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Development of an intervention to improve informational continuity of care in older patients with polypharmacy at the interface between general practice and hospital care: protocol for a participatory qualitative study in Germany

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ABSTRACT

Introduction Older patients with multimorbidity, polypharmacy and related complex care needs represent a growing proportion of the population and a challenge for healthcare systems. Particularly in transitional care (hospital admission and hospital discharge), medical errors, inappropriate treatment, patient concerns and lack of confidence in healthcare are major problems that may arise from a lack of information continuity. The aim of this study is to develop an intervention to improve informational continuity of care at the interface between general practice and hospital care.

Methods and analysis A qualitative approach will be used to develop our participatory intervention. Overall, 32 semistructured interviews with relevant stakeholders will be conducted and analysed. The stakeholders will include healthcare professionals from the outpatient setting (general practitioners, healthcare assistants, ambulatory care nurses) and the inpatient setting (clinical doctors, nurses, pharmacists, clinical information scientists) as well as patients and informal caregivers. At a series of workshops based on the results of the stakeholder analyses, we aim to develop a participatory intervention that will then be implemented in a subsequent pilot study. The same stakeholder groups will be invited for participation in the workshops.

Ethics and dissemination Ethical approval for this study was waived by the Ethics Committee of Goethe University Frankfurt because of the nature of the proposed study. Written informed consent will be obtained from all study participants prior to participation. Results will be tested in a pilot study and disseminated at (inter)national conferences and via publication in peer-reviewed journals.

Trial registation number Clinical Trials Register: registration number DRKS00027649.

Strengths and limitations of this study

- The proposed study takes a participatory approach and considers stakeholders' perspectives in all phases of the project.
- Based on the results of qualitative stakeholder analysis, a complex intervention will be developed that takes into account existing structures and stakeholders' and patients' needs.
- As the COVID-19 pandemic will make it necessary to conduct all interviews and workshops online, older adults and people with technical challenges may not be able to participate in the study or only with the support of relatives.

INTRODUCTION

In transitional care (hospital admission and hospital discharge), a lack of information continuity often leads to medication problems such as medical errors, inappropriate treatment, patient concerns and a lack of confidence in healthcare.[1 2] Studies have underlined the potential risk of unintended medication discrepancies at transitions of care and demonstrated that these can lead to an increase in adverse effects, drug interactions and undertreatment or overtreatment. They have further shown that when hospitals fail to quickly provide information on treatments after discharge, a lack of both coordination and quality can result, which further increases risk to patients.[3–7] Multimorbidity and polypharmacy may further contribute

to the complexity and to the potential consequences of medication changes at points of transition. Patients with multimorbidity and polypharmacy tend to have worse outcomes (lower quality of life, higher mortality, longer hospital stays, more postoperative complications) and experience poorer health. The 2020 drug report by the German statutory health insurer BARMER emphasises problems at the transitions of care such as insufficient information on patients' medication at the time of admission and of discharge.[8] Of hospitalised patients, 44.9% regularly take more than five medications (polypharmacy). Furthermore, 50% of insured persons taking more than 10 medications are admitted to hospital at least once a year. As patients with multimorbidity, polypharmacy and subsequent complex care needs represent a growing proportion of the population,[9] a smooth transition from the inpatient to the outpatient sector is becoming increasingly important.[1] In this context, both general practitioners (GPs) and hospital physicians see a strong need to improve continuity of care.[1 10] Information continuity at the interface between primary care physicians and clinics is essential for high-quality care and the prevention of treatment errors.[1]

Scientific evidence shows that improved continuity of care can moderate the healthcare risks surrounding multimorbidity and polypharmacy and improve treatment outcomes. It also shows that (complex) interventions in polypharmacy (eg, drug reviews) can improve care processes and outcomes.[11] Interventions to optimise medication use in polypharmacy and multimorbidity are often complex, which complicates their development, implementation and evaluation. In addition, delayed, unreliable and poor communication at the interface between family practices and hospitals further increases complexity.[12]

Guidance on intervention development recommends planning the development process by first identifying, defining and operationalising the problem.[13 14] In order to design a successful intervention, it is also important to understand the problem within its specific context[13] and to consider the perspectives of participating stakeholder groups. Qualitative methods can help explore, define and describe stakeholders' problems and their differing views.[15]

The Heading to ContinuitY of Prescribing in ElderRly with MultImOrbidity iN Transitional Care (HYPERION-TransCare) project will therefore address the described challenges and involve relevant stakeholders in all stages of the development process. To ensure acceptance and implementability, the development of a complex intervention and study design will include healthcare professionals involved in the care of hospitalised older patients with multimorbidity and polypharmacy from different settings (general practices, hospitals, ambulatory care services), as well as patient (representatives) and their informal caregivers.[16] As the theoretical importance of an individual process increases when it is considered as part of a whole, real course of events, information obtained in the research process will not be considered alone, but be interpreted as part of a process flow.[17] The aim of the project is to use a participatory approach involving all relevant stakeholders to (1) develop and (2) pilot-test an intervention to improve informational continuity of care.

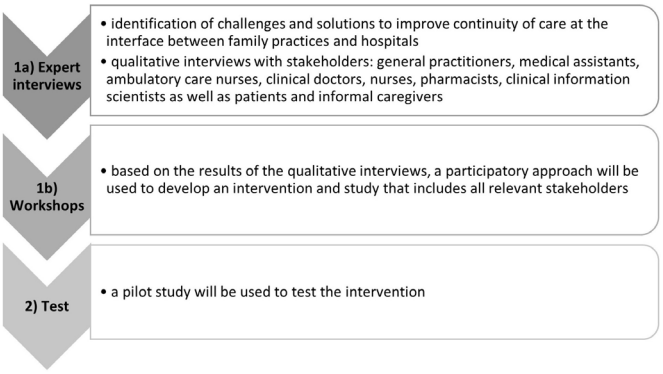

Figure 1 Flowchart of the HYPERION-TransCare-Study.

METHODS AND ANALYSIS

HYPERION-TransCare project

This work is embedded in the HYPERION-TransCare project (grant number 01GK1906A). HYPERION-TransCare is one of the two research projects that is being conducted under the umbrella of SaxoForN,[18] which is a transregional practice-based research network in primary care that is being established in the German states of Saxony and Hesse (SaxoForN). HYPERION-TransCare consists of two substudies: in substudy 1, a complex intervention will be developed to improve continuity of care at the interface between outpatient and inpatient care, while in substudy 2, a pilot study will be used to test the intervention for feasibility and implementability (see figure 1). This study protocol concerns substudy 1 of the HYPERION-TransCare project.

Research objectives of the expert interviews

- Identification of stakeholders (professionals and non-professionals)
  - Who plays an important role in the transitional care of older patients with multimorbidity and polypharmacy in cases of (un)planned hospitalisation, including patients' return home? What processes are they involved in and how?
- Identification of target group with greatest need of an intervention
  - Which patients are at risk of experiencing limited continuity/quality of care (with a focus on drug therapy) due to an (un)planned hospital stay? What risk factors do stakeholders mention?
- Examination of the organisation of transitional drug therapy
  - What is the current situation with regard to the flow of information on medications before, during and after a hospital stay? What communication

tools are used to pass on information (written documents, contact by phone, e-mail, etc)?
- Identification of deficiencies in transitional drug therapies
  - Where is the flow of information on patients' drug therapies interrupted, both during hospital stays and when they are admitted and discharged? What further uncertainties and problems exist?
- Identification of barriers and facilitators of transitional drug therapy
  - What are the barriers and facilitators?
  - What needs to change and what might help in the implementation of the necessary changes?
- Identification of possible solutions to improve transitional drug therapy
  - In the past, what changes have been made to improve transitional drug therapy?
  - What best practices do stakeholders use in the organisation of drug therapy for their patients before, during and after a stay in hospital?
  - What wishes/ideas/suggestions/solutions do the stakeholders recommend for consideration in the future?
- Participatory development of (a) a study design to examine transitional drug therapy for older people with multimorbidity and polypharmacy and (b) a complex intervention on appropriateness and continuity of drug treatment to improve it
  - What group of patients should the intervention focus on?
  - In order to improve transitional drug therapy, what elements should such an intervention include?
  - What study design/instruments/outcome measures will be implementable and feasible for study participants?

Aims of the workshops

- To define the goals of a change in standard practice in transitional medication care.
- To select the elements of an innovative medication management intervention in transitional care (these might include computer-assisted strategies and communication procedures).[2]
- To adapt and tailor the intervention components to form a complex intervention design.
- To analyse barriers and facilitators of the complex intervention and study design.
- To select and define implementation strategies that address the local context.

Study design

In accordance with SaxoForN's guidelines for stakeholders participating in research,[19] the aim of this study is to use a participatory approach in the development of an intervention that improves continuity of care at the interface between family practice and hospital care. In a first step, (1) qualitative expert interviews will be conducted with the aim of exploring the challenges and medication-related problems experienced by different stakeholders. Results from the interviews will be presented to and discussed with other stakeholders in (2) subsequent interdisciplinary workshops in order to develop a new intervention that will then be tested in a pilot study.

Participants

In order to understand complex care at the interface between inpatient and outpatient care, the following stakeholders involved in the care of older hospitalised patients with polypharmacy will be included. This preliminary selection of participants can be changed and extended based on interview results:

- Genral Practicioners, as they often function as the last point of contact before a hospital admission and the first point of contact after a discharge.
- Clinical doctors from the internal medicine and surgical wards, as they have an overview of patients' health conditions and are involved in providing treatment, selecting medication and in the patient's hospital stay overall.
- Clinical nurses from the internal medicine and surgical wards, as they play a central role in administering medications.
- Staff at outpatient care services in home care settings, as they often assist when patients are no longer able to manage their medications.
- Healthcare assistants, as, in view of limited resources and increasing complexity in healthcare, delegation is necessary where feasible and acceptable. In Germany, healthcare assistants work under the supervision of a GP, but are often trained to share responsibility and take on additional tasks.[20]
- Patients/informal caregivers/patient representatives, as the care of patients with multimorbidity and polypharmacy typically involves multiple healthcare providers and settings. In view of their complex therapeutic regimens and needs, high-quality transitional care is therefore particularly important in this vulnerable patient population. When the transition from home to hospital and back home is poor and patients and caregivers do not receive the necessary information and education, the risk of adverse events, rehospitalisation and dissatisfaction is high.[21] Studies have shown that an improvement in quality and satisfaction, as well as a reduction in costs, can be achieved by involving patients and caregivers in medication management.[22]
- Pharmacists, as the involvement of pharmacists in medication reconciliation and education can reduce adverse drug events and rehospitalisation. Their involvement results in greater patient satisfaction and continuity of care, especially in patients with complex therapeutic regimens.[23]
- IT experts who are familiar with the interface between primary care and hospital care.

GPs and medical assistants will be recruited via the practice-based research network SaxoForN. All other

professions, patients and informal caregivers will be recruited from multiple hospitals and care services by using purposive sampling. Patients and informal caregivers will be recruited via GP practices. We will also include a certified patient representative from the Federal Joint Committee ('Gemeinsamer Bundesausschuss') who will present the broader views of patients. If possible, we plan to stratify the sample by gender, type of hospital and location of hospital/GP in urban/rural region, to reflect the heterogeneity of care and possible differences in needs and care processes. We aim for equal distribution of stakeholders from both regions (Saxony and Hesse).

Data collection

Four researchers (A-AK, LR, M-SB, TSD) will conduct a total of 32 telephone interviews with stakeholders (approximately 30–45 min each) to explore setting-specific and stakeholder-specific views relating to the problem of drug therapy continuity in transitional care. We aim to include about four participants from each stakeholder group. The interviews will focus on the perceived need for change and the barriers and aspects that could potentially promote the implementation of such change. In data collection, a semistructured interview guide will be developed for each of the stakeholders. The guides will focus on their patients' medication-related experiences on admission to hospital, during hospital stays, on discharge from hospital and on their return home (including the first follow-up visit to their GP). As an example, an interdisciplinary qualitative research group at the Institute of General Practice in Frankfurt will intensively discuss one of the guides. All guides will be pretested in pilot interviews and adapted if necessary. Interviews will be audio recorded and transcribed verbatim. In order to protect participants' anonymity, transcripts will not include the names of persons or institutions.

Data analysis

All transcripts will be imported to MAXQDA 2018—interviews with inpatient medical personnel will be analysed by LR and M-SB, and interviews with outpatient medical personnel, patients and informal caregivers will be analysed by A-AK and TSD.

In the literature, a wide range of analysis methods are described.[24 25] Which analysis techniques a specific study should use depends not only on the objective, the methodological approach and the research questions but also on the amount of time, human resources and research funds available. We aim to gather process knowledge of procedures, processes and events by systematically asking interviewees about their experiences and to share their practical knowledge.[26] When it comes to gathering information from interviews, qualitative content analysis[27] is the evaluation method of choice.[26]

Workshops

Based on the analysis, we aim to conduct a series of workshops with stakeholders. The workshops, which will consist of several 'intensive workshops (IWS)' and 'synthesis workshops (SWS)', will focus on developing and shaping an intervention. We will first conduct five IWS to identify barriers and facilitators in transitional drug therapy. Two additional SWS will focus on the development of solutions to improve transitional drug therapy. The workshops will be held in both ambulatory and hospital care and with mixed stakeholder groups (see table 1).

Table 1 Workshop overview

Workshop	Stakeholders
Pre-workshop	Patients and informal caregivers
IWS 1	Patients, patient representatives and informal caregivers
IWS 2	Healthcare assistants, clinical nurses, staff of outpatient care services
IWS 3	Patients, patient representatives and informal caregivers, healthcare assistants, clinical nurses, staff of outpatient care services
IWS 4	Clinical doctors, clinical pharmacists, clinical information scientists
IWS 5	Clinical doctors, clinical pharmacists, clinical information scientists
SWS 1	All stakeholders
SWS 2	All stakeholders

IWS, intensive workshops; SWS, synthesis workshops.

Intensive workshops

IWS 1, 2 and 4 will concentrate on problems and stakeholder experiences with polypharmacy at the interface between outpatient and inpatient care, whereby the participants will conduct problem analysis based on the results of the expert interviews.

IWS 3 and 5 will focus on management processes and develop ideas on how to solve and break down the identified problems/barriers. Afterwards, participants will proceed to work on developing solutions to the problems they prioritised in IWS 1, 2 and 4 and then discuss which solutions are feasible in view of their busy daily routines. Workshop participants will be asked to use colours or numbers to prioritise the ideas they regard as the most important. The most highly ranked 3–5 ideas will then be considered in the next step (synthesis workshop).

Synthesis workshops

The results of the IWS will subsequently be discussed in a final series of two synthesis workshops (SWS 1 and 2) involving participants from all stakeholder groups. In the first synthesis workshop (SWS 1), all the solutions proposed in the IWS will be presented to the stakeholders and discussed in terms of their feasibility and importance. The aim of SWS 1 is to reach a consensus across all stakeholder groups on the most promising intervention ideas. In the second synthesis workshop (SWS 2), the preferred

intervention ideas will be further discussed and elaborated in preparation for a planned randomised-controlled trial, where the intervention will be implemented and evaluated in a pilot study (substudy 2).

As a result of COVID-19-related restrictions to meeting in groups, workshops will be held online using the video conference software BigBlueButton (BBB). BBB software provides data protection in accordance with current European General Data Protection Regulations.

Each IWS is intended to be about 1.5 hours long, while the synthesis workshops should last 2–3 hours. External moderators will help direct the workshops.

A pre-workshop will be conducted for patients and their caregivers to ensure their adequate involvement and participation and to prepare them for the online workshops. The aims of the pre-workshop are: first, to ensure patients have the necessary technical skills and equipment, and second, to explain and emphasise the importance of patient involvement in research. Patients will be offered individual (technical) assistance prior and during the workshops, and a qualified patient representative will explain the importance of patients' perspectives during the workshops. Furthermore, patients will gradually be familiarised with the online-workshop setting. Patients will participate in five workshops overall (pre-workshop, IWS 1, IWS 3, SWS 1 and SWS 2). The purpose of the first two workshops (pre-workshop and IWS 1), which will only include patients, their informal caregivers and a patient representative, is to introduce patients to their peer group and to accustom them to the setting. In the next workshop (IWS 3), they will be introduced to the group of healthcare assistants/nurses/staff from outpatient care services. In view of their responsibilities, these stakeholders will inevitably communicate with patients and their informal caregivers. Studies have shown that particularly older patients value the basic personal healthcare and support provided by these stakeholder groups.[28] In the final two workshops (SWS 1 and SWS 2), all stakeholder groups will be present. The external moderator will further be instructed to obtain views from all participating stakeholders and to make sure that all views are heard.

Documentation and analysis of the workshops

Protocol notes taken from the group work and the resulting work materials (meta plans, flip charts, etc) will be documented and evaluated by the authors (A-AK, TSD, M-SB, KV, MvdA). At the end of each workshop, we will conduct a brief evaluation to explore possible design improvements that could be made to future workshops (eg, to reduce technical barriers and obstacles to the involvement of all stakeholders in discussions).

Evaluation of the participatory process

After the workshops have been completed, telephone interviews will be conducted with workshop participants to assess the success of the participatory study design from the perspective of stakeholders, that is, whether they felt they could speak freely and whether their suggestions were listened to.

Patient and public involvement

Patients and the broader public were not involved in designing the study and will not be involved in its conduct, reporting or dissemination of the results.

ETHICS AND DISSEMINATION

In the Federal State of Hesse, Germany, formal ethical approval will not be required for this investigation. However, the local ethics committee has been informed about our intention to conduct this study. The authors discussed the project with the Ethics Committee of Goethe University and ethical approval was waived. All participants will receive the data information sheet and sign the consent form. All data will be pseudonymised on transcription. The original audio files will be saved in a password-secured cloud.

Results will be tested in a pilot study, disseminated at (inter)national conferences and published in peer-reviewed journals.

Study status

The study began in October 2020. Final analyses and reporting of the results of the study are planned for the second half of 2022.

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