BMJ Open

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Journal:	*BMJ Open*
Manuscript ID	bmjopen-2021-058016
Article Type:	Protocol
Date Submitted by the Author:	06-Oct-2021
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Keywords:	PRIMARY CARE, GENERAL MEDICINE (see Internal Medicine), HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Organisation of health services < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

TITLE

Continuity of care in elderly patients with polypharmacy at the interface between family practice and hospital – a study protocol

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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 health care systems. Particularly in transitional care (hospital admission and hospital discharge), medical errors, inappropriate treatment, patient concerns and lack of confidence in health care are major problems that may arise from a lack of information continuity.

Methods and analysis

Our participatory research approach will involve relevant stakeholders from an ambulatory setting (general practitioners, medical assistants, ambulatory care nurses), from hospitals (clinical doctors, nurses, pharmacists, clinical information scientists), as well as patients and informal caregivers. We will conduct stakeholder analysis based on qualitative expert interviews with stakeholders and include the results in the participatory development of an intervention.

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

STRENGTHS AND LIMITATIONS OF THIS STUDY

- The proposed study includes a participatory approach including stakeholders' perspectives in all phases of the project.
- Based on the results of a qualitative stakeholder analysis, a complex intervention will be participatory developed with stakeholders, which will be adapted to the existing structures and stakeholders' and patients' needs.
- In times of the Corona pandemic, all interviews and workshops will take place online. Especially elderly people 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 health care [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 under- 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 emphasizes known problems at the transitions of care such as insufficient information on patients' medication at the time of admission and of discharge [8]. Of hospitalized 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 consequent 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 health care risks surrounding multimorbidity and polypharmacy and improve treatment outcomes. It also shows that (complex) interventions in polypharmacy (e.g. drug reviews) can improve care processes and outcomes [11]. Interventions to optimize 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 operationalizing 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 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 health care professionals involved in the care of hospitalized older patients with multimorbidity and polypharmacy from different target settings (general practices, hospitals, ambulatory care services), as well as patient (representatives) and their informal caregivers [16]. Information obtained in the research process will not be considered alone, but be interpreted as part of a process flow, as the theoretical importance of an individual process increases when considered as part of a whole real course of events [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.

METHODS

HYPERION-TransCare project

This work is embedded in the HYPERION-TransCare project (Heading to ContinuitY of Prescribing in ElderRly with MultImOrbidity iN Transitional Care, grant number 01GK1906A). HYPERION-TransCare is one of 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 Saxony and Hesse (SaxoForN). HYPERION-TransCare consists of two sub-studies: in sub-study 1, a complex intervention will be developed to improve continuity of care at the interface between outpatient and inpatient care, while in sub-study 2, a pilot study will be used to test the intervention for feasibility and implementability (see **Figure 1**). This study protocol concerns sub-study 1 of the HYPERION-TransCare project.

[About here: Figure 1]

Research objectives of the expert interviews

1. **Identification of stakeholders (professionals and non-professionals)**
   - Who plays an important role in the transitional care of elderly patients with multimorbidity and polypharmacy in cases of (un-)planned hospitalization, including patients' return home? What processes are they involved in and how?
2. **Identification of target group with greatest need of an intervention**
   - What 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?
3. **Examination of the organization of transitional drug therapy**
   - What is the current situation with regard to the flow of drug information before, during and after a hospital stay? What communication tools are used to pass on information (written documents, contact by phone, e-mail etc.)?

4. **Identification of deficiencies in** transitional drug therapies

- With regard to patients' drug treatment during hospitalization and at the time of admission and discharge from hospital, where is the flow of information interrupted. What further uncertainties and problems exist?

5. **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?

6. **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 organization of drug therapy for their patients before, during and after a stay in hospital?
- What wishes, ideas/suggestions/solutions do the stakeholders mention for the future?

7. **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 components should such an intervention include?
- What study design/instruments/outcome measures will be implementable and feasible for study participants?

Aims of the workshops

- (1) to define the goals of a change in general practice in transitional medication care,
- (2) to select the components of a medication management intervention in transitional care, such as computer-assisted strategies and communication procedures, [2].
- (3) to adapt and tailor the intervention components to form a complex intervention design,
- (4) to analyze barriers and facilitators of the complex intervention and study design,
- (5) to select and define implementation strategies that address the local context.

Study design

According to SaxoForN research standards of participating stakeholders 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. In a first step, 1) qualitative expert interviews will be conducted with the aim of exploring the challenges and medication-related problems experienced by the 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, the following stakeholders involved in the care of older hospitalized patients with polypharmacy will be included. This preliminary selection of participants can be changed and extended based on interview results:

1. **General practitioners,** as they often function as the last point of contact before hospital admission and the first point of contact after discharge
2. **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
3. **Clinical nurses** from the internal medicine and surgical wards, as they play a central role in administering the medications
4. **Staff of out-patient care services** in home care settings when patients are no longer able to manage their medications
5. **Health care assistants** as, in view of limited resources and increasing complexity in health care, delegation is necessary where feasible and acceptable. In Germany, health care assistants work under the supervision of a general practitioner, but often are trained to share responsibility and take on additional tasks [20].
6. **Patients/informal caregivers,** as the care of patients with multimorbidity and polypharmacy typically involves multiple health care 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, rehospitalization 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].
7. **Pharmacists,** as the involvement of pharmacists in medication reconciliation and education can reduce adverse drug events and rehospitalization. This results in greater patient satisfaction and continuity of care, especially in patients with complex therapeutic regimens [23].
8. **IT** experts that are familiar with the interface between primary care and hospital

GPs, and medical assistants, will be recruited via the practice based research network SaxoForN. All other professions, patients and informal caregivers will be recruited using

purposive sampling. If possible, we plan to stratify the sample by gender, type of hospital, location of hospital/GP in urban/rural region, to reflect the heterogeneity of care and possible differences in needs and care processes.

Data collection

Approximately 30 telephone interviews with stakeholders will be conducted (approx. 30-45 min.) by four different researchers (AK, LR, MSB, TSD) to explore setting and stakeholder-specific views relating to the problem of drug therapy continuity in transitional care. 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 semi-structured interview guide will be developed for each of the different stakeholders. The guide will focus on their 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, one guideline will be discussed intensively by an interdisciplinary qualitative research group at the Institute of General Practice in Frankfurt. All guidelines will be pre-tested 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 analyzed by LR and MSB, and interviews with outpatient medical personnel, patients and informal caregivers will be analyzed by AK and TSD.

The diversity of possible analysis methods can be seen in literature [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 that are focusing the development and shaping of an intervention. These will consist of several "intensive workshops" and "synthesis workshops". We will first conduct five intensive workshops (IWS) to identify barriers and facilitators in transitional drug therapy. Two additional synthesis workshops (SWS) will focus on the development of solutions to improve tansitional

drug therapy. The workshops will be held cross-setting (ambulatory and hospital care) and with mixed stakeholder groups (see Table 1).

Table 1. Workshop overview

Workshop	Stakeholders
IWS1	Patients, patient representatives and informal caregivers
IWS2	medical assistants, clinical nurses, staff of out-patient care services
IWS3	Patients, patient representatives and informal caregivers, medical assistants, clinical nurses, staff of out-patient care services
IWS4	Clinical doctors, clinical pharmacists, clinical information scientists
IWS5	Clinical doctors, clinical pharmacists, clinical information scientists
SWS1	All stakeholders
SWS2	All stakeholders

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

IWS 3 and 5 will focus on management 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 prioritized in IWS 1, 2 and 4 and then discuss which solutions are feasible in view of their busy daily routines.

The results of the intensive workshops will subsequently be discussed in a final series of two synthesis workshops (SWS 1, 2) with participants from all stakeholder groups, with the aim of developing a complex intervention and study design to be implemented and evaluated in our planned pilot study (sub-study 2).

As a result of Covid-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 intensive workshop is intended to be about 1.5 hours long, while the synthesis workshops should last 2 to 3 hours. Independent persons will moderate the workshops.

Documentation and analysis of the workshops

Protocol notes taken from the group work and the resulting work materials (meta plan, flip chart, etc.) will be documented and evaluated by the authors (AK, TSD, MSB, KV, MVDA). At the end of each workshop, we will conduct a brief evaluation to explore challenges regarding the workshop design we could address to optimize in the following workshop (i.e. technical barriers, fair possibilities for conversation).

Evaluation of the participatory process

Following the conduction of all workshops, telephone interviews will be conducted with workshop participants to assess the success of the participatory study design from stakeholders' perspective i.e. whether they felt free to speak and their suggestions were heard.

ETHICS AND DISSEMINATION

In the Federal State of Hesse/Germany, formal ethical approval in accordance with the Medical Association's professional code of conduct is not required for this investigation. However, the local ethics committee was informed about our intention to conduct this study. The authors discussed the project with the ethics committee of Goethe-University and received a waiver to conduct the interviews and workshops. All participants will receive the data information sheet and sign the consent form. All data will be anonymized upon 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.

Patient and public involvement

Patients or the public were not involved in the design, or conduct, or reporting, or dissemination plans of the study.

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Authors' contributions

CM and KV developed the idea for this project and handled the grant application. MSB and TSD wrote the initial draft of the protocol. MSB, TSD, LR, AK conducted and analyzed the interviews. MSB, TSD, LR, AK, KV, MVDA, JP, KM, JE and FB developed the interview guidelines and the content of the workshops. All authors contributed to the protocol.

Funding statement

This work was supported by the Federal Ministry of Education and Research in Germany [BMBF], grant number [01GK1906A].

Competing interests statement

The authors state to have no competing interests.

Acknowledgement

We would like to thank Phillip Elliott for editing the manuscript.

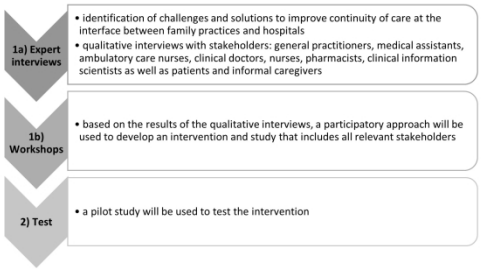

Figure 1. Flowchart for the HYPERION-TransCare study

338x190mm (300 x 300 DPI)

BMJ Open

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Journal:	*BMJ Open*
Manuscript ID	bmjopen-2021-058016.R1
Article Type:	Protocol
Date Submitted by the Author:	01-Mar-2022
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Primary Subject Heading:	General practice / Family practice
Secondary Subject Heading:	Qualitative research, Research methods, Patient-centred medicine
Keywords:	PRIMARY CARE, GENERAL MEDICINE (see Internal Medicine), HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Organisation of health services < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

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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 health care systems. Particularly in transitional care (hospital admission and hospital discharge), medical errors, inappropriate treatment, patient concerns and lack of confidence in health care 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 semi-structured interviews with relevant stakeholders will be conducted and analyzed. 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.

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 health care [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 under- 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 emphasizes problems at the transitions of care such as insufficient information on patients' medication at the time of admission and of discharge [8]. Of hospitalized 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 health care risks surrounding multimorbidity and polypharmacy and improve treatment outcomes. It also shows that (complex) interventions in polypharmacy (e.g. drug reviews) can improve care processes and outcomes [11]. Interventions to optimize 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 operationalizing 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 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 health care professionals involved in the care of hospitalized 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.

METHODS AND ANALYSIS

HYPERION-TransCare project

This work is embedded in the HYPERION-TransCare project (Heading to ContinuitY of Prescribing in ElderRly with MultImOrbidity iN Transitional Care, grant number 01GK1906A). HYPERION-TransCare is one of 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 sub-studies: in sub-study 1, a complex intervention will be developed to improve continuity of care at the interface between outpatient and inpatient care, while in sub-study 2, a pilot study will be used to test the intervention for feasibility and implementability (see **Figure 1**). This study protocol concerns sub-study 1 of the HYPERION-TransCare project.

[About here: Figure 1]

Research objectives of the expert interviews

1. **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 hospitalization, including patients' return home? What processes are they involved in and how?
2. **Identification of target group with greatest need of an intervention**
   - What 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?
3. **Examination of the organization 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.)?

4. **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?

5. **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?

6. **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 organization 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?

7. **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

- (1) to define the goals of a change in standard practice in transitional medication care,
- (2) to select the elements of an innovative medication management intervention in transitional care (these might include computer-assisted strategies and communication procedures) [2].
- (3) to adapt and tailor the intervention components to form a complex intervention design,
- (4) to analyze barriers and facilitators of the complex intervention and study design,
- (5) 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 hospitalized patients with polypharmacy will be included. This preliminary selection of participants can be changed and extended based on interview results:

1. **General practitioners,** as they often function as the last point of contact before a hospital admission and the first point of contact after a discharge.
2. **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.
3. **Clinical nurses** from the internal medicine and surgical wards, as they play a central role in administering medications.
4. **Staff at out-patient care services** in home care settings, as they often assist when patients are no longer able to manage their medications.
5. **Health care assistants** as, in view of limited resources and increasing complexity in health care, delegation is necessary where feasible and acceptable. In Germany, health care assistants work under the supervision of a general practitioner, but are often trained to share responsibility and take on additional tasks [20].
6. **Patients/informal caregivers/patient representatives,** as the care of patients with multimorbidity and polypharmacy typically involves multiple health care 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, rehospitalization 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].

7. **Pharmacists,** as the involvement of pharmacists in medication reconciliation and education can reduce adverse drug events and rehospitalization. Their involvement results in greater patient satisfaction and continuity of care, especially in patients with complex therapeutic regimens [23].
8. **IT** experts that 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, 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 (AK, LR, MSB, TSD) will conduct a total of 32 telephone interviews with stakeholders (approx. 30-45 min. each) to explore setting- 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 semi-structured 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 pre-tested 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 analyzed by LR and MSB, and interviews with outpatient medical personnel, patients and informal caregivers will be analyzed by 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" and "synthesis workshops" will focus on developing and shaping an intervention. We will first conduct five intensive workshops (IWS) to identify barriers and facilitators in transitional drug therapy. Two additional synthesis workshops (SWS) will focus on the development of solutions to improve transitional drug therapy. The workshops will be held 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
IWS1	Patients, patient representatives and informal caregivers
IWS2	Healthcare assistants, clinical nurses, staff of out-patient care services
IWS3	Patients, patient representatives and informal caregivers, healthcare assistants, clinical nurses, staff of out-patient care services
IWS4	Clinical doctors, clinical pharmacists, clinical information scientists
IWS5	Clinical doctors, clinical pharmacists, clinical information scientists
SWS1	All stakeholders
SWS2	All stakeholders

Abbreviations: IW=intensive workshop, SW=synthesis workshop

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 prioritized 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 colors or numbers to prioritize the ideas they regard as the most important. The most highly ranked 3 to 5 ideas will then be considered in the next step (synthesis workshop).

Synthesis workshops

The results of the intensive workshops will subsequently be discussed in a final series of two synthesis workshops (SWS 1, 2) involving participants from all stakeholder groups. In the first synthesis workshop (SWS1), all the solutions proposed in the intensive workshops will be presented to the stakeholders and discussed in terms of their feasibility and importance. The aim of SWS1 is to reach a consensus across all stakeholder groups on the most promising intervention ideas. In the second synthesis workshop (SWS2), the preferred intervention ideas will be further discussed and elaborated in preparation for a planned randomized-controlled trial, where the intervention will be implemented and evaluated in a pilot study (sub-study 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 intensive workshop is intended to be about 1.5 hours long, while the synthesis workshops should last 2 to 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 aim of the pre-workshop is, firstly to ensure patients have the necessary technical skills and equipment, and secondly, to explain and emphasize 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 familiarized with the online-workshop setting. Patients will participate in five workshops overall (pre-workshop, IWS1, IWS3, SWS1 and SWS2). The purpose of the first two workshops (pre-workshop and IWS1), 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 (IWS3), they will be introduced to the group of healthcare assistants/nurses/staff from out-patient 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 health care and support provided by these stakeholder groups [28]. In the final two workshops (SWS1 and SWS2), 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 (AK, TSD, MSB, 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 (e.g. 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, i.e. 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 pseudonymized upon 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.

** ** **

Contributors

CM and KV developed the idea for this project and handled the grant application. The research idea was further developed by AIG, CM, KV and MVDA. MSB and TSD wrote the initial draft of the protocol. MSB, TSD, LR, AAK conducted and analyzed the interviews. MSB, TSD, LR, AAK, KV, MVDA, JP, KM, JE and FB developed the interview guides and the content of the workshops. MSB, TSD, LR, AAK, SSR, JP and FB recruited study participants. MSB, TSD, LR, AAK, KV, MVDA, JP, KM, JE and FB conducted the workshops. All authors contributed to the protocol.

Funding

This work was supported by the Federal Ministry of Education and Research in Germany [BMBF], grant number [01GK1906A].

Competing interests

The authors state to have no competing interests.

Acknowledgments

We would like to thank Phillip Elliott for editing the manuscript.

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Figure 1. Flowchart of the HYPERION-TransCare study

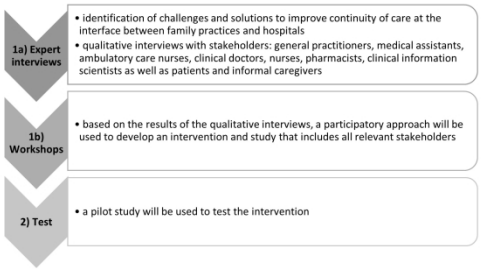

Figure 1. Flowchart for the HYPERION-TransCare study

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