German-speaking countries Germany, Austria, and Switzerland. Second, the agreement between experts concerning the relevance of the items was low. Hence, the addition of a third expert round might have improved the agreement between experts. Third, the process map of the BM-LQ is limited to the primary health care system of (Northwestern) Switzerland and can not be generalized to other countries.

Conclusion

The MRB-QoL tool was successfully translated into German. The adaption resulted in a shortened 17-item tool, named the BM-LQ. Health care representatives saw its field of use in primary patient care with interprofessional cooperation. Next, the German BM-LQ will be validated in this setting.

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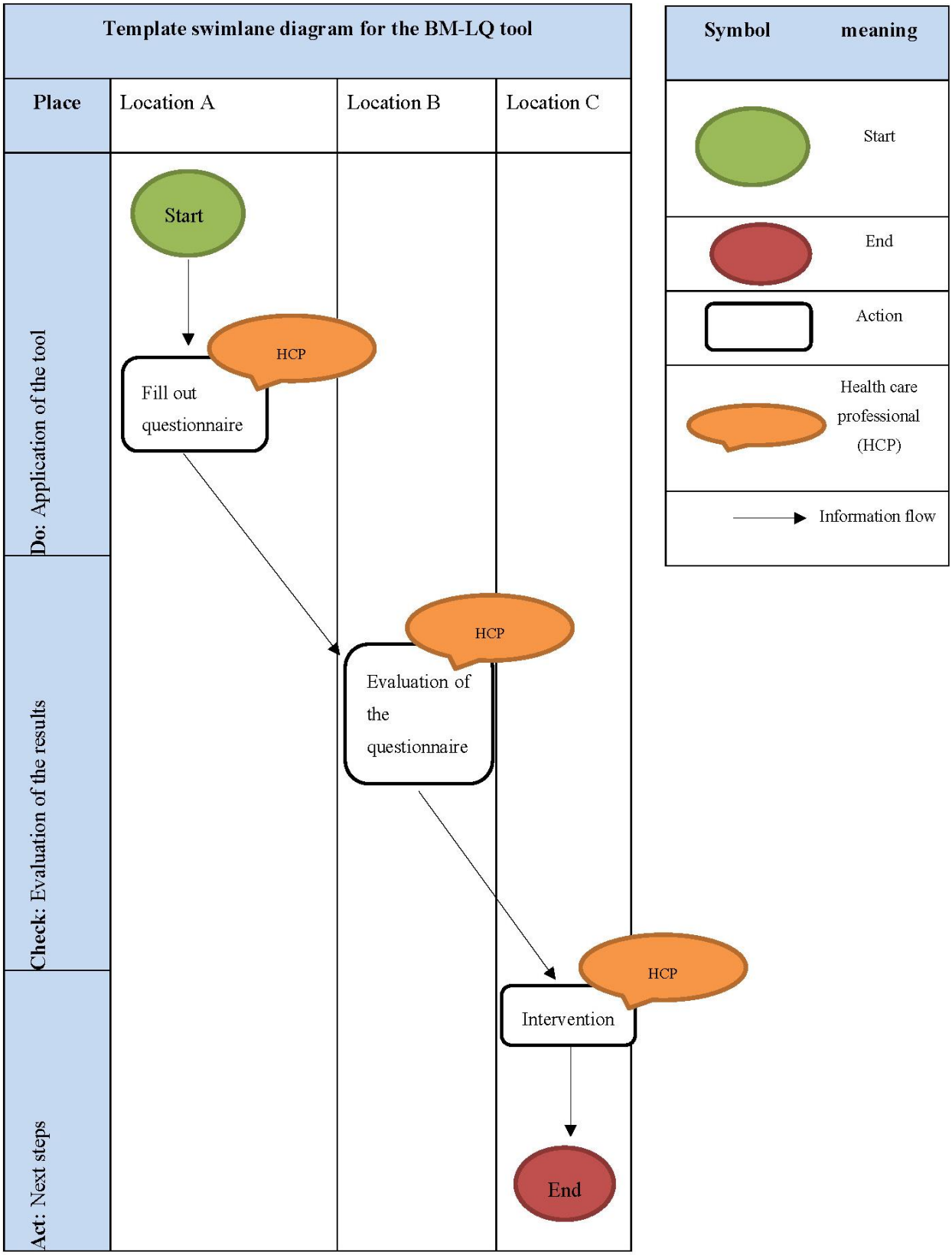
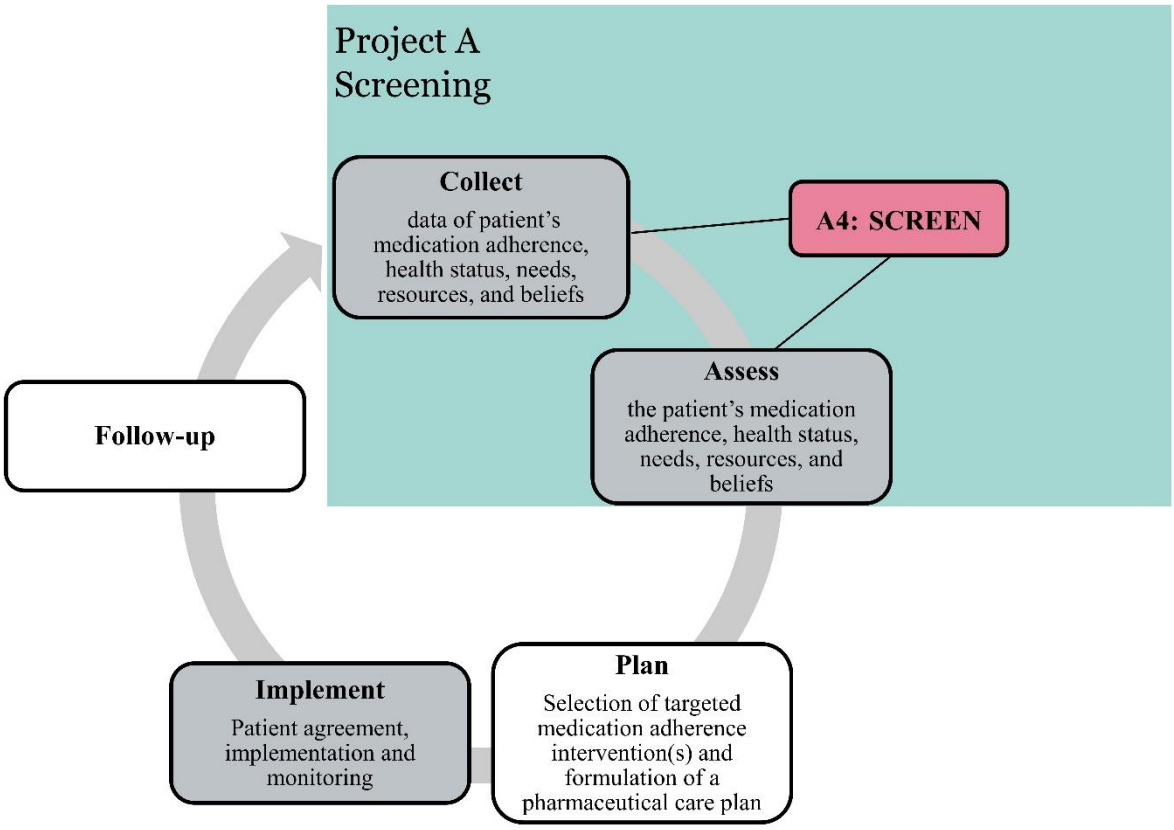
Appendix A Template of a swimlane diagram



A4- SCREEN: Proposing a framework for a strategy addressing medication adherence in community pharmacies



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Development and testing of a framework for defining a strategy to address medication adherence during patient encounters in community pharmacies

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Social marketing

ABSTRACT

Background: Counseling patients on medication adherence could be ameliorated in pharmacy practice. There is a lack of simple and practical strategies to address medication adherence with patients in daily practice. The goal was to develop and test a framework that allows pharmacy teams to define and apply a strategy to address medication adherence in community pharmacies.

Methods: A framework based on the principles of social marketing was developed. It consisted of 3 items: the target patient ("Who"), the target plan ("How"), and the target goal ("How many"). To test the framework, each participating pharmacy team developed their strategy by defining the 3 items and applied them during one pilot day. A master student observed the encounters between patients and pharmacy team members and used a structured checklist to document the patient's characteristics, counseling content, and strategy use. Pharmacy teams answered a feedback questionnaire at the end of the pilot day.

Results: Ten pharmacy teams were included. During a brainstorming session that lasted on average 31 ± 8 min, unique strategies comprised 18 different target patients and 20 different target plans. The planned target goal was a mean of 31 patients (range: 1 to "all"). A total of 325 encounters were observed, of which 208 patients (64%) corresponded to the predefined target patients. Medication adherence was addressed with 73 patients (22.5%), and adherence counseling was performed with 50 patients (15%). The pharmacy teams accepted the framework and judged it feasible and adaptable to their needs.

Conclusion: The proposed framework represents a simple tool that enables pharmacy teams to develop a strategy for addressing medication adherence in community pharmacies. Its adoption by pharmacy teams occurred without additional training and its integration into daily practice without difficulties. A further study is now needed to investigate if pharmacy teams can successfully engage patients in discussion on medication adherence and ultimately propose targeted adherence interventions.

1. Introduction

Pharmaceutical care is recognized as "the pharmacist's contribution to the care of individuals to optimize medicines use and improve health outcomes"[1] and has shifted the pharmacist's role toward more patient-centered activities. Mostly, the community pharmacist plays a pivotal part in promoting purposeful intake behavior: patients' adherence to prescribed treatments.[2] Medication nonadherence can have far-reaching clinical consequences for the patient,[3,4] and generates high costs for the healthcare system.[5,6] Nonadherence is ubiquitous across all diseases, indications, and patient groups.[7] Pharmacists are well-positioned to address nonadherence as they are trained to identify and resolve drug-related problems, including medication management and intake difficulties.[8] In addition, pharmacists are confident in their ability to address nonadherence and prepared to tackle this problem.[9] However, a discrepancy exists between attitudes and actions. An observational study in community pharmacies revealed that about 54% of patients received counseling, but only 7% were about medication adherence.[10] The identification of nonadherence in current practice relies mostly on the analysis of refilled prescriptions with pharmacy software and is performed without the patient's involvement.[11] Efforts have been made to facilitate the detection and monitoring of potentially nonadherent patients by improving pharmacy management systems,[12] up to suggesting specific interventions to improve medication adherence.[13] There are few theoretical frameworks for adherence strategies.[14,15] However, in daily routine, pharmacists often decide ad hoc to ask a patient about their medication adherence rather than following a systematic approach.[16,17] Addressing medication adherence in pharmacy practice remains a challenge for the pharmacy teams.[16] The goal of this study was to develop and test a framework that allows pharmacy teams to define and apply a strategy to address medication adherence in community pharmacies.

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2. Methods

2.1. Development of the framework

The framework was rooted in the principles of social marketing theory that applies techniques from commercial marketing to public health.[18] The social marketing theory has established the STP approach (Segmentation, Targeting, Positioning)[19] from successful commercial marketers who changed customers' behavior. The goal-setting theory[20] and the SMART criteria (Specific, Measurable, Attainable, Relevant, Time-bound)[21] were also considered to define the 3 items of the framework. The first item, "target patient," divides potential nonadherent patients into subgroups according to common characteristics (Segmentation from the STP-approach) and determines which subgroup represents the best fit for targeting patients in the pharmacy (Targeting from the STP-approach). The second item "target plan" enables to present the medication adherence counseling (i.e., the offer) in a way that fits to the target group (Positioning from the STP-approach). The third item "target number" allows the pharmacy team to set a goal for addressing patients that is specific, measurable, attainable, relevant, and time-bound (SMART criteria, Table 1).

2.2. Testing of the framework

To test the framework, an experimental study was conducted in community pharmacies in the German-speaking part of Switzerland between February and April 2019. A purposive convenience sample of community pharmacies was selected that were already experienced in participating in research studies.[22] The pharmacies were visited twice. All observed pharmacy team members agreed to participate.

At the first visit, a moderator (PB or NC) conducted a face-to-face brainstorming session with at least one pharmacist and one pharmacy technician in each pharmacy. This group creativity technique is generally used to develop new ideas and promote problem-solving.[23] First, the moderator explained the objective of the brainstorming, i.e., using the framework to determine a tailored strategy for approaching patients in the pharmacy and talking to them about their medication adherence. Then, the moderator harvested the current habits, i.e., which patients are currently approached ("Who") and how they are approached ("How") by the participants. Second, the pharmacy team proposed targets for the patients ("Who") and the plan ("How") according to the pharmacy's characteristics on the patient, provider, and system level. Finally, the participants defined one strategy by selecting one or several plausible target patients and target plans from the proposals listed beforehand. Lastly, participants defined the target number of patients that should be addressed ("How many") during one observation day. The discussion was closed when a consensus was reached among the participants. Then, the date of the second visit was defined, which had to take place during the following 4 weeks. Brainstorming sessions were audio recorded on an APPLE iPad, and sessions' outputs were noted on a whiteboard for archiving purposes. A transcription was not performed.

At the second visit, the pharmacy teams used their predefined strategy during one working day (so-called "pilot day"). One researcher (NC) visited all pharmacies. At the beginning of the pilot day, the pharmacy team was shortly briefed because some team members did not participate in the brainstorming sessions. The predefined strategy was repeated, and the documenting procedure with the checklist (see Appendix A) was explained. NC documented all sequential encounters between a pharmacy team member and a patient as a silent observer with the checklist. An encounter was defined as starting with the greeting and ending with the farewell of a patient. Mentioning the silent observer was permitted when the pharmacy staff obtained verbal consent from patients, including that NC listened to and documented their discussions. No patient data were collected, except for gender and age that were estimated by physical appearance. The characteristics of the participating pharmacy team members (age, gender, function, working experience) were registered with a short questionnaire at the beginning of the pilot day, and written consent of the pharmacy teams members was obtained. For this study, no ethics committee approval was needed according to local guidelines.

2.3. Checklist to document encounters

The checklist to document encounters was adapted from a former checklist that had been developed for the manual coding of pharmacy encounters with a focus on medication adherence counseling (Appendix A).[10] This checklist includes 68 predefined topics in nine categories: patients characteristics, details about the medication, type of encounter, counseling topics, situation, resulting activities, follow-up, strategies for addressing medication adherence, and topics of medication adherence counseling. Three tick boxes were added that focus on the 3-item strategy: if the patient corresponded to the target patient if the patient was approached verbally about medication adherence with/without the target plan, and if the patient was counseled about medication adherence.

2.4. Training of the researchers

The study was conducted by a Ph.D. student (PB) and a Master's student (NC) in pharmacy who had working experience in a community pharmacy for 3 and 1 years, respectively. The two researchers were trained in moderator skills by pilot-testing one brainstorming session with two pharmacists from the research group. Additionally, they were trained in coding pharmacy encounters in a community pharmacy not included in the study. During 4 consecutive hours, they pilot-tested the checklist in daily practice by coding independently the same patient encounters and compared their results. Discordant coding was solved by discussion; no major discrepancies or irregularities were found between the two coders, and no adaptation of the checklist was needed.

2.5. Immediate team feedback

A short survey on the framework was developed that used questions from a previous interview guide[10] and questionnaire.[25] It explored its usefulness and appropriateness (5 items), the impact on the patient (2 items), and the goal-setting (2 items). Answers were given using a four-point Likert scale[26] from 1 (disagree) to 4 (agree). Each pharmacy team member filled in the survey at the end of the pilot day.

2.6. Data analysis

Two researchers (PB and NC) summarized the harvested items of the brainstorming sessions and categorized target patients ("Who") and target plans ("How") inductively according to the trigger that was induced. The consensus was reached verbally. Medication adherence counseling was addressed when at least one of the eight topics of medication adherence counseling proposed by Boeni et al. was explicitly counseled: positive reinforcement, organization, therapy/ disease understanding, motivation, appointment keeping, skills, barriers, the meaning of nonadherence.[10] Data

Table 1
Framework with 3 items defining a strategy that enables addressing medication adherence during patient encounters in community pharmacies.

Item	Definition of the item for the strategy	Question	Question word
1	Target patients	Which patients do you want to approach?	Who?
2	Target plan	How do you want to approach the target patients?	How?
3	Target number	How many target patients do you want to approach?	How many?

from the checklists and surveys were entered in and analyzed using the Statistical Package for the Social Sciences (SPSS; Version 25.0 IBM Corporation, Armonk, NY, USA), Microsoft Excel (Microsoft Office Home and Student 2016, Microsoft Corporation, Redmond WA, USA), or Tableau Desktop Professional Edition Version (2019.3.0, Tableau Software, Seattle, WA, USA). Data from the checklists and answers from the survey were calculated and given as means with standard deviation (SD) or percentages, where appropriate.

3. Results

3.1. Defining the strategy

A total of 34 individuals (mean: 3.4 participants per pharmacy; range: 2 to 7) attended the brainstorming sessions in the 10 included pharmacies (Appendix B). The discussion lasted on average 31 ± 8 min. During the brainstorming sessions, the pharmacy teams named a total of 81 potential target patients, of which on average 1.8 (range: 1–4) were selected for the strategy. The target patients were classified into the three categories: "request," "medication," and "traits." The category "request" encompassed patients with a permanent prescription, a first prescription, a refill, or an OTC purchase. Patients in the category "medication" would need medicines with a presumed high probability of nonadherence and were defined as, for example: "Patient with antihypertensive medicines"; or "Patients with sensitive medicines such as antibiotics, narcotics, benzodiazepines." Patients' "traits" are characteristics concerning demographics (e.g., age, gender, etc.), behavior (e.g., patients refills too late), psychography (e.g., lifestyle, social, or personality), or whether they have been discharged from a hospital. The pharmacy teams selected in total 18 plausible target patients who belonged most often to the category "medication" ($n = 7$) or "request" ($n = 6$). Two pharmacies selected "all patients" without further specifications.

The pharmacy teams mentioned 60 different approach techniques for addressing medication adherence. Twenty were selected as plausible target plans (mean: 2 target plans per pharmacy; range: 1–4). Two types of techniques were observed: first, an information-centered approach using a leaflet that addressed medication adherence ($n = 2$) or promoted a campaign about medication adherence ($n = 1$); and second, a patient-centered approach that defined the communication style with the patient (e.g., using open-ended questions; $n = 6$) or used prime questions ($n = 11$). The prime questions can be further divided into three subcategories: questioning the patient about their therapy regime (e.g., "How often do you take the medication?"; $n = 7$); inquiring about the patient's experience with their therapy (e.g., "Are you satisfied with your medication?"; $n = 3$), and confronting the patient (e.g., "How often do you forget your medication?"; $n = 1$). Seven pharmacy teams selected the patient-centered approach, while two selected the information-centered approach. One pharmacy team combined both approaches in their target plan. The average target number of patients was 31 and ranged from 1 to 2 patients with a specific request (e.g., laxatives) to all patients with a refill prescription. Three teams intended to target 50 patients. See Appendix C for the selected target patients, target plans, and target numbers. See Appendix D for the categorization of the strategies.

3.2. Testing the strategy

Thirty-nine pharmacy team members performed 325 encounters during 72 h and 15 min. An average of 32.5 ± 7 encounters (range: 22–45) per pharmacy were documented during a mean of 7 h and 12 min (± 34 min). Consultation time lasted on average 7.3 ± 5.0 min. A total of 230 (70.8%) encounters concerned 153 refill prescriptions (47.1%) and 77 first prescriptions (23.7%). The remaining 95 (28.2%) encounters concerned OTC sales. Overall, 208 patients (64%) met the criteria of the preliminarily defined target patients. The pharmacy teams approached 73 patients (22.5%) to address their medication adherence (range: 2–14). All patients but one belonged to one of the predefined target patients. From the 18 predefined plausible target patient groups, seven were not used during the pilot day, either because no patients corresponded to the target group (e.g., a patient with a benzodiazepine; $n = 3$) or because the pharmacy team deliberately reduced the number of target patients at the beginning of the observation day from originally four to one. The predefined target plans were used with 46 (63.0%) of the 73 patients. The pharmacy teams addressed medication adherence on average 3.7 ± 3.3 min (range: 0–17 min) after the start of the conversation. On average, the pharmacy teams used one target plan (range: 0–2) and addressed medication adherence with 7.3 patients (range: 2–14) on average. One (10%) pharmacy reached its target number of seven patients. Of the 73 approached patients, 23 (31.5%) did not want to engage in counseling on medication adherence, resulting in 50 (15.4% of all patients) explicitly counseled patients (See Fig. 1).

3.3. Evaluating the framework

According to the pharmacy teams, most patients were willing to talk when medication adherence was addressed (94.9%; Fig. 2). The pharmacy teams judged the framework as useful for defining a strategy (3.59 on a 4-point Likert scale), and 33 (84.6%) of the team members agreed that their strategy could easily be integrated into the daily routine of their pharmacy. All pharmacy team members agreed that "Who" was mandatory for any strategy. Agreement was 92.1% for "How" and 67.6% for "How many."

4. Discussion

The proposed framework is grounded in social-marketing theories that are widely used in developing health-education programs[27] and are thus of significant interest for pharmacy practice. It was developed as a simple method consisting of three items (Who, How, How many) for guiding community pharmacies in addressing medication adherence with patients. However, each user, that is, each pharmacy team, must define its items because each pharmacy has unique characteristics on the patient, provider, and system levels. Pharmacy teams judged the framework as useful and quickly adaptable. The 10 participating pharmacy teams developed unique strategies during a short brainstorming session, which resulted in counseling 50 (15%) patients on medication adherence during one working day. The use of the framework seems promising for increasing adherence counseling compared to a previous study with a similar methodology and setting that reported a rate of medication-adherence counseling of 6.7%.[10]

4.1. Target patient ("Who")

In contrast to dedicated screening campaigns in community pharmacies, such as for undiagnosed patients with diabetes with elevated Hb1Ac,[28] there are no explicit markers of nonadherent patients.[29] In fact, pharmacy teams cannot solve all adherence issues, particularly when related to unmodifiable factors such as age or costs.[30] Similarly, obvious determinants of nonadherence such as "forgetfulness" are difficult to assess because a pharmacy encounter only provides limited information about patients and time with them.[16,31] The challenge for pharmacy teams is defining target patients and recognizing them in the daily routine. In this study, the 81 named target patients for addressing medication adherence were categorized into request, medication, or trait. For example, a regular patient that occasionally forgets to take his medication enters the pharmacy with a repeat prescription for an ACE inhibitor. The medication (ACE inhibitor) and request (repeat prescription) can be identified at the beginning of the consultation, while the trait (forgetfulness) is either known from the pharmacist's experience or discovered during the consultation (e.g., when checking the medication history). Much of the research on medication adherence focuses solely on patient-related factors such as knowledge, skills, and personality traits, which are supposed to cause or lead to poor medication adherence.[32,33] In this study, the minority of pharmacy teams selected patient traits ($n = 2$). The majority focused on triggers from medication or request. This strategy proved to be judicious, as 208 (64%) of the 325 observed patients corresponded to a target patient. To conclude, defining a

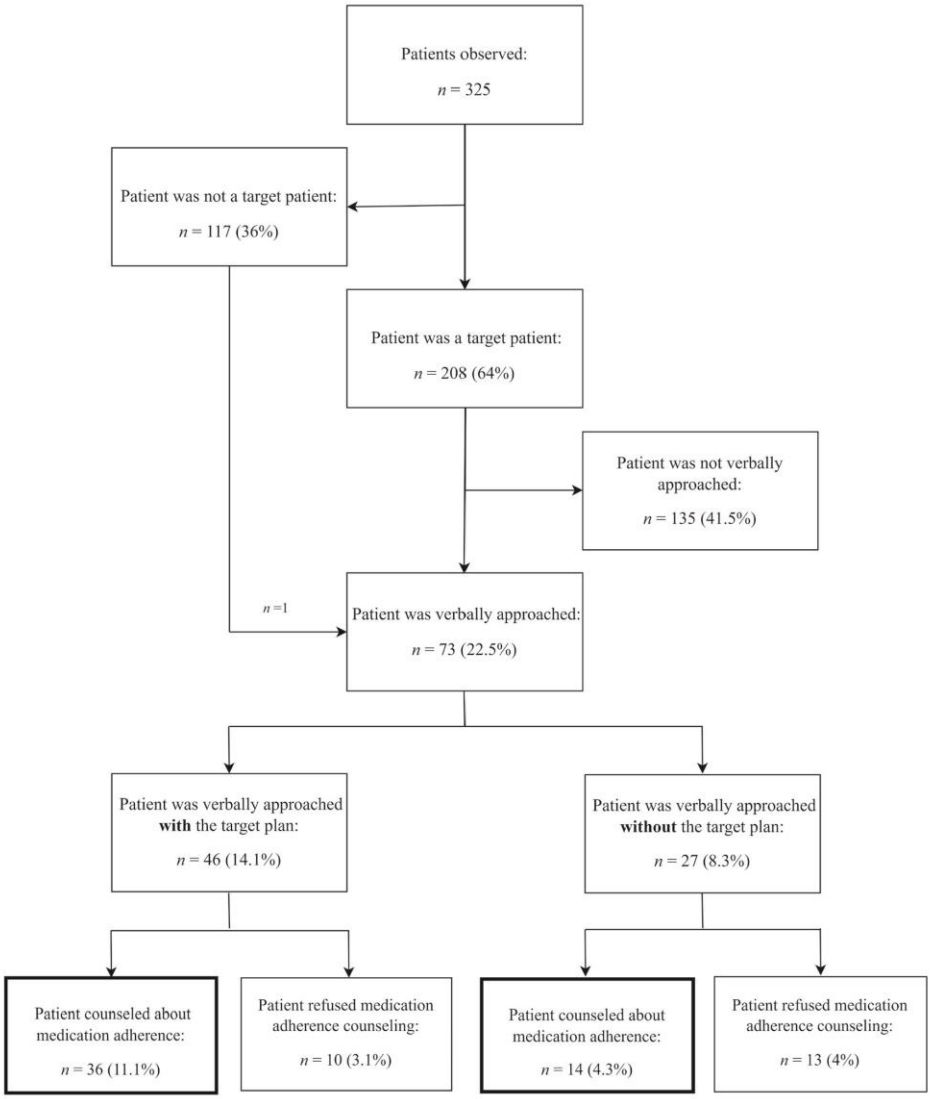

Fig. 1. Flow chart of the 325 encounters observed in 10 pharmacies.

realistic target patient during a short brainstorming session is a important first step for pharmacy teams who want to develop their own strategy before engaging patients in conversations about health behaviors.

4.2. Target plan ("How")

The decision to address a patient may be influenced by the assessment method (e.g., having a negative attitude toward consultation),[34] the course of the conversation, and personal barriers (e.g., shyness, being unmotivated).[35,36] Most notably, pharmacists still see patient rejection as the main hindrance to discussing medication adherence in practice.[1010] In this study, the pharmacy teams selected either an information-centered or a patient-centered approach as their target plan. The three pharmacies that used an information-centered approach opted for educating patients about medication adherence with a patient information leaflet or with an "action day of adherence." Information campaigns have proven to be an effective opportunity for pharmacists to sensitize and screen patients.[37] Educational materials such as patient information leaflets have also been shown to encourage patients to engage in the care they receive.[38,39] In this study, eight pharmacies embraced a patient-centered communication style by using either open-ended questions or prime questions. This approach makes patients more open to discussing their intake behavior and may include a shared definition of the problem and shared decision-making.[40] Patient-centered communication has also been shown to have a promising effect on detecting and addressing nonadherence.[41] There is a favorable relationship between the use of open-ended questions and the amount of information given by patients.[42] Prime questions have also demonstrated their usefulness in better structuring patient conversations. For

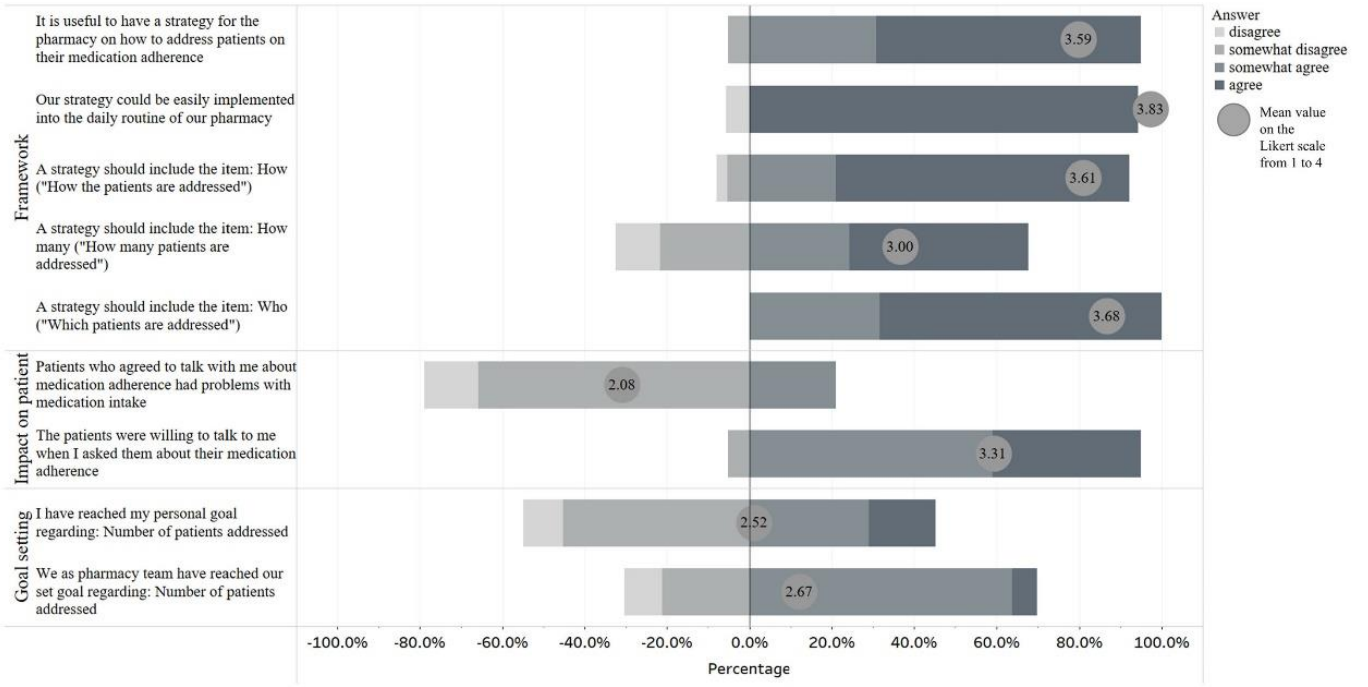

Fig. 2. Responses of the 39 pharmacy team members concerning the framework, impact on the patient, and goal-setting.

example, the Indian Health Service (IHS) counseling techniques propose three prime questions for engaging users of medicines: (1) What are you using this medication to treat? (2) How do you take this medication? (3) What problems are you experiencing with this medication?[43] These questions should help improve patients' understanding of their medicines and lead to short-term improvement in medication adherence.[44] In this study, all pharmacy teams were able to address patients independent of the chosen target plans. In a further step, the teams reflected on how to address the issue of medication adherence. They estimated that most patients would respond positively to a conversation about their medication adherence, which was supported by the observation that 50 out of 73 patients accepted a discussion about medication adherence. To conclude, information-centered and patient-centered communication styles seemed equally successful as ways for pharmacy teams to discuss health behavior with patients, as long as they were preceded and followed by reflection.

4.3. Target number ("How many")

During the brainstorming sessions, the pharmacy teams determined a high target number of patients (up to 100 patients) and finally addressed a mean of 7.3 patients during the pilot day. Nevertheless, most of the pharmacy teams self-evaluated that the goal of the pilot day had been reached, which means that they had overestimated their target numbers. However, while the term "goal" was defined as corresponding to a preset number, it can be interpreted in many other ways. Further, both the target numbers and the target patients heavily depended on the traffic at the pharmacy, which was easily influenced by factors that were out of reach of the pharmacy teams, such as the weather. To conclude, even if the target patient numbers were out of reach, they allowed the pharmacy teams to define a measurable goal. Studies have demonstrated that setting measurable and realistic goals leads to higher performance levels.[20,45] Ultimately, setting target numbers closer to reality is more likely to be achieved through experience with using the three-item framework.

4.4. Meaning for practice

A critical evaluation of the results indicates that pharmacy teams can develop a strategy based on a simple three-item framework with social-marketing components. The structure of the three-item framework has several implications for practice. First, it makes it possible to tailor a strategy to the conditions and needs of an individual pharmacy. This might be why the participating pharmacy teams accepted the three-item framework and were willing to apply the strategy in the future. Second, the strategy can be developed within a 30-min brainstorming session without training or preparation. In pharmacy practice, where time is precious, the possibility of finalizing a strategy in a short time is of utmost importance. Third, according to common quality-improvement concepts such as the Deming Cycle, the three items can be easily modified, continuously adapted, and improved (e.g., by choosing different target patients or target plans).[46] Thus, once a pharmacy team has internalized the concept, they can duplicate it to other services and gain confidence and time. Fourth, the generic modular structure of the framework has the potential to promote other critical counseling themes such as "alcohol and medication" or "driving and medication."

4.5. Strengths and limitations

This study has several strengths, especially concerning its methodology. First, the researcher who observed all the encounters was highly knowledgeable about the strategy developed by the pharmacy teams. This allowed him to immediately recognize the predefined strategies during the pilot day and document the observed encounters on the checklist without hesitation. Second, following the principles of action research, our approach integrated the pharmacy teams in the design of the strategy.[47] This represents a collaborative problem-solving relationship, a promising method that has already been successfully used in pharmacy practice.[48,49]

There are also several limitations to this study. First, there was no control group. Thus, the true effect of the strategy on medication adherence counseling was not estimated. But this study did not aim to prove an effect. Second, although the silent observer represents a minimally intrusive method, an observer can cue pharmacy teams to engage more in counseling than usual (Hawthorne effect).[50] Third, observing and documenting patient encounters is a subjective assessment. Thus, the researcher might influence the reliability of the results. However, the researcher was trained in the relevant skills, and researcher bias was thus reduced. Nevertheless, doubling the data with a second observer might have delivered more reliable results. Fourth, it is impossible to assess how patients and pharmacy teams accepted the strategy after observing the pharmacy practices for only one working day. Nevertheless, the positive opinions of the pharmacy teams after the pilot day can be considered indicative of acceptability over time for the teams and their patients. Fifth, a sample of community pharmacies that had already participated in a medication adherence campaign was chosen, so it is possible that the pharmacy teams had a preexisting interest in the topic and a greater motivation to participate.

5. Conclusion

The proposed framework is a simple tool to develop a strategy for addressing medication adherence in community pharmacies during daily practice. The generic modular structure of the framework that combines a target patient ("Who"), a target plan ("How"), and a target number ("How many") allowed the 10 participating pharmacy teams to develop and apply their unique strategies successfully. The framework was accepted by the pharmacy teams and judged adaptable and feasible. A further study will investigate if pharmacy teams can successfully engage patients in a counseling conversation on medication adherence and ultimately propose targeted medication adherence interventions.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Acknowledgements

The study was funded by the Pharmaceutical Care Research Group.

Appendix A. Checklist used for documenting the encounters[1]

Screen study 2019

Pharmacy-No. 1☐☐ **Customer No.** 2☐☐☐ **Observer** 3☐☐ **Time**4☐☐:☐☐-☐☐:☐☐

Information about the customer

05☐Male 06☐Female
07☐Regular Customer 08☐New customer
09☐Present 10☐Relative
11☐<20y 12☐21-40y
13☐41-65y 14☐65-80y
15☐>80y

Situation during the consultation

16☐Interruption 17☐Waiting customer
18☐High noise level 19☐Language barrier
20☐Time pressure 21☐Not assessable

Prescription

22☐First fill 23☐Repetition
24☐In advance 25☐Without a prescription
26☐Hospital discharge 27☐Ambulant

28☐OTC

Details about the medications

Number29☐

30☐PMC criteria met (>4 Medication /for >3 months according to Swissmedic)

Counseling

31☐Counseling offer
32☐Consultation in separate room
33☐Refused counseling
34#Number of medications: _____
35☐Medications known

Counseling themes

Before A	Before E		After A	After E
36☐	☐	Type of application	☐	☐
36.1☐	☐	Instruction	☐	☐
37☐	☐	Therapy duration	☐	☐
38☐	☐	Frequency of intake	☐	☐
39☐	☐	Time of intake	☐	☐
40☐	☐	Modality of intake	☐	☐
41☐	☐	Indication	☐	☐
42☐	☐	Mechanism of action	☐	☐
43☐	☐	Effect	☐	☐
44☐	☐	Therapy goal	☐	☐
45☐	☐	Adverse drug reaction	☐	☐
46☐	☐	Problems during treatment	☐	☐
47☐	☐	Importance of intake	☐	☐

Addressing of potentially non-adherent patients:

Time48☐☐:☐☐-☐☐:☐☐

49 Who is addressed?

Corresponds to		is addressed
Who 1	☐	☐
Who 2	☐	☐
Who 3	☐	☐
Who 4	☐	☐

Who:_____

50 How is the patient addressed?

How 1 ☐
How 2 ☐
How 3 ☐
How 4 ☐
Others:_____

51Successfully addressed?
☐Yes ☐No

What is being addressed about adherence?

52☐Positive reinforcement
53☐Motivation
54☐Organization
55☐Dates
56☐Barriers
57☐Skills
58☐Therapy / Disease Understanding
59☐What does nonadherence mean?

Flyer used60☐

Results

61☐Delivery of a flyer
62☐Dispensing adherence aid:
_____

63☐Appointment for PMC
64☐Switch to a dose dispenser
65☐Other services_____

Aftercare

66☐Follow-up
67☐Do you have any questions?
68**Open remark field**

[1] A = Patient asks; E = Pharmacy team member explains. The items 49–50 were adapted for each pharmacy. Forward translation in English was performed by the researchers.

Appendix B. Characteristics of the pharmacy team members of the 10 participating pharmacies

	Participated in the development of the strategy $N = 34$	Participated in the pilot day $N = 39$
Female [n (%)]	30 (88.2%)	35 (89.7%)
Mean age [years ± SD]	34.9 ± 13.4	33.3 ± 10.7
Work experience [years ± SD]	12.6 ± 10.4	9.5 ± 8.3
Mean working time percentage [% ± SD]	83.9 ± 25.2	85.5 ± 23.4
Degree [n (%)]		
Pharmacist	13 (38.2%)	13 (33.3%)
Pharmacy technician	11 (32.4%)	17 (43.6%)
Advanced pharmacy technician	4 (11.8%)	4 (10.3%)
Apprentice	3 (8.8%)	1 (2.6%)
Druggist	2 (6%)	4 (10.3%)
Pharmacist in training	1 (3%)	-

Appendix C. Target patients, target plans and target goals of the 10 pharmacies

Pharmacy number	Who? (target patient)	How? (target plan)	How many? (target number)
A01	As many patient as possible with a prescription, as diverse as possible	Situational With open questions By showing a flyer	10
A02	Everyone	By showing a flyer	2
A03	Patients with permanent prescriptions Patients with sensitive medicines (e.g. antibiotics, narcotics, benzodiazepines.) Patients discharged from the hospital	Promoting an action day "adherence"	12
A04	Patients with laxatives (OTC)	Through conversation in the consultation room	1–2 patients
	Patients with prescriptions	By asking direct questions after checking the patient's history	10 patients
A05	Patients with prescriptions	"How do you take the medicines?"	12 patients, 2 per person
	Patients with osteoporosis medicines	"How much do you know about osteoporosis?"	
	Patients with blood-thinning medicines	"The medication is optimal for your blood circulation, so it is important to take daily, when do you take it?"	
	Patient with antihypertensive medication	"Do you know your blood pressure?" "Do you notice when your blood pressure is too high?" (possibly offering measurement)	
A06	All customers with refill prescriptions	With a unitary key sentence: "Are you satisfied with your medication?"	100
A07	Patients with polymedication, chronic diseases or critical indications (e.g. asthma, diabetes, epilepsy or hypertension)	With open questions "Are you satisfied with the effectiveness of the medication?" "How often do you forget your medication?"	7
A08	All patients	Everyone has their own strategy, depending on what fits the situation	50 + 4 Polymedicationcheck (PMC)
A09	Regular customers with refill prescriptions with inconsistent history	"How often do you take it?" "When and how do you take it?"	10 to 20% of customers
	Patients whose medication is labelled with "according to doctor's prescription" (especially inhalation devices and sprays)	"Are you interested to be shown how to use it again?"	2
A10	Everyone with a prescription Critical OTC medication: Pain killers, laxatives	"Did something change?" "Did it work well?" "Is it for you?"	8

Appendix D. Target patients and target plans according to categories with corresponding definitions and results

a) Target patient

Category	Definition	Results
Request	purchase of the patient (e.g. first prescription, refill, OTC purchase)	Patients with prescriptions ($n = 4$) Patients with permanent prescriptions All customers with refill prescriptions
Medication	medicines with a high probability of nonadherence	Patients with osteoporosis medicines Patients with blood-thinning medicines Patient with antihypertensive medication Patients with polypharmacy, chronic diseases, or critical indications (e.g. asthma, diabetes, epilepsy, or hypertension) Patients with laxatives (OTC) Critical OTC medicines such as pain killers, laxatives Patients with sensitive medicines (e.g. antibiotics, narcotics, benzodiazepines.)
Traits	demography (e.g., age, gender), behavior (e.g., patients refills too late), and psychography (lifestyle, social, personality)	Patients discharged from the hospital Regular customers with refill prescriptions with an inconsistent history
No explicit instruction of use	Several refills of the same medication with no instruction of use	Medication is labelled with "according to doctor's instruction" (e.g. inhalation devices and sprays)

b) Target plan

Type of approach	Aid	Results
Information-centered	using a leaflet	Showing a flyer ($n = 2$)
	promoting a campaign	Promoting an action day "adherence"
Patient-centered	using prime questions	Questioning the patient about their therapy regime: "How much do you know

(*continued*)

a) Target patient		
Category	Definition	Results
		about osteoporosis?" "The medication is optimal for your blood circulation, so it is important to take it daily, when do you take it?" "Do you know your blood pressure?" "Do you notice when your blood pressure is too high?" (possibly offering measurement) "How often do you take it?" "When and how do you take it?" "Are you interested to be shown how to use it again?" "Did something change?" Inquiring about the patient's experience with their therapy: "Are you satisfied with your medication?" "Are you satisfied with the effectiveness of the medication?" "Did it work well?" "Is it for you?" Confronting the patient: "How often do you forget your medication?" By asking direct questions after checking the patient's history
	defining the style of communication	Through conversation in the consultation room Situational Everyone has their strategy, depending on what fits the situation

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.rcsop.2022.100123.

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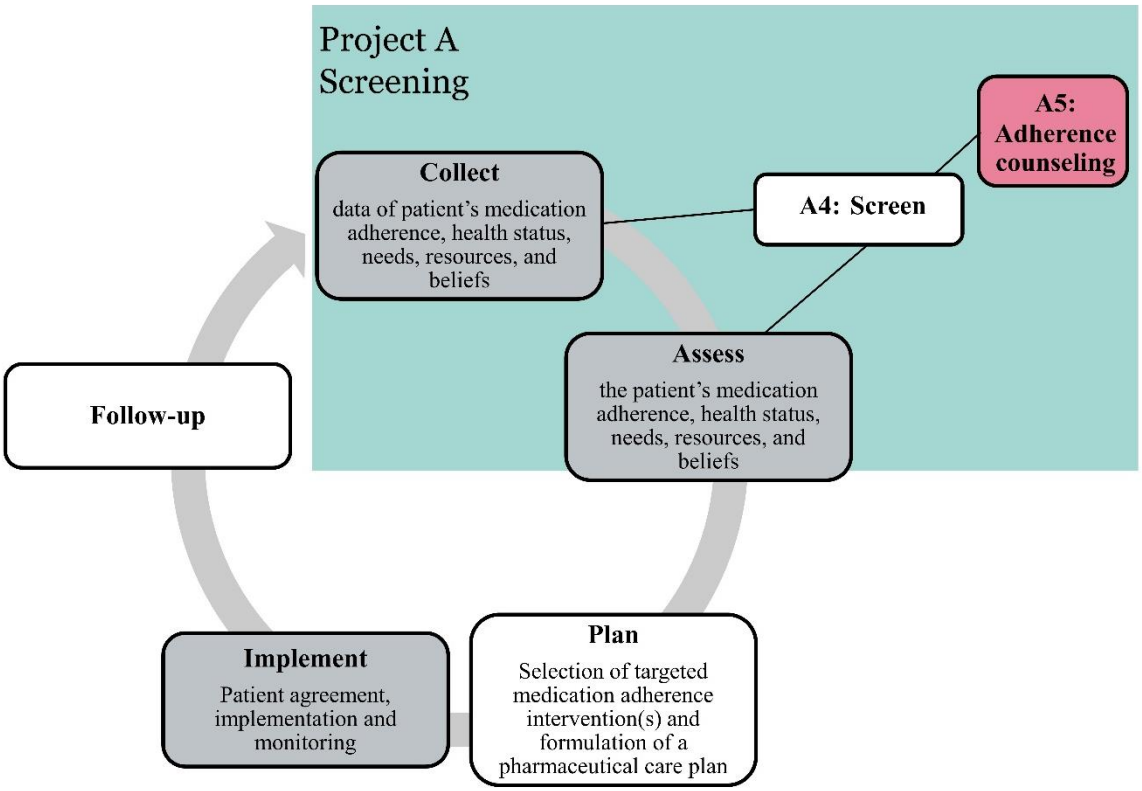
A5- Adherence counseling: Analyzing patient encounters with pharmacy teams with a focus on medication adherence



Short Report: Characteristics of medication adherence counseling encounters in community pharmacies

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Draft ready for review by co-authors

Abstract

Background

In community pharmacies, the extent of counseling on medication adherence appears to be low and is not well documented. Our goals were to characterize the adherence counseling encounters in community pharmacies, and compare the encounters with and those without addressed medication adherence.

Methods

We conducted a subanalysis of an observational study performed in 10 community pharmacies in Switzerland that was focusing on medication adherence counseling (Project A4). In brief, a silent observer (master Student) coded the content of encounters with the help of a checklist. We characterized encounters in which medication adherence was addressed (frequency of counseled medication adherence topic) and compared them with encounters where medication adherence was not addressed by applying Chi-Square, Fisher's Exact Test, Spearman, and Mann-Whitney U tests where appropriate.

Results

In 325 observed encounters, medication adherence was addressed with 73 (21.9%) patients, and adherence counseling on any topic was performed with 50 (15%) patients. The encounters with adherence counseling were on average 1.6 minutes longer (7.5 ± 5.2 min vs. 5.9 ± 4.8, $p = 0.002$). The

number of counseling topics (excluding medication adherence counseling) was on average two per encounter and did not differ between both groups (2.04 ± 2.04 vs. 1.93 ± 1.93, *p = 0.762*). On average, 1.4 ± 0.6 topics of medication adherence were thematized during adherence counseling, mainly addressing patient-related issues.

Conclusion

Community pharmacy teams are able to counsel on a broad spectrum of patient-related issues when addressing medication adherence. Addressing medication adherence during patient counseling is not time-consuming and does not affect other counseling activities.

Background

In the daily activities of community pharmacies, the amount of counseling on medication adherence appears to be low. An observational study in community pharmacies found that only 7% of the patients were receiving counseling about medication adherence [1]. In project A4, we tested a framework to address medication adherence during daily encounters that consisted of three items: the target customer (Who), the target plan (How), and the target goal (How many). The pharmacy teams accepted the framework and applied it during one working day while counseling (= pilot day). However, the content of the observed pharmacy team-patient interactions during the encounters with medication adherence counseling was not further analyzed. Our goals were to characterize the content of the medication adherence counseling encounters in community pharmacies and to compare the encounters with addressed medication adherence with those not addressed.

Methods

We conducted a subanalysis of the observational study performed in 10 pharmacies in Switzerland that was focusing on medication adherence (see Project A4). During the pilot day, a silent observer (master student) coded the encounters content with the help of a checklist. We adapted an existing checklist that has been developed for the coding of pharmacy encounters with a focus on medication adherence counseling.[1] The original checklist includes 68 predefined topics in nine categories: patient characteristics, details about the medicines, type of encounter, counseling topics, situation, resulting activities, follow-up, strategies for addressing medication adherence, and topics of medication adherence counseling. In addition, Boeni et al. proposed eight topics for medication adherence: positive reinforcement, organization, therapy/ disease understanding, motivation, appointment keeping, skills, and barriers, the meaning of nonadherence.[1] We defined medication adherence counseling as performed when at least one of the eight above-mentioned topics was coded. The observer coded the content of sequential encounters between any pharmacy team member and any patient. We defined an encounter as starting with the greeting and ending with the farewell of a patient. No patient data were collected, except for gender and age that were estimated. No ethics committee approval was needed. The data of the checklists were entered in and analyzed with the Statistical Package for the Social

Sciences (SPSS; Version 25.0 IBM Corporation, Armonk, NY, USA), or Microsoft Excel (Microsoft Office Home and Student 2016, Microsoft Corporation, Redmond WA, USA), or Tableau Desktop Professional Edition Version (2019.3.0, Tableau Software, Seattle, WA, USA).

Statistical analysis

We characterized encounters by the frequency of counseled medication adherence topics, and compared those where medication adherence was addressed with those where medication adherence was not addressed. We applied Chi-Square, Fisher's Exact Test, Spearman, and Mann-Whitney U tests to compare variables of the two groups (medication adherence addressed vs. medication adherence not addressed) where appropriate. We considered a *p*-value of <.05 as statistically significant.

Result

A total of 325 encounters were observed during a total of 72 hours and 15 minutes. The pharmacy teams approached 73 patients (22.5%) to address medication adherence. Addressing medication adherence took place on average 3.7±3.3 minutes (range: 0-17 minutes) after the start of the encounter. Of the 73 approached patients, 23 (31.5%) refused to engage in counseling on medication adherence, resulting in 50 (15.4% of all patients) counseled patients.

Characteristics of the encounters with medication adherence counseling

On average, 1.4 ± 0.6 topics of medication adherence were addressed, with positive reinforcement being the most frequent (see Table 1). Compared to encounters without medication adherence counseling, the duration of encounters with counseling was on average 1.6 minutes longer (+ 27%; 7.5±5.2min vs. 5.9±4.8, $p = 0.002$), and 1.57 more topics were discussed (3.5±2.2 vs. 1.93±1.93, $p < 0.0001$). The number of counseling topics (excluding medication adherence counseling) was on average two per encounter and did not differ between both groups (2.04±2.04 vs. 1.93±1.93, $p = 0.762$).

Table 1 Definition of the medication adherence topics that were discussed during 50 encounters, adapted from [1], with frequency; multiple topics are possible

Medication adherence topic [1]	Definition	Number of patients counseled n (%)
Positive reinforcement	Acknowledging and encouraging the patient's efforts to behave in an adherent manner	25 (50%)
Organization	The patient is presented with options that make it easier for him/her to organize his/her medication. These include: labels, dosettes, agenda, timer, telephone, the inclusion of social support from family and friends or home care nursing	19 (38%)
Therapy / Disease understanding	Information explaining the therapy or the disease is passed on to the patient. The information is used to understand why he/she is receiving a particular medicine and should therefore be guided by certain behavioral patterns	10 (20%)
Motivation	The patient's motivation towards taking the medication is assessed and, if necessary, supported by the pharmacy	6 (12%)
Dates	Reminding the patient of appointments (refill, self/monitoring, physician)	6 (12%)
Skills	Physical barriers such as visual impairment, poor dexterity, aspect (size, shape, smell, taste), method of application, and swallowing difficulties are addressed	4 (8%)
Barriers	Includes psychological barriers such as forgetfulness, lifestyle, fear of side effects, or downplaying the severity of the illness	2 (4%)
What does nonadherence mean?	The term nonadherence is explained.	0 (0%)

Characteristics of all encounters

From the total 13 documented counseling topics, “adverse drug reaction” and “therapy goal” were significantly more often discussed during encounters where the patients were explicitly counseled about medication adherence (14% vs. 4.4%, *p = 0.016;* 12% vs. 2.9%, *p = 0.011;* Figure 1). Less than 10% of all patients were actively asking questions about their medication regime, with no difference between the two groups (10% without medication adherence counseling vs. 8% with medication adherence counseling, *p = 0.582*, data not shown).

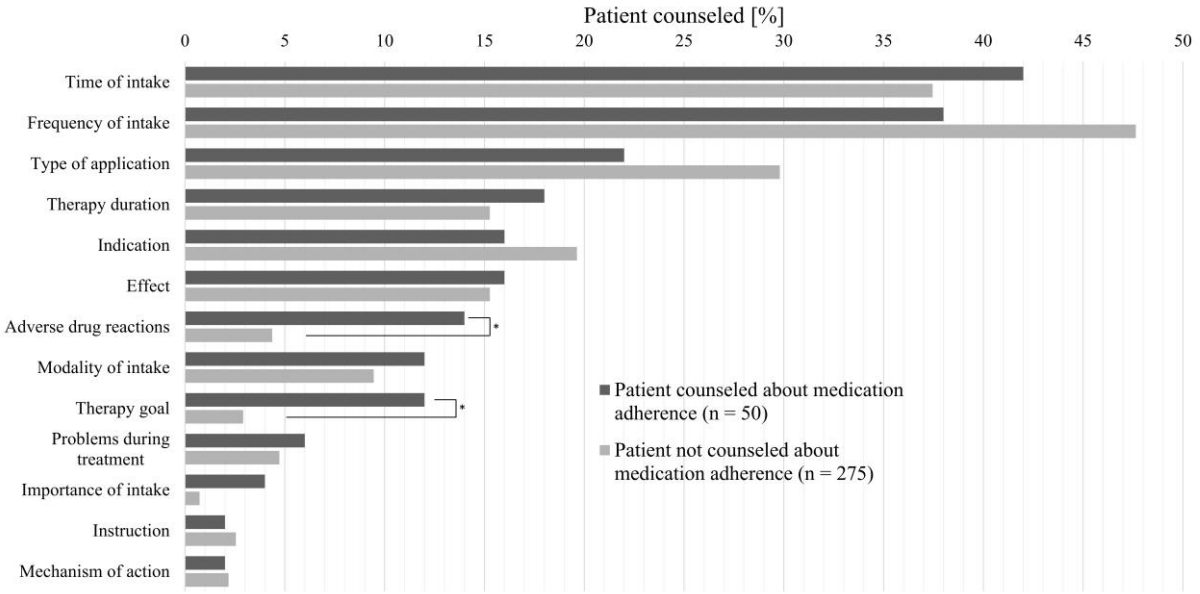

Figure 1 Percentage of counseled patients according to the counseling topics during encounters with medication adherence counseling (dark grey; n =50) and without (light grey; n = 275). A significant difference is marked with an asterisk (*).

Discussion

Overall, approximately 1 out of 7 patients (15.4% of all patients) was counseled about medication adherence during daily activities in community pharmacies. Our analysis shows that addressing medication adherence does not affect overall counseling activity (number/frequency of counseling topics), only the counseling length (on average 1.6 minutes longer). This result contradicts the commonly mentioned barrier “lack of time” that prevents pharmacy teams from addressing medication adherence during encounters [2, 3]. During the medication adherence counseling, different issues regarding medication adherence were discussed such as medication-centered barriers (i.e., organizational problems). However, patient-centered issues (motivation, positive reinforcement) were mainly the focus of the consultation. This contradicts the general statement that pharmacists primarily focus on medication-centered issues [4]. The limiting factor of this study is that effect of the counseling was not documented. Nevertheless, it was possible to document that pharmacy teams discuss a broad spectrum of medication adherence issues with the patient, demonstrating the ability to tailor counseling to the patient's needs. This is of utmost importance in light of a growing body of evidence showing that interventions are only successful if they are tailored to the specific needs of the patient [5, 6].

Conclusion

The community pharmacy teams counseled a broad spectrum of patient-related issues when they addressed medication adherence during encounters with patients. This activity is not time-consuming and does not affect other counseling activities.

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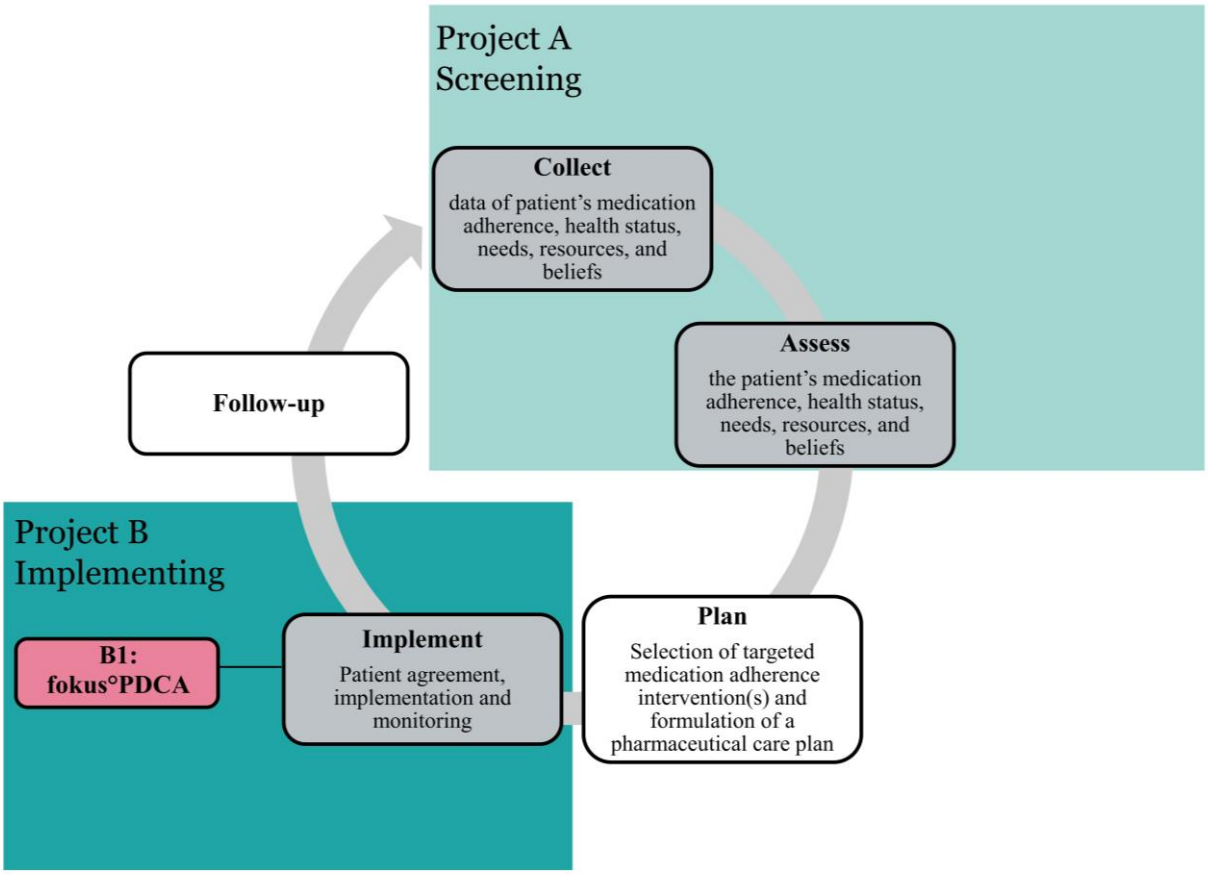
PROJECT B

Using implementation concepts to establish professional pharmacy services in community pharmacies

B1- fokus°PDCA: Developing an implementation strategy for professional pharmacy services



Development and piloting of an implementation strategy for professional pharmacy services: introducing the fokus°PDCA

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Abstract

Background: In recent years worldwide, professional pharmacy services have been developed, piloted, and implemented, but few have reached sustainability. Implementation strategies should act as facilitators to overcome implementation barriers. Ideally, the strategies should be clearly defined, tailored to the setting, and piloted by practitioners to guide the implementation process. The Deming or PDCA cycle is a promising core structure for a comprehensive implementation strategy.

Goal: Our goal was to develop an implementation strategy for professional pharmacy services in community pharmacies based on the PDCA cycle.

Methods: We conducted a pragmatic literature search to retrieve implementation strategies for pharmacy practice based on the PDCA cycle. We used the Framework for the Implementation of Services in Pharmacy (FISpH) to tailor the strategy to the setting. We performed the pilot-testing in three consecutive steps with three different groups and subsequent adaptions: i) Pharmacy master students evaluated the usability and comprehensibility; ii) Community pharmacists evaluated the acceptability, feasibility, and appropriateness; iii) Community pharmacists used the strategy to implement a new professional pharmacy service and revaluated acceptability, feasibility, and appropriateness. All variables were evaluated with answering to questions on a 4-point Likert scale.

Results: We found six published variations of the PDCA cycle used in the health care setting. We developed an implementation strategy named "fokus°PDCA" where each letter stands for one step. Fourteen pharmacy master students rated the usability and comprehensibility of the first version of fokus°PDCA at 3.6±0.2 and 3.7±0.3, respectively. Fourteen community pharmacists rated the acceptability, feasibility, and appropriateness of an amended version at 3.6±0.4, 3.4±0.3 and 3.6±0.3, respectively. Eight community pharmacists used the strategy to implement a professional pharmacy adherence service (n = 5), a vaccination service (n = 2), or a labor analysis service (n = 1), and rated the acceptability, feasibility, and appropriateness at 3.2±0.1, 3.6±0.2 and 3.3±0.2, respectively.

Conclusion: We have successfully developed an implementation strategy for professional pharmacy services. First evaluations resulted in good scores for usability, comprehensibility, acceptability,

feasibility, and appropriateness. In the next step, the strategy will be used for implementing a new professional pharmacy service and effectiveness will be assessed.

Keywords: Implementation strategies[1], implementation barriers[2], tailoring[3], pharmaceutical care[4], pharmacy practice[5], community pharmacy[6]. (Min.5-Max. 8)

Introduction

Innovations in health care aim to change practice, reduce costs, improve outcomes and/or redefine the tasks and responsibilities of health care professionals (Flessa and Huebner, 2021). The professional profile of pharmacists has changed from a pure medication expert to a patient-focused medication provider with a more important role in primary care (Wiedenmayer et al., 2006). Many professional pharmacy services have been designed and evaluated extensively in research studies (Crespo-Gonzalez et al., 2017), such as pharmacist-led patient diabetes monitoring programs (Ali et al., 2012), smoking cessation assistance (Carson-Chahhoud et al., 2019), or medication therapy management services (Houle et al., 2014;Messerli et al., 2016). However, few services have been implemented sustainably. In a European survey about professional pharmacy services, nearly half of the services (40/81) had reported low levels of implementation (Soares et al., 2020). The reasons for this imbalance are manifold and depend predominantly on the implementation factors that are defined as *"elements that moderate the implementation of evidence-based services"* (Garcia-Cardenas et al., 2018). These factors can act as facilitators or barriers during the process of implementing professional pharmacy services (Garcia-Cardenas et al., 2018). To improve the implementation process, strategies should be used to overcome implementation barriers. Implementation strategies are known as *"methods or techniques used to enhance the adoption, implementation, and sustainability of a clinical program or practice"* (Powell et al., 2015). For the implementation of services in community pharmacies, many strategies have been applied with different degrees of complexity (for example, discrete or multifaceted), at different levels (for example, micro-level to macro-level), and at different times (Moullin et al., 2016). As in intervention research, implementation strategies should be clearly defined and preceded by a development and evaluation process (Craig et al., 2008). In most community pharmacies, however, time, money, and human resources are limited when it comes to implement a new professional pharmacy service (van de Pol et al., 2019). Thus, effective strategies should be in place. Unfortunately, names, definitions, and specifications of most underlying strategies are lacking in published implementation studies (Proctor et al., 2013). Therefore, comparing different strategies is difficult, and it is still unclear whether multifaceted strategies or single-component strategies are more efficacious (Squires et al.,

2014). Powell et al. have already defined 73 discrete strategies (Powell et al., 2015) and mapped them for their importance and feasibility (Waltz et al., 2015). The development and implementation of strategies for quality monitoring has been reported as a strategy with the highest feasibility and importance (Waltz et al., 2015). Quality monitoring and improvement methods are already increasingly used in the health care sector for existing processes (Varkey et al., 2007;Walshe, 2009;Brown et al., 2018;Christoff, 2018). The prominent Deming cycle, also called the PDCA cycle, describes the four stages of planning (Plan), execution (Do), review (Check), and adjustment (Act) (Sokovic et al., 2010). It is used for point-by-point perfection or optimization of a process by applying iterative, sequential cycles (Waser and Peter, 2016). The existing processes are repeatedly questioned and evaluated, which is often missed when applying complex implementation strategies (Moullin et al., 2016). Therefore, we hypothesize that the PDCA cycle can serve to develop a feasible and appropriate implementation strategy for professional pharmacy services. Our goal was to develop an implementation strategy for professional pharmacy services in community pharmacies based on the PDCA cycle.

Methods

We performed a pragmatic literature search (13.1.2020) to find implementation strategies using the PDCA cycle in the health care setting. The search was conducted in PubMed and Google Scholar with the terms “PDSA”, “PDCA”, “Deming cycle”, and “health*care” and their synonyms. We then developed a tailored strategy to the community pharmacy setting, and tested the implementation strategy with community pharmacists.

Tailoring the strategy to the community pharmacy setting

The first draft of the strategy was amended according to the Framework for the Implementation of Services in Pharmacy (FISpH)(Moullin et al., 2016). The FISpH defines six process steps during an implementation: Development/discovery, exploration, preparation, testing, operation, and sustainability. The purpose of each step was defined with corresponding questions in order to enable reflection on the implementation process.

Testing the strategy with community pharmacists

Test groups

The strategy was tested in three consecutive groups and subsequently adapted: Pharmacy master students during their internship in a community pharmacy (Group 1), pharmacists working in a community pharmacy (Group 2), and pharmacists working in a community pharmacy just about to implement a new professional pharmacy service (Group 3). Participants were recruited in the acquaintance of the investigators. Participants of Group 3 were engaged via three channels: a regional pharmacy association “Aargauer Apothekerverband”, the Swiss pharmacy association's continuing education program “FPH Offizin”, and a group of independent pharmacies “TopPharm” that were piloting a new professional pharmacy service in selected pharmacies. Participants were provided with a folder containing the instructions for the use of the strategy, and a two-part instructional video.

Test settings

A simulated and a real life implementation of a professional pharmacy service were used. The simulated implementation concerned a vaccination program, and was given to participants of Group1 and Group 2. The real life implementation concerned a new professional service that participants of Group 3 were about to implement in their community pharmacy.

Evaluation of the strategy

The strategy was evaluated with two questionnaires assessing usability, comprehensibility, acceptability, feasibility, and appropriateness (see Table 1). Answers were given on a 4-point Likert scale (agree; somewhat agree; somewhat disagree; disagree; see Table 1). In March 2020, participants of Group 1 applied the implementation strategy during a workshop and evaluated its usability and comprehensibility (Table 1) with a 10-item questionnaire. In April 2020, participants of Group 2 obtained the implementation strategy and instructions per mail. They evaluated the implementation strategy's acceptability, feasibility, and appropriateness with a 15-item questionnaire. The participants of Group 3 tested the strategy during three months or completed at least two PDCA cycles between November 2020 and July 2021. When finished, they evaluated the strategy's acceptability, feasibility, and appropriateness with the 15-item questionnaire. The implementation strategy was amended according to the comments of each group, if needed.

Data analysis

Microsoft Excel (Microsoft Office Home and Student 2016, Microsoft Corporation, Redmond WA, USA) or Tableau (Desktop Professional Edition Version 2021.1, Tableau Software, Seattle, WA, USA) were used for data analysis. Means with standard deviation (s.d.) and percentages for the answers to the questionnaires were calculated.

Table 1 Variables used for the evaluation of implementation strategies, with the definition from literature including references, and derived item for assessing the variable with a questionnaire

Variable	Definition in literature (reference)	Derived item for assessing the variable with a questionnaire
Comprehensibility	"The quality of being easy or possible to understand"(Cambridge, 2022)	Is the strategy formulated and structured understandably?
Usability	"Extent to which a system, product or service can be used by specified users to achieve specified goals with effectiveness, efficiency, and satisfaction in a specified context of use"(ISO, 2018)	Is the use of the strategy associated with a high level of satisfaction by the pharmacists
Acceptability	"Is the instrument acceptable to patients?"(Fitzpatrick et al., 1998)	Are pharmacists motivated to use the strategy?
Appropriateness	"Is the content of the instrument appropriate to the questions which the clinical trial is intended to address?"(Fitzpatrick et al., 1998)	Is the strategy suitable to support the implementation of professional pharmacy services?
Feasibility	"Is the instrument easy to administer and process?"(Fitzpatrick et al., 1998)	Is the strategy easy to use?

Results

Pragmatic literature research

Six PDCA variations were retrieved from the literature (see Table 2). Two quality improvement methods seemed suitable to build the core structure of a new implementation strategy, the FOCUS-PDCA (Taylor et al., 2014) and the MFI (Langley et al., 2009). The FOCUS-PDCA was favored because it is more comprehensive.

Table 2 Variations of the PDCA cycle published in implementation articles, with corresponding reference, acronym, and definition

Acronym	Definition
PDCA (Deming, 1986)	**P**lan, **D**o, **C**heck, **A**ct
PDSA (Deming, 1993)	**P**lan, **D**o, **S**tudy, **A**ct
SDCA-PDCA (Imai, 1993)	**S**tandardize, **D**o, **C**heck, **A**ct – **P**lan, **D**o, **C**heck, **A**ct
FOCUS-PDCA (Taylor et al., 2014)	**F**ind a process to improve, **O**rganize to improve the process, **C**larify current knowledge of the process, **U**nderstand sources of process variation, **S**elect the process improvement – **P**lan, **D**o, **C**heck, **A**ct
MFI (Langley et al., 2009)	**M**odel **F**or **I**mprovement
RADAR (Waser and Peter, 2016)	**R**esults, **A**pproach, **D**eploy, **A**ssess, **R**efine

Tailoring the strategy to the community pharmacy setting

The FOCUS-PDCA was amended to fit the implementation process of professional pharmacy services according to the FISpH (Moullin et al., 2016). The original tasks were reformulated. The steps were defined in German, resulting in the implementation strategy “fokus°PDCA”(see Table 3). Each letter stands for one step, and each step has a specific objective. This results in a nine-step process consisting

of a five-step preparation part (“fokus”) and a four-step repetitive part (“PDCA”, see Figure 1). We defined additional specific questions or tasks for each step, and created a manual for the user. We characterized the elements of the implementation strategy according to Proctor et al. by defining the following variables: the actor, the action, the target of the action, temporality, dose, implementation outcome, and justification (Proctor et al., 2013). For the specification of the elements, see Appendix A.

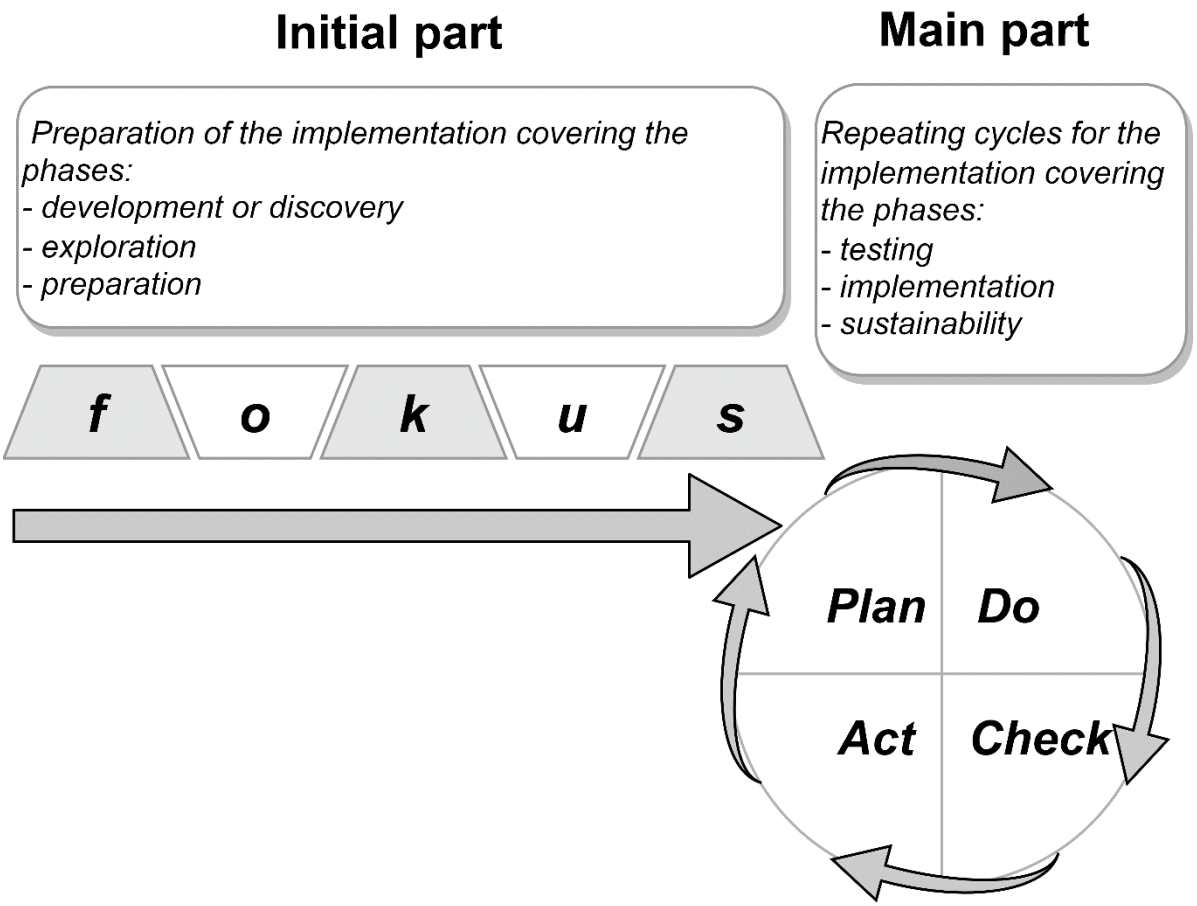

Figure 1 fokus°PDCA implementation strategy with five preparation steps (“fokus”, initial part) and four reiterative steps (“PDCA”, main part) with the corresponding six stages of the implementation process defined by the FISpH (in boxes) (Moullin et al., 2016).

Table 3 Conversion of the original quality improvement method FOCUS-PDCA (Taylor et al., 2014) to the implementation strategy fokus°PDCA with acronyms, including the six stages of the FISpH (Moullin et al., 2016).

Original FOCUS-PDCA for quality improvement (Taylor et al., 2014)		**Developed fokus°PDCA for community pharmacy**		**Purpose of the step**	**Question enabling to define the step**	**Six stages of the FISpH (Moullin et al., 2016)**
F	**F**ind a process to improve	**f**	**f**ind a service to implement	Name the service	What kind of service is it?	- **Development or discovery:** Development of the service by the pharmacy or pharmacy group and/or discover externally developed services. - **Exploration:** Assessment of whether the service fits into the pharmacy, as well as what benefits the service brings to the pharmacy. - **Preparation:** Preparing the delivery of the service
O	**O**rganize to improve the process	**o**	**o**rganize the resources for the service	Document necessary competencies and infrastructure	What competencies must the pharmacy team fulfill to be able to offer the service? What infrastructure is required to implement the service?	
C	**C**larify current knowledge of the process	**k**	**c**larify (*in German:* ***k****lären*) the significance of the service for your pharmacy	Document benefits, additional expenditure, and service concept	What benefits does the pharmacy expect from the service? What changes in the day-to-day work of the pharmacy does the service entail? Does the service fit into the concept of the pharmacy?	
U	**U**nderstand sources of process variation	**u**	**u**nderstand your surroundings	Assess the demand	How does the pharmacy assess the demand for the service among its customers?	
S	**S**elect the process improvement	**s**	**s**elect the strategy for implementing the service	Consider individual strategy with tasks, deadlines, and responsibilities	What is the primary goal of the implementation? What tasks are necessary to achieve the main goal? Who should perform the task? When should the task be executed?	

P	**P**lan	**P**	**P**lan	Plan	What tasks are to be performed during the period of this cycle? Who should carry these tasks out? How to recognize if a task is successfully implemented (i.e., indicators for success)?	**- Testing**: Trialing the service, operating for a defined period or with limited numbers **- Operation**: Full rollout of the service **- Sustainability:** Ongoing service provision, maintenance of supportive conditions, and persistence of service outcomes
D	**D**o	**D**	**D**o	Do	Was the plan executed as expected? What was noticed during the execution?	
C	**C**heck	**C**	**C**heck	Check	Were the tasks successfully implemented (i.e., were the indicators of success achieved)? Where is room for improvement? What new tasks were discovered through the cycle?	
A	**A**ct	**A**	**A**ct	Act	What tasks were successful and will continue to be performed in the next cycle? What tasks will be revised/adjusted for the next cycle? What task will be added in the next cycle?	

Testing the strategy with three groups of community pharmacists

Fourteen master's pharmacy students (78.5 % female) estimated the comprehensibility and usability of the first draft of the fokus°PDCA to be high with mean scores of 3.7 ± 0.3 and 3.6 ± 0.2, respectively (see Figure 2). No adaptation was needed, neither to the fokus°PDCA itself nor to the accompanying documents.

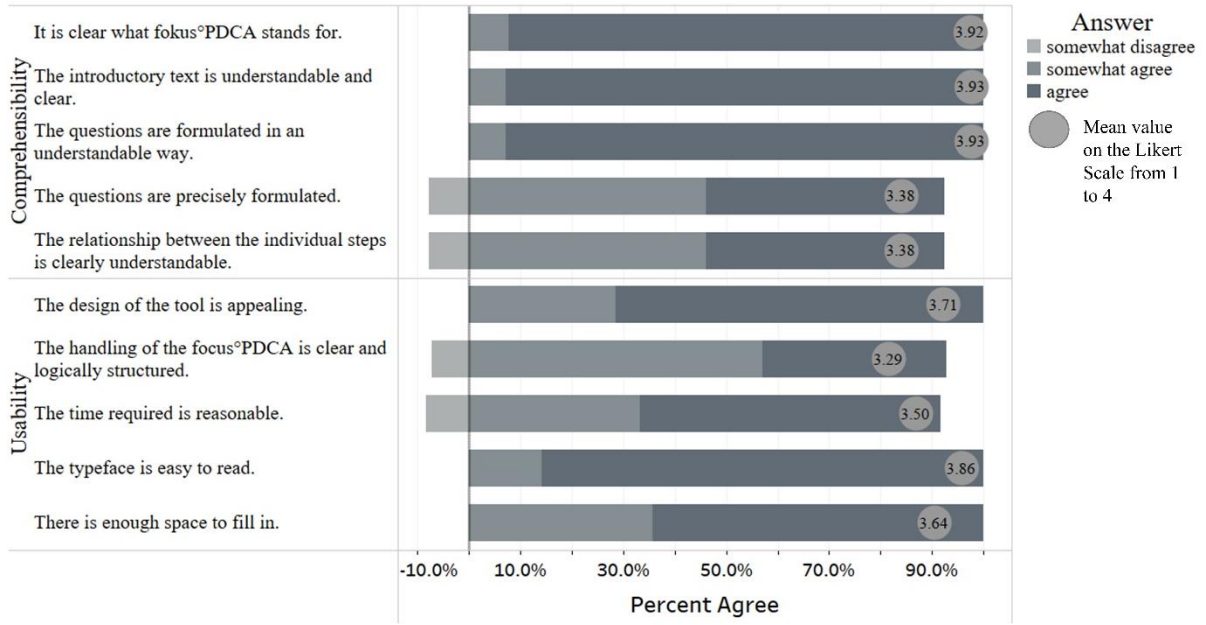

Figure 2 Estimates of the comprehensibility and usability of the fokus°PDCA on a 10-item questionnaire by pharmacy master students (n = 14)

A total of 22 pharmacists (see demographics in Table 4) rated the acceptability, appropriateness, and feasibility of the fokus°PDCA. All participants indicated high acceptability, feasibility, and appropriateness with an overall mean of 3.5 ± 0.7 (see Figure 3). Fourteen community pharmacists (Group 2) rated acceptability, feasibility, and appropriateness at 3.6 ± 0.4, 3.4 ± 0.3, and 3.6 ± 0.3, respectively. In Group 3, eight community pharmacists used the strategy to implement a professional pharmacy adherence service (n = 5), a vaccination service (n = 2), or a labor analysis service (n = 1), and rated the acceptability, feasibility, and appropriateness at 3.2 ± 0.1, 3.6 ± 0.2 and 3.3 ± 0.2, respectively. No adaptation was needed, neither to the fokus°PDCA itself nor to the accompanying documents.

Table 4 Demographics of the 22 pharmacist participants of Group 2 and Group 3

	Group 2 (N = 14)	**Group 3 (N = 8)**
Female n (%)	13 (92.9)	7 (87.5)
Median age (IQR) [years]	31.5 (29.8 – 35.5)	29.5 (27.3 – 33.5)
Median work experience (IQR) [years]	3.3 (2 – 7.6)	3.0 (2 – 6.3)
Function n (%)		
Managing director pharmacy	5 (35.7)	4 (50.0%)
Employed pharmacist	9 (64.3)	3 (37.5%)
Pharmacy technician	0 (0)	1 (12.5%)

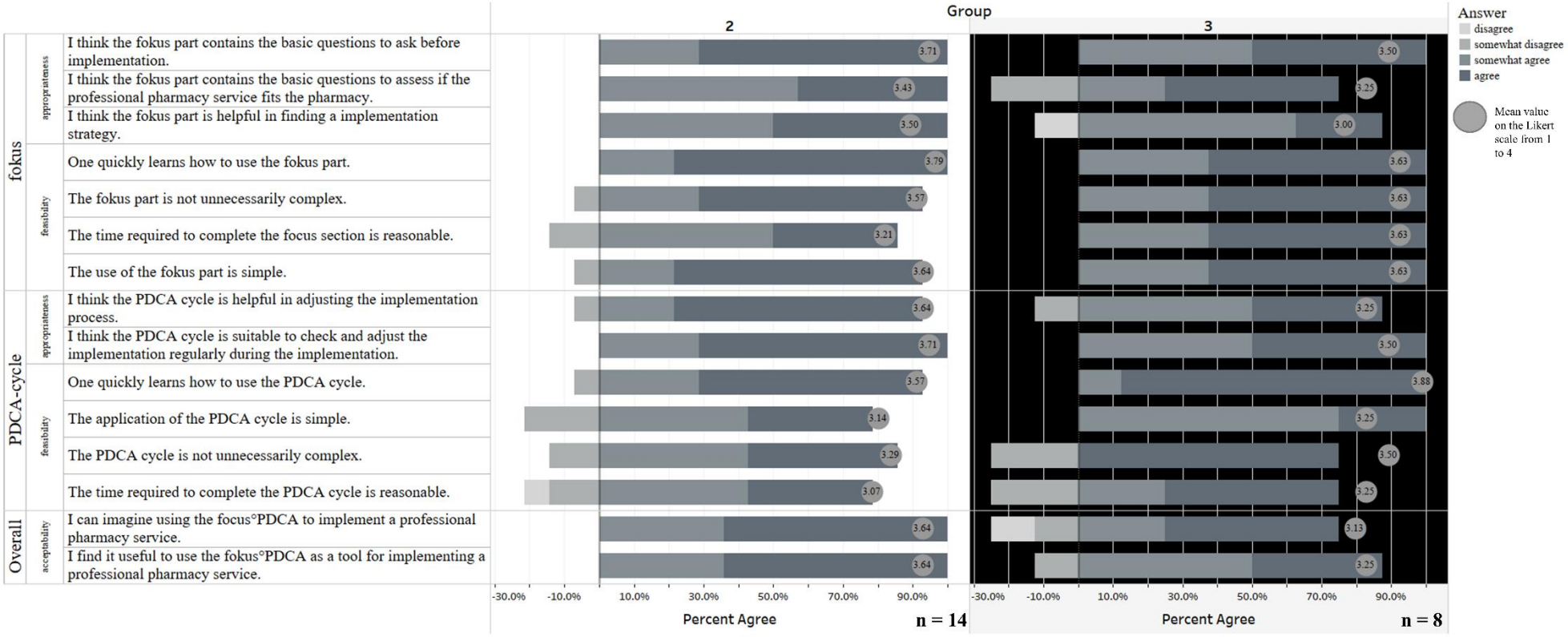

Figure 3 Estimates of the acceptability, appropriateness, and feasibility of the fokus°PDCA on a 15-item questionnaire by pharmacists applying the fokus°PDCA in a simulated setting (Group 2; left, white background) and in a real life setting (Group 3; right, black background

Discussion

We developed an implementation strategy for professional pharmacy services named fokus°PDCA. We obtained the nine steps of the strategy by tailoring a published quality improvement method, the PDCA cycle, to the pharmacy setting. The new strategy was tested with community pharmacists. The first evaluation of fokus°PDCA has shown good scores for the variables: usability, comprehensibility, acceptability, feasibility, and appropriateness.

Tailoring the strategy to the community pharmacy setting

The process of tailoring implementation strategies has been stressed out as a possible solution to improve the implementation and the effectiveness of implementation strategies. The most common approach is to match implementation strategies to identified implementation barriers. However, there is no consensus on the best way to overcome a specific barrier (Waltz et al., 2019). Additionally, the methods used to identify barriers are often not clearly defined (Baker et al., 2015) and are mostly not feasible in the community pharmacy setting with its limited resources (van de Pol et al., 2019). Therefore, we chose the approach to select one strategy, the PDCA cycle, and to tailor its steps to the entire implementation process in the pharmacy setting. We hypothesize that the PDCA cycle encourages the user to constantly identify implementation barriers (Check, Act) and address them in the next cycle (Plan, Do). To adapt the PDCA cycle to the full implementation process, we used the FISpH (Moullin et al., 2016). Frameworks are recommended to tailor implementation strategies (Moullin et al., 2020) as they try to represent and explain the key concepts, variables, and factors of the implementation process (Flaspohler et al., 2008;Kitson et al., 2008;Meyers et al., 2012;Farley et al., 2013). The FISpH is based on the Generic Implementation Framework (GIF) (Moullin et al., 2015) and adapted to the community pharmacy setting. It covers the basic concepts of implementing professional pharmacy services in community pharmacies and has already been used to describe the implementation process of a medication analysis service in pharmacies (Lelubre et al., 2019). We defined that the implementation strategy should incorporate the six implementation stages: A one-time initial part that includes the first three stages ("development or discovery", "exploration", and "preparation") and the repeating main part that includes the three other stages ("testing", "implementation", and "sustainability"). This two-part

structure should provide practical guidance in the planning and execution of the implementation. We have deliberately emphasized the first three stages because of the importance of the pre-implementation phases, although little attention is paid to them (Garcia-Cardenas et al., 2017).

Testing the strategy with community pharmacists

The strategy showed good scores for the variables comprehensibility and usability. Good scores for these variables are essential because the strategy should be self-explanatory and used by the pharmacy team without background knowledge about the concept of the PDCA cycle. Similarly, the variables acceptability, feasibility, and appropriateness showed good scores in both evaluation rounds, indicating that pharmacists are willing to use the strategy. The evaluation of the appropriateness and acceptability of the strategy is our contribution and is not mentioned by Waltz et al., who rated implementation strategies according to their importance and feasibility (Waltz et al., 2015). We are convinced that appropriateness and acceptability are essential to estimate the potential of implementation strategies. Thus, these variables should be assessed before applying the strategies in effectiveness-implementation hybrid designs Type II and III. Of note, we have tested the fokus°PDCA first with future users of the strategy rather than with an expert consensus approach (Waltz et al., 2015). This is in line with recommendations regarding the development of complex interventions, where strategies should be thoroughly tested by future users to potentially avoid problems with acceptability, fidelity, and the delivery of the strategy (O'Cathain et al., 2019). During the testing phase, the strategy can be constantly improved by getting feedback from the users, what allows to identify problems and improve the strategy (O'Cathain et al., 2019).

Strengths

First, in analogy to intervention research, our intervention, i.e., the fokus°PDCA, has been clearly defined and preceded by a development and testing process (Craig et al., 2008). This transparency should facilitate the uptake of the fokus°PDCA in community pharmacies just about to implement new professional services. Also, this procedure might improve the measurement and reproducibility of the fokus°PDCA as an implementation strategy, which is considered essential for future evaluation (Squires et al., 2014). Second, we adapted the PDCA cycle according to the FISpH. This framework is specific

to the pharmacy, and consequently, we claim that our implementation strategy is tailored to the pharmacy setting. Third, potential users were engaged through the whole development process of the fokus°PDCA. This might facilitate the implementation of the strategy in the future. Fourth, the fokus°PDCA was tested with three different professional pharmacy services. This tends to demonstrate its unlimited nature for the implementation of professional pharmacy services.

Limitations

First, we have developed the fokus°PDCA according to literature, enriched by a pharmacy-specific framework, and not with methods such as concept mapping, group model building, conjoint analysis, or intervention mapping. Although these methods are suggested by implementation researchers (Powell et al., 2017), we claim that simplification can be powerful when it comes to adding work in the community pharmacy's processes. Thus, we searched for a ubiquitous and simple concept to start the development of our implementation strategy. Second, the pharmacists who participated in the testing of the strategy were highly motivated. Thus, we cannot exclude a selection bias of the users. However, with a selected group of participants, we relied on experienced personal in implementing new services and documenting the tasks performed. This process guarantees valid data. Third, the fokus°PDCA was tested in a regional context in Switzerland. We cannot claim that it is generalizable to other countries, although the unlimited nature of the fokus°PDCA should permit its use in other health care systems. Fourth, the real-life users evaluated the fokus°PDCA after one or two cycles without long-term experience. Nevertheless, we claim that this lapse of time is sufficient to estimate the usefulness and other variables of the strategy, especially when it comes to implement a new service in its own community pharmacy.

Conclusion

We were able to tailor a defined, specific and standardized implementation strategy for professional services. The fokus°PDCA is based on theory, including a pharmacy-specific framework, and showed good acceptance. In the next step, the fokus°PDCA will be tested for effectiveness in an implementation study of a professional pharmacy service.

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Appendix A: Variables needed to characterize the implementation outcomes according to Proctor et al. (Proctor et al., 2013) with definition and transfer to the fokus°PDCA

Variable	Definition	Transfer to the fokus°PDCA strategy	
The actor	Identify who enacts the strategy (e.g., administrators, payers, providers, patients/consumers, advocates, etc.)	Pharmacy teams	
The action	Use active verb statements to specify the specific actions, steps, or processes that need to be enacted	Use an adapted form of the PDCA cycle with the four steps: Plan-Do-Check-Act	
Action target	Specify targets according to conceptual models of implementation Identify unit of analysis for measuring implementation outcomes	Target the six defined stages of an implementation of a professional pharmacy service according to the FISpH (Moullin et al., 2016) by documenting and improving the implementation process on the pharmacy level	
Temporality	Specify when the strategy is used	Use the strategy during the six stages of the FISpH (Moullin et al., 2016): 1. Development/Discovery 2. Exploration 3. Preparation 4. Testing 5. Operation 6. Sustainability	
Dose	Specify dosage of the implementation strategy	Each pharmacy can choose an individual number of PDCA cycles during the implementation process	
Implementation outcome affected according to Proctor et al. (Proctor et al., 2011)	Identify and measure the implementation outcome(s) likely to be affected by each strategy Rate with: Not at all likely, Slightly likely. Moderately likely, very likely, Completely likely	Acceptability	Slightly likely
		Adoption	Very likely
		Appropriateness	Slightly likely
		Feasibility	Moderately likely
		Fidelity	Very likely

		Implementation cost	Moderately likely
		Penetration	Very likely
		Sustainability	Very likely
Justification	Provide empirical, theoretical, or pragmatic justification for the choice of implementation strategies.	The PDCA cycle of Deming (Deming, 1986) is one of the most frequently applied quality improvement methods in the health care sector (Varkey et al., 2007;Brown et al., 2018;Christoff, 2018)	

Appendix B: The final fokus°PDCA

Universität Basel
Departement Pharmazeutische Wissenschaften

DEPARTMENT OF PHARMACEUTICAL SCIENCES

fokus°PDCA

Das folgende Arbeitstool dient als Unterstützung, um die Implementierung einer neuen pharmazeutischen Dienstleistung in Ihrer Apotheke besser zu strukturieren, zu planen und umzusetzen. Damit Sie das Arbeitstool optimal nutzen können, finden Sie hier einige Informationen zum Aufbau:

Das Arbeitstool besteht aus zwei Teilen:

1. Der erste Teil, welcher als «fokus» bezeichnet wird, dient zur Vorbereitung und Entwicklung einer Implementierungsstrategie und soll die wesentlichen Aspekte rund um die Implementierung einer neuen Dienstleistung abdecken.
   Der «fokus» Teil wird **einmalig vor** der Implementierung ausgefüllt.
2. Der zweite Teil, welcher aus PDCA-Zyklen besteht, wird dann während der Umsetzung der Implementierungsstrategie benutzt. Jeder Zyklus beginnt mit der Planung von Aufgaben (= Plan), die dann über einen bestimmten Zeitraum durchgeführt werden (= Do). Anschliessend wird überprüft, ob der Plan erfolgreich war (= Check). Im nächsten Schritt werden Anpassungen vorgenommen (= Act). Diese Anpassungen werden im darauffolgenden Zyklus aufgenommen. Die Idee ist, dass die Zyklen über einen kurzen Zeitraum (ca. 1-8 Wochen) gewählt werden, so dass Aufgaben Schritt für Schritt ausgeführt und überprüft werden können.
   Durch die aufeinanderfolgenden Zyklen kommt es zu einer kontinuierlichen Verbesserung und Überprüfung der Implementierungsstrategie, weil diese immer wieder neu an die Umstände angepasst werden kann. Die Anzahl PDCA-Zyklen, die benötigt wird, ist individuell.
   Die PDCA-Zyklen werden **wiederholt während** der Implementierung gebraucht.

Bei der Anwendung wird empfohlen, mit Stichwörtern zu arbeiten und Kürzel für die einzelnen Mitarbeiter zu verwenden. Wichtig ist, dass Sie eine Strategie entwickeln, welche individuell auf Ihre Apotheke zugeschnitten ist. Das Arbeitstool kann alleine, in einer kleinen Gruppe oder mit dem gesamten Team ausgefüllt werden.

Viel Erfolg bei der Implementierung Ihrer neuen Dienstleistung

f o k u s

f **«Finden einer Dienstleistung, die implementiert werden soll»**

Um welche Dienstleistung handelt es sich?

o **«Organisation der Ressourcen für die Dienstleistung»**

Welche **Kompetenzen** muss das Apothekenteam erfüllen, um die Dienstleistung anbieten zu können?	Welche **Infrastruktur** ist nötig, um die Dienstleistung zu implementieren?
Sind diese Kompetenzen vorhanden? ☐ *Ja* ☐ *Nein* ☐ *Teilweise*	Ist diese Infrastruktur vorhanden? ☐ *Ja* ☐ *Nein* ☐ *Teilweise*
Falls "*Nein*" bzw. "*Teilweise*": Können die fehlenden Kompetenzen z.B. durch Schulungen erlangt werden? ☐ *Ja* ☐ *Nein*	Falls "*Nein*" bzw. "*Teilweise*": Kann die fehlende Infrastruktur beschafft werden? ☐ *Ja* ☐ *Nein*

Kann aus den oben genannten Antworten geschlossen werden, dass **genügend Kapazität** vorhanden ist *bzw. vorhanden sein wird*, um die Dienstleistung zu implementieren?
☐ *Ja* ☐ *Nein**
** Falls "Nein" kann die Dienstleistung mit den momentanen Ressourcen nicht implementiert werden.*

k **«Klärung der Bedeutung der Dienstleistung für die Apotheke»**

Welchen **Nutzen** verspricht sich die Apotheke aus der Dienstleistung?

Welche **Veränderungen** im Arbeitsalltag der Apotheke bringt die Dienstleistung mit sich?
(Mehraufwand, Dokumentation, Follow-up, Beratung etc.)

Passt die Dienstleistung in das **Konzept** der Apotheke? ☐ *Ja* ☐ *Nein*

u **«Umgebung berücksichtigen»**

Wie schätzt die Apotheke die **Nachfrage** nach der Dienstleistung bei der eigenen Kundschaft ein?

Gering	Eher Gering	Eher Gross	Gross
☐	☐	☐	☐

Wie begründen Sie diese Abschätzung?

f o k u s

s **«Strategie zur Implementierung der Dienstleistung entwickeln»**

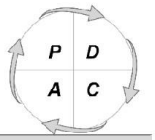
Ausgehend von den vorherigen Antworten kann nun überlegt werden, wie das Vorgehen zu wählen ist, um die Dienstleistung zu implementieren.
Dazu soll zunächst das **Hauptziel** der Implementierung definiert werden:

Nun können konkrete Aufgaben formuliert werden, damit das Hauptziel schrittweise erreicht werden kann (oberer Teil der Tabelle). Ausserdem wird festgelegt, wer sich in welcher Frist um welche Aufgaben kümmert (unterer Teil der Tabelle).
(Anregungen: Verantwortlichkeiten, Schulungen, Anschaffungen, Dokumentation, Reminder etc.)

Nr.	Welche Aufgaben sind notwendig um das Hauptziel zu erreichen?

Nr.	Durch wen soll die Aufgabe ausgeführt werden?	Bis wann soll die Aufgabe ausgeführt werden?

Nach Festlegen der Strategie, kann mit der Planung im zweitenTeil des Arbeitstools, dem PDCA-Zyklus, fortgefahren werden. Beachten Sie: Die Aufgaben der Strategie können im 1. PDCA-Zyklus mit der hier verwendeten Nummerierung angegeben werden und müssen nicht nochmals ausformuliert werden.



Name der Dienstleistung:_____

Datum: Zyklus vom _____ bis _____ Zyklus-Nr.: _____

P «Plan» → Planung

Welche Aufgaben sollen im Zeitraum **dieses** Zyklus ausgeführt werden? Durch wen sollen diese Aufgaben ausgeführt werden? Wie wird erkannt, ob eine Aufgabe erfolgreich umgesetzt wird (= Indikator für Erfolg)?

Nr.	Aufgaben	Wer	Indikator für Erfolg

D «Do» → Durchführung des Plans

Der Plan wurde wie erwartet durchgeführt:

Trifft nicht zu	Trifft eher nicht zu	Trifft eher zu	Trifft zu
☐	☐	☐	☐

Was fiel während der Durchführung auf?

C «Check» → Überprüfung

Die Aufgaben wurden erfolgreich umgesetzt (d.h. die Indikatoren für den Erfolg wurden erreicht):

Trifft nicht zu	Trifft eher nicht zu	Trifft eher zu	Trifft zu
☐	☐	☐	☐

Wo gibt es Verbesserungsmöglichkeiten?

Welche neuen Aufgaben wurden durch den Zyklus entdeckt?

A «Act» → Anpassung

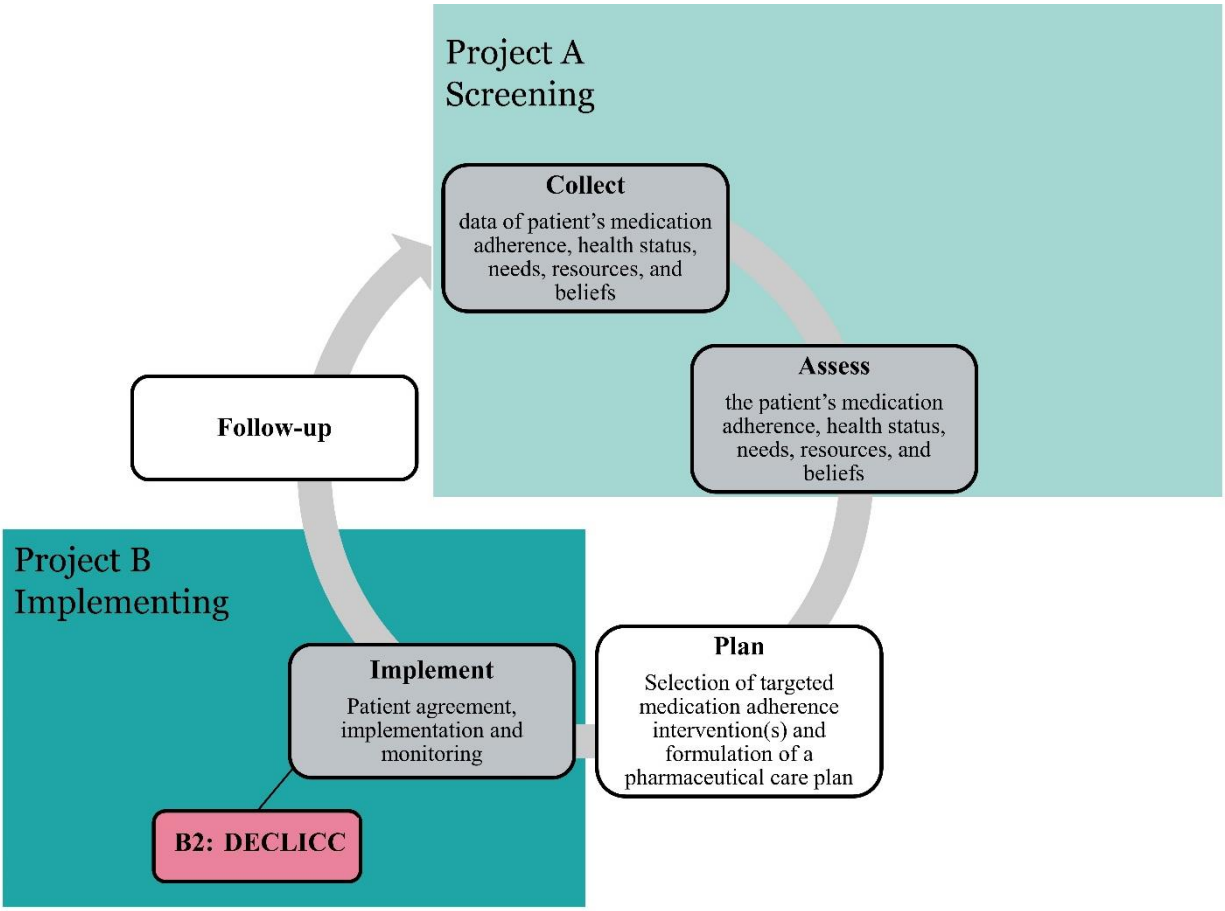
Folgende Aufgaben waren erfolgreich **und** werden im nächsten Zyklus weiterhin ausgeführt:

Folgende Aufgaben werden für den nächsten Zyklus überarbeitet/angepasst:

Folgende Aufgaben kommen im nächsten Zyklus neu dazu:

Nach Beenden dieses Zyklus werden die Aufgaben aus «A» im nächsten PDCA-Zyklus unter «P» ausgearbeitet.

B2- DECLICC: Documenting the implementation of a professional pharmacy service



Short report: How to prospectively document the implementation outcomes of a professional pharmacy service? - A case study

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Draft ready for review by co-authors

Abstract

Introduction

Outcomes for the implementation of professional pharmacy services are rarely defined. The impact of an implemented service is mainly defined by economic, clinical, and humanistic outcomes (ECHO). These outcomes are predominantly obtained via randomized controlled studies that can be applied to a limited type of services. Therefore, it is essential to develop other pragmatic outcome measures and to test them with appropriate study designs. This work aimed to evaluate the adequacy of the implementation outcomes defined by Proctor et al. when a pharmacy team implements a new professional pharmacy service named TopCompliance. In brief, the software application TopCompliance includes a reminder function, which reminds patients via email, SMS, or telephone to obtain their medication from their pharmacy before running out of supply.

Methods

We conducted a pilot study in selected pharmacies that were about to implement TopCompliance. We used seven predefined outcomes to assess the implementation over six months. The primary outcome was defined as the number of active users of the service TopCompliance. The implementation outcomes acceptability, adoption, appropriateness, feasibility were measured with two short questionnaires distributed at the study start and one month later. The implementation outcomes penetration and sustainability were measured six months later.

Results

Five pharmacies were included that had on average 3.3±2 active users of the service during 6 months. The number of users fluctuated over time and between pharmacies, with a maximum of 5.4 ± 1 users per pharmacy in month 5. At the study start, the agreement between pharmacy team members (n = 28) was high for appropriateness (75%) and adoption (92.3%), and unsure for acceptability (50%). At month 1, the three variables dropped remarkably (appropriateness: 36.5%, adoption: 53.8%, and acceptability: 3.8%). Feasibility was scored at 2.8 ± 0.2 on a 4 point Likert scale. At month 6, penetration was high with 4 pharmacies still using the service (80%), and sustainability was low, with two pharmacies planning to continue working with TopCompliance (40%).

Conclusion

We evaluated the implementation of a new professional pharmacy service named TopCompliance in selected community pharmacies and used the outcomes proposed by Proctor et al.. We found that the outcomes were suitable to repeatedly and thoroughly evaluate the implementation process of professional pharmacy services. The next step will be to apply the developed measures in larger studies that implement professional pharmacy services.

Introduction

The development of complex interventions can be divided into four steps: Development, feasibility/ piloting, evaluation, and implementation.[1] Most scientific studies end with the evaluation step. Therefore, the final step of transferring an intervention from a controlled research study setting to a routinely provided service in a real-life setting often fails.[2] Many new patient-centered services have been developed in the community pharmacy setting, but few are implemented sustainably. The reasons for implementation failure are manifold[3], but generally, the implementation success is impacted by the intervention, the setting, and the implementation process.[4] The implementation process itself is a complex *non-linear, recursive, reiterative progression of implementation*.[5] Therefore, to ensure the long-term sustainability of new professional pharmacy services, more active approaches are needed to apply evidence-based methods that are grounded in implementation theory and research. Implementation research focuses on evaluating the most effective methods for implementing interventions. It can be defined as *the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice, and, hence, to improve the quality and effectiveness of health services.[6]* A focus in implementation research has been laid on defining implementation outcomes that document and evaluate the complex effect of implementation actions during the implementation process. Implementation outcomes can evaluate new evidence-based interventions besides clinical and economic outcomes.[7] They are increasingly applied in interventions with so-called effectiveness-implementation hybrid designs.[8-10] However, in the case of professional pharmacy services, implementation outcomes are rarely defined.[5, 11-13] The implemented service defines its success mainly described by economic, clinical, and humanistic outcomes (ECHO). These outcomes are predominantly obtained via randomized controlled study designs that can only be applied to a limited type of services.[14] Therefore, it is essential to develop further outcome measures and to test them with appropriate study designs. Powell et al. defined four distinct pragmatic criteria for implementation outcomes: acceptable, compatible, easy, and useful.[15] In recent years, advancements have been made to simplify the measurement of implementation outcomes with the introduction of new computational and technical approaches.[16] However and most prominently, eight distinct

implementation outcomes have been defined by Proctor et al.: acceptability, appropriateness, feasibility, adoption, fidelity, implementation cost, penetration, and sustainability.[7, 17] These outcomes cover a wide range of aspects that should be considered for implementation. For example, evaluating acceptability, feasibility, and appropriateness might explain why providers are not adopting a new professional pharmacy service. Similarly, fidelity and penetration might provide insight into the contexts and explain why a new professional pharmacy service has not achieved its intended effects.[18] Therefore, it is essential to select and define robust outcomes that are needed to evaluate the implementation success of a new professional pharmacy service. This work aimed to evaluate the adequacy of the implementation outcomes defined by Proctor et al. when a pharmacy team implements a new professional pharmacy service named TopCompliance.

Methods

Study design

We conducted a pilot implementation study for a professional pharmacy service in a small sample of community pharmacies. We analyzed data with mixed methods.

Professional pharmacy service named TopCompliance

The software application TopCompliance includes a reminder function, which reminds patients via email, SMS, or telephone to obtain their medication from their pharmacy before running out of supply. The reminder is sent to the patient twice on predefined days before the supply expires. The pharmacy team can define the two reminders individually according to the ATC codes of their choice.

Setting

We recruited community pharmacies from 28 TopPharm pharmacies located in the German-speaking part of Switzerland. TopPharm is a cooperative of independent pharmacies that runs joint campaigns, training courses, and share software solutions. Each participating pharmacy nominated a local champion among the employees according to their own criteria. The local champion was provided with a working folder explaining the procedure needed to collect data prospectively. The working folder included the instructions for TopCompliance, questionnaires on the implementation outcomes, and a package with implementation strategies.

Implementation strategies

We used a blended implementation strategy and developed a formal blueprint. The strategy package included three distinct implementation tools: A framework for screening eligible patients (see Project A4); the goal attainment scale[19]; and the fokus°PDCA, an implementation tool for professional pharmacy services (see Project B1). The fokus°PDCA should enable the local champion to document additional implementation strategies. Additionally, the research team conducted three on-site visits to support the local champion’s pharmacy team. The strategies provided to the pharmacies are summarized and categorized according to Powell and Waltz[20, 21] in Table 1.

Table 1 Implementation strategies provided during the study, categorized according to Powell and Waltz.[20, 21]

Main category[21]	Subcategory[20]	Strategy for TopCompliance
Main implementation strategies		
Use evaluative and iterative strategies	Develop a formal implementation blueprint	The implementers used a working folder for implementing the service that included three specific implementation strategies
Included strategies in the working folder		
Use evaluative and iterative strategies	Conduct small cyclical tests of change	Use of the implementation tool fokus°PDCA during the implementation
Adapt and tailor to context	Tailor strategies	The 3-item framework from Project A4 for addressing medication adherence was adapted for TopCompliance to screen for patients that would benefit from the service.
-	Goal attainment scale	Use of the goal attainment scale during the implementation [19]
Additional implementation strategies		
Develop stakeholder interrelationships	Identify and prepare champions	In each pharmacy, a local champion was defined that led and documented the implementation with the working folder
Provide interactive assistance	Provide local technical assistance	The pharmacies were visited three times during the six months. The study leader also provided help via phone.
Train and educate stakeholders	Distribute educational materials	The working folder included extensive instruction regarding the service and the implementation process

Outcome measures

The primary outcome was defined as the number of active users of TopCompliance. We followed a three-step process to define the implementation outcomes: (1) selecting appropriate implementation outcomes, (2) adapting the outcomes to the innovation and setting, and (3) defining the measurement methods for the implementation outcomes. As implementation outcomes, we selected acceptability, adoption, appropriateness, feasibility, penetration, and sustainability (see Table 2). Acceptability, adoption, appropriateness, and feasibility were measured with two short questionnaires distributed at the study start and one month later. At study start, the questionnaire included five items for the variables acceptability (n = 2), appropriateness (n = 2), and adoption (n = 1). The answer possibilities were dichotomous (Yes/No). The questionnaire a month later included four items for the variables acceptability (n = 1), appropriateness (n = 2), adoption (n = 1), and feasibility (n = 3). The answer options were dichotomous (Yes/No) for acceptability, appropriateness, and adoption, and a 4 point Likert scale (from 1: disagree to 4: agree) for feasibility.[22] The outcome penetration was measured six months later with the number of pharmacies still using the service. Sustainability was obtained with the local champion's answer as to whether the service was still planned to be continued on a report sheet.

Table 2 Adaption of the implementation outcomes of Proctor et al.[7] by the researcher for TopCompliance

Variable[7]	Definition[7]	When should it be measured[7]	Adaption to the setting and service	Questions for TopCompliance	Measuring method	Score	Who is surveyed/ data source	T0: Start	T1: month 1	T2: month 6
Acceptability	is the perception among implementation stakeholders that a given treatment, service, practice, or innovation is agreeable, platable or satisfactory	Early for adoption	The acceptance of TopCompliance in the pharmacy	Is TopCompliance accepted? - by the pharmacy team members - by the patients	Questionnaire	Percentage of pharmacy team members that accept TopCompliance.	Pharmacy team	**X**	**X**	
Appropriateness	is the preceived fit, relevance, or compatibility of the evidence-based practice for a given practice setting provider, or consumer; and/or perceived fit of the innovation to address a particular issue or problem	Early prior adoption	The appropriateness of TopCompliance for the individual pharmacies	Does TopCompliance fit into the pharmacy?	Questionnaire	Percentage of pharmacy team members that find TopCompliance suitable as a pharmacy service for their pharmacy.	Pharmacy team	**X**		
Feasibility	the extent to which a new treatment or an innovation can be successfully used or carried out within a given agency or setting	Early during adoption	The feasibility of TopCompliance in the pharmacy setting	Is TopCompliance easy to manage in daily business	Questionnaire	Score on a 4 point Likert scale.	Pharmacy team		**X**	
Adoption	is the defined as the intention, inital decision or action to try or employ an innovation or evidence-based practice	Early to mid	Is TopCompliance used by the pharmacy team	How many pharmacy team members offer TopCompliance?	Questionnaire	Percentage of people using TopCompliance after 1 month.	Pharmacy team		**X**	
Penetration	is defined as the integration of a practice within a service setting and its subsystems	Mid to late	The penetration (frequency of use) of the service	Do the pharmacies still work with TopCompliance after 6 months?	Administrative database	Precentage of pharmacies working with TopCompliance after 6 months.	Pharmacy Software, Local Champion			**X**
Sustainability	is the extent to which an evidence-based intervention can deliver its intended benefits over an extended period of time after external support	Late	TopCompliance continues to be used after the implementation phase	Will TopCompliance continue to be offered after 6 months?	Questionnaire	Precentage of pharmacies planning to continue using TopCompliance after 6 months.	Local champion			**X**

Data analysis

User data and data from the working folder, including the questionnaires' answers, were entered into and analyzed with Microsoft Excel (Microsoft Office Home and Student 2016, Microsoft Corporation, Redmond WA, USA). Descriptive statistics were used for quantitative data that are percentage agreement for implementation outcomes; mean, standard deviation, minimum and maximum for user data and pharmacy characteristics.

Result

From the 28 TopPharm pharmacies that were approached in 2020, five agreed to participate (17.9%). Four pharmacies were located in a village (< 10'000 inhabitants) and one in a city (> 100'000 inhabitants). For the characteristics of the pharmacies, see Table 3.

Table 3 Characteristics of the five participating TopPharm pharmacies

Pharmacy	**1**	**2**	**3**	**4**	**5**
Number of employees	9	8	19	16	15
Number of customer sales/month	3402	4001	9000*	4750	5015
Number of prescription sales/ month	1381	2203	6000*	4750	3137
Number of OTC sales/ month	2021	1797	3000*	1960	1878
Number of services provided by the pharmacy	17	6	25	5	12

*estimated by the local champion

Main outcome

The pharmacies had on average 3.3 ± 2 active users of the service during the 6 month. Overall, the number of active users showed an upward trend with fluctuation over time and between pharmacies (see Figure 1). The maximum number of active users was 27 (5.4 ± 1 per pharmacy) at month 5 (see Figure 1A). The fluctuation was strongest at Pharmacy 1. Pharmacy 5 decided to stop the service after month 1. Pharmacies 2 and 3 showed upward trends with increased user numbers per month. Pharmacy 3 presented the same trend until month 5, resulting in a collapse of users in month 6 due to the absence of the local champion(see Figure 1B).

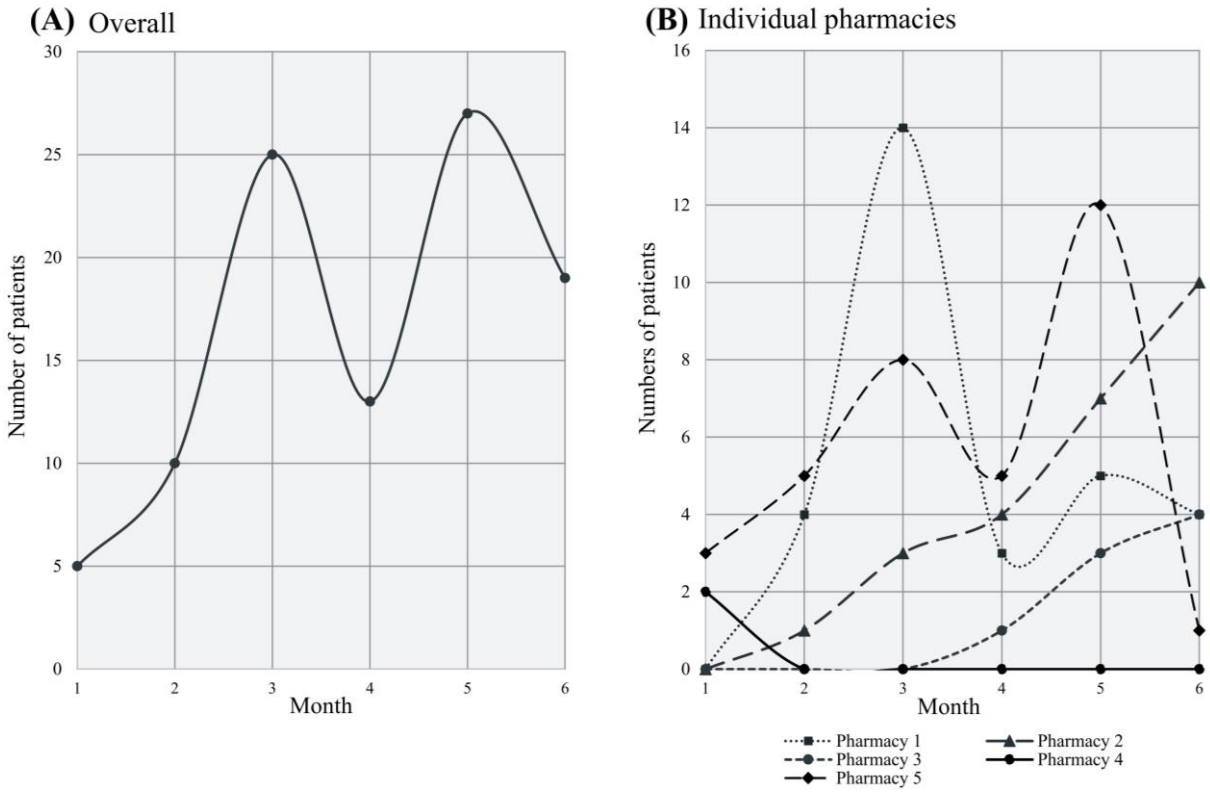

Figure 1 Number of users per month over all the pharmacies (A), and per pharmacy (B)

Implementation outcomes

The first questionnaire was answered by 28 pharmacy team members at the start of the study. Twenty-five pharmacy team members answered the second questionnaire a month later. At the start of the study, 75% of the pharmacy team members agreed that the service was appropriate for their pharmacy, and 92.3% agreed that they were willing to provide the service. Acceptability of the service by the patients was agreed on by 50% of the team members. A month later, the three variables dropped to 53.8% appropriateness (- 38.5 percentage points), 3.8% adoption (- 46.2 percentage points), and 36.5% acceptability (- 39.1 percentage points). For an overview, see Figure 2. Feasibility reached a mean value of 2.8±0.2 on the 4 point Likert scale (see Figure 3). After six months, 4 out of the 5 pharmacies were still using the service (penetration: 80%), and two pharmacies planned to continue working with TopCompliance (sustainability: 40%). One pharmacy planned to use the service provisionally for another six months before reevaluation of the service.

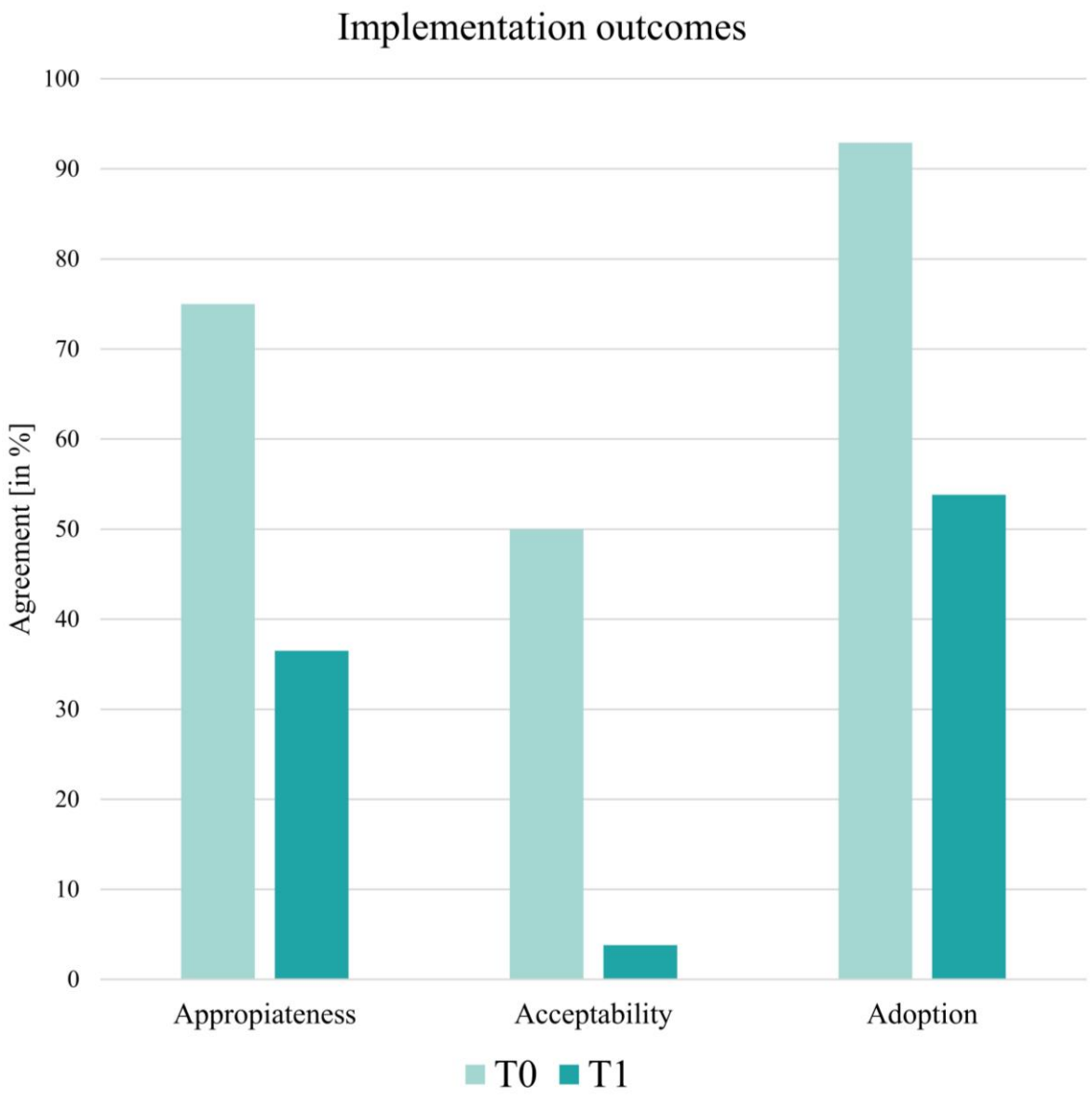

Figure 2 Agreement on three implementation outcomes at the start of the study (T0; N = 28), and 1 month later (T1; N = 25)

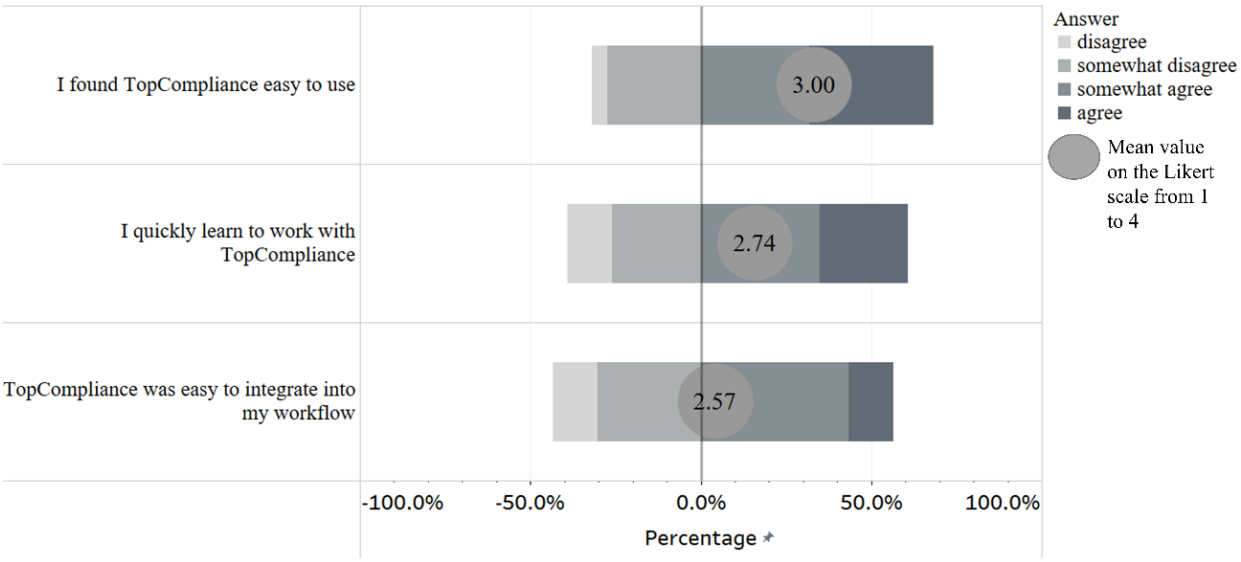

Figure 3 Evaluation of the implementation outcome feasibility by the pharmacy team members

(N = 25)

Discussion

In this pilot study, we evaluated the implementation of the professional pharmacy service named TopCompliance and the adequacy of the implementation outcomes defined by Proctor et al.[7] The main outcome measure “number of active users” showed an upward trend over time, indicating an active promotion of the services by the pharmacy team members and an interest in the service by the patients. However, there were considerable differences between the pharmacies. While, for example, pharmacy 4 discontinued the service after month 1, pharmacy 2 steadily gained users. Also, only two pharmacies were planning on sustaining the service. The possible reasons why most pharmacies decided to discontinue the service can be due to the service itself and/or a suboptimal implementation process[4], on which both the selected implementation outcomes by Proctor can deliver more depth. In general, the willingness to systematically collect implementation data in the pharmacy setting is low[23], and a focus should be placed on usability.[15] We selected questionnaires because they represent an ideal measurement method that can simplify, standardize and reduce the measurement burden. Unsurprisingly, Procor et al. suggested a questionnaire as a potential measurement method for most implementation outcomes, and proposed to measure the outcomes at different stages of the implementation process.[7] We measured the outcomes at three different time points and repeatedly. The outcomes of acceptability and appropriateness declined rapidly within a month, suggesting that the appropriateness and acceptability of the service had been overestimated before implementing it. Also, the adoption, i.e., the willingness to provide the service, decreased during the first month. These three outcomes suggest that implementation outcomes can be dynamic during the implementation process. Therefore, measuring implementation outcomes continuously and prospectively enables an early evaluation and decision on whether new implementation strategies are needed to improve the implementation. Similarly, by detecting implementation outcome changes during implementation, the effect of implementation strategies can be better documented, which can help to improve the sparse evidence on the effectiveness of implementation strategies.[23] A limitation of the outcomes of Proctor et al. is that the relationship between the outcomes is not defined.[7] However, it is evident that implementation outcomes are strongly interdependent and influence each other.[24] For TopCompliance, the low sustainability can be at least partly explained by the low acceptability and

appropriateness of the service after the month 1. Therefore, acceptability and appropriateness as an indicator of sustainability should be explored in the future so that implementations predestined to fail can be discontinued early, potentially saving resources in time, cost, and effort.

Strengths

This study has several strengths. First, our implementation outcomes are based on literature and tailored to the professional pharmacy service. We claim to have delivered robust instruments to the pharmacy teams by doing this. Second, we have developed pragmatic implementation outcome measures that assess the implementation process prospectively. Thus, the participating pharmacy teams were enclined to collect data in real-time and deliver insight in their daily practice. Third, the whole pharmacy team was asked for their opinion on the appropriateness, acceptability, adaption, and feasibility. This gives a better picture of the implementation of a new service compared to the retrospective evaluation of the service given by selected employees of a study pharmacy. Fourth, we measured the implementation outcome at different times. This enabled us to document the dynamics of an implementation process.

Limitations

We acknowledge some limitations. First, we did not assess the impact of the implementation strategies on the implementation success, which is usually the focus of implementation studies. However, this was not the focus of this study. Nevertheless, an analysis of the implementation strategies used by the pharmacy teams during this pilot might be an interesting project for the future. Second, we did not test the questionnaires for psychometric properties. Although this is not the standard in implementation science[18], proper validation of implementation outcomes measurement tools should be a focus to improve the quality and comparability of implementation studies. Third, we recruited five pharmacies from 28, which denotes a poor interest in the project. Nevertheless, because each community pharmacy is unique, we claim that the number of 28 team members is sufficient to draw firm conclusions.

Conclusion

We evaluated the implementation of a new professional pharmacy service named TopCompliance in selected community pharmacies and used the outcomes proposed by Proctor et al. The next step will be to use the developed measures in larger implementation studies for professional pharmacy services.

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GENERAL DISCUSSION

The goal of this thesis was the development and testing of strategies for professional pharmacy services, with medication adherence as an illustrative example. In general, services have already been implemented in community pharmacies. For example, the service “Polymedicationcheck” in Switzerland provided a solution for discussing patients' medication and potentially improving medication adherence. Although the service was thoroughly designed, remunerated, and evaluated by the government, the pharmacy teams were still hesitant to promote and use the service, resulting in the decommissioning of the service in 2020.[147, 148] This illustrative example shows that a sustainable implementation is defined not only by the professional pharmacy service but also “where” the service is implemented (implementation setting) and “how” it is implemented (implementation process). The pharmacy teams need a toolbox of practicable methods and strategies to deliver professional pharmacy services to the patient. Only recently (January 2022), the International Pharmaceutical Federation (FIP) published the report: “Medication review and medicines use review - a toolkit for pharmacists.”[149] The report provides a toolkit that defines a step-by-step process for implementing medication reviews and medicines use reviews. Furthermore, the report emphasizes that the development of screening tools for patients in need of such services should be prioritized.[150] Similarly to this report, this thesis provides first strategies for adherence screening in community pharmacies (Project A) and tools based on implementation concepts to establish a new professional pharmacy service (Project B). All projects were anchored in the pharmaceutical care process.

Project A: Strategies for screening

Project A aimed at developing strategies for screening for patients in need of an intervention or professional pharmacy services focusing on medication adherence. According to the pharmaceutical care process, collecting data on a patient's medication and health status is needed to identify and prioritize medication-related problems. Different data collection and evaluation methods can be used to screen for nonadherence. The previously mentioned FIP report stated that the two primary data sources involve medication history and patient information. **Projects A1** and **A2** focused on developing strategies to evaluate medication history data. **Project A3-A5** focused on collecting and evaluating patient information.

Evaluating the medication history data of patients

In **Project A1,** a new absolute adherence estimate from refill data was developed. Currently, only a few medication adherence measures are implemented to allow pharmacy teams to monitor medication adherence and screen for nonadherence. Examples are the Pharmacy Quality Alliance measures that use the Proportion of days covered (PDC) [151, 152] or the Med Screen Compliance program that uses the Medication Possession Ratio (MPR).[153] These Continuous Multiple interval measures of medication Availability (CMAs) estimate the possession ratio over several refills. The newly introduced medication adherence measure ΔT can characterize every refill event, and quantify patient refill behavior. This allows better data differentiation, standardization, interpretation, and visualization:

- Differentiation: The standard adherence estimates usually evaluate a prescribed use of medicine related to the estimated use over a defined time, and report medication adherence as a rate. By reporting adherence estimates as rates, the information about where the adherence estimate is derived from is lost. However, data quantity and quality between adherence estimates are remarkably different: An adherence rate of 80% for patients over a half year can be calculated based on 150 data points from every intake event (electronic data monitoring) or 3 data points (refill events). Nonetheless, the different parameters are compared for reviews, resulting in a large distribution of adherence rates for the same disease.[154, 155] Moreover, different

adherence rates are being reported for the same patient.[31] In comparison, ΔT quantifies the refill behavior expressed as days.

- Standardization: CMAs such as the PDC and the MPR have different operationalization and interpretation in the literature. [32-34] ΔT is derived from the ABC taxonomy[10] and the TEOS framework.[11] Therefore, ΔT is clearly defined, allowing standardized calculation and reducing the risk of misinterpretation.
- Interpretation: A value of ΔT – 7 days might be more self-explanatory than a possession ratio of 80%, especially for non-experts in medication adherence. Community pharmacists should increasingly use available data to monitor and screen medication adherence. Therefore, ΔT is ideal for screening purposes because it represents the current refill behavior of the patient and the theoretically remaining tablets at each refill event. In addition, ΔT gives a better understanding of the oversupplied group. Usually, the interest is on patients with a medication possession ratio below 80%. Values over 100% are often cut-off or even impossible with measures such as the PDC.[156] In the investigated direct oral anticoagulants (DOAC) population, the majority of the patients were oversupplied. Hence, oversupplying can be a critical refill behavior and has been associated with higher hospitalization rates.[157, 158] A key role of the community pharmacist should be the effective medication therapy management, including preventing medication wastage and medication overuse.[3]
- Visualization: A main tool for screening for nonadherent patients should be that the pharmacy teams can visually detect a potentially nonadherent patient in their pharmacy software.[159] The presented visualization of ΔT as a heat map with the traffic light scheme color code has already been used to visualize adherence in electronic health records[16] and merits greater exploration as an option for continuously screening nonadherent patients.

Although there are several strengths of ΔT, there are also aspects that have to be better investigated to evaluate the full potential of the measure:

- Observation period: The fact that ΔT is independent of the observation period is an advantage for the reproducibility of the results compared to other CMAs [33, 160], but it has

disadvantages: As this project has established when comparing several refill events, the probability that the observation period length differs is high. The variability in observation periods can be a limiting factor for the application of ΔT in observational studies that generally are based on fixed observation periods.

- Package size: The influence of the package size on the refill behavior is unclear and has not been investigated in this project. Because ΔT as a relative measure (standardized on the received days' supply) could be a valuable further development of the measure to investigate this relationship.
- Oversupply: The oversupply was included in the calculation of ΔT to prevent underestimation of medication adherence at the patient level over time.[161, 162] It was assumed that patients would terminate the oversupply before using the new supply. This assumption is based on theoretical considerations and observational studies[20, 21] and must be confirmed with further qualitative studies such as patient interviews.
- The relation of ΔT to clinical outcomes and other adherence measures has to be established. There is already an ongoing study[163] investigating the relationship between ΔT and electronic monitoring, but further studies are needed.

Defining a threshold to screen for nonadherent patient

New adherence measures such as ΔT might help characterize the refill behavior, but do not solve the problem of selecting and targeting the patients who should profit most from an intervention. It is common sense that achieving a target clinical outcome requires a certain level of medication intake, but it is still unclear where the threshold is to distinguish adherent from nonadherent patients. Usually and traditionally, the 80% threshold is applied for all adherence parameters.[44] **Project A2** searched for studies that defined medication adherence thresholds that were derived from clinical outcome data. To our knowledge, very few studies have defined thresholds for adherence in the context of clinical outcomes. The systematic literature search yielded six articles that have assessed clinical outcomes linked to adherence rates in seven chronic disease states. Five out of the six articles obtained adherence thresholds between 46% and 92%, questioning the 80% threshold. Since its publication, the article has

already been cited 71 times (February 22), and additional articles have been published that define a threshold value.[164-166] The new articles define thresholds for diabetes and for DOACs [164, 166]. The same research group conducted the two DOAC studies. The authors defined a threshold of 90% for DOACs in the first study after conducting a simulation study.[166] In the second study, they defined thresholds at 78% for rivaroxaban and 80% for apixaban by analyzing Health Insurance Claims Data [164]. These two studies show that the data source and calculation methods affect the result. Therefore, it is highly advised to develop recommendations on how to best conduct studies that define thresholds for medication adherence in the future. Our five recommendations in the conclusion of this project can lay a basic foundation for this:

1. *Specify the medication linked to the target clinical outcome;*
2. *Define adherence measures; calculations have to be replicable;*
3. *Select an observation period sufficiently long to detect the clinical outcome; orient to high-quality studies such as randomized controlled trials;*
4. *Select statistic methods for threshold determination carefully, in order to avoid loss of information;*
5. *Put the adherence threshold in context to clinical relevance.*

Collecting and evaluating patient information

A standard method for the systematic collection of patient information is the self-report questionnaire. **Project A3** aimed to translate the Medication-Related Burden Quality of Life (MRB-QoL) tool into German and assess its practicality in the primary health care process. The MRB-QoL is a 31-item questionnaire developed in English to measure the burden of medication on patients' psychological, social, physical, and financial well-being. The MRB-QoL was successfully translated into a shortened 17-item version in German called “Das Tool zur Erfassung der Belastung durch die Medikation und der Lebensqualität” (BM-LQ). To our knowledge, the BM-LQ is the first tool in the German language to measure medication-related burden. Health care practitioners see its practical importance in primary patient care and have defined the ideal process as follows: Patients at risk for medication-related burden should complete the tool in the general practitioners' office or home care setting. The answers should be evaluated by the primary care physician who should initiate and implement a targeted intervention in collaboration with nurses and pharmacists.

Methodological consideration: Defining primary care processes with swimlane diagrams

We used swimlane diagrams with the stakeholders to describe the process model for the BM-LQ. Process models have already been used to improve the processes in the hospital setting.[167] Compared to the hospital setting, where care processes are usually defined within a single organization, a patient's journey in primary care is much more complex and unique. Also, in the primary setting, the process is often described from one point of view. For example, it summarizes the different services provided by community pharmacies to a patient[168] or the process of medication use in primary care.[169] Therefore, the swimlane diagram offers a way to simplify the complex patient processes in primary health care and allow future application in interprofessional process improvement, which is one of the main goals of process modeling.[170]

Reducing the medication-related burden: a chance for interprofessional collaboration

The developer of the MRB-QoL mainly designed the tool to assess the changes of quality of life in patients after pharmaceutical care interventions.[68] However, as the defined process model shows and as all stakeholders agreed on, reducing the medication-related burden can only be resolved with interprofessional collaboration. The pharmacist-centered development process of the MRB-QoL showcases that most often, screening tools and interventions focused on DRPs are solely designed for the own profession rather than for the whole primary care health system. However, a key component of patient-centered care is being collaborative and coordinated.[171, 172] Therefore, for the next steps, the piloting and implementation of the MRB-QoL in primary care stakeholders should be included throughout the process. In addition, engaging stakeholders from the beginning in the co-development of professional pharmacy services may deliver a promising strategy to increase implementation success.[173]

Addressing the patient

In **Project A4**, we developed and tested a framework that allows pharmacy teams to define and apply a strategy to address medication adherence in community pharmacies. It seems that the need of pharmacy patients for adherence counseling is high, with reported nonadherence rates of 25%[45] to 50%[23]. Hence, the actual adherence counseling of the pharmacy team is low.[174] Studies' reported barriers hindering adherence counseling are mainly on the pharmacist side e.g., shyness, being unmotivated[175, 176], or fear of rejection by the patients.[174] Therefore, we hypothesized that the pharmacy teams need simple tools that help them increase counseling. During the study, the teams developed strategies within 30 minutes that resulted in 50 (15%) patients being counseled on medication adherence during one working day. We used interdisciplinary approaches by using concepts from social marketing theory to develop the framework as well as aspects of action research for the development process of the strategy with the pharmacy teams. These two approaches are not widely used in pharmacy practice and are discussed in more detail.

Methodological consideration: Using social marketing theory to structure screening

According to social marketing theory, the potential market is only a fragment of the total population. Of the potential customers, only a fraction of customers become actual customers.[177] With this principle in mind, a 3-item framework was designed. We wanted to give the pharmacy teams a simple framework that structures and optimizes the screening process and increases the number of patients counseled on medication adherence. The 3-item structure has several benefits:

- The framework enables the pharmacy teams to define feasible target groups. The development process included an empirical segmenting of the potential nonadherent patient into different groups based on common characteristics, followed by targeting the patient group (target patient) that should profit most when addressed. Most pharmacy teams focused on pragmatic triggers to detect potential nonadherent patients, such as the patient's medication or request, rather than patient-related factors (gender, age, traits) as suggested by the literature.[178, 179]
- In the past, rejection by the patient was named as a primary hurdle to adherence counseling.[174] A potential part of the explanation can be negativity bias, meaning that

negative experiences are more often remembered than positive experiences, resulting in negative memories.[180] With the framework, the individual pharmacy team members can consciously gain a series of new experiences with adherence counseling.

- By defining a target goal for the screening process, adherence screening becomes measurable. This is likely to lead to higher performance levels in adherence counseling in the future.[181, 182]

Methodological consideration: Using action research to tailor screening

The strategies were developed during a brainstorming session, allowing the pharmacy team to define their strategy. The active inclusion of the pharmacy team corresponds to the principles of action research.[183] This promising method has already been successfully used in pharmacy practice.[184, 185] Normally, four steps define action research: *1. Diagnosing and analyzing problems—purpose, goals, aims, and vision; 2. Planning—plans and strategy; 3. Taking action—implementation and performance; 4. Evaluating—results, consequences, and effects*.[186] We conducted all four steps with the pharmacy team by defining, testing, and evaluating the strategy during this project. The inclusion of the pharmacy team throughout the research process might be a reason why the pharmacy teams rated the acceptability and appropriateness of the framework as high and were willing to apply the strategy in the future. Still, we missed a key characteristic of action research: The application of ongoing cycles of the four steps of action research.[186] In our study, the pharmacy teams only performed one cycle. Therefore, the next step should be that the pharmacy teams use the strategy for a more extended period to document the long-term experience, potential modification, and effectiveness. A collection of proven strategies can be a valuable tool for pharmacy practice to screen more systematically for nonadherent patients and reduce barriers for pharmacy team members to address medication adherence.[187]

A critical point remains

The main limitation of this project is that suitability of the addressed patients was not proven, although the screening process for nonadherent patients can be optimized with the 3-item framework. During the study, the patient's adherence was not measured by the research team, but the pharmacy teams were allowed to use all tools that they potentially had available to evaluate the patient's medication adherence.

The pharmacy teams focused on pragmatic triggers for target groups and did not rely on adherence estimates or the refill history. The lack of information concerning medication adherence before starting a patient encounter is a known problem that has not yet been solved.[76] Therefore, more usable and objective methods to estimate and visualize adherence are needed to support the pharmacy teams in screening for nonadherent patients, such as ΔT. Nevertheless, the refill behavior of the patients is only an indicator of nonadherence and includes a lot of "false positive" nonadherent patients.[188] Ultimately, the actual intake behavior can only be clarified during the consultation.

Documenting adherence counseling

During Project A4, we observed 325 encounters in community pharmacies during which 73 (21.9%) patients were asked about medication adherence, and 50 (15%) adherence counselings were performed. **Project A5** aimed to characterize adherence counseling and compare encounters with and those without medication adherence addressed in community pharmacies by conducting a subanalysis of Project A4. It was documented that addressing medication adherence during patient counseling is not time-consuming (1.6 minutes longer) and does not affect other counseling activities. On average, the pharmacy teams addressed 1.4 ± 0.6 medication adherence topics during adherence counseling, with mainly patient-related issues being raised. This work is one of the few studies that has systematically documented adherence counseling in community pharmacies.[174] In daily practice, medication adherence activities are already routinely documented with for example, notes in the patient chart.[188] However, this form of documentation is not undertaken systematically and does not allow the specification of adherence counseling. In the future, methods should be developed to routinely and systematically document adherence counseling.[189] We used the method of a silent observer, a proven method to precisely document counseling activities.[174, 190] However, this method is not feasible for daily pharmacy practice. There are already tools available and implemented for documenting drug-related problems (DRPs) in the hospital setting, such as the GSASA classification system.[191]. In community pharmacies, such tools are rarely applied. Examples of documentation systems that have been applied in community pharmacies are the PCNE classification system[192] and the Pharm-DISC system.[193] However, they are not implemented in community pharmacies, and their feasibility in daily practice is low.[192] For documentation in Project A5, we used a checklist with a focus on medication

adherence counseling, which had already been used in earlier studies.[174] The checklist includes eight adherence counseling categories that allowed the silent observer to document adherence counseling quickly. An adaptation of the checklist could be a base for a documenting system that could routinely document data on adherence counseling in community pharmacies.

Project B: Using implementation concepts to establish a new professional pharmacy service in community pharmacies

Implementing new professional services represents an area where community pharmacy has had limited experience.[93] This lack of knowledge on how to successfully implement new services has been chiefly attributed to pharmacists, as it is believed that they still focus on dispensing as the main source of income.[194] However, an alternative hypothesis is that pharmacists are not provided with enough tools derived from implementation science in order to implement a new professional pharmacy service successfully. **Project B** used implementation concepts to establish a new professional pharmacy service in community pharmacies. We focused on two main aspects of implementation science: implementation strategies and outcomes.

A tailored implementation strategy for the implementation of professional pharmacy services

In **Project B1,** the goal was to develop an implementation strategy for professional pharmacy services in community pharmacies that contains the PDCA cycle in a structured process. The PDCA cycle originates in the car manufacturing industry and is a central concept for quality improvement and monitoring.[120] In recent decades, the cycle has been disseminated into the health care sector and is used most often in the hospital setting to improve existing processes.[195-198] More recently, QI methods such as the PDCA cycle have also been used to implement innovations into practice.[110, 122] Unfortunately, most studies do not specify how exactly, how often, and by whom the PDCA cycle was used during the implementation. In general, when the PDCA cycle has been applied in an implementation study, more generic terms were used to report the strategy, such as “use of quality improvement tools.” Therefore, due to the lack of documentation, there is also a lack of evidence of the effectiveness of implementation strategies.[134] To establish the PDCA cycle as fully documented implementation strategy, we applied the following key aspects during the project, which are discussed in more detail here.

Expanding the principles of the PDCA cycle to the implementation process

We have expanded the PDCA cycle concept from improving an existing process to implementing a new process by adding the “fokus” part during the development process. This was achieved by inserting the process steps of the Framework for the Implementation of Services in Pharmacy (FISpH) [110] and adopting a more appropriate version of the PDCA cycle.[199] We have emphasized these first stages of implementation by adding the “fokus” part because, despite their importance, little attention has been paid to the pre-implementation phases.[200] The “fokus” part should help to structure the planning and execution of the first step of the implementation. Repeating the PDCA cycle part should encourage the user to constantly identify implementation barriers (Check, Act) and address them in the next cycle (Plan, Do) during the progression of the implementation. We claim that our conceptual adaptation of the PDCA cycle can be an important step toward better establishing the PDCA cycle as a pragmatic but scientific-based implementation strategy.[119] The fokus°PDCA structure allows documenting the implementation process thoroughly, which is a key aspect of the principle PDCA cycle that is often missed in studies reporting the use of the PDCA cycle.[118]

Methodological considerations: Developing implementation strategies in analogy to intervention research

As in intervention research, implementation strategies should be clearly defined and preceded by a development and evaluation process.[83, 94] Therefore, we developed the fokus°PDCA following a two-step approach with the underlying rationales:

- Tailoring the strategy should improve implementation and effectiveness.[201]
- Testing the strategy with future users should prevent issues with the acceptability, fidelity, and delivery of the strategy.[173]

With this two-step approach, the strategy is clearly defined and offers a feasible approach for designing implementation strategies for the implementation process of professional pharmacy services.

The next steps for the fokus°PDCA

The first evaluation of the strategy showed good scores for the variables: usability, comprehensibility, acceptability, feasibility, and appropriateness. Still, the strategy had only been evaluated after one to two PDCA cycles without long-term experience. Further, effectiveness has not been evaluated. Although quality improvement methods are seen as one of the most feasible and important implementation strategies[130], the evidence on effectiveness is sparse. In comparison, the Cochrane Collaboration's Effective Practice and Organization of Care (EPOC) group has published reviews for other implementation strategies such as educational meetings[202], audit and feedback[203], printed educational materials[204], and local opinion leaders.[205] It was only recently that a systematic review was published that has systematically investigated quality improvement methods for improving health care outcomes.[206] The authors concluded that the effect is uncertain due to the poor reporting and evaluation quality of the strategies.[206] In the systematic review, the strategies were mainly evaluated for improving healthcare outcomes, including clinical process outcomes and patient outcomes. [206] Considering that the characteristics of the PDCA cycle focus on process improvement, it makes potentially more sense in the future to evaluate outcomes that are specific to the implementation such as implementation outcomes.[112]

Implementation outcomes for professional pharmacy services

In **Project B2**, the study's goal was to adapt Proctor's implementation outcomes for evaluating the implementation of a new professional pharmacy service named “TopCompliance.” In general, a great challenge is defining implementation outcomes that are pragmatic but precise.[207] The proposed measurement methods are administrative databases, on-site observational assessments, or surveys.[112] The latter is commonly used to assess attitudes and perceptions of providers and patients, but surveys with appropriate psychometric properties are sparse.[208] Moreover, there are no comprehensive, validated measures for all implementation outcomes to use in pharmacy practice. The few studies that assess implementation outcomes for professional pharmacy services mainly used administrative data[200, 209] with exceptions for those already using questionnaires. Only recently, an implementation outcome questionnaire was developed and validated for medication optimization services, the “implementation outcome questionnaire.” This questionnaire is a 40-item self-report instrument for the

same six implementation outcomes that we have used in this thesis: adoption, acceptability, feasibility, appropriateness, penetration, and sustainability.[210] We have developed and used two short questionnaires without previously psychometrically testing them, which is a limitation of this project. We chose a pragmatic approach by omitting a long development and validation phase and focused on a fast implementation of the service. This is in line with the common opinions of implementation experts to reduce the measurement burden for implementation.[209, 211] Our questionnaires have to be proven to document implementation outcomes in a valuable manner. Therefore, the next step would be to validate the questionnaires to be disseminated as a tool for pharmacy practitioners in order to evaluate professional pharmacy services. Based on the experiences and reflection on Project B2**,** the following aspects should be explored to push forward the concept of implementation outcomes for professional pharmacy services:

- Complete coverage of Proctor et al.'s implementation outcomes for pharmacy practice: The limiting factor of Project B2 is that not all implementation outcomes proposed by Proctor et al. are covered in the questionnaires. For example, the implementation outcomes "fidelity" and "implementation cost" are missing.
- Defining the optimal time point and dose for assessing implementation outcomes: We measured the outcome's acceptability and appropriateness within one month. These outcomes rapidly changed for TopCompliance, suggesting that these outcomes potentially should have been measured in shorter intervals.
- Exploring the relationship between implementation outcomes: Implementation outcomes are strongly interdependent and influence each other[207], but a limitation of the outcomes of Proctor et al. is that the relationship between outcomes is not defined.[112] A few outcomes, including acceptability and appropriateness, can be measured in the first month of the implementation process. Therefore, it would be interesting to explore acceptability and appropriateness as indicators of sustainability so that implementation predestined to fail can be discontinued early.
- Evaluation of different implementation outcomes measurement methods: We focused on developing feasible questionnaires for evaluating implementation outcomes. Depending on the

implementation outcomes, different measurement methods are more appropriate.[112] For example, questionnaires were also developed to measure the fidelity of professional pharmacy services.[209] However, it is questionable whether self-report questionnaires are the most appropriate measurement method for assessing fidelity. Other measurement methods, such as audits or administrative databases, must be explored.[212]

- Assessing the potential of combining measurement methods: A potential model for evaluating the implementation of professional pharmacy services could be to use the pharmacy's electronic administrative databases for gathering data on implementation processes and strategies continuously, in combination with questionnaires that regularly measure the implementation more precisely.

Strengths

In the past, pharmaceutical care research has focused mainly on developing and evaluating professional services. The implementation gap (i.e., the poor implementation of these services) has only been acknowledged in the last decade by adapting implementation concepts to the pharmacy setting. To our knowledge, this thesis is one of the first that has placed a particular focus on the process and the deliverer i.e., the pharmacy teams of professional pharmacy services:

- by providing the pharmacy team with screening tools for nonadherent patients;
- by applying implementation science concepts, including strategies and outcomes, to the pharmacy setting.

This thesis also showcases how to mix methods and interdisciplinary approaches of medication adherence and implementation science. Implementation science has been an interdisciplinary science from the very beginning, while medication adherence is increasingly becoming so. New methods and theories from social science or economics have been brought in with social marketing theory, process models, or the PDCA cycle. All these methods were tested and used by the pharmacy team members. This corresponds to action research principles that actively incorporate the pharmacy team in co-designed tools and strategies in order to help to deliver pharmaceutical care.

Limitations

The limitations of each project were discussed in detail for each study. The general limitations of this work are presented here:

- For most studies of this thesis, no actual medication adherence data or clinical data were available except for Project A1 and A2. Thus, for the developed strategies in Project A3, it is unclear if the use of the 3-item framework has affected patient medication adherence and/or clinical outcome.
- The generalizability of the studies is modest. Most studies have been designed as pilot studies with small numbers and local settings. The developed strategies need to be evaluated in larger-scale studies to determine the actual effect of the presented concepts.

- A selection bias was present in the studies, as all participants voluntarily took part in the studies and can be described as early adopters of the concept of pharmaceutical care.
- There was a lack of interdisciplinary and interprofessional collaboration except for the MRB-QoL project. Although interdisciplinary methods were used, pharmacists designed and supervised the studies. The inclusion of experts from other fields (e.g., social marketing or implementation experts) could be a potential direction to improve pharmaceutical care research in the future.

Conclusion

This thesis developed and tested practicable strategies for professional pharmacy services anchored in the pharmaceutical care process focusing on medication adherence. Despite all the mentioned biases and limitations, we could pave a first way for robust but straightforward methods and strategies to better screen for nonadherent patients and implement new professional pharmacy services. These tools can be the basis for a toolbox of workable methods and strategies for pharmacy teams to better implement and deliver professional pharmacy services in primary care in the future.

Outlook

The ambition in upcoming projects should be to disseminate the findings together with implementing the developed tools and strategies in pharmacy practice. In analogy to the MRC[83], the projects were assessed according to their progression during this thesis (Table 8). During the thesis, the projects reached, at most, the level of "evaluation." For the outlook of this thesis, the next steps for the projects are outlined.

Table 8 The stage that the projects reached during the thesis according to the stages of the MRC.[83] Gray color: Not applicable.

	Development	Feasibility/piloting	Evaluation	Implementation
A1: DYANA		**X**		
A2: Adherence threshold			**X**	
A3: MRB-QoL	**X**			
A4/A5: SCREEN/Adherence counseling			**X**	
B1: fokus°PDCA		**X**		
B2: DECLICC		**X**		

Project A1 reached the piloting step by using ΔT in an observational study. The next steps should be:

- For observational research, ΔT should be used in a larger population, in different diseases, linked to clinical outcomes, and correlated to other adherence measures.
- For interventional research, ΔT should be piloted as an adherence measure for interventions that target refill behavior, such as medication synchronization or reminder programs.
- In practice: The available automated software system screening nonadherent patients leads to many false-positive nonadherence alerts.[188] ΔT should be piloted as an adherence measure for better screening in community pharmacies.

Project A2: The project revealed a large research gap in determining medication adherence thresholds in relation to clinical outcome data. In the systematic review, only 6 studies could be included. Therefore:

- Another systematic review is needed to collect additional studies linking clinical outcomes with adherence thresholds so that studies can be compared quantitatively to finally reject or confirm the 80% threshold.
- With better evidence on defining thresholds, recommendations on conducting best studies to define thresholds for medication adherence similar to the TEOS Framework[42] should be formulated.

Project A3: The German-language version of the MRB-QoL was developed and named BM-LQ.

- The questionnaire should be piloted and validated fully in the primary care setting.

Project A4: The framework was piloted with a small number of pharmacies in a local setting:

- A scaled-up and more extended piloting phase: The framework needs to be tested for longer and with more pharmacies to evaluate effectiveness.
- New development: The framework could be expanded to screen for target patients in other critical counseling themes such as “alcohol and medication” or promote new innovative services such as pharmacogenetic analysis.[213]

Project A5: Based on the experience in this study and earlier studies[174], new projects should be initiated that:

- Develop a feasible documentation system systematically collecting adherence counseling data in community pharmacies.

Project B1: A first small pilot phase for the fokus°PDCA was successful. A second and extended pilot phase is suggested, characterized by:

- A scaled-up and longer observation phase: The strategy should be used for implementing a professional pharmacy service in Switzerland and assessed for effectiveness in a large-scale study.

Project B2: A first case study on how to prospectively document implementation outcomes of a professional pharmacy service was performed. The next steps should be:

- To validate the developed measures properly and use them in more extensive implementation studies for professional pharmacy services.
- To develop additional simple outcomes measures that cover all outcomes defined by Proctor with the aim of making available a full outcome set that can be tailored to the implementation of the professional service under investigation.

General outlook- Closing the gap in the pharmaceutical care process loop

To exploit the full potential of this thesis, the individual findings and strategies should be linked so that the process of pharmaceutical care in the area of medication adherence can be improved and professional pharmacy services can be delivered to the patients. Findings from Project A should be used to screen for potential patients in need of medication adherence intervention. Findings from Project B should be used to implement professional pharmacy services. To fully connect Project A and B and close the process loop, the stage “plan interventions” should be integrated. This step was not part of this thesis but offers potential for future projects. Promising approaches exist already, such as the tool BIOTICA designed by Haag et al. to assess adherence barriers in primary care patients with prescribed antibiotics

preemptively and tailor interventions.[214] Currently, processes to tailor adherence interventions to the patient are not implemented in daily practice. Therefore, the next step is to develop tools that allow matching the already available interventions to the patient (see Figure 10). Future projects should also expand on the idea of delivering a toolbox of strategies to the pharmacy teams for screening for nonadherent patients and implementing services. Besides developing new strategies and tools, a focus should be on collecting and evaluating existing strategies. In the future, the pharmacy teams should have a toolbox of practicable methods and strategies to screen for nonadherent patients and deliver professional pharmacy services to the patients.

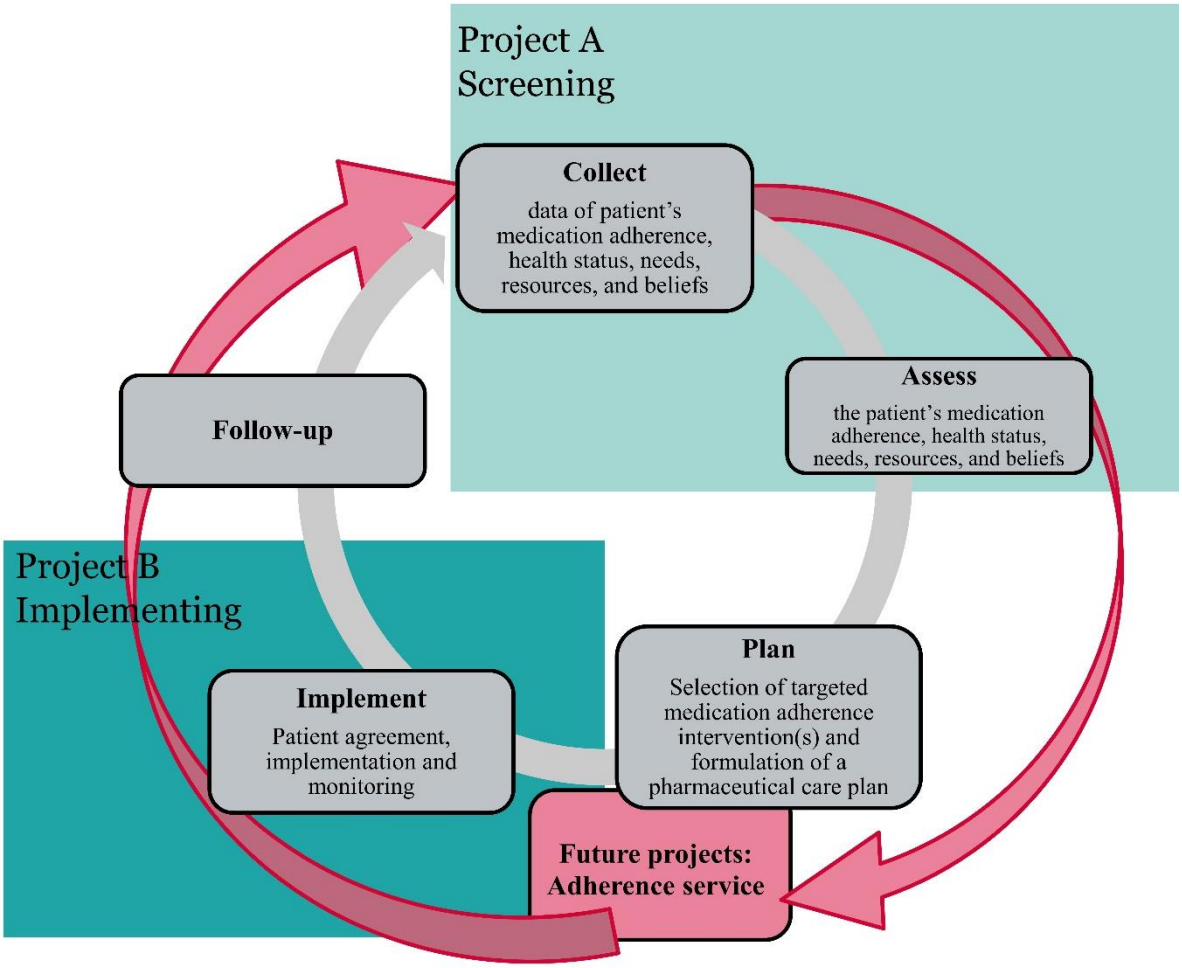

Figure 10 Potential future projects in the "plan step" (red box) focusing on adherence services that all step of pharmaceutical care process can be connected in the future (red arrows)

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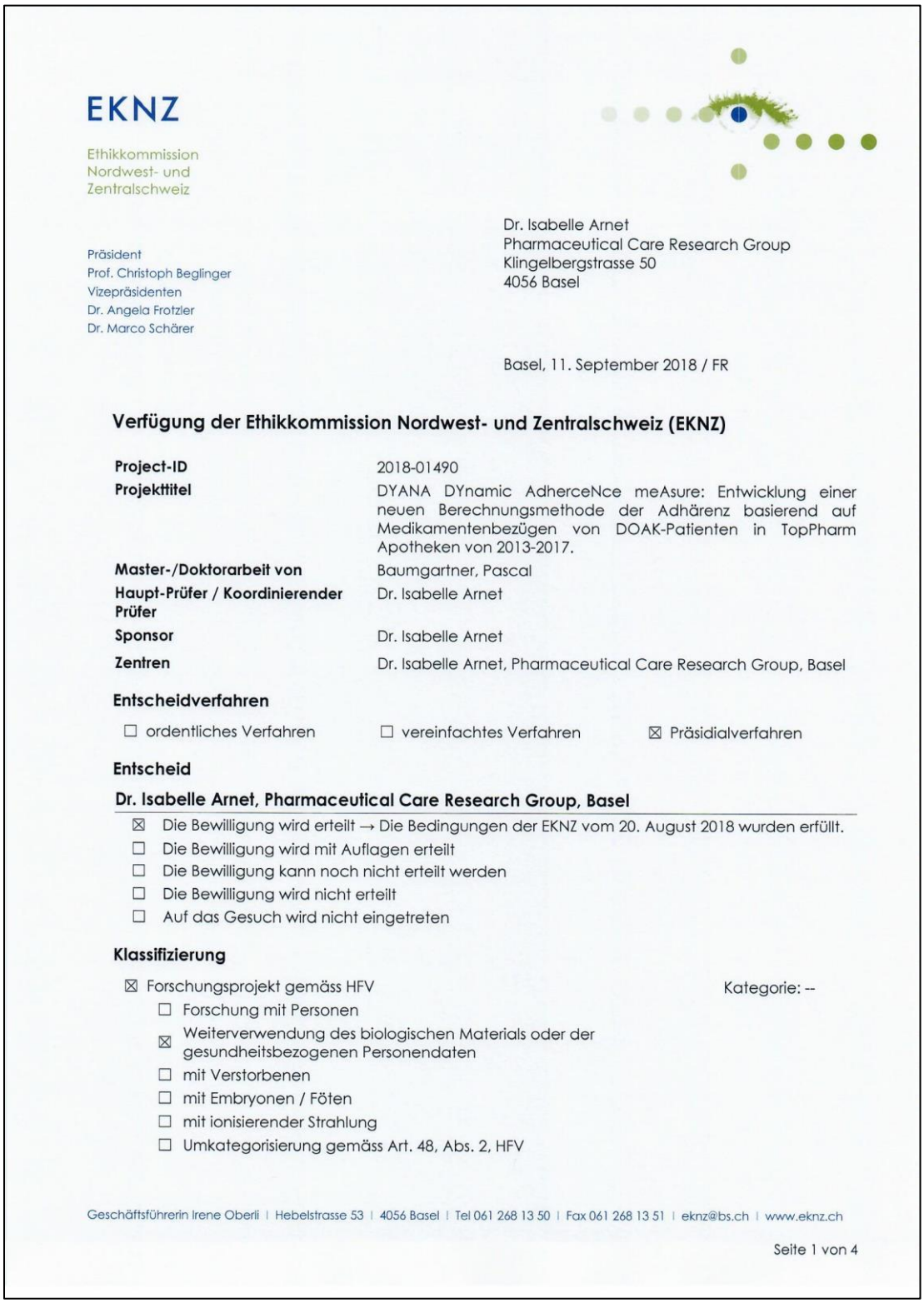
APPENDIX

The following appendix is limited to the main documents used within the different projects. For further information, please send a request to the author.

Project A

A1

I. Ethics approval



EKNZ

Ethikkommission
Nordwest- und
Zentralschweiz

Präsident
Prof. Christoph Beglinger
Vizepräsidenten
Dr. Angela Frotzler
Dr. Marco Schärer

Dr. Isabelle Arnet
Pharmaceutical Care Research Group
Klingelbergstrasse 50
4056 Basel

Basel, 11. September 2018 / FR

Verfügung der Ethikkommission Nordwest- und Zentralschweiz (EKNZ)

Project-ID	2018-01490
Projekttitel	DYANA DYnamic AdherceNce meAsure: Entwicklung einer neuen Berechnungsmethode der Adhärenz basierend auf Medikamentenbezügen von DOAK-Patienten in TopPharm Apotheken von 2013-2017.
Master-/Doktorarbeit von	Baumgartner, Pascal
Haupt-Prüfer / Koordinierender Prüfer	Dr. Isabelle Arnet
Sponsor	Dr. Isabelle Arnet
Zentren	Dr. Isabelle Arnet, Pharmaceutical Care Research Group, Basel

Entscheidverfahren

☐ ordentliches Verfahren ☐ vereinfachtes Verfahren ☒ Präsidialverfahren

Entscheid

Dr. Isabelle Arnet, Pharmaceutical Care Research Group, Basel

- ☒ Die Bewilligung wird erteilt → Die Bedingungen der EKNZ vom 20. August 2018 wurden erfüllt.
- ☐ Die Bewilligung wird mit Auflagen erteilt
- ☐ Die Bewilligung kann noch nicht erteilt werden
- ☐ Die Bewilligung wird nicht erteilt
- ☐ Auf das Gesuch wird nicht eingetreten

Klassifizierung

☒ Forschungsprojekt gemäss HFV Kategorie: --

- ☐ Forschung mit Personen
- ☒ Weiterverwendung des biologischen Materials oder der gesundheitsbezogenen Personendaten
- ☐ mit Verstorbenen
- ☐ mit Embryonen / Föten
- ☐ mit ionisierender Strahlung
- ☐ Umkategorisierung gemäss Art. 48, Abs. 2, HFV

Geschäftsführerin Irene Oberli | Hebelstrasse 53 | 4056 Basel | Tel 061 268 13 50 | Fax 061 268 13 51 | eknz@bs.ch | www.eknz.ch

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☒ Das Forschungsprojekt ist eine Weiterverwendung biologischen Materials und gesundheitsbezogener Personendaten bei fehlender Einwilligung (Art. 34 HFG, Art. 37-40 HFV)

a. Zweck der Weiterverwendung:

Medikamentbezugsdaten direkter oralen Antikoagulantien von Patienten aus TopPharm Apotheken aus den Jahren: 2013-2017.

b. Bezeichnung des biologischen Materials/der gesundheitsbezogenen Personendaten:

Anonymisiert elektronischen Bezugsdaten von DOAK-Patienten von ausgewählten Schweizer Apotheken der Jahre 2013-2017. Zielgrössen sind Medikamentendaten (Bezugsdatum, DOAK-Name, Stärke, Packungsgrösse, Dosierung und Dosierungstext, Name und Anzahl weiterer Medikamente), Patientendaten (Geburtsjahr und Geschlecht) und Apothekendaten (Postleitzahl der Apotheke).

c. Personen, die berechtigt sind biologisches Material und gesundheitsbezogenen Personendaten weiterzugeben:

Die verantwortlichen Apotheker/innen von Toppharm Apotheken mit dem Informatikssystem Propharma geben mit ihrer Unterschrift die Erlaubnis, dass der Systembetreiber Propharma AG die definierten Medikamentenbezugsdaten vom lokalen Datenträger extrahiert, eine anonymsierte Datenbank generiert und diese der Forschungsgruppe zur Verfügung stellt.

d. Personen, die berechtigt sind biologisches Material und gesundheitsbezogene Personendaten entgegenzunehmen:

Dr. Isabelle Arnet
Pharmaceutical Care Research Group
Klingelbergstrasse 50
4056-Basel
+41612071567
isabelle.arnet@unibas.ch

Gebühren

Tarifcode: **Betrag:**

Gemäss der geltenden Gebührenordnung von swissethics.

Rekursmöglichkeiten

Gegen diesen Entscheid kann an den Regierungsrat des Kantons Basel-Stadt (Rathaus, Marktplatz 9, 4051 Basel) rekurriert werden. Der Rekurs ist innert 10 Tagen seit Eröffnung des Entscheides bei der Rekursinstanz anzumelden; innert 30 Tagen, vom gleichen Zeitpunkt an gerechnet, ist die Rekursbegründung einzureichen, welche die Anträge und deren Begründung mit Angabe der Beweismittel zu enthalten hat. Bei völliger oder teilweiser Abweisung des Rekurses können die Kosten der Rekurrentin respektive dem Rekurrenten ganz oder teilweise auferlegt werden.

Kopie an

☐ BAG
☐ Andere

Unterschriften

Dr. pharm. Marco Schärer
Vizepräsident

Anhang:
1. Pflichten des Gesuchstellers / Bedeutung der möglichen Entscheide
2. Eingereichte Dokumente (Stand: 10.09.2018)

Anhang 1

Pflichten des Gesuchstellers (Sponsor oder Prüfer):

Einreichung Dokumente: revidierte Dokumente und neue Dokumente zur Studie/zum Projekt sollen ausschliesslich über das Web-Portal BASEC eingereicht werden, auf der entsprechenden Formularseite des betreffenden Gesuches. Obsolete Dokumente sind dabei zu entfernen und Datums- und Versionsangaben entsprechend zu ergänzen. Die erfolgten Änderungen müssen im Korrekturmodus abgefasst werden und zusätzlich als ‚clean'-Version eingereicht werden. Die Studieninformationen und -einwilligungen, das Protokoll und die Amendments müssen in durchsuchbaren PDF-Dateien eingereicht werden, insbesondere müssen gescannte Dokumente eine Texterkennung durchlaufen haben (OCR). Das unterschriebene und datierte Begleitschreiben muss die Antworten auf eventuell von der EK gestellte Fragen enthalten. Revidierte Dokumente sind auch den weiteren Zulassungsbehörden zuzustellen, sofern diese involviert sind.

Anmerkung: Die zuständige Ethikkommission überprüft im Rahmen des Bewilligungsverfahrens Aufklärungsbogen und Einwilligungserklärung in einer der Amtssprachen Deutsch, Französisch oder Italienisch. Aufklärungsbogen und Einwilligungserklärung in einer anderen Sprache werden von der Ethikkommission lediglich zur Kenntnis genommen. Für die korrekte Übersetzung ist der Sponsor oder die Projektleitung verantwortlich.

Meldepflichten: Die rechtlich bindenden Melde- resp. Bewilligungspflichten an die Ethikkommission für wesentliche Änderungen, einen vorzeitigen Studienabbruch, unerwünschte Ereignisse u.a. sind einzuhalten (Verordnungen des Bundes). Der Abschlussbericht ist spätesten ein Jahr nach Studienende der Ethikkommission einzureichen.

Registrierungspflicht: Der Sponsor muss – falls es sich um einen klinischen Versuch handelt – diesen in einem WHO-Primärregister oder im Register der Nationalen Medizinbibliothek der USA (clinicaltrials.gov) erfassen und anschliessend diese Nummer im BASEC-Portal eingeben. Die Übertragung der erforderlichen Daten in das Swiss National Clinical Trials Portal (SNCTP) kann nach Bewilligung der Ethikkommission und Zustimmung des Gesuchstellers automatisch erfolgen. Die Informationen über den klinischen Versuch sind in beiden Registern öffentlich zugänglich. Zusätzlich veröffentlicht swissethics wenige Informationen wie Titel, Projekttyp oder Leit-Ethikkommission aller durch die kantonalen Ethikkommissionen bewilligten Gesuche auf swissethics.ch (ausser Phase-I-Studien).

Die Ethikkommission bestätigt, dass sie nach ICH-GCP arbeitet.

Anmerkung: detaillierte Anleitungen zur Einreichung auf BASEC befinden sich im Portal selbst.

Bedeutung der möglichen Entscheide

Die Bewilligung wird erteilt: Das Vorhaben gemäss bewilligtem Forschungsplan kann gestartet und im Rahmen der anwendbaren rechtlichen Bestimmungen durchgeführt werden.
Bewilligungen für klinische Versuche mit Heilmitteln der Kategorie B und C stehen unter dem Vorbehalt, dass

1. allfällig durch die zuständige eidgenössische Zulassungbehörde (Swissmedic/BAG) festgestellte Mangel keine Änderungen der von der Ethikkommission evaluierten Unterlagen erfordern, und dass
2. die Bewilligung der eidgenössischen Zulassungsbehörde (Swissmedic/BAG) vorliegt.

Die Bewilligung wird mit Auflagen erteilt: Das Vorhaben gemäss bewilligtem Forschungsplan kann gestartet und im Rahmen der anwendbaren rechtlichen Bestimmungen durchgeführt werden. Die Auflagen sind innert 30 Tagen zu erfüllen und in jedem Fall vor der Rekrutierung des ersten Patienten. Die revidierten Dokumente werden nach Einreichung im präsidentialen Verfahren geprüft.

Die Bewilligung kann noch nicht erteilt werden: Das Vorhaben kann noch nicht gestartet werden. Die nachfolgenden Bedingungen sind zu erfüllen. Die revidierten Dokumente werden nach Einreichung von der Ethikkommission geprüft.

Die Bewilligung wird nicht erteilt: Das Vorhaben kann in der vorliegenden Form nicht durchgeführt werden. Eine Neueinreichung ist möglich.

Auf das Gesuch wird nicht eingetreten: Die Ethikkommission ist für die Beurteilung rechtlich nicht zuständig. Entweder ist eine andere Stelle für die Bewilligung zuständig, oder das Vorhaben kann ohne Bewilligung durchgeführt werden.

Anhang 2

Eingereichte Dokumente für das Hauptzentrum

Dr. Isabelle Arnet, Pharmaceutical Care Research Group, Basel	
Dokument	Dok.Datum
Erläuterungen zum Projekt Dyana.pdf	10.09.2018
AGB_TopPharmCardPlus.pdf	10.09.2018

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A2

II. Search terms for the systematic literature search

PubMed
(((((Adherence[ti]) OR compliance[ti] OR medication[ti])) AND (((((((cut$point*[ti]) OR cut$off*[ti]) OR boundary*[ti]) OR threshold*[ti]) OR set$point*[ti]) OR reference value*[ti]) OR limit value*[ti]))) Filters: Publication date from 1900/01/01 to 2017/12/31; English
Embase®
(adherence:ti OR compliance:ti OR medication:ti) AND (cutpoint:ti OR cutoff:ti OR boundary:ti OR threshold:ti OR setpoint:ti OR reference*value:ti OR limit*value:ti) AND [english]/lim AND [<1966-2018]/py
Web of Science™
(TI=(adherence OR compliance OR medication)) AND (TI = (cutpoint OR cutoff OR boundary OR threshold OR setpoint OR reference value OR limit value))

A3

III. Questionnaire “Cognitive debriefing”

26.4.2021 Evaluation nach Verständlichkeit der deutschen Version des MRB-QoL Fragebogens

Evaluation nach Verständlichkeit der deutschen Version des MRB-QoL Fragebogens

Ziel der Evaluation
Wir wollen die deutsche Version des MRB-QoL (Medication-Related Burden Quality of Life) Fragebogen nach Verständlichkeit testen. Bitte beachten Sie, dass das Konzept des Fragebogens von uns nicht in Frage gestellt wurde.

Auftrag
Wir sind Ihnen sehr dankbar, wenn Sie die 33 Elemente des Fragebogens einzeln nach dem Kriterium der inhaltlichen Verständlichkeit beurteilen würden

Sie beurteilen dabei:
- Die Anleitung des Fragebogens
- 11 Aussagen zum Abschnitt A Therapie und Routine
- 6 Aussagen zum Abschnitt B psychischen Wohlbefinden
- 7 Aussagen zum Abschnitt C körperlichen Wohlbefinden
- 3 Aussagen zum Abschnitt D Gesundheitsversorgung
- 4 Aussagen zum Abschnitt E soziales Wohlbefinden
- Generischer Einleitungstext zu den Abschnitten A-E
- Validierungsfrage

Wichtig: Wenn Sie bei einem Element mit "Nein" antworten, bitten wir Sie Ihre Bewertung im vorgegebenen Bereich zu kommentieren. Falls möglich geben Sie dabei dabei ein Umformulierung an in Anführungszeichen:

Beispiel einer Aussage: "Fragebogen ausfüllen ist eine mühsame Aufgabe"

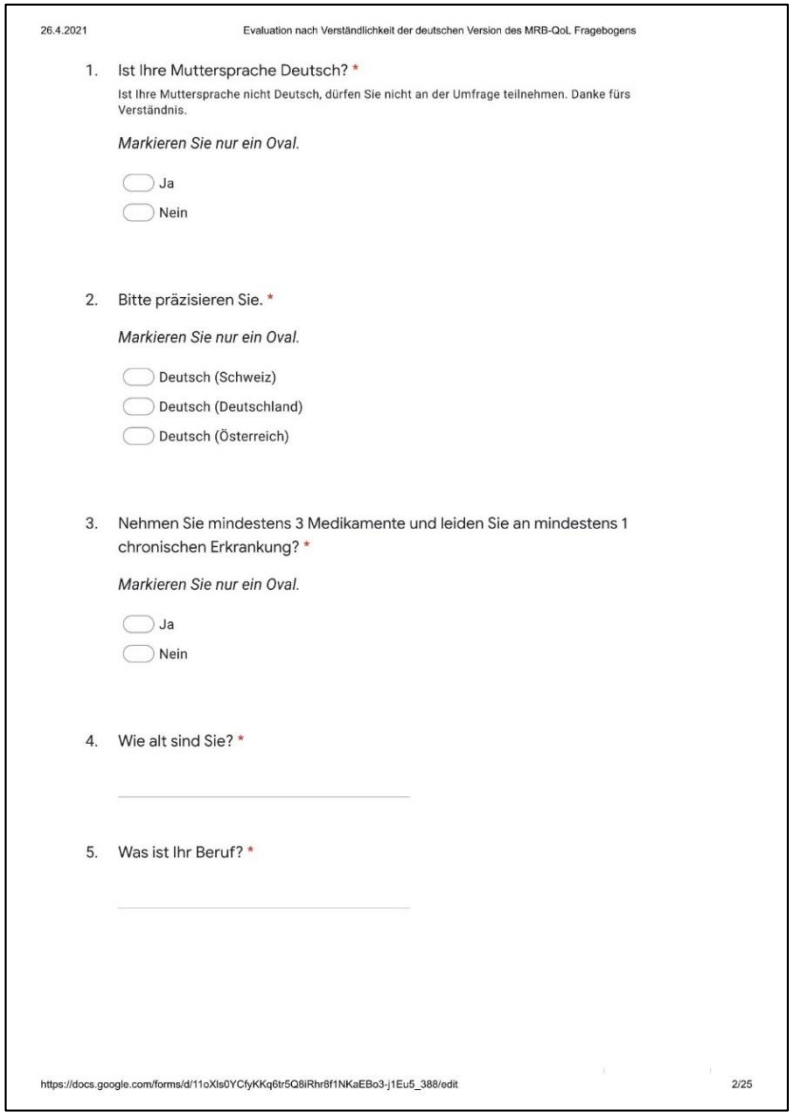
Kommentar: Zu allgemeine Aussage nicht personenbezogen. Umformulierung: "Ich finde es eine mühsame Aufgabe einen Fragebogen auszufüllen."

Vielen Dank!

Olivier Kunz, Pascal Baumgartner

* Erforderlich

https://docs.google.com/forms/d/11oXls0YCfyKKq6tr5Q8iRhr8f1NKaEBo3-j1Eu5_388/edit 1/25



26.4.2021 Evaluation nach Verständlichkeit der deutschen Version des MRB-QoL Fragebogens

1. Ist Ihre Muttersprache Deutsch? *
   Ist Ihre Muttersprache nicht Deutsch, dürfen Sie nicht an der Umfrage teilnehmen. Danke fürs Verständnis.
   Markieren Sie nur ein Oval.
   - ◯ Ja
   - ◯ Nein

2. Bitte präzisieren Sie. *
   Markieren Sie nur ein Oval.
   - ◯ Deutsch (Schweiz)
   - ◯ Deutsch (Deutschland)
   - ◯ Deutsch (Österreich)

3. Nehmen Sie mindestens 3 Medikamente und leiden Sie an mindestens 1 chronischen Erkrankung? *
   Markieren Sie nur ein Oval.
   - ◯ Ja
   - ◯ Nein

4. Wie alt sind Sie? *

5. Was ist Ihr Beruf? *

https://docs.google.com/forms/d/11oXls0YCfyKKq6tr5Q8iRhr8f1NKaEBo3-j1Eu5_388/edit 2/25

Anleitung zum Fragebogen

"Wir interessieren uns für die Auswirkungen von Medikamenten auf die Gesundheit und das Wohlbefinden. Da Sie selbst Medikamente anwenden, sind Sie die ideale Person um einschätzen zu können, wie die Medikamente Ihre Gesundheit und Ihr Wohlbefinden beeinflussen. Nachfolgend haben wir Aussagen aufgelistet, die anderen Personen in diesem Zusammenhang wichtig waren. Beantworten Sie jede Frage indem Sie das passende Kästchen ankreuzen."

6. 0.1 Ist die Anleitung inhaltlich verständlich? *

Markieren Sie nur ein Oval.

- ◯ Ja
- ◯ Nein

7. 0.2 Falls Sie mit "Nein" geantwortet haben, bitte kommentieren Sie Ihre Entscheidung! Geben Sie in Anführungszeichen an wie Sie den/die Satz/Sätze umformulieren würden:

Aussage 1 (Abschnitt Therapie und Routine)

"Ich finde es schwierig, meine Medikamente zu organisieren"

8. 1.1 Ist diese Aussage inhaltlich verständlich? *

Markieren Sie nur ein Oval.

- ◯ Ja
- ◯ Nein

9. 1.2 Falls Sie mit "Nein" geantwortet haben, bitte kommentieren Sie Ihre Entscheidung! Geben Sie in Anführungszeichen an wie Sie den Satz umformulieren würden:

Aussage 2 (Abschnitt Therapie und Routine)

"Ich finde es schwierig, den Überblick über die Unterlagen zu meinen Medikamenten zu behalten"

10. 2.1 Ist diese Aussage inhaltlich verständlich? *

Markieren Sie nur ein Oval.

- ◯ Ja
- ◯ Nein

11. 2.2 Falls Sie mit "Nein" geantwortet haben, bitte kommentieren Sie Ihre Entscheidung! Geben Sie in Anführungszeichen an wie Sie den Satz umformulieren würden:

Aussage 3 (Abschnitt Therapie und Routine)

"Es fällt mir schwer, die Routine um die Medikamenteneinnahme zu bewältigen"

12. 3.1 Ist diese Aussage inhaltlich verständlich? *

Markieren Sie nur ein Oval.

- Ja
- Nein

13. 3.2 Falls Sie mit "Nein" geantwortet haben, bitte kommentieren Sie Ihre Entscheidung! Geben Sie in Anführungszeichen an wie Sie den Satz umformulieren würden:

"Es ist für mich eine schwierige Aufgabe, die Routine um meine Medikamente in meinen Tagesablauf zu integrieren"

Aussage 4 (Abschnitt Therapie und Routine)

14. 4.1 Ist diese Aussage inhaltlich verständlich? *

Markieren Sie nur ein Oval.

- Ja
- Nein

15. 4.2 Falls Sie mit "Nein" geantwortet haben, bitte kommentieren Sie Ihre Entscheidung! Geben Sie in Anführungszeichen an wie Sie den Satz umformulieren würden:

"Die Medikamenteneinnahme beeinträchtigt meine körperlichen Aktivitäten"

Aussage 5 (Abschnitt Therapie und Routine)

16. 5.1 Ist diese Aussage inhaltlich verständlich? *

Markieren Sie nur ein Oval.

- Ja
- Nein

17. 5.2 Falls Sie mit "Nein" geantwortet haben, bitte kommentieren Sie Ihre Entscheidung! Geben Sie in Anführungszeichen an wie Sie den Satz umformulieren würden:

"Es fällt mir schwer, die Medikamenteneinnahme mit meinem Tagesablauf in Einklang zu bringen"

Aussage 6 (Abschnitt Therapie und Routine)

18. 6.1 Ist diese Aussage inhaltlich verständlich? *

Markieren Sie nur ein Oval.

- Ja
- Nein

19. 6.2 Falls Sie mit "Nein" geantwortet haben, bitte kommentieren Sie Ihre Entscheidung! Geben Sie in Anführungszeichen an wie Sie den Satz umformulieren würden:

"Meine derzeitige medikamentöse Therapie ist für mich nicht einfach zu handhaben (z. B. Injektionen, Tabletten, Augentropfen)"

Aussage 7 (Abschnitt Therapie und Routine)

20. 7.1 Ist diese Aussage inhaltlich verständlich? *

Markieren Sie nur ein Oval.

- ◯ Ja
- ◯ Nein

21. 7.2 Falls Sie mit "Nein" geantwortet haben, bitte kommentieren Sie Ihre Entscheidung! Geben Sie in Anführungszeichen an wie Sie den Satz umformulieren würden:

"Manchmal fällt es mir schwer, die Instruktionen zu meinen Medikamenten zu verstehen"

Aussage 8 (Abschnitt Therapie und Routine)

22. 8.1 Ist diese Aussage inhaltlich verständlich? *

Markieren Sie nur ein Oval.

- ◯ Ja
- ◯ Nein

23. 8.2 Falls Sie mit "Nein" geantwortet haben, bitte kommentieren Sie Ihre Entscheidung! Geben Sie in Anführungszeichen an wie Sie den Satz umformulieren würden:

"Mein(e) derzeitige(s) Medikament(e) ist/sind nicht in einer für mich angenehmen Form zum Einnehmen (z. B. schwer zu schlucken, unangenehmer Geschmack/Geruch)"

Aussage 9 (Abschnitt Therapie und Routine)

24. 9.1 Ist diese Aussage inhaltlich verständlich? *

Markieren Sie nur ein Oval.

- ◯ Ja
- ◯ Nein

25. 9.2 Falls Sie mit "Nein" geantwortet haben, bitte kommentieren Sie Ihre Entscheidung! Geben Sie in Anführungszeichen an wie Sie den Satz umformulieren würden:

"Manchmal muss ich meine Termine wegen meiner Medikamente absagen"

Aussage 10 (Abschnitt Therapie und Routine)

26. 10.1 Ist diese Aussage inhaltlich verständlich? *

Markieren Sie nur ein Oval.

- Ja
- Nein

27. 10.2 Falls Sie mit "Nein" geantwortet haben, bitte kommentieren Sie Ihre Entscheidung! Geben Sie in Anführungszeichen an wie Sie den Satz umformulieren würden:

"Manchmal fällt es mir schwer die Verpackung meiner Medikamente zu öffnen (z. B. wegen kindersicheren Verschlüssen)"

Aussage 11 (Abschnitt Therapie und Routine)

28. 11.1 Ist diese Aussage inhaltlich verständlich? *

Markieren Sie nur ein Oval.

- Ja
- Nein

29. 11.2 Falls Sie mit "Nein" geantwortet haben, bitte kommentieren Sie Ihre Entscheidung! Geben Sie in Anführungszeichen an wie Sie den Satz umformulieren würden:

"Es beschäftigt mich, dass ich dauerhaft Medikamente einnehmen muss"

Aussage 12 (Abschnitt psychisches Wohlbefinden)

30. 12.1 Ist diese Aussage inhaltlich verständlich? *

Markieren Sie nur ein Oval.

- Ja
- Nein

31. 12.2 Falls Sie mit "Nein" geantwortet haben, bitte kommentieren Sie Ihre Entscheidung! Geben Sie in Anführungszeichen an wie Sie den Satz umformulieren würden:

"Ich bin besorgt über die Anzahl der Medikamente, die ich einnehme"

Aussage 13 (psychisches Wohlbefinden)

32. 13.1 Ist diese Aussage inhaltlich verständlich? *

Markieren Sie nur ein Oval.

- ◯ Ja
- ◯ Nein

33. 13.2 Falls Sie mit "Nein" geantwortet haben, bitte kommentieren Sie Ihre Entscheidung! Geben Sie in Anführungszeichen an wie Sie den Satz umformulieren würden:

"Ich mache mir Sorgen über die Langzeitfolgen von Medikamenten auf meine Gesundheit"

Aussage 14 (psychisches Wohlbefinden)

34. 14.1 Ist diese Aussage inhaltlich verständlich? *

Markieren Sie nur ein Oval.

- ◯ Ja
- ◯ Nein

35. 14.2 Falls Sie mit "Nein" geantwortet haben, bitte kommentieren Sie Ihre Entscheidung! Geben Sie in Anführungszeichen an wie Sie den Satz umformulieren würden:

"Die regelmässige Medikamenteneinnahme erinnert mich an meine gesundheitlichen Probleme"

Aussage 15 (Abschnitt psychisches Wohlbefinden)

36. 15.1 Ist diese Aussage inhaltlich verständlich? *

Markieren Sie nur ein Oval.

- ◯ Ja
- ◯ Nein

37. 15.2 Falls Sie mit "Nein" geantwortet haben, bitte kommentieren Sie Ihre Entscheidung! Geben Sie in Anführungszeichen an wie Sie den Satz umformulieren würden:

"Ich bin besorgt, dass meine Medikamente miteinander interagieren könnten"

Aussage 16 (Abschnitt psychisches Wohlbefinden)

38. 16.1 Ist diese Aussage inhaltlich verständlich? *

Markieren Sie nur ein Oval.

- ◯ Ja
- ◯ Nein

39. 16.2 Falls Sie mit "Nein" geantwortet haben, bitte kommentieren Sie Ihre Entscheidung! Geben Sie in Anführungszeichen an wie Sie den Satz umformulieren würden:

"Meine Medikamente zeigen mir, dass ich nicht gesund bin"

Aussage 17 (Abschnitt psychisches Wohlbefinden)

40. 17.1 Ist diese Aussage inhaltlich verständlich? *

Markieren Sie nur ein Oval.

- ◯ Ja
- ◯ Nein

41. 17.2 Falls Sie mit "Nein" geantwortet haben, bitte kommentieren Sie Ihre Entscheidung! Geben Sie in Anführungszeichen an wie Sie den Satz umformulieren würden:

"Manchmal bin ich sexuell frustriert wegen meiner Medikamente"

Aussage 18 (Abschnitt körperliches Wohlbefinden)

42. 18.1 Ist diese Aussage inhaltlich verständlich? *

Markieren Sie nur ein Oval.

- ◯ Ja
- ◯ Nein

43. 18.2 Falls Sie mit "Nein" geantwortet haben, bitte kommentieren Sie Ihre Entscheidung! Geben Sie in Anführungszeichen an wie Sie den Satz umformulieren würden:

"Ich kann mich aufgrund meiner Medikamente nicht entspannen und den Sex geniessen"

Aussage 19 (Abschnitt körperliches Wohlbefinden)

44. 19.1 Ist diese Aussage inhaltlich verständlich? *

Markieren Sie nur ein Oval.

- ◯ Ja
- ◯ Nein

45. 19.2 Falls Sie mit "Nein" geantwortet haben, bitte kommentieren Sie Ihre Entscheidung! Geben Sie in Anführungszeichen an wie Sie den Satz umformulieren würden:

"Einige meiner Medikamente reduzieren meine körperliche Gesundheit"

Aussage 20 (Abschnitt körperliches Wohlbefinden)

46. 20.1 Ist diese Aussage inhaltlich verständlich? *

Markieren Sie nur ein Oval.

- ◯ Ja
- ◯ Nein

47. 20.2 Falls Sie mit "Nein" geantwortet haben, bitte kommentieren Sie Ihre Entscheidung! Geben Sie in Anführungszeichen an wie Sie den Satz umformulieren würden:

"Ich schlafe oft schlecht wegen meiner Medikamente"

Aussage 21 (Abschnitt körperliches Wohlbefinden)

48. 21.1 Ist diese Aussage inhaltlich verständlich? *

Markieren Sie nur ein Oval.

- ◯ Ja
- ◯ Nein

49. 21.2 Falls Sie mit "Nein" geantwortet haben, bitte kommentieren Sie Ihre Entscheidung! Geben Sie in Anführungszeichen an wie Sie den Satz umformulieren würden:

"Aufgrund meiner Medikamente fühle ich mich zu müde, um körperliche Aktivitäten durchzuführen"

Aussage 22 (Abschnitt körperliches Wohlbefinden)

50. 22.1 Ist diese Aussage inhaltlich verständlich? *

Markieren Sie nur ein Oval.

- ◯ Ja
- ◯ Nein

51. 22.2 Falls Sie mit "Nein" geantwortet haben, bitte kommentieren Sie Ihre Entscheidung! Geben Sie in Anführungszeichen an wie Sie den Satz umformulieren würden:

"Aufgrund der Wirkung der Medikamente, arbeite ich weniger wie gewohnt"

Aussage 23 (Abschnitt körperliches Wohlbefinden)

52. 23.1 Ist diese Aussage inhaltlich verständlich? *

Markieren Sie nur ein Oval.

- ◯ Ja
- ◯ Nein

53. 23.2 Falls Sie mit "Nein" geantwortet haben, bitte kommentieren Sie Ihre Entscheidung! Geben Sie in Anführungszeichen an wie Sie den Satz umformulieren würden:

"Bei einigen meiner Medikamente fühle ich mich aufgrund der Nebenwirkungen unwohl"

Aussage 24 (Abschnitt körperliches Wohlbefinden)

54. 24.1 Ist diese Aussage inhaltlich verständlich? *

Markieren Sie nur ein Oval.

- ◯ Ja
- ◯ Nein

55. 24.2 Falls Sie mit "Nein" geantwortet haben, bitte kommentieren Sie Ihre Entscheidung! Geben Sie in Anführungszeichen an wie Sie den Satz umformulieren würden:

"Ich werde als Patient*in nicht mit Respekt und Würde behandelt"

Aussage 25 (Abschnitt Gesundheitsversorgung)

56. 25.1 Ist diese Aussage inhaltlich verständlich? *

Markieren Sie nur ein Oval.

- ◯ Ja
- ◯ Nein

57. 25.2 Falls Sie mit "Nein" geantwortet haben, bitte kommentieren Sie Ihre Entscheidung! Geben Sie in Anführungszeichen an wie Sie den Satz umformulieren würden:

"Meine Ärzt*in nimmt keine Rücksicht auf die Gesundheit meines Körpers, Geistes und meiner Seele"

Aussage 26 (Abschnitt Gesundheitsversorgung)

58. 26.1 Ist diese Aussage inhaltlich verständlich? *

Markieren Sie nur ein Oval.

- Ja
- Nein

59. 26.2 Falls Sie mit "Nein" geantwortet haben, bitte kommentieren Sie Ihre Entscheidung! Geben Sie in Anführungszeichen an wie Sie den Satz umformulieren würden:

"Meine Ärzt*innen sprechen über meine Medikamente, als ob ich nicht da wäre"

Aussage 27 (Abschnitt Gesundheitsversorgung)

60. 27.1 Ist diese Aussage inhaltlich verständlich? *

Markieren Sie nur ein Oval.

- Ja
- Nein

61. 27.2 Falls Sie mit "Nein" geantwortet haben, bitte kommentieren Sie Ihre Entscheidung! Geben Sie in Anführungszeichen an wie Sie den Satz umformulieren würden:

"Ich möchte anderen lieber nicht erzählen, dass ich regelmässig Medikamente einnehme"

Aussage 28 (Abschnitt soziales Wohlbefinden)

62. 28.1 Ist diese Aussage inhaltlich verständlich? *

Markieren Sie nur ein Oval.

- Ja
- Nein

63. 28.2 Falls Sie mit "Nein" geantwortet haben, bitte kommentieren Sie Ihre Entscheidung! Geben Sie in Anführungszeichen an wie Sie den Satz umformulieren würden:

"Es ist mir peinlich, meine Medikamente in der Öffentlichkeit einzunehmen/anzuwenden"

Aussage 29 (Abschnitt soziales Wohlbefinden)

64. 29.1 Ist diese Aussage inhaltlich verständlich? *

Markieren Sie nur ein Oval.

- Ja
- Nein

65. 29.2 Falls Sie mit "Nein" geantwortet haben, bitte kommentieren Sie Ihre Entscheidung! Geben Sie in Anführungszeichen an wie Sie den Satz umformulieren würden:

"Ich fühle mich stigmatisiert durch das, was die Leute über meine Medikamente sagen"

Aussage 30 (Abschnitt soziales Wohlbefinden)

66. 30.1 Ist diese Aussage inhaltlich verständlich? *

Markieren Sie nur ein Oval.

- ◯ Ja
- ◯ Nein

67. 30.2 Falls Sie mit "Nein" geantwortet haben, bitte kommentieren Sie Ihre Entscheidung! Geben Sie in Anführungszeichen an wie Sie den Satz umformulieren würden:

"Die Leute würden mich als schwach ansehen, wenn sie herausfinden würden, dass ich Medikamente einnehme"

Aussage 31 (Abschnitt soziales Wohlbefinden)

68. 31.1 Ist diese Aussage inhaltlich verständlich? *

Markieren Sie nur ein Oval.

- ◯ Ja
- ◯ Nein

69. 31.2 Falls Sie mit "Nein" geantwortet haben, bitte kommentieren Sie Ihre Entscheidung! Geben Sie in Anführungszeichen an wie Sie den Satz umformulieren würden:

Die Einleitungstexte zu den Abschnitten haben wir in eine Bewertung zusammengefasst. Das leere Feld ist der Platzhalter für die verschiedenen Abschnitte.

"Die folgenden Aussagen beziehen sich auf _____(A, B, C, D, E). Betrachten Sie die letzten zwei Wochen und geben Sie an, wie sehr Sie jeder Aussage zustimmen oder nicht zustimmen."

Abschnittsbeschreibung (Grundsatz)

70. 32.1 Ist der Grundsatz inhaltlich verständlich? *

Markieren Sie nur ein Oval.

- ◯ Ja
- ◯ Nein

71. 32.2 Falls Sie mit "Nein" geantwortet haben, bitte kommentieren Sie Ihre Entscheidung! Geben Sie in Anführungszeichen an wie Sie den Satz umformulieren würden:

Abschnitt A: "die Belastung im Zusammenhang mit der medikamentösen Therapie und der Routine um die Medikamenteneinnahme"

Abschnitt B: "die Auswirkung der medikationsbezogenen Belastung auf das psychische Wohlbefinden"

Abschnitt C: "die Auswirkungen der medikationsbezogenen Belastung auf das körperliche Wohlbefinden"

Abschnitt D: "die medikationsbezogene Belastung im Zusammenhang mit der Gesundheitsversorgung"

Abschnitt E: "die Auswirkungen der medikationsbezogenen Belastung auf das soziale Wohlbefinden"

72. 32.3 Sind die verschiedenen Abschnitte inhaltlich verständlich? *

Markieren Sie nur ein Oval pro Zeile.

	Ja	Nein
Abschnitt A	◯	◯
Abschnitt B	◯	◯
Abschnitt C	◯	◯
Abschnitt D	◯	◯
Abschnitt E	◯	◯

73. 32.4 Falls Sie bei einem Abschnitt mit "Nein" geantwortet haben, bitte kommentieren Sie Ihre Entscheidung! Erwähnen Sie den betroffenen Abschnitt und geben Sie in Anführungszeichen an wie Sie den Satz umformulieren würden:

"Betrachten Sie die letzten 14 Tage. Geben Sie an, wie sehr Ihre Lebensqualität durch Ihre Medikation belastet wurde auf einer Skala von 0 bis 10. (0 = keine Belastung, 10 = höchste Belastung)"

Aussage zur Validierung

74. 33.1 Ist diese Aussage inhaltlich verständlich? *

Markieren Sie nur ein Oval.

◯ Ja
◯ Nein

75. 33.2 Falls Sie mit "Nein" geantwortet haben, bitte kommentieren Sie Ihre Entscheidung! Geben Sie in Anführungszeichen an wie Sie den Satz umformulieren würden:

Allgemeine Kommentare

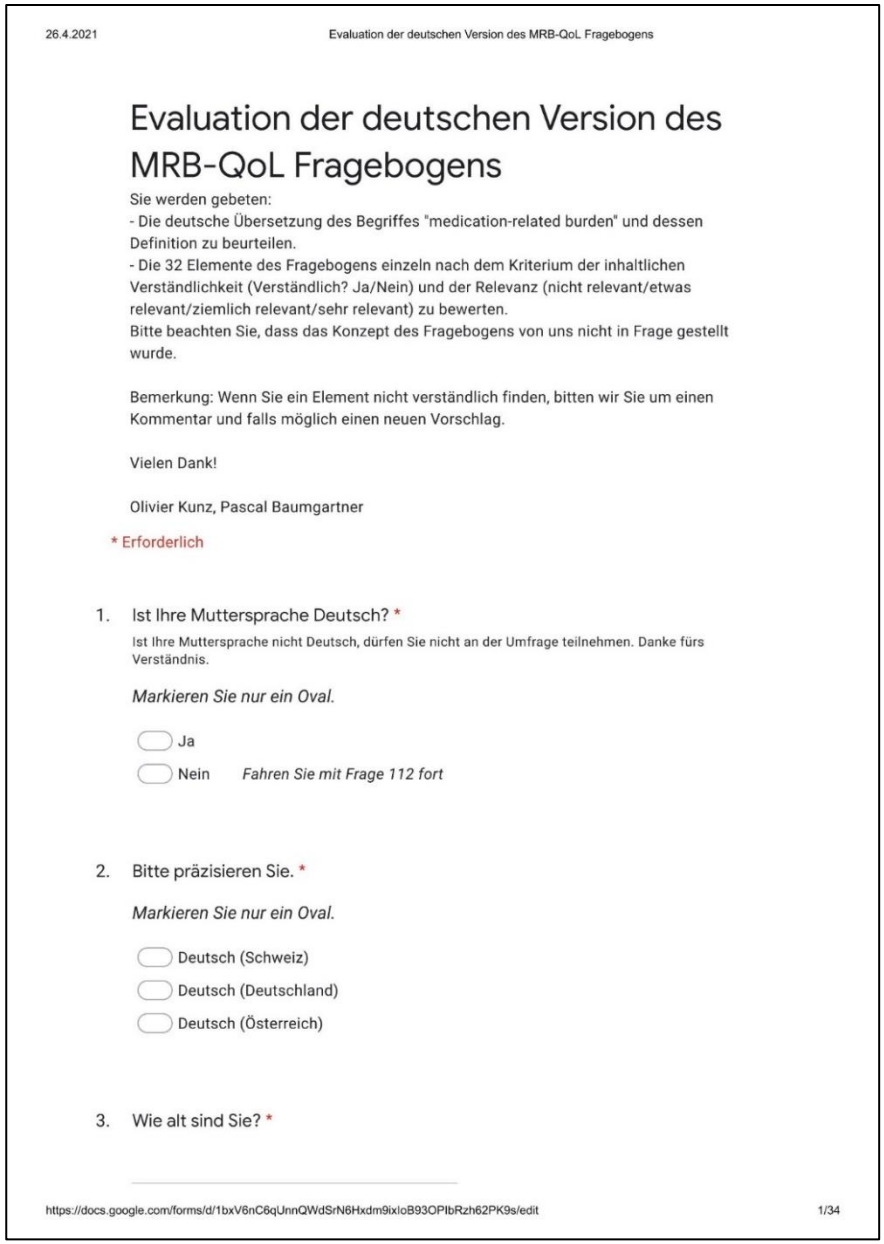
76. Wenn Sie noch einen allgemeinen Kommentar zum Fragebogen abgeben möchten, dürfen Sie das im vorgegebenen Feld machen:

Vielen herzlichen Dank für Ihre Bewertung!

77. Wenn Sie gerne an der Verlosung teilnehmen möchten, dürfen Sie hier noch Ihre E-Mailadresse angeben:

3]

IV. First evaluation round of the experts



26.4.2021 Evaluation der deutschen Version des MRB-QoL Fragebogens

Evaluation der deutschen Version des MRB-QoL Fragebogens

Sie werden gebeten:
- Die deutsche Übersetzung des Begriffes "medication-related burden" und dessen Definition zu beurteilen.
- Die 32 Elemente des Fragebogens einzeln nach dem Kriterium der inhaltlichen Verständlichkeit (Verständlich? Ja/Nein) und der Relevanz (nicht relevant/etwas relevant/ziemlich relevant/sehr relevant) zu bewerten.

Bitte beachten Sie, dass das Konzept des Fragebogens von uns nicht in Frage gestellt wurde.

Bemerkung: Wenn Sie ein Element nicht verständlich finden, bitten wir Sie um einen Kommentar und falls möglich einen neuen Vorschlag.

Vielen Dank!

Olivier Kunz, Pascal Baumgartner

* Erforderlich

1. Ist Ihre Muttersprache Deutsch? *

Ist Ihre Muttersprache nicht Deutsch, dürfen Sie nicht an der Umfrage teilnehmen. Danke fürs Verständnis.

Markieren Sie nur ein Oval.

- ◯ Ja
- ◯ Nein *Fahren Sie mit Frage 112 fort*

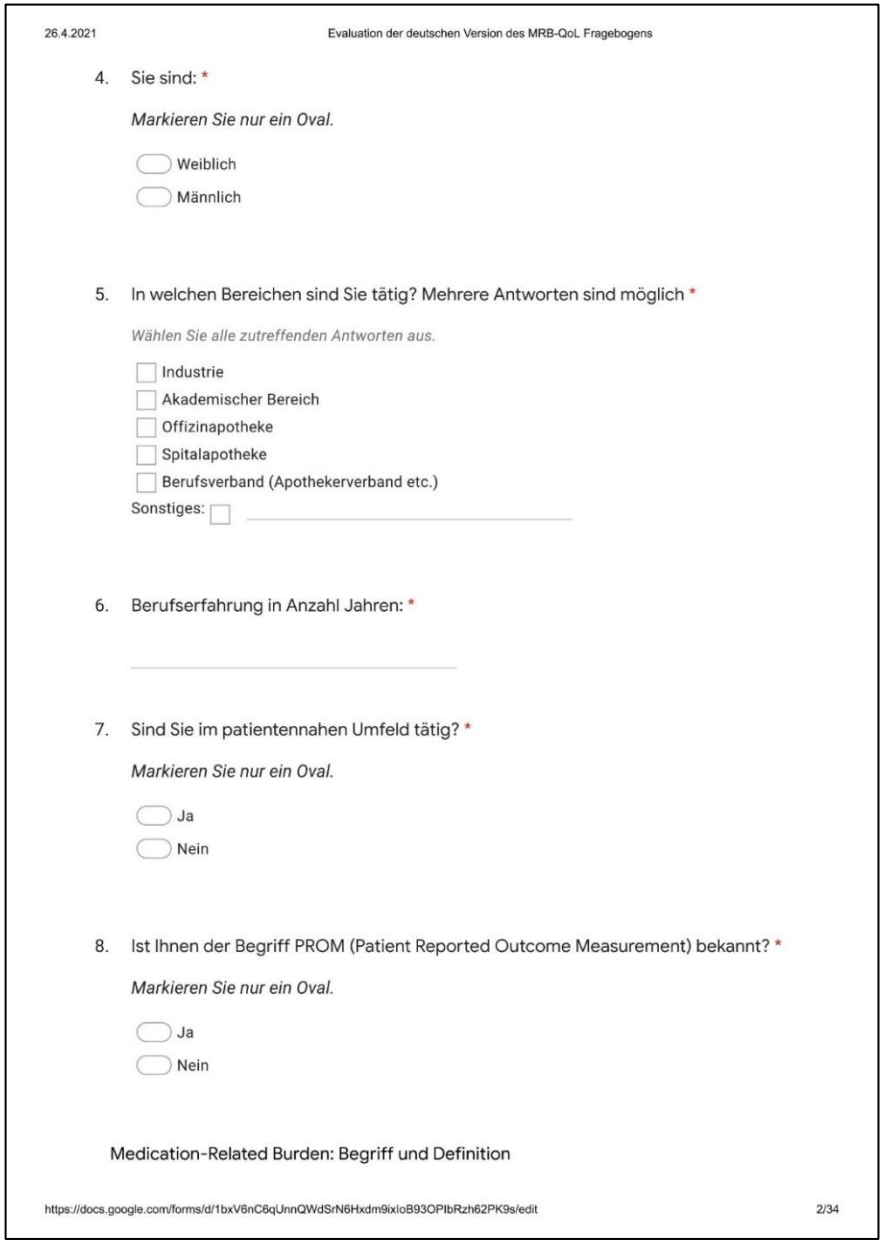
2. Bitte präzisieren Sie. *

Markieren Sie nur ein Oval.

- ◯ Deutsch (Schweiz)
- ◯ Deutsch (Deutschland)
- ◯ Deutsch (Österreich)

3. Wie alt sind Sie? *

https://docs.google.com/forms/d/1bxV6nC6qUnnQWdSrN6Hxdm9ixloB93OPIbRzh62PK9s/edit 1/34



26.4.2021 Evaluation der deutschen Version des MRB-QoL Fragebogens

4. Sie sind: *

Markieren Sie nur ein Oval.

- ◯ Weiblich
- ◯ Männlich

5. In welchen Bereichen sind Sie tätig? Mehrere Antworten sind möglich *

Wählen Sie alle zutreffenden Antworten aus.

- ☐ Industrie
- ☐ Akademischer Bereich
- ☐ Offizinapotheke
- ☐ Spitalapotheke
- ☐ Berufsverband (Apothekerverband etc.)
- Sonstiges: ☐ _____

6. Berufserfahrung in Anzahl Jahren: *

_____

7. Sind Sie im patientennahen Umfeld tätig? *

Markieren Sie nur ein Oval.

- ◯ Ja
- ◯ Nein

8. Ist Ihnen der Begriff PROM (Patient Reported Outcome Measurement) bekannt? *

Markieren Sie nur ein Oval.

- ◯ Ja
- ◯ Nein

Medication-Related Burden: Begriff und Definition

https://docs.google.com/forms/d/1bxV6nC6qUnnQWdSrN6Hxdm9ixloB93OPIbRzh62PK9s/edit 2/34

[204]

Medication-Related Burden: medikationsbezogene Belastung

Begriff

9. Ist der deutsche Begriff verständlich? *

Markieren Sie nur ein Oval.

- ◯ Ja
- ◯ Nein

10. Falls "Nein", bitte kommentieren Sie Ihre Entscheidung!

"Die medikationsbezogene Belastung kann definiert werden als eine negative Erfahrung mit Medikamenten, welche sich auf das psychologische, soziale, physische und finanzielle Wohlbefinden einer Person auswirken kann."

11. Ist die Definition verständlich? *

Markieren Sie nur ein Oval.

- ◯ Ja
- ◯ Nein

12. Falls "Nein", bitte kommentieren Sie Ihre Entscheidung!

Bewertung der Elemente des Fragebogens

Anleitung zum Fragebogen

"Wir interessieren uns für die Auswirkungen von Medikamenten auf die Gesundheit und das Wohlbefinden. Da Sie selbst Medikamente anwenden, sind Sie die ideale Person um einschätzen zu können, wie die Medikamente Ihre Gesundheit und Ihr Wohlbefinden beeinflussen. Nachfolgend haben wir Aussagen aufgelistet, die anderen Personen in diesem Zusammenhang wichtig waren. Beantworten Sie jede Frage indem Sie das passende Kästchen ankreuzen."

13. 0.1 Ist die Anleitung verständlich? *

Markieren Sie nur ein Oval.

- ◯ Ja
- ◯ Nein

14. 0.2 Falls "Nein", machen Sie bitte konkrete Formulierungsvorschläge:

Aussage 1 (Abschnitt Therapie und Routine)

"Ich finde es schwierig, meine Medikamente zu organisieren (z. B. beschaffen, bereitstellen)"

15. 1.1 Ist diese Aussage verständlich? *

Markieren Sie nur ein Oval.

- ◯ Ja
- ◯ Nein

16. 1.2 Falls "Nein", machen Sie bitte konkrete Formulierungsvorschläge:

17. 1.3 Ist ihrer Meinung nach die Aussage relevant um die medikationsbezogene Belastung zu messen? *

Markieren Sie nur ein Oval.

- Nicht relevant
- Etwas relevant
- Ziemlich relevant
- Sehr relevant

"Ich finde es schwierig, den Überblick über die Unterlagen zu meinen Medikamenten zu behalten"

Aussage 2 (Abschnitt Therapie und Routine)

18. 2.1 Ist diese Aussage verständlich? *

Markieren Sie nur ein Oval.

- Ja
- Nein

19. 2.2 Falls "Nein", machen Sie bitte konkrete Formulierungsvorschläge:

20. 2.3 Ist ihrer Meinung nach die Aussage relevant um die medikationsbezogene Belastung zu messen? *

Markieren Sie nur ein Oval.

- Nicht relevant
- Etwas relevant
- Ziemlich relevant
- Sehr relevant

"Es fällt mir schwer, die mit der Medikamenteneinnahme verbundenen Tätigkeiten zu bewältigen"

Aussage 3 (Abschnitt Therapie und Routine)

21. 3.1 Ist diese Aussage verständlich? *

Markieren Sie nur ein Oval.

- Ja
- Nein

22. 3.2 Falls "Nein", machen Sie bitte konkrete Formulierungsvorschläge:

23. 3.3 Ist ihrer Meinung nach die Aussage relevant um die medikationsbezogene Belastung zu messen? *

Markieren Sie nur ein Oval.

- Nicht relevant
- Etwas relevant
- Ziemlich relevant
- Sehr relevant

"Die Medikamenteneinnahme beeinträchtigt meine körperlichen Aktivitäten"

Aussage 4 (Abschnitt Therapie und Routine)

24. 4.1 Ist diese Aussage verständlich? *

Markieren Sie nur ein Oval.

- ◯ Ja
- ◯ Nein

25. 4.2 Falls "Nein", machen Sie bitte konkrete Formulierungsvorschläge:

_____

26. 4.3 Ist ihrer Meinung nach die Aussage relevant um die medikationsbezogene Belastung zu messen? *

Markieren Sie nur ein Oval.

- ◯ Nicht relevant
- ◯ Etwas relevant
- ◯ Ziemlich relevant
- ◯ Sehr relevant

"Es fällt mir schwer, die Medikamenteneinnahme mit meinem Tagesablauf in Einklang zu bringen"

Aussage 5 (Abschnitt Therapie und Routine)

27. 5.1 Ist diese Aussage verständlich? *

Markieren Sie nur ein Oval.

- ◯ Ja
- ◯ Nein

28. 5.2 Falls "Nein", machen Sie bitte konkrete Formulierungsvorschläge:

_____

29. 5.3 Ist ihrer Meinung nach die Aussage relevant um die medikationsbezogene Belastung zu messen? *

Markieren Sie nur ein Oval.

- ◯ Nicht relevant
- ◯ Etwas relevant
- ◯ Ziemlich relevant
- ◯ Sehr relevant

"Meine derzeitige medikamentöse Therapie ist für mich nicht einfach zu handhaben (z. B. Injektionen, Tabletten, Augentropfen)"

Aussage 6 (Abschnitt Therapie und Routine)

30. 6.1 Ist diese Aussage verständlich? *

Markieren Sie nur ein Oval.

- ◯ Ja
- ◯ Nein

31. 6.2 Falls "Nein", machen Sie bitte konkrete Formulierungsvorschläge:

_____

32. 6.3 Ist ihrer Meinung nach die Aussage relevant um die medikationsbezogene Belastung zu messen? *

Markieren Sie nur ein Oval.

- ◯ Nicht relevant
- ◯ Etwas relevant
- ◯ Ziemlich relevant
- ◯ Sehr relevant

"Manchmal fällt es mir schwer zu verstehen, wie ich meine Medikamente anwenden soll"

Aussage 7 (Abschnitt Therapie und Routine)

33. 7.1 Ist diese Aussage verständlich? *

Markieren Sie nur ein Oval.

- ◯ Ja
- ◯ Nein

34. 7.2 Falls "Nein", machen Sie bitte konkrete Formulierungsvorschläge:

_____

35. 7.3 Ist ihrer Meinung nach die Aussage relevant um die medikationsbezogene Belastung zu messen? *

Markieren Sie nur ein Oval.

- ◯ Nicht relevant
- ◯ Etwas relevant
- ◯ Ziemlich relevant
- ◯ Sehr relevant

"Mein(e) derzeitige(s) Medikament(e) ist/sind nicht in einer für mich angenehmen Form zum Einnehmen (z. B. schwer zu schlucken, unangenehmer Geschmack/Geruch)"

Aussage 8 (Abschnitt Therapie und Routine)

36. 8.1 Ist diese Aussage verständlich? *

Markieren Sie nur ein Oval.

- ◯ Ja
- ◯ Nein

37. 8.2 Falls "Nein", machen Sie bitte konkrete Formulierungsvorschläge:

_____

38. 8.3 Ist ihrer Meinung nach die Aussage relevant um die medikationsbezogene Belastung zu messen? *

Markieren Sie nur ein Oval.

- ◯ Nicht relevant
- ◯ Etwas relevant
- ◯ Ziemlich relevant
- ◯ Sehr relevant

"Manchmal muss ich meine Termine wegen meiner Medikamente absagen"

Aussage 9 (Abschnitt Therapie und Routine)

39. 9.1 Ist diese Aussage verständlich? *

Markieren Sie nur ein Oval.

- ◯ Ja
- ◯ Nein

40. 9.2 Falls "Nein", machen Sie bitte konkrete Formulierungsvorschläge:

_____

41. 9.3 Ist ihrer Meinung nach die Aussage relevant um die medikationsbezogene Belastung zu messen? *

Markieren Sie nur ein Oval.

- ◯ Nicht relevant
- ◯ Etwas relevant
- ◯ Ziemlich relevant
- ◯ Sehr relevant

"Manchmal fällt es mir schwer die Verpackung meiner Medikamente zu öffnen (z. B. wegen kindersicheren Verschlüssen)"

Aussage 10 (Abschnitt Therapie und Routine)

42. 10.1 Ist diese Aussage verständlich? *

Markieren Sie nur ein Oval.

- Ja
- Nein

43. 10.2 Falls "Nein", machen Sie bitte konkrete Formulierungsvorschläge:

44. 10.3 Ist ihrer Meinung nach die Aussage relevant um die medikationsbezogene Belastung zu messen? *

Markieren Sie nur ein Oval.

- Nicht relevant
- Etwas relevant
- Ziemlich relevant
- Sehr relevant

"Es beschäftigt mich, dass ich dauerhaft Medikamente einnehmen muss"

Aussage 11 (Abschnitt psychisches Wohlbefinden)

45. 11.1 Ist diese Aussage verständlich? *

Markieren Sie nur ein Oval.

- Ja
- Nein

46. 11.2 Falls "Nein", machen Sie bitte konkrete Formulierungsvorschläge:

47. 11.3 Ist ihrer Meinung nach die Aussage relevant um die medikationsbezogene Belastung zu messen? *

Markieren Sie nur ein Oval.

- Nicht relevant
- Etwas relevant
- Ziemlich relevant
- Sehr relevant

"Ich bin besorgt über die Anzahl der Medikamente die ich einnehme"

Aussage 12 (psychisches Wohlbefinden)

48. 12.1 Ist diese Aussage verständlich? *

Markieren Sie nur ein Oval.

- Ja
- Nein

49. 12.2 Falls "Nein", machen Sie bitte konkrete Formulierungsvorschläge:

50. 12.3 Ist ihrer Meinung nach die Aussage relevant um die medikationsbezogene Belastung zu messen? *

Markieren Sie nur ein Oval.

- ◯ Nicht relevant
- ◯ Etwas relevant
- ◯ Ziemlich relevant
- ◯ Sehr relevant

"Ich mache mir Sorgen über die Langzeitfolgen von Medikamenten auf meine Gesundheit"

Aussage 13 (psychisches Wohlbefinden)

51. 13.1 Ist diese Aussage verständlich? *

Markieren Sie nur ein Oval.

- ◯ Ja
- ◯ Nein

52. 13.2 Falls "Nein", machen Sie bitte konkrete Formulierungsvorschläge:

53. 13.3 Ist ihrer Meinung nach die Aussage relevant um die medikationsbezogene Belastung zu messen? *

Markieren Sie nur ein Oval.

- ◯ Nicht relevant
- ◯ Etwas relevant
- ◯ Ziemlich relevant
- ◯ Sehr relevant

"Die regelmässige Medikamenteneinnahme erinnert mich an meine gesundheitlichen Probleme"

Aussage 14 (Abschnitt psychisches Wohlbefinden)

54. 14.1 Ist diese Aussage verständlich? *

Markieren Sie nur ein Oval.

- ◯ Ja
- ◯ Nein

55. 14.2 Falls "Nein", machen Sie bitte konkrete Formulierungsvorschläge:

56. 14.3 Ist ihrer Meinung nach die Aussage relevant um die medikationsbezogene Belastung zu messen? *

Markieren Sie nur ein Oval.

- ◯ Nicht relevant
- ◯ Etwas relevant
- ◯ Ziemlich relevant
- ◯ Sehr relevant

"Ich bin besorgt, dass meine Medikamente sich gegenseitig beeinflussen könnten"

Aussage 15 (Abschnitt psychisches Wohlbefinden)

57. 15.1 Ist diese Aussage verständlich? *

Markieren Sie nur ein Oval.

- ◯ Ja
- ◯ Nein

58. 15.2 Falls "Nein", machen Sie bitte konkrete Formulierungsvorschläge:

59. 15.3 Ist ihrer Meinung nach die Aussage relevant um die medikationsbezogene Belastung zu messen? *

Markieren Sie nur ein Oval.

- ◯ Nicht relevant
- ◯ Etwas relevant
- ◯ Ziemlich relevant
- ◯ Sehr relevant

"Meine Medikamente zeigen mir, dass ich nicht gesund bin"

Aussage 16 (Abschnitt psychisches Wohlbefinden)

60. 16.1 Ist diese Aussage verständlich? *

Markieren Sie nur ein Oval.

- ◯ Ja
- ◯ Nein

61. 16.2 Falls "Nein", machen Sie bitte konkrete Formulierungsvorschläge:

62. 16.3 Ist ihrer Meinung nach die Aussage relevant um die medikationsbezogene Belastung zu messen? *

Markieren Sie nur ein Oval.

- ◯ Nicht relevant
- ◯ Etwas relevant
- ◯ Ziemlich relevant
- ◯ Sehr relevant

"Manchmal beeinträchtigen meine Medikamente mein Sexualleben"

Aussage 17 (Abschnitt körperliches Wohlbefinden)

63. 17.1 Ist diese Aussage verständlich? *

Markieren Sie nur ein Oval.

- ◯ Ja
- ◯ Nein

64. 17.2 Falls "Nein", machen Sie bitte konkrete Formulierungsvorschläge:

65. 17.3 Ist ihrer Meinung nach die Aussage relevant um die medikationsbezogene Belastung zu messen? *

Markieren Sie nur ein Oval.

- ◯ Nicht relevant
- ◯ Etwas relevant
- ◯ Ziemlich relevant
- ◯ Sehr relevant

"Ich kann mich aufgrund meiner Medikamente nicht entspannen und den Sex geniessen"

Aussage 18 (Abschnitt körperliches Wohlbefinden)

66. 18.1 Ist diese Aussage verständlich? *

Markieren Sie nur ein Oval.

- ◯ Ja
- ◯ Nein

67. 18.2 Falls "Nein", machen Sie bitte konkrete Formulierungsvorschläge:

68. 18.3 Ist ihrer Meinung nach die Aussage relevant um die medikationsbezogene Belastung zu messen? *

Markieren Sie nur ein Oval.

- ◯ Nicht relevant
- ◯ Etwas relevant
- ◯ Ziemlich relevant
- ◯ Sehr relevant

"Einige meiner Medikamente reduzieren meine körperliche Gesundheit"

Aussage 19 (Abschnitt körperliches Wohlbefinden)

69. 19.1 Ist diese Aussage verständlich? *

Markieren Sie nur ein Oval.

- ◯ Ja
- ◯ Nein

70. 19.2 Falls "Nein", machen Sie bitte konkrete Formulierungsvorschläge:

71. 19.3 Ist ihrer Meinung nach die Aussage relevant um die medikationsbezogene Belastung zu messen? *

Markieren Sie nur ein Oval.

- ◯ Nicht relevant
- ◯ Etwas relevant
- ◯ Ziemlich relevant
- ◯ Sehr relevant

"Ich schlafe oft schlecht wegen meiner Medikamente"

Aussage 20 (Abschnitt körperliches Wohlbefinden)

72. 20.1 Ist diese Aussage verständlich? *

Markieren Sie nur ein Oval.

- ◯ Ja
- ◯ Nein

73. 20.2 Falls "Nein", machen Sie bitte konkrete Formulierungsvorschläge:

74. 20.3 Ist ihrer Meinung nach die Aussage relevant um die medikationsbezogene Belastung zu messen? *

Markieren Sie nur ein Oval.

- ◯ Nicht relevant
- ◯ Etwas relevant
- ◯ Ziemlich relevant
- ◯ Sehr relevant

"Aufgrund meiner Medikamente fühle ich mich zu müde, um körperliche Aktivitäten durchzuführen"

Aussage 21 (Abschnitt körperliches Wohlbefinden)

75. 21.1 Ist diese Aussage verständlich? *

Markieren Sie nur ein Oval.

- ◯ Ja
- ◯ Nein

76. 21.2 Falls "Nein", machen Sie bitte konkrete Formulierungsvorschläge:

77. 21.3 Ist ihrer Meinung nach die Aussage relevant um die medikationsbezogene Belastung zu messen? *

Markieren Sie nur ein Oval.

- ◯ Nicht relevant
- ◯ Etwas relevant
- ◯ Ziemlich relevant
- ◯ Sehr relevant

"Aufgrund der Wirkung der Medikamente arbeite ich weniger als gewohnt"

Aussage 22 (Abschnitt körperliches Wohlbefinden)

78. 22.1 Ist diese Aussage verständlich? *

Markieren Sie nur ein Oval.

- ◯ Ja
- ◯ Nein

79. 22.2 Falls "Nein", machen Sie bitte konkrete Formulierungsvorschläge:

80. 22.3 Ist ihrer Meinung nach die Aussage relevant um die medikationsbezogene Belastung zu messen? *

Markieren Sie nur ein Oval.

- ◯ Nicht relevant
- ◯ Etwas relevant
- ◯ Ziemlich relevant
- ◯ Sehr relevant

"Bei einigen meiner Medikamente fühle ich mich aufgrund der Nebenwirkungen unwohl"

Aussage 23 (Abschnitt körperliches Wohlbefinden)

81. 23.1 Ist diese Aussage verständlich? *

Markieren Sie nur ein Oval.

- ◯ Ja
- ◯ Nein

82. 23.2 Falls "Nein", machen Sie bitte konkrete Formulierungsvorschläge:

83. 23.3 Ist ihrer Meinung nach die Aussage relevant um die medikationsbezogene Belastung zu messen? *

Markieren Sie nur ein Oval.

- ◯ Nicht relevant
- ◯ Etwas relevant
- ◯ Ziemlich relevant
- ◯ Sehr relevant

"Ich werde als Patient*in nicht mit Respekt und Würde behandelt"

Aussage 24 (Abschnitt Gesundheitsversorgung)

84. 24.1 Ist diese Aussage verständlich? *

Markieren Sie nur ein Oval.

- ◯ Ja
- ◯ Nein

85. 24.2 Falls "Nein", machen Sie bitte konkrete Formulierungsvorschläge:

86. 24.3 Ist ihrer Meinung nach die Aussage relevant um die medikationsbezogene Belastung zu messen? *

Markieren Sie nur ein Oval.

- ◯ Nicht relevant
- ◯ Etwas relevant
- ◯ Ziemlich relevant
- ◯ Sehr relevant

"Meine Ärzt*in nimmt zu wenig Rücksicht auf meine körperliche, geistige und seelische Gesundheit"

Aussage 25 (Abschnitt Gesundheitsversorgung)

87. 25.1 Ist diese Aussage verständlich? *

Markieren Sie nur ein Oval.

- ◯ Ja
- ◯ Nein

88. 25.2 Falls "Nein", machen Sie bitte konkrete Formulierungsvorschläge:

89. 25.3 Ist ihrer Meinung nach die Aussage relevant um die medikationsbezogene Belastung zu messen? *

Markieren Sie nur ein Oval.

- ◯ Nicht relevant
- ◯ Etwas relevant
- ◯ Ziemlich relevant
- ◯ Sehr relevant

"Meine Ärzt*innen sprechen über meine Medikamente, als ob ich nicht da wäre"

Aussage 26 (Abschnitt Gesundheitsversorgung)

90. 26.1 Ist diese Aussage verständlich? *

Markieren Sie nur ein Oval.

- ◯ Ja
- ◯ Nein

91. 26.2 Falls "Nein", machen Sie bitte konkrete Formulierungsvorschläge:

92. 26.3 Ist ihrer Meinung nach die Aussage relevant um die medikationsbezogene Belastung zu messen? *

Markieren Sie nur ein Oval.

- ◯ Nicht relevant
- ◯ Etwas relevant
- ◯ Ziemlich relevant
- ◯ Sehr relevant

"Ich möchte anderen lieber nicht erzählen, dass ich regelmässig Medikamente einnehme"

Aussage 27 (Abschnitt soziales Wohlbefinden)

93. 27.1 Ist diese Aussage verständlich? *

Markieren Sie nur ein Oval.

- ◯ Ja
- ◯ Nein

94. 27.2 Falls "Nein", machen Sie bitte konkrete Formulierungsvorschläge:

95. 27.3 Ist ihrer Meinung nach die Aussage relevant um die medikationsbezogene Belastung zu messen? *

Markieren Sie nur ein Oval.

- ◯ Nicht relevant
- ◯ Etwas relevant
- ◯ Ziemlich relevant
- ◯ Sehr relevant

"Es ist mir peinlich, meine Medikamente in der Öffentlichkeit einzunehmen/anzuwenden"

Aussage 28 (Abschnitt soziales Wohlbefinden)

96. 28.1 Ist diese Aussage verständlich? *

Markieren Sie nur ein Oval.

- ◯ Ja
- ◯ Nein

97. 28.2 Falls "Nein", machen Sie bitte konkrete Formulierungsvorschläge:

98. 28.3 Ist ihrer Meinung nach die Aussage relevant um die medikationsbezogene Belastung zu messen? *

Markieren Sie nur ein Oval.

- ◯ Nicht relevant
- ◯ Etwas relevant
- ◯ Ziemlich relevant
- ◯ Sehr relevant

"Ich fühle mich verurteilt durch das, was die Leute über meine Medikamente sagen"

Aussage 29 (Abschnitt soziales Wohlbefinden)

99. 29.1 Ist diese Aussage verständlich? *

Markieren Sie nur ein Oval.

- ◯ Ja
- ◯ Nein

100. 29.2 Falls "Nein", machen Sie bitte konkrete Formulierungsvorschläge:

101. 29.3 Ist ihrer Meinung nach die Aussage relevant um die medikationsbezogene Belastung zu messen? *

Markieren Sie nur ein Oval.

- ◯ Nicht relevant
- ◯ Etwas relevant
- ◯ Ziemlich relevant
- ◯ Sehr relevant

"Die Leute würden mich als schwach ansehen, wenn sie herausfinden würden, dass ich Medikamente einnehme"

Aussage 30 (Abschnitt soziales Wohlbefinden)

102. 30.1 Ist diese Aussage verständlich? *

Markieren Sie nur ein Oval.

- ◯ Ja
- ◯ Nein

103. 30.2 Falls "Nein", machen Sie bitte konkrete Formulierungsvorschläge:

104. 30.3 Ist ihrer Meinung nach die Aussage relevant um die medikationsbezogene Belastung zu messen? *

Markieren Sie nur ein Oval.

- ◯ Nicht relevant
- ◯ Etwas relevant
- ◯ Ziemlich relevant
- ◯ Sehr relevant

Die Einleitungstexte zu den Abschnitten haben wir in eine Bewertung zusammengefasst. Das leere Feld ist der Platzhalter für die verschiedenen Abschnitte.

"Die folgenden Aussagen beziehen sich auf _____(A, B, C, D, E). Betrachten Sie die letzten zwei Wochen und geben Sie an, wie sehr Sie jeder Aussage zustimmen oder nicht zustimmen."
Abschnittsbeschreibung (Grundsatz)

105. 31.1 Ist der Grundsatz verständlich? *

Markieren Sie nur ein Oval.

- ◯ Ja
- ◯ Nein

106. 31.2 Falls "Nein", machen Sie bitte konkrete Formulierungsvorschläge:

Abschnitt A: "die Belastung im Zusammenhang mit der medikamentösen Therapie und der Routine der Medikamenteneinnahme"

Abschnitt B: "die Auswirkung der medikationsbezogenen Belastung auf das psychische Wohlbefinden"

Abschnitt C: "die Auswirkungen der medikationsbezogenen Belastung auf das körperliche Wohlbefinden"

Abschnitt D: "die medikationsbezogene Belastung im Zusammenhang mit der Gesundheitsversorgung"

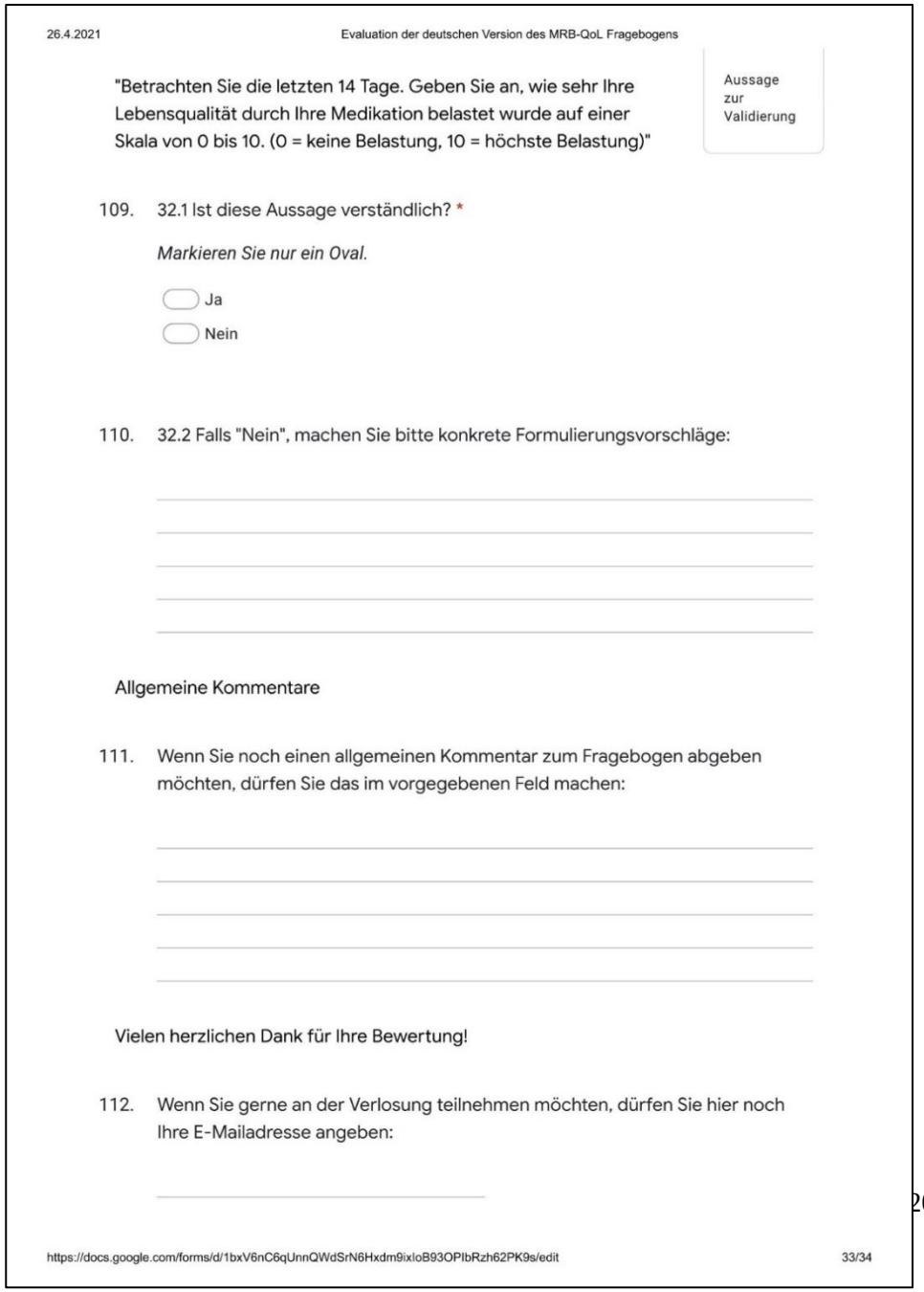
Abschnitt E: "die Auswirkungen der medikationsbezogenen Belastung auf das soziale Wohlbefinden"

107. 31.3 Sind die verschiedenen Abschnitte verständlich? *

Markieren Sie nur ein Oval pro Zeile.

	Ja	Nein
Abschnitt A	◯	◯
Abschnitt B	◯	◯
Abschnitt C	◯	◯
Abschnitt D	◯	◯
Abschnitt E	◯	◯

108. 31.4 Falls Sie bei einem Abschnitt mit "Nein" geantwortet haben, erwähnen Sie den betroffenen Abschnitt und geben Sie einen Formulierungsvorschlag:



26.4.2021 Evaluation der deutschen Version des MRB-QoL Fragebogens

"Betrachten Sie die letzten 14 Tage. Geben Sie an, wie sehr Ihre Lebensqualität durch Ihre Medikation belastet wurde auf einer Skala von 0 bis 10. (0 = keine Belastung, 10 = höchste Belastung)"

Aussage zur Validierung

109. 32.1 Ist diese Aussage verständlich? *

Markieren Sie nur ein Oval.

- Ja
- Nein

110. 32.2 Falls "Nein", machen Sie bitte konkrete Formulierungsvorschläge:

Allgemeine Kommentare

111. Wenn Sie noch einen allgemeinen Kommentar zum Fragebogen abgeben möchten, dürfen Sie das im vorgegebenen Feld machen:

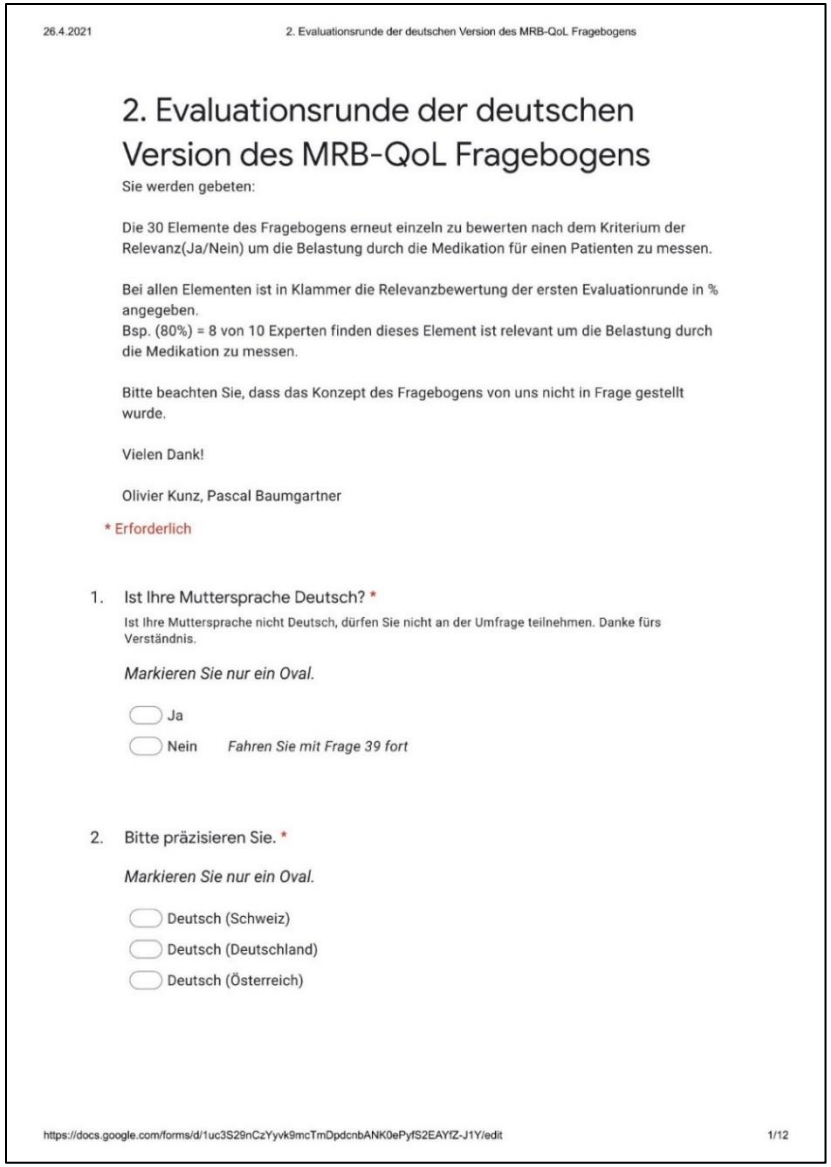
Vielen herzlichen Dank für Ihre Bewertung!

112. Wenn Sie gerne an der Verlosung teilnehmen möchten, dürfen Sie hier noch Ihre E-Mailadresse angeben:

https://docs.google.com/forms/d/1bxV6nC6qUnnQWdSrN6Hxdm9ixloB93OPIbRzh62PK9s/edit 33/34

20]

V. Second evaluation round of the experts



26.4.2021 2. Evaluationsrunde der deutschen Version des MRB-QoL Fragebogens

2. Evaluationsrunde der deutschen Version des MRB-QoL Fragebogens

Sie werden gebeten:

Die 30 Elemente des Fragebogens erneut einzeln zu bewerten nach dem Kriterium der Relevanz(Ja/Nein) um die Belastung durch die Medikation für einen Patienten zu messen.

Bei allen Elementen ist in Klammer die Relevanzbewertung der ersten Evaluationrunde in % angegeben.
Bsp. (80%) = 8 von 10 Experten finden dieses Element ist relevant um die Belastung durch die Medikation zu messen.

Bitte beachten Sie, dass das Konzept des Fragebogens von uns nicht in Frage gestellt wurde.

Vielen Dank!

Olivier Kunz, Pascal Baumgartner

* Erforderlich

1. Ist Ihre Muttersprache Deutsch? *

Ist Ihre Muttersprache nicht Deutsch, dürfen Sie nicht an der Umfrage teilnehmen. Danke fürs Verständnis.

Markieren Sie nur ein Oval.

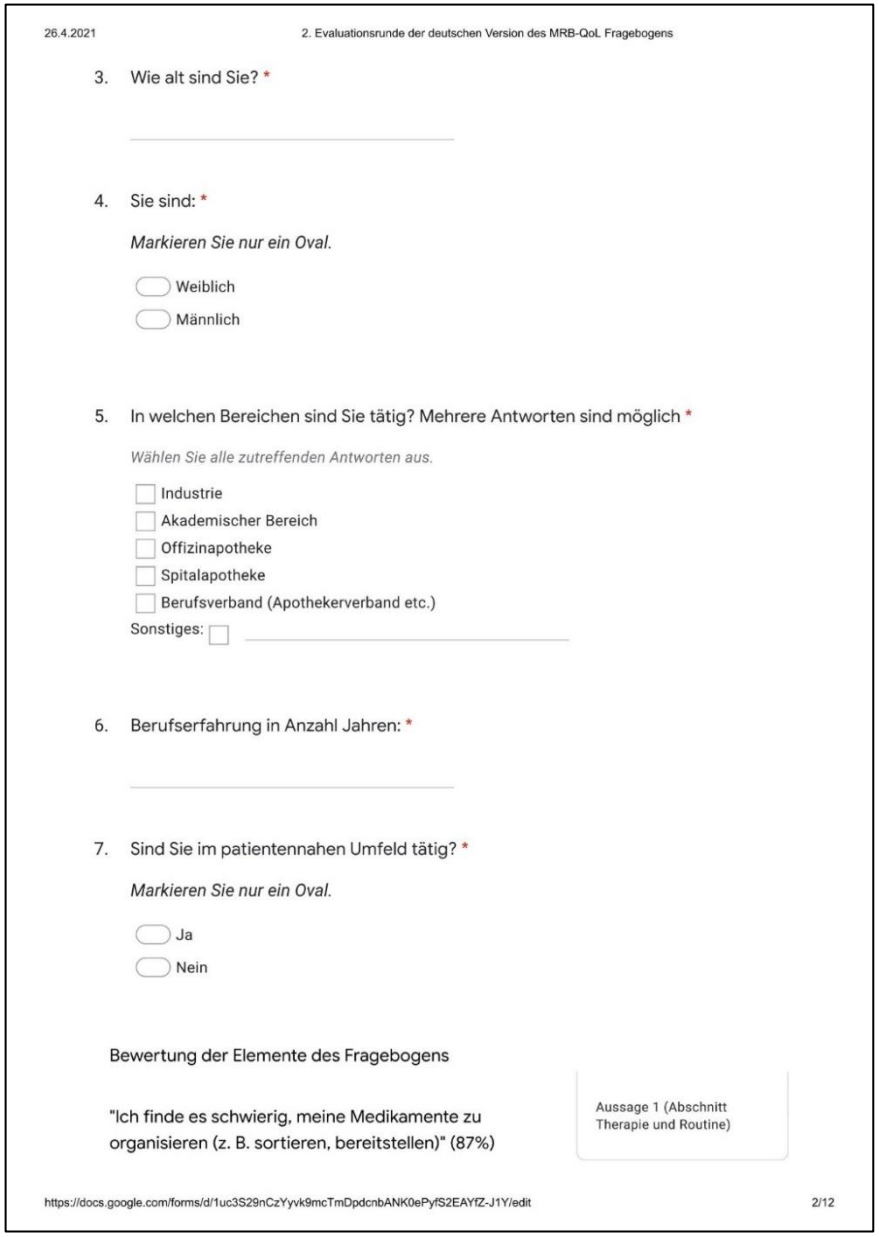
- ◯ Ja
- ◯ Nein *Fahren Sie mit Frage 39 fort*

2. Bitte präzisieren Sie. *

Markieren Sie nur ein Oval.

- ◯ Deutsch (Schweiz)
- ◯ Deutsch (Deutschland)
- ◯ Deutsch (Österreich)

https://docs.google.com/forms/d/1uc3S29nCzYyvk9mcTmDpdcnbANK0ePyfS2EAYfZ-J1Y/edit 1/12



26.4.2021 2. Evaluationsrunde der deutschen Version des MRB-QoL Fragebogens

3. Wie alt sind Sie? *

4. Sie sind: *

Markieren Sie nur ein Oval.

- ◯ Weiblich
- ◯ Männlich

5. In welchen Bereichen sind Sie tätig? Mehrere Antworten sind möglich *

Wählen Sie alle zutreffenden Antworten aus.

- ☐ Industrie
- ☐ Akademischer Bereich
- ☐ Offizinapotheke
- ☐ Spitalapotheke
- ☐ Berufsverband (Apothekerverband etc.)
- Sonstiges: ☐

6. Berufserfahrung in Anzahl Jahren: *

7. Sind Sie im patientennahen Umfeld tätig? *

Markieren Sie nur ein Oval.

- ◯ Ja
- ◯ Nein

Bewertung der Elemente des Fragebogens

"Ich finde es schwierig, meine Medikamente zu organisieren (z. B. sortieren, bereitstellen)" (87%)

Aussage 1 (Abschnitt Therapie und Routine)

https://docs.google.com/forms/d/1uc3S29nCzYyvk9mcTmDpdcnbANK0ePyfS2EAYfZ-J1Y/edit 2/12

8. 1 Dieses Element ist für mich relevant: *

Markieren Sie nur ein Oval.

- Ja
- Nein

"Ich finde es schwierig, den Überblick über die Unterlagen zu meinen Medikamenten zu behalten (z. B. Medikationspläne, Rezepte, Arztberichte)" (60%)

Aussage 2 (Abschnitt Therapie und Routine)

9. 2 Dieses Element ist für mich relevant: *

Markieren Sie nur ein Oval.

- Ja
- Nein

"Es fällt mir schwer, die mit der Medikamenteneinnahme verbundenen Tätigkeiten zu bewältigen (z. B. Zubereitung, Routine)" (60%)

Aussage 3 (Abschnitt Therapie und Routine)

10. 3 Dieses Element ist für mich relevant: *

Markieren Sie nur ein Oval.

- Ja
- Nein

"Das Einnehmen von Medikamenten beeinträchtigt meine körperlichen Aktivitäten" (93%)

Aussage 4 (Abschnitt Therapie und Routine)

11. 4 Dieses Element ist für mich relevant: *

Markieren Sie nur ein Oval.

- Ja
- Nein

"Es fällt mir schwer, die Medikamenteneinnahme mit meinem Tagesablauf in Einklang zu bringen" (100%)

Aussage 5 (Abschnitt Therapie und Routine)

12. 5 Dieses Element ist für mich relevant: *

Markieren Sie nur ein Oval.

- Ja
- Nein

"Meine derzeitige medikamentöse Therapie ist für mich schwierig zu handhaben (z. B. Injektionen, Tabletten, Augentropfen)" (100%)

Aussage 6 (Abschnitt Therapie und Routine)

13. 6 Dieses Element ist für mich relevant: *

Markieren Sie nur ein Oval.

- Ja
- Nein

"Manchmal fällt es mir schwer zu verstehen, wie ich meine Medikamente anwenden soll" (93%)

Aussage 7 (Abschnitt Therapie und Routine)

14. 7 Dieses Element ist für mich relevant: *

Markieren Sie nur ein Oval.

- Ja
- Nein

"Meine derzeitigen Medikamente haben eine für mich unangenehme Form zum Einnehmen (z. B. schwer zu schlucken, unangenehmer Geschmack/Geruch)" (93%)

Aussage 8 (Abschnitt Therapie und Routine)

15. 8 Dieses Element ist für mich relevant: *

Markieren Sie nur ein Oval.

- Ja
- Nein

"Manchmal muss ich meine Termine wegen meiner Medikamente absagen" (80%)

Aussage 9 (Abschnitt Therapie und Routine)

16. 9 Dieses Element ist für mich relevant: *

Markieren Sie nur ein Oval.

- Ja
- Nein

"Manchmal fällt es mir schwer die Verpackung meiner Medikamente zu öffnen (z. B. wegen kindersicheren Verschlüssen)" (87%)

Aussage 10 (Abschnitt Therapie und Routine)

17. 10 Dieses Element ist für mich relevant: *

Markieren Sie nur ein Oval.

- Ja
- Nein

"Es beschäftigt mich, dass ich dauerhaft Medikamente einnehmen muss" (87%)

Aussage 11 (Abschnitt psychisches Wohlbefinden)

18. 11 Dieses Element ist für mich relevant: *

Markieren Sie nur ein Oval.

- Ja
- Nein

"Ich bin besorgt über die Anzahl der Medikamente die ich einnehme" (100%)

Aussage 12 (psychisches Wohlbefinden)

19. 12 Dieses Element ist für mich relevant: *

Markieren Sie nur ein Oval.

- Ja
- Nein

"Ich mache mir Sorgen über die Langzeitfolgen von Medikamenten auf meine Gesundheit" (100%)

Aussage 13 (psychisches Wohlbefinden)

20. 13 Dieses Element ist für mich relevant: *

Markieren Sie nur ein Oval.

- Ja
- Nein

"Die regelmässige Medikamenteneinnahme erinnert mich an meine gesundheitlichen Probleme" (73%)

Aussage 14 (Abschnitt psychisches Wohlbefinden)

21. 14 Dieses Element ist für mich relevant: *

Markieren Sie nur ein Oval.

- Ja
- Nein

"Ich bin besorgt, dass meine Medikamente sich gegenseitig beeinflussen könnten" (100%)

Aussage 15 (Abschnitt psychisches Wohlbefinden)

22. 15 Dieses Element ist für mich relevant: *

Markieren Sie nur ein Oval.

- Ja
- Nein

"Meine Medikamente zeigen mir, dass ich nicht gesund bin" (73%)

Aussage 16 (Abschnitt psychisches Wohlbefinden)

23. 16 Dieses Element ist für mich relevant: *

Markieren Sie nur ein Oval.

- Ja
- Nein

"Manchmal beeinträchtigen meine Medikamente mein Sexualleben" (93%)

Aussage 17 (Abschnitt körperliches Wohlbefinden)

24. 17 Dieses Element ist für mich relevant: *

Markieren Sie nur ein Oval.

- Ja
- Nein

"Ich kann mich aufgrund meiner Medikamente nicht entspannen und den Sex geniessen" (53%)

Aussage 18 (Abschnitt körperliches Wohlbefinden)

25. 18 Dieses Element ist für mich relevant: *

Markieren Sie nur ein Oval.

- Ja
- Nein

"Einige meiner Medikamente schränken meine körperliche Gesundheit ein" (87%)

Aussage 19 (Abschnitt körperliches Wohlbefinden)

26. 19 Dieses Element ist für mich relevant: *

Markieren Sie nur ein Oval.

- Ja
- Nein

"Ich schlafe oft schlecht wegen meiner Medikamente" (93%)

Aussage 20 (Abschnitt körperliches Wohlbefinden)

27. 20 Dieses Element ist für mich relevant: *

Markieren Sie nur ein Oval.

- Ja
- Nein

"Aufgrund meiner Medikamente fühle ich mich zu müde, um körperliche Aktivitäten durchzuführen" (87%)

Aussage 21 (Abschnitt körperliches Wohlbefinden)

28. 21 Dieses Element ist für mich relevant: *

Markieren Sie nur ein Oval.

- Ja
- Nein

"Aufgrund der Wirkung meiner Medikamente kann ich nicht so arbeiten wie gewohnt" (80%)

Aussage 22 (Abschnitt körperliches Wohlbefinden)

29. 22 Dieses Element ist für mich relevant: *

Markieren Sie nur ein Oval.

- Ja
- Nein

"Bei einigen meiner Medikamente fühle ich mich aufgrund der Nebenwirkungen unwohl" (87%)

Aussage 23 (Abschnitt körperliches Wohlbefinden)

30. 23 Dieses Element ist für mich relevant: *

Markieren Sie nur ein Oval.

- Ja
- Nein

"Ich werde als Patient*in nicht mit Respekt und Würde behandelt" (60%)

Aussage 24 (Abschnitt Gesundheitsversorgung)

31. 24 Dieses Element ist für mich relevant: *

Markieren Sie nur ein Oval.

- Ja
- Nein

"Meine Ärzt*in nimmt zu wenig Rücksicht auf meine körperliche, geistige und seelische Gesundheit" (67%)

Aussage 25 (Abschnitt Gesundheitsversorgung)

32. 25 Dieses Element ist für mich relevant: *

Markieren Sie nur ein Oval.

- Ja
- Nein

"Meine Ärzt*innen sprechen über meine Medikamente, als ob ich nicht da wäre" (53%)

Aussage 26 (Abschnitt Gesundheitsversorgung)

33. 26 Dieses Element ist für mich relevant: *

Markieren Sie nur ein Oval.

- Ja
- Nein

"Ich möchte anderen lieber nicht erzählen, dass ich regelmässig Medikamente einnehme" (87%)

Aussage 27 (Abschnitt soziales Wohlbefinden)

34. 27 Dieses Element ist für mich relevant: *

Markieren Sie nur ein Oval.

- Ja
- Nein

"Es ist mir peinlich, meine Medikamente in der Öffentlichkeit einzunehmen/anzuwenden" (67%)

Aussage 28 (Abschnitt soziales Wohlbefinden)

35. 28 Dieses Element ist für mich relevant: *

Markieren Sie nur ein Oval.

- Ja
- Nein

"Ich fühle mich verurteilt durch das, was die Leute über meine Medikamente sagen" (67%)

Aussage 29 (Abschnitt soziales Wohlbefinden)

36. 29 Dieses Element ist für mich relevant: *

Markieren Sie nur ein Oval.

- Ja
- Nein

"Die Leute würden mich als schwach ansehen, wenn sie herausfinden würden, dass ich Medikamente einnehme" (47%)

Aussage 30 (Abschnitt soziales Wohlbefinden)

37. 30 Dieses Element ist für mich relevant: *

Markieren Sie nur ein Oval.

- Ja
- Nein

Allgemeine Kommentare

38. Wenn Sie noch einen allgemeinen Kommentar zum Fragebogen abgeben möchten, dürfen Sie das im vorgegebenen Feld machen:

Vielen herzlichen Dank für Ihre Bewertung!

39. Wenn Sie gerne an der Verlosung teilnehmen möchten, dürfen Sie hier noch Ihre E-Mailadresse angeben:

VI. Interview guide process mapping

Name des Abschnitts		Ziel des Abschnitts	Fragen	Bemerkung	Nr.
Einleitung			Doch zuerst starten wir mit einer kurzen Vorstellungsrunde und Fragen zu Ihnen. Sagen Sie bitte Ihren Beruf, wie lange Sie in Ihrem Fachgebiet arbeiten und was gehört zu Ihren täglichen Aufgaben.		1
			Haben Sie in Ihrem Berufsalltag bereits Erfahrungen gemacht, dass Ihre Patient*innen durch die Einnahme der Medikamente belastet sind oder waren? Bei Patient*innen: Belasten Sie Ihre Medikamente?	Bei Patient*innen entfällt diese Frage	2
			Nun haben wir einen Fragebogen, um dies zu erheben. Ist es Ihrer Meinung nach sinnvoll, einen solchen Fragebogen zu haben?		3a
			Sie haben xx gesagt. Warum diese Antwort?		3b
PDCA-Zyklus	**P**lan	Einsatzort finden	Könnten Sie sich vorstellen, diesen Fragebogen in Ihrem Beruf anzuwenden?	Bei Patient*innen entfällt diese Frage	4
			Wo wäre der optimale Einsatzort um diesen Fragebogen von Patient*innen ausfüllen zu lassen?		5
			Warum haben Sie sich für diesen Einsatzort entschieden?		6
	Do	Anwendung Fragebogen	Denken Sie an Ihren Alltag und die vielen Prozesse. Welcher Zeitpunkt wäre optimal, um diese Fragebogen von Patient*innen ausfüllen zu lassen?		7a
			Warum ist das aus Ihrer Sicht ein geeigneter Zeitpunkt in Ihren Prozessen?		7b
	Check	Auswertung und Interpretation der Resultate	Nehmen wir an, der Fragebogen ist von einer Ihrer Patient*in ausgefüllt worden. Wer sollte nun den Fragebogen auswerten und ein Resultat generieren? Das Resultat könnte sein, dass diese/r Patient*in eine sehr starke Belastung durch seine/ihre Medikation empfindet.		8
			Nehmen wir jetzt an, der Fragebogen ist von xx ausgewertet worden und das Resultat liegt vor. Wer sollte nun das Resultat erhalten und die Schlüsse ziehen?		9
			Warum haben Sie diese Person gewählt?		10
	Act	Weitere Schritte	Nehmen wir an, der Fragebogen ist von Ihrem/r Patient*in ausgefüllt worden, er ist von xx ausgewertet worden und xx hat die Schlüsse gezogen. Was könnte ein nächster Schritt sein, wenn z.B. eine sehr hohe Belastung durch die Medikamente erkannt wurde?		11
			Wer sollte diese Schritte einleiten?		12
Abschluss			Was sind die Stärken und Schwächen des Fragebogens?		13
			Möchten Sie etwas ergänzen, was Ihnen noch wichtig ist?		14
			Denken Sie der/die Patient*in sollte für diese Dienstleistung bezahlen?	Fachperson	15a
			Würden Sie etwas für diese Dienstleistung bezahlen?	Patient*in	15b

A4

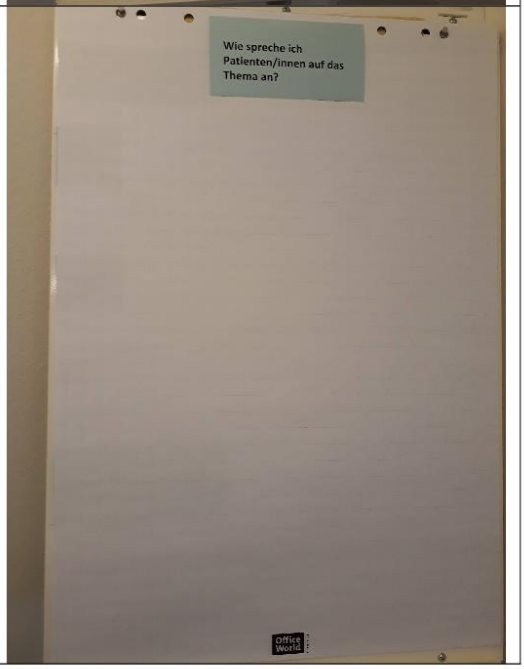
VII. Brainstorming interview guide

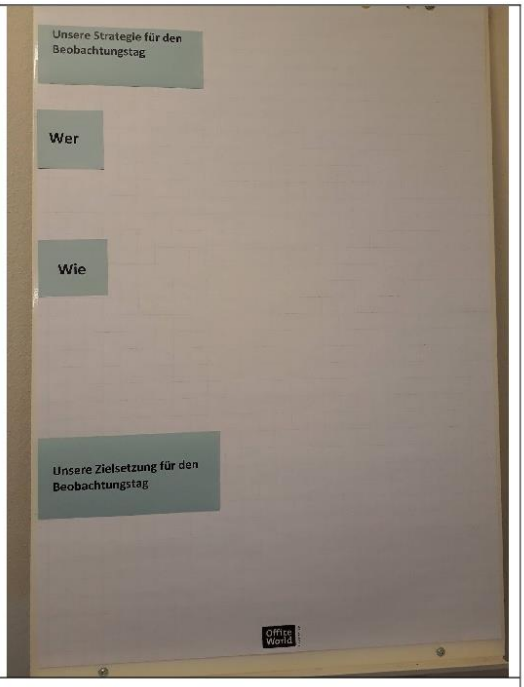
Studientag 1, Besprechung und Brainstorming

Inhalt	Methode	Outcome
Begrüssung und Einführung *Hallo zusammen, wir begrüssen euch herzlich zum ersten Tag der SCREEN-Studie. Wir sind von der Pharmaceutical Care Research Group der Uni Basel. Die Studie wird im Rahmen meiner Masterarbeit durchgeführt. Mein Name ist Nicolas Comment und das ist mein Betreuer Pascal Baumgartner, der die anschliessende Diskussion leiten wird. Ich werde eure Inputs protokollieren. Bevor ich das Wort an Pascal übergebe, erkläre ich euch kurz, um was es bei meiner Arbeit genau geht. Ich untersuche, wie Patienten in der Apotheke auf das Thema Adhärenz angesprochen werden und mit welchen Methoden man die besten Resultate erzielt. Adhärenz oder auch Compliance, für alle die mit dem Begriff nicht vertraut sind, bedeutet nach Definition: das Ausmass der Übereinstimmung zwischen dem Verhalten einer Person* *und pharmazeutischen Empfehlungen. Ein kurzes Beispiel dazu: Herr Müller nimmt seine Schilddrüsenmedikament Euthyrox jeden Tag, wie verschrieben, eine halbe Stunde vor dem Essen ein. Er ist also adhärent. Herr Meier hingegen vergisst die Einnahme oft oder nimmt die Tablette erst am Nachmittag ein. Er ist also weniger adhärent. Ihn kann man als non adhärent bezeichnen. Konkret ist also gemeint, wie zuverlässig und korrekt die Medikamente genommen werden. Die Adhärenz-Beratung ist in der Apotheke ein aus verschiedenen Gründen oft vernachlässigtes Thema. Eine unserer Studien belegt, dass nur rund jeder 12. Kunde in der Apotheke zu dieses Thema beraten wird. Um das Thema zu untersuchen, brauchen wir nun von euch, die jeden Tag mit Patienten zu tun haben und uns sicher viele Erfahrungen mitteilen können, Hilfe.* *Diese erste Diskussion soll dazu dienen, eure Erfahrungen, Ansichten und Ideen zu diesem Thema zu sammeln. Am zweiten Tag der Studie wird es dann darum gehen, die gesammelten Ideen praktisch umzusetzen und Kunden gezielt auf Adhärenz anzusprechen. Heute spielt der fachliche Hintergrund keine Rolle. Jede Äusserung ist wertvoll. Es gibt keine falschen Äusserungen. Ebenso ist alles, was ihr sagt, vertraulich. Ich werde die Daten zwar in meiner Arbeit festhalten, allerdings ohne Nennung eurer Namen. Wir werden die Diskussion aufnehmen, dies dient allerdings nur zur Dokumentation. Ist das so für alle in Ordnung?*	Moderation	Einführung, Etablieren der Rahmenbedingungen
Teil 1: Welcher Patient wird auf Adhärenz angesprochen?		
Erläuterung zu Patienten-Faktoren («Katalysatoren», promoting factors);		
Wir beginnen mit dem ersten Thema. Die meisten von euch haben schon Kunden in der Apotheke bedient und bei einigen seid ihr vermutlich auch auf das Thema Adhärenz zu sprechen gekommen. Ich möchte nun von euch hören, welchen Patienten ihr auf die Adhärenz aktiv ansprecht bzw. ob er seine Medikamente korrekt einnimmt. Diese Gründe können zahlreich sein, wir wollen jetzt aber nur patientenbezogene Faktoren sammeln.	Moderation	Einführung in fördernde Faktoren

Beginn Diskussion, Besprechung der patientenbezogenen Faktoren		
Ich möchte euch bitten, mir zu erläutern, welche Voraussetzungen für euch erfüllt sein müssen, damit ihr bei euren Kunden Adhärenz thematisiert. *Konkret: Welcher Patient wird darauf angesprochen, ob er seine Medikamente korrekt einnimmt?*	Offene Diskussion Genannte Kriterien werden auf einem Flipchart für alle sichtbar notiert. Flipchart Seite 1	Erstellen einer Sammlung möglicher fördernder Faktoren.
Teil 2: Wie wird ein Patient auf das Thema Adhärenz angesprochen?		
Besprechung der *Methode/Technik* *Danke für die vielen Beiträge. Damit kommen wir nun zum nächsten Thema, bei dem es darum geht, wie ihr bei diesen Kunden auf das Thema Adhärenz zu sprechen kommt.* *Auch hier möchte ich euch wieder bitten, mir der Reihe nach zu erklären, wie ihr konkret vorgeht.* *Beispiel: ihr könnt einen bestimmten Satz sagen oder eine bestimmte Sache beschreiben, die ihr tut.*	Offene Diskussion Genannte Methoden werden auf Flipchart notiert. Flipchart Seite 2	Erstellen einer Sammlung von Methoden zum Ansprechen der Kunden auf Adhärenz.
Teil 3: Festlegung einer Strategie		
Ziel am zweiten Tag ist es, mindestens zehn Leute auf ihre Adhärenz anzusprechen und diesen einen Flyer abzugeben. *Nun würden wir gerne von euch hören, wie ihr das anstellen wollt? Zuerst stelle ich euch den Flyer vor.*	Moderation	
Vorstellung des Flyers		
Der Flyer besteht aus zwei Seiten. Auf der ersten Seite wird darauf aufmerksam gemacht, dass bis zu der Hälfte der Patienten ihre Medikamente nicht richtig einnimmt sowie auf den Unterschied zwischen willentlicher und unwillentlicher fehlerhafter Medikamenteneinnahme. Auf der Rückseite werden 6 einfach Tipps und Tricks beschrieben für die korrekte Medikamenteneinnahme.	Der Flyer wird den Teilnehmer verteilt. Einführung und Erklärung des Flyers.	
Festlegung der Strategie		
Nun würden wir gerne von euch hören, was eure Strategie ist, um zehn Patienten auf ihre Adhärenz anzusprechen und ihnen den Flyer abzugeben. *Also **wer** ihr ansprecht?* *Und **wie** ihr das tun wollt?* *Beispiel: Ihr legt euch auf die Strategie fest, dass ihr ausschliesslich alte Frauen mit Stock ansprecht **(WER)** und zwar mit der Frage: «Vergessen Sie manchmal Ihre Medikamente zu nehmen?» **(WIE)***	Offene Diskussion mit den Teilnehmern. Vorschläge einer Strategie werden auf dem Flipchart notiert. Definitive Strategie nach Einigung zwischen den Teilnehmern	Einigung auf eine einheitliche Strategie.

Moderator verweist nochmals auf Flipchart Seiten 1 + 2 und fasst nochmals kurz zusammen, dass hier bereits **WER**-Kriterien auf Seite 1 zusammengetragen wurden und **WIE** Methoden auf Seite 2 und macht daraus nochmals ein Beispiel.	wird auf dem Clipboard notiert und von den Moderatoren nochmals wiederholt. Flipchart Seite 3	
Festlegung der Ziele für den Beobachtungstag		
Zum Schluss möchte ich euch nun bitten, mir zu sagen, wie viele Kunden ihr gedenkt im Verlauf eines Tages mit dieser Strategie anzusprechen und wie viele Flyer zum Thema Adhärenz ihr verteilen werdet.	Offene Diskussion unter den Teilnehmern, bis Sie sich geeinigt haben. Die Zahlen werden auf der Flipchart notiert. Flipchart Seite 3	Festlegung eines Ziels
Abschluss		
Zum Abschluss möchte ich mich erneut bei euch für eure Mithilfe bedanken. Wir konnten viele neue Erkenntnisse gewinnen. Falls ihr noch Fragen habt, stehen wir euch jetzt noch zur Verfügung oder später auch per Mail.	Moderation	Abschluss

Materialien	
Flipchart Seite 1	
Flipchart Seite 2	

Flipchart Seite 3	

- **2-3** dicke Marker
- Malerband
- Normales Klebeband
- **50** Flyer zu Adhärenz
- Z'nüni/Z'vieri
- Ablaufskript
- Protokollskript
- iPad
- **15** Einverständniserklärungen
- Timer

VIII. Characterization sheet of the pharmacies

Apotheken-Charakterisierung

Angaben zur Apotheke

1. Apo-Nr. ☐☐

2. Ort: ☐Grossstadt(>100'000) ☐Stadt (99'999-10'000) Dorf (<10'000)

3. Lage: ☐Zentrumslage ☐Quartier ☐Einkaufszentrum

4. Selbstdispensation ☐Ja ☐Nein

5. Toppharm: ☐Ja ☐Nein, sondern_____

6. Öffnungszeiten: ☐☐:☐☐-☐☐:☐☐

7. Beobachtete Zeit: ☐☐:☐☐-☐☐:☐☐

8. Anzahl Mitarbeiter: ☐☐

9. Anzahl Apotheker/-innen: ☐☐

10. Anzahl Pharmaassistenten/-innen ☐☐

11. Anzahl Drogisten/-innen ☐☐

12: Spezialisierung ☐

Angaben zum Beobachtungstag:

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

14 Öffnungszeiten: ☐☐:☐☐ - ☐☐:☐☐ / ☐☐:☐☐ - ☐☐:☐☐

15 Erfasste Zeit: _____

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): ☐☐☐

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	☐☐.☐

IX. Questionnaire SCREEN-Studie 2019

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Fragebogen zur SCREEN-Studie 2019

Vielen herzlichen Dank, dass Sie am heutigen Tag Ihre Kunden auf das Thema Adhärenz angesprochen haben. Zum Abschluss des Tages würden wir gerne von Ihnen ein Feedback erhalten zu dem Beobachtungstag und der angewandten Strategie. Die erhobenen Daten werden anonymisiert ausgewertet.

Angaben zu Ihrer Person

Beruf: _____

Jahrgang: _____

Geschlecht:
- ☐ Männlich
- ☐ Weiblich

Anzahl Jahre Berufserfahrung in der Offizin: _____

Arbeitspensum in der Apotheke in Prozent: _____

Seite 1/6

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A. Allgemeines Feedback

1	Der Begriff Adhärenz war mir bereits vor dieser Studie bekannt	☐Ja	☐Nein

		Stimme nicht zu	Stimme eher nicht zu	Stimme eher zu	Stimme zu
2	Die Kunden liessen sich auf ein Gespräch mit mir ein, wenn ich sie auf ihre Adhärenz angesprochen habe	☐	☐	☐	☐
3	Kunden, die sich mit mir auf ein Gespräch über Adhärenz einliessen, hatten Probleme mit der Medikamenteneinnahme	☐	☐	☐	☐
4	Heute konnte ich folgende Erkenntnisse zum Thema Adhärenz gewinnen:				

Seite 2/6

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B. Feedback Flyer

		Stimme nicht zu	Stimme eher nicht zu	Stimme eher zu	Stimme zu
5	Der Inhalt des Flyers erachte ich als sinnvoll	☐	☐	☐	☐
6	Die Abgabe eines Flyers ist eine geeignete Methode zur Sensibilisierung des Patienten auf das Thema Adhärenz	☐	☐	☐	☐
7	Kommentar zum Flyer:				
8	Verbesserungsvorschläge zum Flyer				

Seite 3/6

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C. Feedback Strategie

		Stimme nicht zu	Stimme eher nicht zu	Stimme eher zu	Stimme zu
9	Es ist sinnvoll eine Strategie für die Apotheke zu haben, wie man Patienten auf Ihre Adhärenz anspricht	☐	☐	☐	☐
10	Eine Strategie sollte die heute angewandten Teilaspekte beinhalten:				
10.1	-***WER*** («Welche Kunden angesprochen werden»)	☐	☐	☐	☐
10.2	- ***WIE*** («Wie die Kunden angesprochen werden»)	☐	☐	☐	☐
10.3	- ***WIE VIELE*** (Zielsetzung: «Wie viele Kunden angesprochen werden»)	☐	☐	☐	☐
Kommentar					

Teilaspekt 1: WER («Welche Kunden von uns angesprochen wurden»)

		Stimme nicht zu	Stimme eher nicht zu	Stimme eher zu	Stimme zu
11.1	Es hat sich heute bewährt:..... ***(WER 1)***	☐	☐	☐	☐
	Kommentar:				
		Stimme nicht zu	Stimme eher nicht zu	Stimme eher zu	Stimme zu
11.2	Es hat sich heute bewährt: ..... ***(WER 2)***	☐	☐	☐	☐
	Kommentar:				

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Teilaspekt 2: WIE («Wie die Kunden von uns angesprochen wurden»)					
		Stimme nicht zu	Stimme eher nicht zu	Stimme eher zu	Stimme zu
12.1	Es hat sich bewährt: …….. ***(WIE 1)***	☐	☐	☐	☐
	Kommentar:				
		Stimme nicht zu	Stimme eher nicht zu	Stimme eher zu	Stimme zu
12.2	Es hat sich bewährt: ……***(WIE 2)***	☐	☐	☐	☐
	Kommentar:				
		Stimme nicht zu	Stimme eher nicht zu	Stimme eher zu	Stimme zu
12.3	Es hat sich bewährt: …… ***(WIE 3)***	☐	☐	☐	☐
	Kommentar:				

Teilaspekt 3: ***WIE VIELE (Zielsetzung «Wie viele Kunden angesprochen werden»)***					
		Stimme nicht zu	Stimme eher nicht zu	Stimme eher zu	Stimme zu
13	Wir, das Apothekenteam, haben unser gesetztes Ziel bezüglich: - Anzahl angesprochener Personen erreicht	☐	☐	☐	☐
14	- Anzahl verteilter Flyer erreicht	☐	☐	☐	☐
15	Ich habe mein persönlich gesetztes Ziel bezüglich: - Anzahl angesprochener Personen erreicht	☐	☐	☐	☐
16	- Anzahl verteilter Flyer erreicht	☐	☐	☐	☐

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Gesamtbeurteilung unserer Strategie (WER + WIE + WIE VIELE)			
17	Unsere Strategie wäre gut einbaubar in die tägliche Routine unserer Apotheke	☐Ja	☐Nein
18.1	Falls **Ja** warum:		
18.2	Falls **Nein** warum nicht:		
19	**Verbesserungsvorschläge zu der heute angewandten Strategie:**		

Vielen herzlichen Dank für das Ausfüllen des Fragebogens!

Ihr SCREEN-Team

Seite 6/6

Project B

B1

X. Questionnaire fokus°PDCA Part I: usability and comprehensibility

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Rückmeldeformular zum Implementierungs-Hilfsmittel «FOKUS-PDCA»

Bitte nehmen Sie zu folgenden Aussagen Stellung. Bei einer Vergabe einer Note von 1 oder 2, begründen Sie die Bewertung bitte in den Kommentaren. Gerne dürfen Sie Kommentare und Verbesserungsvorschläge direkt in das leere Hilfsmittel notieren.

Vielen Dank für Ihre wertvolle Rückmeldung.

Notenskala: 1 = trifft nicht zu, 2 = trifft eher nicht zu, 3 = trifft eher zu, 4 = trifft zu		
1. Die Fragen sind **allgemein verständlich** formuliert.	Note: ____	Kommentar:_____ _____
2. Die Fragen sind **präzise** formuliert.	Note: ____	Kommentar:_____ _____
3. Das Schriftbild ist **gut lesbar**.	Note: ____	Kommentar:_____ _____
4. Die Handhabung ist **klar und logisch** aufgebaut.	Note: ____	Kommentar:_____ _____
5. Der Einleitungstext ist **verständlich und klar.**	Note: ____	Kommentar:_____ _____
6. Es ist **genügend** Platz zum Ausfüllen vorhanden.	Note: ____	Kommentar:_____ _____
7. Das Design des Hilfsmittels ist **ansprechend.**	Note: ____	Kommentar:_____ _____

Masterarbeit Elisabeth Scherer - Universität Basel – Februar 2020

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8. Der Zusammenhang zwischen den einzelnen Schritten ist **klar verständlich**.	Note: ____	Kommentar:_____ _____
9. Es ist **klar,** wofür FOKUS-PDCA steht.	Note: ____	Kommentar:_____ _____
10. Die benötigte Zeit ist **angemessen**.	Note: ____	Kommentar:_____ _____

Masterarbeit Elisabeth Scherer - Universität Basel – Februar 2020

XI. Scenario "Vaccination"

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Impfszenario für FOKUS-PDCA

Liebe Kollegin, lieber Kollege,

Um zu überprüfen, ob das Implementierungshilfsmittel FOKUS-PDCA verständlich ist, bitte ich dich, dieses mit Hilfe der folgenden Szenarien auszufüllen. Anschliessend fülle bitte das beiliegende Rückmeldeformular aus. Eure Daten werden vertraulich behandelt.
Danke für eure wertvollen Rückmeldungen!

1. Teil des Szenarios

Lies bitte das folgende Szenario einer fiktiven Apotheke durch:

*Du bist Geschäftsführer*In einer Quartierapotheke in Stadtnähe mit ca. 300 Kunden täglich. Dein Team umfasst 10 Pharmaassistentinnen, 2 Lehrtöchter und 5 Apotheker. Die Apotheke hat ein kleines Labor im Untergeschoss und ein separates Beratungszimmer.*
Deine Apotheke bietet eine breite Palette an pharmazeutischen Dienstleistungen und ist engagiert in Präventionsprogrammen. Jeden Monat habt ihr eine Dienstleistung, für welche ihr mit Flyern und Plakaten speziell werbt. Für die Werbung ist eine Pharmaassistentin verantwortlich (PA1).
Nun willst du das Dienstleistungsangebot erweitern und überlegst dir, Impfungen anzubieten, weil schon einige Kunden (darunter auch potentielle Neukunden) nach der Grippe- und FSME-Impfung gefragt haben. Weil momentan keine Apotheke in unmittelbarer Nähe Impfungen anbietet, siehst du es als Chance, dich von diesen abzuheben.
Neben dir hat noch eine weitere Apothekerin (Apo1) die Impfausbildung abgeschlossen, welche motiviert ist, dir bei der Implementierung zu helfen.
Das separate Beratungszimmer der Apotheke beinhaltet alles was zur Durchführung einer Impfung benötigt wird, ausser einer Liegemöglichkeit. Der Arzneimittel-Kühlschrank bietet genügend Platz für Impfstoff.
In etwas mehr als zwei Monaten startet die Grippeimpfzeit, was du als optimalen Start für die Implementierung von Impfungen in deiner Apotheke siehst. Um deine Apotheke als "Impfapotheke" bei den Kunden bekannt zu machen, würdest du gerne 100 Kunden während der Grippeimpfzeit impfen. Durch Werbung und direkte Terminvereinbarung hoffst du dies zu erreichen.
Ziel ist es, dass bis in einem Jahr die Implementierung abgeschlossen ist und somit das Impfen Teil des normalen Alltags in deiner Apotheke wird.

Bitte fülle nun den gesamten 1. Teil (= FOKUS) des Implementierungshilfsmittels und den Plan des 2. Teils (Buchstabe P des PDCA-Zyklus) aus.
Falls dir etwas im Szenario fehlt, kannst du auf eigene Erfahrungen zurückgreifen, um das Hilfsmittel auszufüllen.
Für Personen können Abkürzungen verwendet werden: GF → Geschäftsführerin, APO → Apotheker, PA → Pharmaassistentinnen, LT → Lehrtöchter.

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2. Teil des Szenarios

Lies nun die Fortsetzung des Szenarios durch:

Zwei Monate nach dem Beschluss, die Dienstleistung Impfen zu implementieren, stehst du kurz vor Beginn der Grippeimpfzeit. Du hast in der Zwischenzeit eine Liege besorgt und den Grippeimpfstoff bestellt, welcher schon im Kühlschrank bereitliegt.
Die meisten Aufgaben in diesem Zyklus wurden gut ausgeführt, so verteilen z.B. alle im Team fleissig Flyer an die Kunden, die Interesse zeigen und viele Fragen zur Grippeimpfung stellen. Allerdings ist dein Team teilweise sehr unsicher und kann die Fragen nur ungenügend beantworten. Du vermutest, dass deswegen auch erst 5 Kunden einen Termin für die Impfung vereinbart haben.

Bitte fülle nun den restlichen 2. Teil des Hilfsmittels aus (Buchstaben D, C & A) sowie vom neuen PDCA-Zyklus den Buchstaben P.

XII. Questionnaire fokus°PDCA Part II: acceptability, feasibility, and appropriateness

Universität Basel

Departement
Pharmazeutische Wissenschaften

DEPARTMENT OF PHARMACEUTICAL SCIENCES

Universität Basel, Departement Pharmazeutische Wissenschaften, Klingelbergstr. 50, 4056 Basel

Basel, 20. Februar 2020

Evaluierung des FOKUS-PDCA

Guten Tag,

Um die Implementierung von pharmazeutischen Dienstleistungen in den Apotheken zu unterstützen, wurde im Rahmen meiner Masterarbeit ein Hilfsmittel entwickelt: der FOKUS-PDCA. Dieser soll einerseits dabei helfen sich vor der Implementierung mit wichtigen Fragen rund um die Dienstleistung und deren Implementierung auseinanderzusetzen (= FOKUS). Andererseits soll er während der Implementierung eine kontinuierliche Überprüfung und Anpassung der Implementierungsstrategie ermöglichen (=PDCA-Zyklen). Das Hilfsmittel basiert auf dem bewährten Deming-Regelkreis (PDCA: Plan, Do, Check, Act).
Zur Evaluierung des FOKUS-PDCA sind wir auf Ihre Mithilfe angewiesen. Deswegen würden wir Sie gerne bitten den beiliegenden Fragebogen auszufüllen. Dazu erhalten Sie ein Szenario mit welchem Sie den FOKUS-PDCA anwenden und basierend auf dieser Erfahrung dann den Fragebogen ausfüllen können. Das genaue Vorgehen finden Sie auf der folgenden Seite.
Der zeitliche Aufwand zur Evaluierung wird auf 20-30 Minuten geschätzt.

Zur Evaluierung sollten Sie die folgenden Dokumente erhalten haben, welche in der Kopfzeile nach dem Alphabet nummeriert sind. Beachten Sie, dass die Dokumente doppelseitig bedruckt sind.

- Vorgehen zur Evaluierung des FOKUS-PDCA (A)
- Teil 1 des Szenarios (B)
- FOKUS-PDCA komplett (C)
- Teil 2 des Szenarios (D)
- PDCA-Zyklus (E)
- Fragebogen inkl. leerem FOKUS-PDCA für Rückmeldungen (F)
- Ein frankiertes und adressiertes Couvert zur Rücksendung der Dokumente.

Sobald wir Ihre ausgefüllten Dokumente erhalten haben, werden wir Ihnen einen Reka-Check im Wert von CHF 10.- zukommen lassen.

Sollte ein Dokument fehlen oder Fragen auftauchen, melden Sie sich bitte unter:
T +41 61 207 61 79
M +41 79 651 70 97
elisabeth.scherer@stud.unibas.ch

Wir bedanken uns bereits im Voraus für Ihre wertvolle Unterstützung!
Mit freundlichen Grüssen

Elisabeth Scherer
Masterstudentin

Pascal Baumgartner
Betreuer, Eig dipl. Apotheker

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Universität Basel
Departement Pharmazeutische Wissenschaften

DEPARTMENT OF PHARMACEUTICAL SCIENCES

A

Vorgehen zur Evaluierung des FOKUS-PDCA

1. Lesen Sie Teil 1 des Szenarios durch (B)
2. Füllen Sie aufgrund des Szenarios…
   a. … den FOKUS-Teil komplett (= «F, O, K, U, S») und (C)
   b. … den Plan des 1. PDCA-Zyklus (= «P») aus (C)
3. Lesen Sie Teil 2 des Szenarios durch (D)
4. Füllen Sie aufgrund des Szenarios…
   a. … den restlichen 1. PDCA-Zyklus (= «D, C & A») und (C)
   b. … den Plan des 2. PDCA-Zyklus (=«P») aus (E)
5. Abschliessend füllen Sie den Fragebogen aus (F)
6. Senden Sie uns alle Dokumente im beiliegenden Couvert bis am **06.03.2020** zurück

Ihre Daten werden vertraulich und anonymisiert behandelt. Ihre Rückmeldung leistet einen wichtigen Beitrag, für welchen wir sehr dankbar sind.

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B

Teil 1 des Szenarios

Lesen Sie bitte das folgende Szenario einer fiktiven Apotheke durch:

*Sie sind Geschäftsführer*In einer Quartierapotheke in Stadtnähe mit ca. 300 Kunden täglich. Ihr Team umfasst 10 Pharmaassistentinnen, 2 Lehrtöchter und 5 Apotheker*Innen. Die Apotheke hat ein kleines Labor im Untergeschoss und ein separates Beratungszimmer.*
Die Apotheke bietet eine breite Palette an pharmazeutischen Dienstleistungen und ist engagiert in Präventionsprogrammen. Jeden Monat gibt es eine Dienstleistung, für welche ihr mit Flyern und Plakaten speziell werbt. Für die Werbung ist eine Pharmaassistentin verantwortlich (PA1).
Nun wollen Sie das Dienstleistungsangebot erweitern und überlegen sich Impfungen anzubieten, weil schon einige Kunden (darunter auch potentielle Neukunden) nach der Grippe- und FSME-Impfung gefragt haben. Es bietet momentan keine Apotheke in unmittelbarer Nähe Impfungen an.
Neben Ihnen hat noch eine weitere Apothekerin (Apo1) die Impfausbildung abgeschlossen, welche motiviert ist, Ihnen bei der Implementierung zu helfen.
Das separate Beratungszimmer der Apotheke beinhaltet alles was zur Durchführung einer Impfung benötigt wird, ausser einer Liegemöglichkeit. Der Arzneimittel-Kühlschrank bietet genügend Platz für die Lagerung von Impfstoffen.
In etwas mehr als zwei Monaten startet die Grippeimpfzeit, was Sie als optimalen Start für die Implementierung von Impfungen in Ihrer Apotheke betrachten. Um die Apotheke als "Impfapotheke" bei den Kunden bekannt zu machen, würden Sie gerne 100 Kunden während der Grippeimpfzeit impfen. Durch Werbung und direkte Terminvereinbarung hoffen Sie dies zu erreichen.
Ziel ist es, dass bis in einem Jahr die Implementierung abgeschlossen ist und somit das Impfen Teil des normalen Alltags in Ihrer Apotheke wird.

Bitte füllen Sie nun vom FOKUS-PDCA (C)…

a. … den gesamten 1. Teil (FOKUS) und
b. … den Plan des 2. Teils (Buchstabe P des PDCA-Zyklus) aus.

Für den Zyklus soll eine Dauer von 2 Monaten gewählt werden.
Falls Ihnen eine Information im Szenario fehlt, können Sie auf eigene Erfahrungen zurückgreifen, um den FOKUS-PDCA auszufüllen.
Für Personen können Abkürzungen verwendet werden: GF → Geschäftsführerin, APO → Apotheker, PA → Pharmaassistentinnen, LT → Lehrtöchter.

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C

Informationen zum Implementierungs-Hilfsmittel FOKUS-PDCA

Das folgende Hilfsmittel dient als Unterstützung, um die Implementierung einer neuen pharmazeutischen Dienstleistung in Ihrer Apotheke besser zu strukturieren, zu planen und umzusetzen. Damit Sie dieses Hilfsmittel optimal nutzen können, finden Sie hier einige Informationen zum Aufbau:

Das Implementierungshilfsmittel besteht aus zwei Teilen:

1. Der erste Teil, welcher als FOKUS bezeichnet wird, dient zur Vorbereitung und Entwicklung einer Implementierungsstrategie und soll die wesentlichen Aspekte rund um die Implementierung einer neuen Dienstleistung abdecken.
   Der FOKUS wird **einmalig vor** der Implementierung ausgefüllt.
2. Der zweite Teil, welcher aus PDCA-Zyklen besteht, wird dann während der Umsetzung der Implementierungsstrategie benutzt. Jeder Zyklus beginnt mit der Planung von Aufgaben (= Plan), die dann über einen bestimmten Zeitraum durchgeführt werden (= Do). Anschliessend wird überprüft, ob der Plan erfolgreich war (= Check). Im nächsten Schritt werden Anpassungen vorgenommen (= Act). Diese Anpassungen werden im darauffolgenden Zyklus aufgenommen. Die Idee ist, dass die Zyklen über einen kurzen Zeitraum (ca. 2-8 Wochen) gewählt werden, so dass Aufgaben Schritt für Schritt ausgeführt und überprüft werden können.
   Durch die aufeinanderfolgenden Zyklen kommt es zu einer kontinuierlichen Verbesserung und Überprüfung der Implementierungsstrategie, weil diese immer wieder neu an die Umstände angepasst werden können. Die Anzahl PDCA-Zyklen, die benötigt werden, ist individuell.
   Die PDCA-Zyklen werden **wiederholt während** der Implementierung gebraucht.

Bei der Anwendung wird empfohlen, mit Stichwörtern zu arbeiten und Kürzel für die einzelnen Mitarbeiter zu verwenden. Wichtig ist, dass Sie eine Strategie entwickeln, welche individuell auf Ihre Apotheke zugeschnitten ist. Das Hilfsmittel kann alleine, in einer kleinen Gruppe oder mit dem gesamten Team ausgefüllt werden.

Viel Erfolg bei der Implementierung Ihrer neuen Dienstleistung!

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C

F O K U S

F «Finden einer Dienstleistung, welche implementiert werden soll»

Um welche Dienstleistung handelt es sich?

O «Organisation der Ressourcen für die Dienstleistung»

Welche **Kompetenzen** muss das Apothekenteam erfüllen, um die Dienstleistung anbieten zu können?	Welche **Infrastruktur** ist nötig um die Dienstleistung zu implementieren?
Sind diese Kompetenzen vorhanden? ☐ *Ja* ☐ *Nein* ☐ *Teilweise*	Ist diese Infrastruktur vorhanden? ☐ *Ja* ☐ *Nein* ☐ *Teilweise*
Falls "*Nein*" bzw. *"Teilweise"*: Können die fehlenden Kompetenzen z.B. durch Schulungen erlangt werden? ☐ *Ja* ☐ *Nein*	Falls "*Nein*" bzw. *"Teilweise"*: Kann die fehlende Infrastruktur beschafft werden? ☐ *Ja* ☐ *Nein*

Kann aus den oben genannten Antworten geschlossen werden, dass **genügend Kapazität** vorhanden ist *bzw. vorhanden sein wird*, um die Dienstleistung zu implementieren?
☐ *Ja* ☐ *Nein**
** Falls "Nein" kann die Dienstleistung mit den momentanen Ressourcen nicht implementiert werden.*

K «Klärung der Bedeutung der Dienstleistung für die Apotheke»

Welchen **Nutzen** verspricht sich die Apotheke aus der Dienstleistung?

Welche **Veränderungen** im Arbeitsalltag der Apotheke bringt die Dienstleistung mit sich?
(Mehraufwand, Dokumentation, Follow-up, Beratung etc.)

Passt die Dienstleistung in das **Konzept** der Apotheke? ☐ *Ja* ☐ *Nein*

U «Umgebung berücksichtigen»

Wie schätzt die Apotheke die **Nachfrage** nach der Dienstleistung bei der eigenen Kundschaft ein?

Gering	Eher Gering	Eher Gross	Gross
☐	☐	☐	☐

Wie begründen Sie diese Abschätzung?

C

F O K U S

S **«Strategie zur Implementierung der Dienstleistung entwickeln»**

Ausgehend von den vorherigen Antworten kann nun überlegt werden, wie das Vorgehen zu wählen ist, um die Dienstleistung zu implementieren.
Dazu soll zunächst das **Hauptziel** der Implementierung definiert werden:

Nun können konkrete Aufgaben formuliert werden, damit das Hauptziel schrittweise erreicht werden kann (oberer Teil der Tabelle). Ausserdem wird festgelegt, wer sich in welcher Frist um welche Aufgaben kümmert (unterer Teil der Tabelle).
(Anregungen: Verantwortlichkeiten, Schulungen, Anschaffungen, Dokumentation, Reminder etc.)

Nr.	Welche Aufgaben sind notwendig um das Hauptziel zu erreichen?

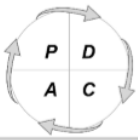
Nr.	Durch wen soll die Aufgabe ausgeführt werden?	Bis wann soll die Aufgabe ausgeführt werden?

Nach Festlegen der Strategie, kann mit der Planung im 2. Teil des Hilfsmittels (PDCA-Zyklus) fortgefahren werden.

Anhang C: Fortsetzung

C

Name der Dienstleistung:_____



Datum: Zyklus vom _____ bis _____ Zyklus-Nr.: _____

P **«Plan» → Planung**

Welche Aufgaben sollen im Zeitraum **dieses** Zyklus ausgeführt werden? Durch wen sollen diese Aufgaben ausgeführt werden? Wie wird erkannt, ob eine Aufgabe erfolgreich umgesetzt wird (= Indikator für Erfolg)?

Nr.	Aufgaben	Wer	Indikator für Erfolg

Lesen Sie Szenario 2 (D), bevor Sie die Buchstaben D, C & A ausfüllen.

D **«Do» → Durchführung des Plans**

Der Plan wurde wie erwartet durchgeführt:

Trifft nicht zu ☐ Trifft eher nicht zu ☐ Trifft eher zu ☐ Trifft zu ☐

Was fiel während der Durchführung auf?

C **«Check» → Überprüfung**

Die Aufgaben wurden erfolgreich umgesetzt (d.h. die Indikatoren für den Erfolg wurden erreicht):

Trifft nicht zu ☐ Trifft eher nicht zu ☐ Trifft eher zu ☐ Trifft zu ☐

Wo gibt es Verbesserungsmöglichkeiten?

Welche neuen Aufgaben wurden durch den Zyklus entdeckt?

A **«Act» → Anpassung**

Folgende Aufgaben waren erfolgreich **und** werden im nächsten Zyklus weiterhin ausgeführt:

Folgende Aufgaben werden für den nächsten Zyklus überarbeitet/angepasst:

Folgende Aufgaben kommen im nächsten Zyklus neu dazu:

Nach Beenden dieses Zyklus werden die Aufgaben aus «A» im nächsten PDCA-Zyklus unter «P» ausgearbeitet.

2. Teil *PDCA-Zyklus* *1/1*

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D

Teil 2 des Szenarios

Lesen Sie nun die Fortsetzung des Szenarios durch:

Zwei Monate nach dem Beschluss, die Dienstleistung Impfen zu implementieren, stehen Sie kurz vor dem Beginn der Grippeimpfzeit. Sie haben in der Zwischenzeit eine Liege besorgt und den Grippeimpfstoff bestellt, welcher schon im Kühlschrank bereitliegt.
Die meisten Aufgaben in diesem Zyklus wurden gut ausgeführt, so verteilen z.B. alle im Team fleissig Flyer an die Kunden. Diese zeigen Interesse und stellen viele Fragen zur Grippeimpfung. Allerdings ist Ihr Team teilweise sehr unsicher und kann die Fragen nur ungenügend beantworten. Sie vermuten, dass deswegen auch erst 5 Kunden einen Termin für die Grippeimpfung vereinbart haben.

Bitte füllen Sie nun…

a. … vom FOKUS-PDCA (C) die Buchstaben D, C & A aus und
b. … vom neuen PDCA-Zyklus (E) den Plan (Buchstabe P) aus.

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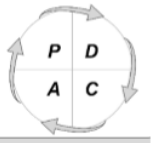
E



Name der Dienstleistung:_____

Datum: Zyklus vom _____ bis _____ Zyklus-Nr.: _____

P **«Plan» → Planung**

Welche Aufgaben sollen im Zeitraum **dieses** Zyklus ausgeführt werden? Durch wen sollen diese Aufgaben ausgeführt werden? Wie wird erkannt, ob eine Aufgabe erfolgreich umgesetzt wird (= Indikator für Erfolg)?

Nr.	Aufgaben	Wer	Indikator für Erfolg

D **«Do» → Durchführung des Plans**

Der Plan wurde wie erwartet durchgeführt:

Trifft nicht zu ☐ Trifft eher nicht zu ☐ Trifft eher zu ☐ Trifft zu ☐

Was fiel während der Durchführung auf?

C **«Check» → Überprüfung**

Die Aufgaben wurden erfolgreich umgesetzt (d.h. die Indikatoren für den Erfolg wurden erreicht):

Trifft nicht zu ☐ Trifft eher nicht zu ☐ Trifft eher zu ☐ Trifft zu ☐

Wo gibt es Verbesserungsmöglichkeiten?

Welche neuen Aufgaben wurden durch den Zyklus entdeckt?

A **«Act» → Anpassung**

Folgende Aufgaben waren erfolgreich **und** werden im nächsten Zyklus weiterhin ausgeführt:

Folgende Aufgaben werden für den nächsten Zyklus überarbeitet/angepasst:

Folgende Aufgaben kommen im nächsten Zyklus neu dazu:

Nach Beenden dieses Zyklus werden die Aufgaben aus «A» im nächsten PDCA-Zyklus unter «P» ausgearbeitet.

2. Teil *PDCA-Zyklus* *1/1*

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F

Rückmeldeformular zum Implementierungs-Hilfsmittel «FOKUS-PDCA»

Bitte nehmen Sie zu folgenden Aussagen Stellung. Bei einer Vergabe einer Note von 1 oder 2, begründen Sie die Bewertung bitte in den Kommentaren. Bitte notieren sie "k.A." falls Sie zu einer Aussage keine Noten geben möchten oder können. Gerne dürfen Sie Kommentare und Verbesserungsvorschläge direkt in den leeren FOKUS-PDCA notieren.
Beachten Sie ferner, dass es sich immer um die Implementierung einer pharmazeutischen Dienstleistung in Offizinapotheken handelt, wenn von Implementierung oder einer Dienstleistung gesprochen wird.
Bitte beachten Sie, dass das Rückmeldeformular aus mehreren Seiten besteht.

Vielen Dank für Ihre wertvolle Rückmeldung.

Notenskala: 1 = trifft nicht zu, 2 = trifft eher nicht zu, 3 = trifft eher zu, 4 = trifft zu

FOKUS-spezifische Fragen			
1.	Die Anwendung des *FOKUS-Teils* ist einfach.	Note: ____	Kommentar:_____ _____
2.	Die benötigte Zeit zum Ausfüllen des *FOKUS-Teils* ist angemessen.	Note: ____	Kommentar:_____ _____
3.	Man lernt schnell wie der *FOKUS-Teil* anzuwenden ist.	Note: ____	Kommentar:_____ _____
4.	Der *FOKUS-Teil* ist **nicht** unnötig komplex.	Note: ____	Kommentar:_____ _____
5.	Ich denke der *FOKUS-Teil* ist hilfreich in der Findung einer Strategie.	Note: ____	Kommentar:_____ _____
6.	Ich denke der *FOKUS-Teil* enthält die grundlegenden Fragen, die man sich vor der Implementierung stellen sollte.	Note: ____	Kommentar:_____ _____
7.	Ich denke der *FOKUS-Teil* enthält die grundlegenden Fragen um abzuschätzen ob die Dienstleistung in die Apotheke passt.	Note: ____	Kommentar:_____ _____

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F

PDCA-Zyklus-spezifische Fragen			
8.	Die Anwendung des *PDCA-Zyklus* ist einfach.	Note: ____	Kommentar:_____ _____
9.	Die benötigte Zeit zum Ausfüllen des *PDCA-Zyklus* ist angemessen.	Note: ____	Kommentar:_____ _____
10.	Man lernt schnell wie der PDCA-Zyklus anzuwenden ist.	Note: ____	Kommentar:_____ _____
11.	Der *PDCA-Zyklus* ist **nicht** unnötig komplex.	Note: ____	Kommentar:_____ _____
12.	Ich denke der *PDCA-Zyklus* ist hilfreich in der Anpassung der Implementierung.	Note: ____	Kommentar:_____ _____
13.	Ich denke der *PDCA-Zyklus* ist geeignet um während der Durchführung die Implementierung regelmässig zu überprüfen und anzupassen.	Note: ____	Kommentar:_____ _____
Fragen zum gesamten FOKUS-PDCA			
14.	Ich finde es sinnvoll den FOKUS-PDCA als Hilfsmittel zur Implementierung einer pharmazeutischen Dienstleistung einzusetzen.	Note: ____	Kommentar:_____ _____
15.	Ich kann mir vorstellen den FOKUS-PDCA zur Implementierung einer Dienstleistung anzuwenden.	Note: ____	Kommentar:_____ _____

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F

Bemerkungen:

Kommentare können auch direkt in den folgenden, leeren FOKUS-PDCA geschrieben werden.

Angaben zu Ihrer Person

Beruf: _____ Jahrgang:_____

Geschäftsführer*In oder stellvertretende Geschäftsführer*In: ☐ Ja ☐ Nein

Anzahl Jahre Berufserfahrung in der Offizin: _____ Geschlecht: ☐ Männlich ☐ Weiblich

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F Bogen für Rückmeldungen F O K U S

F **«Finden einer Dienstleistung, welche implementiert werden soll»**

Um welche Dienstleistung handelt es sich?

O **«Organisation der Ressourcen für die Dienstleistung»**

Welche **Kompetenzen** muss das Apothekenteam erfüllen, um die Dienstleistung anbieten zu können?	Welche **Infrastruktur** ist nötig um die Dienstleistung zu implementieren?
Sind diese Kompetenzen vorhanden? ☐ *Ja* ☐ *Nein* ☐ *Teilweise*	Ist diese Infrastruktur vorhanden? ☐ *Ja* ☐ *Nein* ☐ *Teilweise*
Falls "*Nein*" bzw. "*Teilweise*": Können die fehlenden Kompetenzen z.B. durch Schulungen erlangt werden? ☐ *Ja* ☐ *Nein*	Falls "*Nein*" bzw. "*Teilweise*": Kann die fehlende Infrastruktur beschafft werden? ☐ *Ja* ☐ *Nein*

Kann aus den oben genannten Antworten geschlossen werden, dass **genügend Kapazität** vorhanden ist *bzw. vorhanden sein wird*, um die Dienstleistung zu implementieren?
☐ *Ja* ☐ *Nein**
** Falls "Nein" kann die Dienstleistung mit den momentanen Ressourcen nicht implementiert werden.*

K **«Klärung der Bedeutung der Dienstleistung für die Apotheke»**

Welchen **Nutzen** verspricht sich die Apotheke aus der Dienstleistung?

Welche **Veränderungen** im Arbeitsalltag der Apotheke bringt die Dienstleistung mit sich?
(Mehraufwand, Dokumentation, Follow-up, Beratung etc.)

Passt die Dienstleistung in das **Konzept** der Apotheke? ☐ *Ja* ☐ *Nein*

U **«Umgebung berücksichtigen»**

Wie schätzt die Apotheke die **Nachfrage** nach der Dienstleistung bei der eigenen Kundschaft ein?

Gering	Eher Gering	Eher Gross	Gross
☐	☐	☐	☐

Wie begründen Sie diese Abschätzung?

1. Teil *FOKUS* *1/2*

F Bogen für Rückmeldungen F O K U S

S «Strategie zur Implementierung der Dienstleistung entwickeln»

Ausgehend von den vorherigen Antworten kann nun überlegt werden, wie das Vorgehen zu wählen ist, um die Dienstleistung zu implementieren.
Dazu soll zunächst das **Hauptziel** der Implementierung definiert werden:

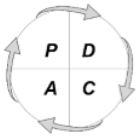
Nun können konkrete Aufgaben formuliert werden, damit das Hauptziel schrittweise erreicht werden kann (oberer Teil der Tabelle). Ausserdem wird festgelegt, wer sich in welcher Frist um welche Aufgaben kümmert (unterer Teil der Tabelle).
(Anregungen: Verantwortlichkeiten, Schulungen, Anschaffungen, Dokumentation, Reminder etc.)

Nr.	Welche Aufgaben sind notwendig um das Hauptziel zu erreichen?

Nr.	Durch wen soll die Aufgabe ausgeführt werden?	Bis wann soll die Aufgabe ausgeführt werden?

Nach Festlegen der Strategie, kann mit der Planung im 2. Teil des Hilfsmittels (PDCA-Zyklus) fortgefahren werden.

F Bogen für Rückmeldungen



Name der Dienstleistung:_____

Datum: Zyklus vom _____ bis _____ Zyklus-Nr.: _____

P **«Plan» → Planung**

Welche Aufgaben sollen im Zeitraum **dieses** Zyklus ausgeführt werden? Durch wen sollen diese Aufgaben ausgeführt werden? Wie wird erkannt, ob eine Aufgabe erfolgreich umgesetzt wird (= Indikator für Erfolg)?

Nr.	Aufgaben	Wer	Indikator für Erfolg

D **«Do» → Durchführung des Plans**

Der Plan wurde wie erwartet durchgeführt:

Trifft nicht zu ☐ Trifft eher nicht zu ☐ Trifft eher zu ☐ Trifft zu ☐

Was fiel während der Durchführung auf?

C **«Check» → Überprüfung**

Die Aufgaben wurden erfolgreich umgesetzt (d.h. die Indikatoren für den Erfolg wurden erreicht):

Trifft nicht zu ☐ Trifft eher nicht zu ☐ Trifft eher zu ☐ Trifft zu ☐

Wo gibt es Verbesserungsmöglichkeiten?

Welche neuen Aufgaben wurden durch den Zyklus entdeckt?

A **«Act» → Anpassung**

Folgende Aufgaben waren erfolgreich **und** werden im nächsten Zyklus weiterhin ausgeführt:

Folgende Aufgaben werden für den nächsten Zyklus überarbeitet/angepasst:

Folgende Aufgaben kommen im nächsten Zyklus neu dazu:

Nach Beenden dieses Zyklus werden die Aufgaben aus «A» im nächsten PDCA-Zyklus unter «P» ausgearbeitet.

2. Teil *PDCA-Zyklus* *1/1*

XIII. Instruction videos fokus°PDCA

For the instruction videos, see:

Part I: https://youtu.be/RGCm3oT6zKs

Part II: https://youtu.be/7EbvPD8Ci1U

B2

XIV. Questionnaire TopCompliance I: Implementation start

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Fragebogen zur Einführung der Medikamenten-Erinnerung TopCompliance in der Apotheke

Bei Ihnen wurde die Medikamenten-Erinnerung TopCompliance als neue Dienstleistung in PropharmaX installiert. Sie haben bereits eine Instruktion dazu erhalten und TopCompliance einen Tag angewendet. Wir würden gerne eine erste Einschätzung erhalten, was Sie von der Medikamenten-Erinnerung TopCompliance halten. Die erhobenen Daten werden anonymisiert erhoben und ausschliesslich von der Universität Basel ausgewertet.

Vielen Dank für Ihre wertvolle Rückmeldung. Datum:_____

Bitte nehmen Sie zu folgenden Aussagen Stellung.

Einschätzung der Medikamenten-Erinnerung TopCompliance			
1.	Ich denke die Medikamenten-Erinnerung TopCompliance passt in das Dienstleistungsangebot unserer Apotheke.	☐ Ja	☐ Nein
	Begründung:		
2.	Ich denke die Medikamenten-Erinnerung TopCompliance ist eine sinnvolle Dienstleistung für unsere Kunden.	☐ Ja	☐ Nein
	Begründung:		

27.8.2020 Version 1

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3.	Ich denke unsere Kunden*innen werden die Medikamenten-Erinnerung TopCompliance nutzen wollen	☐ Ja	☐ Nein
	Begründung:		
4.	Ich denke ich werde unsere Kunden*innen ansprechen ob Sie die Medikamenten-Erinnerung TopCompliance nutzen wollen	☐ Ja	☐ Nein
	Begründung:		

Angaben zu Ihrer Person

Beruf: _____
Jahrgang: _____
Geschlecht:
☐ Männlich
☐ Weiblich

Anzahl Jahre Berufserfahrung in der Offizin: _____Jahre

Arbeitspensum in der Apotheke in Prozent: _____%

27.8.2020 Version 1

XV. Questionnaire TopCompliance II: After 1 Month

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II. Fragebogen zur Medikamenten-Erinnerung TopCompliance

Sie haben nun seit ca. 1 Monat die Medikamenten-Erinnerung «TopCompliance» bei Ihnen auf ProPharma X installiert und mit der Dienstleistung erste Erfahrungen gewonnen. Bitte nehmen Sie zu folgenden Aussagen Stellung. Die Daten werden anonymisiert erhoben und ausschliesslich von der Universität Basel ausgewertet.

Vielen Dank für Ihre wertvolle Rückmeldung.

Einschätzung der Medikamenten-Erinnerung TopCompliance			
1.	Ich denke die Medikamenten-Erinnerung TopCompliance passt in das Dienstleistungsangebot unserer Apotheke.	☐ Ja	☐ Nein
	Begründung:		
2.	Ich denke die Medikamenten-Erinnerung TopCompliance ist eine sinnvolle Dienstleistung für unsere Kunden.	☐ Ja	☐ Nein
	Begründung:		

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Persönliche Anwendung der Medikamenten-Erinnerung TopCompliance			
3.	Fragen Sie die Kunden, ob Sie die Medikamenten-Erinnerung TopCompliance haben wollen?	☐ Ja	☐ Nein
Falls **Nein** warum nicht:			

Bitte nehmen Sie zu folgenden Aussagen Stellung. Bei einer Vergabe einer Note von 1 oder 2, begründen Sie die Bewertung bitte in den Kommentaren. Bitte notieren sie "k.A." falls Sie zu einer Aussage keine Noten geben möchten oder können.

Notenskala: 1 = trifft nicht zu, 2 = trifft eher nicht zu, 3 = trifft eher zu, 4 = trifft zu

Akzeptanz und Anwendungsfreundlichkeit der Medikamenten-Erinnerung TopCompliance			
4.	Unsere Kunden wollen die Medikamenten-Erinnerung TopCompliance nutzen, wenn ich Sie auf das Angebot anspreche.	Note: ____	Kommentar:_____
5.	Ich fand die Medikamenten-Erinnerung TopCompliance einfach zu benutzen.	Note: ____	Kommentar:_____

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6.	Die Medikamenten-Erinnerung TopCompliance war einfach in meinen Arbeitsablauf zu integrieren.	Note: ____	Kommentar:_____
7.	Man lernt schnell mit der die Medikamenten-Erinnerung TopCompliance zu arbeiten.	Note: ____	Kommentar:_____

Kommentare/ Bemerkungen zur Medikamenten-Erinnerung TopCompliance

Angaben zu Ihrer Person
Beruf: _____ Jahrgang: _____ Geschlecht: ☐ Männlich ☐ Weiblich Anzahl Jahre Berufserfahrung in der Offizin: _____ Arbeitspensum in der Apotheke in Prozent: _____

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CURRICULUM VITAE AND PUBLICATION LIST

Lebenslauf

Persönliche Angaben

Name	Pascal Claude Baumgartner
Geburtsdatum	25. Juni 1990
Heimatort	Hasle bei Burgdorf BE/ Winterthur ZH
Zivilstand	ledig, keine Kinder
Nationalität	Schweiz

Ausbildung

02/2021 – 12/2021	**CAS in Nutrition for Disease Prevention and Health** ETH Zürich
09/2017	**Staatsexamen in Pharmazie** **Master in Pharmazie**
09/2015 – 09/2017	**Masterstudium Pharmazie** Universität Basel
09/2011 – 08/2015	**Bachelorstudium Pharmazie** Universität Bern und Basel
11/2010-08/2011	**Militärdienst Sanitätssoldat DD**
01/10-10/10	**Auslandaufenthalt USA**
12/2009	**Matura** Gymnasium Münchenstein, Baselland

Berufsbezogene Arbeitserfahrung

Seit 12/2017	**PhD-Student an der Universität Basel** – Start einer Dissertation an der Universität Basel, Departement für pharmazeutische Wissenschaften, Pharmaceutical Care Research Group Title: Development and testing of practicable strategies for professional pharmacy services, with medication adherence as an illustrative example
Seit 12/2017	**Apotheker Notfallapotheke Basel** – Apotheker 10%: Sonntags –und Abenddienste – Erfahrung im Notfalldienst – Spezialisiert auf den Spitalaustritt

	– Pflichtenheft Tropimed: Instruktion von Mitarbeiter der Notfallapotheke, sowie Studenten der Universität Basel
09/2016 – 07/2017	**Assistenzjahr** Kern- und Mantelassistenz in der Stedtli-Apotheke in Laufen BL
01/2016 – 06/2016	**Masterarbeit** „CLEOde - Translation and Validation of a French Tool to Assess the Impact of Clinical Pharmacists' Interventions" betreut durch Prof. Dr. Kurt Hersberger, Dr. Markus Lampert, Dr. Fabienne Böni und Dominik Stämpfli, Universität Basel

Weitere Ausbildungen

06/2018	**Good Clinical Practice: Basiskurs** Clinical Trial Unit Basel
01/2010	**Pflegehelfer SRK** Im Rahmen der Ausbildung zum Sanitätssoldat mit Funktion Notfallspezialist in der Schweizer Armee

Sprachen

Deutsch	Muttersprache
Englisch	sehr gute Kenntnisse in Wort und Schrift
Französisch	Verständigung möglich, fähig einfache Dialoge zu führen

Publikationen

1. P. C. Baumgartner, B. Vrijens, S. Allemann, K. E. Hersberger and I. Arnet, Delta T, a Useful Indicator for Pharmacy Dispensing Data to Monitor Medication Adherence. Pharmaceutics, 2022. 14(1): p. 103.
2. P. C. Baumgartner, N. Comment, K. E. Hersberger and I. Arnet, Development and testing of a framework for defining a strategy to address medication adherence during patient encounters in community pharmacies, Exploratory Research in Clinical and Social Pharmacy, 2022: p. 100123.
3. P.C. Baumgartner, R.B. Haynes, K.E. Hersberger, and I. Arnet, A Systematic Review of Medication Adherence Thresholds Dependent of Clinical Outcomes. Frontiers in pharmacology, 2018. 9(1290)
4. D. Stämpfli, P. Baumgartner, F. Boeni, P. Bedouch, M.L. Lampert, and K.E. Hersberger, Translation and validation of a tool to assess the impact of clinical pharmacists' interventions. International journal of clinical pharmacy, 2019. 41(1): p. 56-64.
5. Albert, V., P.C. Baumgartner, V. Bernhardt, K.E. Herberger, and I. Arnet, How do elderly outpatients manage polypharmacy including DOAC - A qualitative analysis highlighting a need for counselling. Research in Social and Administrative Pharmacy, 2021.
6. I. Arnet, P.C. Baumgartner, V. Bernhardt, M.L. Lampert, and K.E. Herberger Lessons Learned From Three Months of Pharmaceutical-Care Digital-Education at the University of Basel, Switzerland. The Senior care pharmacist 2020; 35: 479-481
7. Glutenfreie Diät Teil I: Zöliakie und verwandte Krankheitsbilder, i.m@il Offizin 2018; 21
8. Glutenfreie Diät Teil II: Weitere Indikationen, i.m@il Offizin 2018; 22
9. Fruktose: Eine riskante Alternative zu Glukose?, i.m@il Offizin 2019; 11
10. Therapie der Schilddrüsenunterfunktion, i.m@il Offizin 2019; 18
11. Periorale Dermatitis, i.m@il Offizin 2020; 9

12. Update Rosazea, i.m@il Offizin 2020; 10
13. Update Omega-3 Fettsäuren und kardiovaskuläre Erkrankungen, im@il Offizin 2021, 4

Vorträge

P. C. Baumgartner, K. E. Hersberger, I. Arnet; Medication Adherence from dispensing data – Population Characteristics for a new approach to catch dynamic behavior
ESCP International Workshop 2019, Antwerp, Belgium

Poster Präsentationen

1. P. C. Baumgartner, R. B. Haynes, K. E. Hersberger, I. Arnet, How much adherence is needed to reach the desired clinical outcome? A systematic review. ESPACOMP 2018, Dublin, Ireland
2. P. C. Baumgartner, K. E. Hersberger, I. Arnet, A new approach to catch the dynamic of medication adherence with clustering refill patterns in long term medication users. ESPACOMP 2019, Porto, Portugal
3. P. C. Baumgartner, N. Comment, K. E. Hersberger, I. Arnet, How to address medication adherence in daily Swiss pharmacy practice? Proposal of workable strategies. 7th PCNE Working Symposium 2020, Egmond aan Zee, the Netherlands
4. P.C. Baumgartner, E. Scherer, K. E. Hersberger, I. Arnet, fokus°PDCA: Development of an implementation tool for professional pharmacy services, 12th PCNE online Working Congress 2021, Basel, Switzerland