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Empowering the patient? Medicines communication during hospital discharge: A qualitative study at an internal medicines ward in Norway.

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Abstract

Objective

Effective communication and patient empowerment in transition of care is an important step to ensure medication safety. Patients discharged from hospital are often expected to assume self-management, frequently without health care personnel (HCPs) having ensured patients' motivation or skills. The aim of this study was to explore and understand different processes and approaches for medicines communication during hospital discharge, especially:

- how patients are empowered through the discharge process
- how the patient experiences the medicines communication

Design

Qualitative observations combined with semi-structured interviews and drug reconciliation. The content analysis combined data from observations and data from patient interviews focusing on medicines communication.

Setting

The observational study setting was at an internal medicines ward at a university hospital in Norway.

Participants

Nine patients aged 49-90 years were included at the hospital, close to the day of discharge, observed during HCPs encounters, and interviewed 1-2 weeks after discharge.

Results

The analysis revealed the following themes: 1) Patient centred care (PCC) which included 'understanding and involvement in the patient-as-person', 'establishment of a therapeutic alliance', 'sharing power and responsibility', and 2) Biomedical (conventional) care including sub-themes 'HCPs in power and control' and 'optimizing medical outcomes, following guidelines'.

Conclusions

The results give a broader understanding of how patients experience medicines communication during hospital discharge. Even though elements of PCC was observed in several encounters, overall communication was not sufficiently fostering empowerment of the patient. Spending time with patients, building relations based on mutual trust seemed to be undervalued. Both patients and HCPs appear to be inculcated by the biomedical tradition, and uncertain about roles and opportunities associated with PCC. Attention to patient preferences and core elements of the PCC model should be paid from admission to empower patients in self-management of their medications.

Article summary

Strengths and limitations of this study

- This study combined real time observations and patient interviews, which is a powerful approach to understand and describe what actually happened.
- Interviews with patients and HCPs (unpublished focus group interviews with HCPs) found that they were mostly unperturbed by the presence of the observer, arguing inconsiderable observer-effects.
- Researchers with different backgrounds were involved in the analytical process, providing different perspectives (pharmacists, social scientist).
- This study was performed at one internal medicines ward located at one hospital, and it is uncertain how well the study findings inform health care contexts that differ from that in which the original study was undertaken.

Key words

Patient empowerment, patient centred care, hospital discharge, patient perspectives, medicines communication, observational study, Norway

Word count

4208

Introduction

Effective communication and patient empowerment in transition of care has been recognized as one of the most important steps to ensure medication safety (1, 2). Even so, home dwelling patients discharged from hospital are often abruptly expected to assume self-management, frequently without health care personnel (HCPs) having ensured patients' motivation or skills (3-8).

Over the last decades, healthcare systems have shifted focus from the conventional (biomedical) way of practising medicine to an ambition to become involved in the full range of difficulties patients experience (biopsychosocial model), thus covering a larger picture than the purely biological factors (5, 6). In this shift, patients are expected to move from the traditional, passive role, towards being more involved and participate in planning and decision making regarding their health and treatment (5). Patient empowerment and collaboration between patients and HCPs has been implemented in laws and health care reforms in many countries, including Norway (2, 9-12). However, progress towards improving post-discharge health outcomes has been slow and the efficacy of interventions is currently indefinite (2). A recent Cochrane report concludes that 'personalised care planning' leads to improvements in certain indicators of physical and psychological health status, and people's capability to self-manage their condition when compared to usual care (12).

Patient empowerment has been defined as the purpose in the Patient Centered Care (PCC)-framework (13). Patient empowerment is the philosophy of HCPs seeing the patient as an equal, acknowledging them as experts in their own lives (6, 14). PCC focus on dialogues, HCPs listening to and supporting the patients, building the 'therapeutic alliance' between them and patient-as-persons with the patient as an equal party in decision making (6, 15). Patients desire a PCC approach, being encouraged to mediate communication, HCPs recognizing their preferred level of engagement and supporting their self-management after discharge (11). Also highly valued by patients is HCPs' `humaneness' (e.g. warmth, respect and empathy), being given sufficient information and time, being treated as individuals, as well as the establishment of mutual trust (6).

There is extensive research on patient empowerment, PCC and related concepts, however it has to a large degree been viewed through other glasses than the patient's (5, 16). Patient values and perceptions must be appraised in order to make evidence based healthcare services supporting patient empowerment in medicines management after transition of care (17).

At hospital discharge, HCPs empowering patients is essential according to PCC. Little attention has been paid to empowerment of the medicines user during the discharge process, and how patients experience the medicines communication they are provided.

Aim of study:

The aim of this study was to explore and understand different processes and approaches for medicines communication during hospital discharge, especially:

- how patients are empowered through the discharge process
- how the patient experiences the medicines communication

Methodology

Patient and public involvement

A representative from the User's Board at the Hospital Pharmacy Enterprise, South Eastern Norway gave input on the study protocol (see Additional file 1), and ensured that the information sheet to be handed out and explained to the patients, provided a good summary of what the participants needed to know before signing the consent form.

The Norwegian hospital context

Patients admitted to hospitals in Norway receive all their medicines from the hospital during their stay but medicines are not dispensed at discharge. Home dwelling patients who are responsible for handling their medicines will normally have to go to a pharmacy to collect their prescriptions after discharge.

Approach

This study uses a qualitative research design, consisting of mostly unstructured observations with the addition of semi-structured interviews and medicines reconciliation. During the observations, the observer was present and identifiable, but without any role in the social setting (18).

Setting and sampling strategy

The observational study setting was at an internal medicines ward at a university hospital in the Oslo area, Norway. After discharge, patients were interviewed. The interviews took place in the patient's home, at a short-term nursing home department, a café or by telephone 1-2 weeks after discharge.

Inclusion of patients took place from September to December 2019, Monday to Sunday during regular daytime working hours. Twelve hospitalized patients were enrolled in the main study, close to the day of their planned discharge, and followed during HCPs encounters through to hospital discharge. Relevant information from the observations were documented in an observational form, developed and tested in a pilot study (see Additional file 2).

Ten of the patients were interviewed after discharge. An interview guide consisting of a list of items and probing questions guided the interviewer in asking open-ended questions. The guide included questions on experiences of the hospital stay, discharge and the period post-discharge, focusing on medicines information and the patient's beliefs about medicines. Also included were specific questions related to the observations of the individual patient. In connection to the interview, a medicines reconciliation was conducted according to the Integrated Medicines Management (IMM) model adapted to the Norwegian setting (19).

The sampling method was purposive. Patients eligible for inclusion should be home dwelling, responsible for their medicines administration prior to hospital admission, and expected to be discharged to their homes or a short-term nursing home department. Pre-terminal or cognitively impaired patients were not eligible.

Data collection

Patients and HCPs were approached at the hospital, and written informed consent was obtained prior to enrollment. The observers (authors KB, HBL, SER, all female) disclosed their HCP background to the patients i.e. two pharmacy students and one pharmacist. However, during the observations they dressed to appear more as "the girl from university" than HCPs dressed in white (20, 21). The observations had a patient oriented focus on the content in the medicines communication and contextual factors like behaviours, actions, activities and interactions with HCPs. All encounters with physicians or nursing staff involved in medicines communication were observed.

De-identified data were immediately stored on a protected area for sensitive data at the University of Oslo. The observations were audiotaped if the patient had a single room and if patients and HCPs

had consented. Patients gave an additional informed consent to the interview, which was audiotaped (KB, HBL). The Regional Ethics Committee assessed the study and found no ethical approval necessary. The study was approved by the Privacy Ombudsman and the Hospital Investigational Review Board March 08 2019, reference number 2019/6465. A gift (value of 150 NOK – 13 € or 14 USD) was given to the patients participating in the interviews.

Analysis

Criteria for inclusion in the analysis for this sub-study were data from observations at the day of discharge and interviews after discharge. Two patients were excluded for further analysis because of transfer to other hospital wards and one patient did not answer to attempts to arrange the post-discharge interview. This resulted in nine patients being included.

Data were transcribed consecutively to prevent memory bias. All transcribed data were analysed in Norwegian, using conventional content analysis (22). Step 1: The first part of the analysis was inductive; codes were derived directly from the first transcripts and a codebook consisting of codes theoretically relevant to the research question was developed in a first one-day consensus session (KB, HBL, SER, SKS, YA, LM). Individually, transcripts were read and codes suggested by all six analysers. These preliminary codes were put on post-its on the wall. First individually and then together, the post-its were merged (if describing the same), put into groups, or added (if new codes came up during discussions). (22). Step 2: Familiarisation with the data. KB, HBL and SER consecutively transcribed the data, and the transcripts were imported to the NVivo qualitative data analysis software (23), in which the data were coded according to the preliminary codes. A second one-day consensus session (including more transcripts), with all six analysers, was held in which the experience from the coding was discussed, and codes slightly changed. Step 3: The first author (SER) condensed text from selected code-groups into units of meaning focusing on medicines communication in the discharge process). Step 4: SER combined the code groups cross case and the identified units of meaning which were clustered into the two main themes, patient centred care (PCC, biopsychosocial, empowerment) and the biomedical framework (non-empowerment), searching for similarities, differences and connections (24). Step 5: SER reduced the content into a condensate and quotes that seemed to best reflect the themes were selected. In order to keep interpretations as close to the sociocultural context as possible and ensure interpretative validity, translation into English was done after fulfilment of the analysis.

Saturation was considered reached after constantly comparing experiences and responses of the participants against each other and the appraisal of the richness of the data (25).

The patients are presented as anonymized narratives with pseudonyms. Quotes are from observations if not specified with 'int' for interview.

Results

The result section is covering the result of the thematic analysis of observations and interview data consisting of two parts; patient centred care (PCC, empowerment) and the biomedical framework (non-empowerment). A total of 9 patients were observed and interviewed, demographics and other quantitative data are presented in table 1 and table 2.

Table 1 Demographics of the patients.

Demographics	(*n* = 9)
Sex	
Male, ♂	4
Female, ♀	5
Age, median (range)	71 (49-90)
Education	
Compulsory school/unknown	2
Upper secondary school	4
University	3
Length of hospital stay (LOS; days), median (range)	5 (4-18)
Observed days before discharge, median (range)	2 (1-6)
Main diagnoses according to discharge summary	
Atrial fibrillation	2
Pulmonary embolism	2
Pyelonephritis	1
Pulmonary edema	1
Myocardial infarction	1
Gaut	1
Heart failure	1
Citizenship	

Norwegian	8
Other	1

Table 2 Details regarding the semi structured interviews 1-2 weeks after discharge

Duration in minutes, median (range)	55 (33-87)
Location	
Home	4
Temporary sheltered unit	1
Café	3
Telephone	1

PCC: Real interest in the whole patient

When looking at HCPs' behaviour reflecting regarding real interest in the whole patient, essential elements of PCC was observed in several encounters. This could be HCPs listening to and getting to know the person behind "the patient", making an effort to acknowledge patients as experts in their own lives and supporting patients in decision-making (6, 13).

Understanding and involvement in the patient-as-person

HCPs often asked patients about their general condition, sometimes asking patients to prepare questions in advance of the encounter. Some HCPs sat down and listened actively, inviting patients to share what they had on their minds. When patients expressed complex problems, they experienced that HCPs acted on these, e.g. they were offered consultations with a psychologist or social worker.

Doctor: Do you think of something more you are wondering about? Think through or note it down, later today we can go through the medicines together.

Establishment of a therapeutic alliance

Alliances were built when HCPs recognized the patients-as-person, used their names, and included them as partners using the plural form “we”. HCPs could remember what had been important during the hospital stay, e.g. they commented on how the patient’s condition had changed to the better and they showed real interest in the further follow-up. Some of the HCPs acknowledged the patient’s previous experience and knowledge. Sometimes, HCPs could remember details about the patient’s children, jobs and private life, which seemed to have a stimulating impact on the dialogue.

Doctor: That’s definitely a good idea, we will do that.

Nurse: Here are the medicines you are familiar with. Do you want us to go through them together?

HCPs seemed honest and most often kept their promises, like getting back to the patient if they had said they would do that. Some patients experienced continuity in the follow-up and experienced that HCPs informed them about what was going to happen next, and sometimes who would come to visit when.

Nurse: We’ll see you in a while for the doctor’s visit.

Nurse: We’ll be back at 11 o’clock to take your blood pressure.

Doctor: I’ll finish up the papers and the discharge summary and then we can have a little talk around 3 o’ clock.

There were a couple of friendly faces that used to come in quite often and I think that helped because you could ask them the questions and they would get to know why you are asking and not wasting their time. John (♂, 58, int)

Sharing power and responsibility

Most of the HCPs seemed to have a focus on sharing information and increasing both their and the patients' knowledge. Some of the HCPs recognized patients’ information-seeking behaviour, e.g. patients who appeared to desire a certain sense of control in medication management were provided with complete information covering all drug names and doses. HCPs also asked specific questions about patients’ experiences with medicines, and patients were sometimes given the

opportunity to influence decisions. HCPs involved the patient's next of kin when required by the patient, and respected patients expressing not wanting to take on any responsibility in the decision-making.

When one of the patients agreed that the previous, non-compliant use of medicines could have contributed to the hospital admittance, this patient experienced strong urge from HCPs not to quit medicines after discharge. HCPs explained why medicines were important, and made efforts to find good solutions, e.g. when the patient expressed reluctance to take one of the medicines, the HCP changed to another which both parties were satisfied with.

> *I was fussing about the drug combination. Which my body or my stomach is not very fond of. I had to push them before they took my problems seriously, but I argued it through, and got a new medicine. We decided to do that jointly. They explained why I'm getting it, the side effects and that it would take some time.*
>
> *Edvin (♂, 61, int)*

One of the patients experienced getting timely motivation and preparation for self-management.

> *I was quite surprised that they wanted me to do the injections myself right from the beginning. They mentioned it, the second day, "do you want to do it yourself" and I looked at it and thought "I have never given an injection in my whole life" [laughs].*
>
> *John (♂, 58, int)*

The HCPs seemed to focus on providing patients with everything they needed, and sometimes they asked if the patients felt safe about the decision of being discharged. Some of the physicians sat down with the patients while they went through a customized written discharge summary together. One physician made sure that the patient had his glasses so that they both could read. HCPs summed up and repeated information, either to answer questions the patents had or on their own initiative.

> *Doctor: Are you still ok with syringes or do you want to have tablets instead?*

Doctor: You have a huge list of medicines. The changes in medicines are marked in bold. Did you understand what was new? Take care of the sheet and show it to the home care nurse.

Some patients who experienced elements of the PCC-model pointed out in the interviews that more time with and continuity among HCPs and timing of information were specific areas for improvement.

I'd quite like to know why they stopped that one medicine. My suspicion may be early on we did have a discussion, and I was not fully conscious.

John (♂, 58, int)

Staying with the biomedical model

HCPs complied with the biomedical model when they appeared not to show real interest in the patient-as-person or building alliances, treating the patient only based on biomedical parameters like measurements and evidence based therapy guidelines. Less interest in the patient was observed when HCPs interrupted the patients while speaking, or when they talked to each other without including the patients.

Nurses and nurse assistants thought they knew everything. I didn't like their personality. I didn't bother to discuss with them, but when I heard what they said I thought this is some nonsense.

Sigrid (♀, 71, int)

HCPs in power and control

Generally, HCPs were in power and control over the process at the ward. Most often, HCPs told the patients what to expect, e.g. practical planning of the day. However, sometimes the patients were given promises that were not kept, e.g. a nurse saying "I will come back to take a new blood

pressure", but then not coming back. Sometimes the discharge was delayed, without the patient being informed in a timely manner.

Generally, I had to wait for medicines to be delivered to me in the morning, because it was up to the doctors to decide which ones I should have.

Heidi (♀, 53, int)

Most frequently, the patients were informed about changes in their medicines after the decision had been made, and they were not invited into any discussion about options. Some of the HCPs did not seem eager to inform the patients about medicines, although they had opportunities, e.g. when they were administering them. The nurses often talked about other things while handing out the medicines, e.g. practical planning of the day. Some patients experienced that the medicine, name and dose were unknown when asked to swallow it.

Nurse: Here are your medicines. Do you want a glass of water or a slice of bread?

The level of detail in the given information was varying and often depending on the patient's request. The HCPs were sometimes unspecific in their communication about medicines and in the interviews patients expressed that this made them uncertain as to when the responsibility for administration were transferred back to them after hospital discharge.

It says butenamid in the discharge summary, is that the same as burinex? And "against heart failure", isn't it a diuretic? Diuretic because of heart failure would have been more precise.

Alfred (♂, 80, int)

I don't think we ever clarified whether I should be using that medicine (…) on the letter telling me what I need [reading the generic name]. That's the same?

John (♂, 58, int)

One patient experienced how HCPs seemed surprised when she resisted the changes she was presented with.

They said I should start with a new medicine. I said, no I don't want to. And then the nurse, no the doctor was like... what? They probably didn't expect to hear me saying that.

Heidi (♀, 53, int)

Some patients on the other hand seemed to derive security from the 'HCP knows best' perspective. One of the patients (narrative 1, 'Synnøve', Table 3) told about how she was made aware of an error in the hospital doctor's prescription, and how she obeyed the doctor even though she was aware that it was associated with a risk. She trusted her GP to solve the problem.

Table 3 Patient narrative "Synnøve".

I did not have any expectations to the staff. They were nice and dazzling everyone so it was nothing, it was perfectly fine (…) The doctor had finished the papers and when the nurse gave me the discharge summary I could leave the hospital whenever I wanted. It was listed which medicines I should use and which was new. The only thing that was a bit strange was that the doctor had prescribed a new medicine for… I think it was blood clot, and it did not fit with another medicine that I had used from before. And when I got to the pharmacy to collect my prescriptions, she told me "they don't go together". This was a Friday, I let it take its course during the weekend. I had an appointment scheduled with the GP on the following Monday. When I mentioned this, he immediately called the hospital and they replaced the new medicine with another one that was a better fit.

Synnøve (♀, 84, int)

Optimizing medical outcomes, following guidelines

When HCPs informed the patients about why they were given medical treatment, they often explained by referring to biomedical parameters. HCPs focused on optimizing the medical treatment, following standardized evidence based therapy guidelines e.g. for cardiac failure, with less focus on increasing the patients understanding or preparing them for self-management. Some of the patients could not recall why they were using their medicines, or why some medicines had been discontinued at the hospital. HCPs primary focus seemed linked to how the treatment affected the outcomes, not necessary listening to the patient's needs. One patient experienced that while the hospital doctors

adhered to the biomedical model, the GP had a more patient oriented approach, and thus they provided different recommendations.

Nurse: You start on a new medicine today; it is more gentle to the kidneys.

Doctor: The ACE inhibitor is very beneficial for the future of the heart, and you have good reasons to use a beta-blocker to prevent the development of heart failure. Diuretics can be adjusted more as needed.

The side effects are a bit troublesome. We [the GP and I] decided earlier to take it out because it was causing my dizziness. At the hospital, they thought I should continue with lisinopril because of the heart having a little too low capacity. But do you have to go dizzy all the time because you have to think about your heart? It gets a bit… tiring so now we [the GP and I] have reduced to every other day. Alfred (♂, 80, int)

Discussion

This study aimed to explore and understand how the patient experiences the medicines communication during hospital discharge and how they are empowered through it. Both elements are comprised in the two main themes; patient centred care (PCC, empowerment) and the biomedical framework (non-empowerment).

PCC was observed when HCPs were listening to, recognizing and empowering patients in decision-making and self-management. This is known to encourage patients' medication communication and understanding (11). However, HCPs did not systematically tailor the communication to fill the competence gap between themselves and the patients. The patients were sometimes interrupted despite it being well known that interrupting the patient's `voice of the lifeworld', HCPs `voice of medicine' effectively strips away the personal meaning of the illness (6).

High quality communication is known to foster patient empowerment, hence promoting positive health behaviour, e.g. adherence to medicines (7). Empowerment is related to competence and abilities, i.e. high self-efficacy is required to overrule a physician's prescription or knowing when and how to seek medical advice or support (4, 8, 12). One patient in our study, 'Synnøve' (narrative 1, Table 3), was informed about a potential drug-drug interaction at the pharmacy after discharge, that could have led to a reduced effect of the medicine initiated at the hospital. Information seemed not to alter this patient's adherence to her medical treatment. Adherence is known to be positively associated with 'HCP's knows best', and Doctor Health Locus of Control (4). However, attempts to

empower patients when they are stressed and focused on returning home may increase uncertainty and thereby possibly negatively affect empowerment and reduce adherence (4, 11, 14, 26-29).

Patients mostly expressed gratitude and satisfaction during the interviews when asked what opportunities they had for patient participation. Differing patient expectations may explain why some of the patients were positively surprised when experiencing PCC, while others responded negatively with the biomedical model. A long tradition with the 'biomedical model' may have disabled resourceful patients, who always had been led by powerful HCPs, from taking advantage of their knowledge. Patients led by powerful HCPs have an external health locus of control (EHLOC) (4). Another aspect is that patients with an internal health locus of control (IHLOC), i.e. patients with a high degree of self-efficacy is no guarantee for possessing a satisfactory amount of knowledge to take on the required responsibility of making wise decisions (4). Sometimes, it is hard to evaluate the patient's cognitive abilities, and perceived lack of insight because of cognitive limitations can be a barrier to HCPs practicing PCC (8, 30).

Patients taking on different roles, or HCPs prejudices, could have influenced HCPs to deliver either the PCC or the biomedical model (11, 31-33). However, it has been shown that less than 20 % of the variability in patient preferences can be explained by demographic and situational characteristics; e.g. illness or low degree of education can decrease the desire to be involved, whereas age can both increase and decrease it (34). It is important that HCPs review their prejudices because thinking of a patient as for example 'vulnerable', powerless and without agency, may lead to paternalism and incorrect estimation of the patient's capabilities (7, 8, 26, 35-37).

Building therapeutic alliances, an important concept of PCC, comprises more than HCPs recognizing that a friendly and sympathetic demeanour may increase patient adherence to treatment (6). Safeguarding patient autonomy is to build relationships between one self as HCP and the patient, based on mutual trust (6, 26, 38, 39). However, organisational staffing pressure and handover between clinical shifts are barriers in order to build such alliances during hospitalization (7).

According to the biomedical framework, the value of time spent with patients is recognized but not offered great priority (6). In order to further develop PCC, HCPs need to embrace dialogues with patients, negotiating about decisional responsibility, with adjustment for capacity, e.g. the 'sick role' (13, 25). HCPs should share more of their knowledge and power; empowering patients implies acknowledging the person's agency in control of outcomes. Improving several aspects of patients' knowledge and self-confidence and how communication is provided is crucial to empowering patients in the management of medications after discharge. From a patient perspective, HCPs listening more actively could be a good way to inaugurate PCC (1, 40, 41).

This study combined real time observations and patient interviews, which is a powerful approach to understand and describe what actually happened. What patients told, did not always equal what was observed, e.g. one patient talking about a 30 minute long discharge conversation that actually lasted for 10 minutes. Because the whole process from hospital admission to hospital discharge was not observed, all encounters supporting self-management were most certainly not observed, however the interviews made sure that the patient perspective was not lost.

The researchers were aware of how their sociocultural positions and value systems might have affected the results. Interviews with patients and HCPs (unpublished focus group interviews with HCPs) found that they were mostly unperturbed by the presence of the observer, arguing inconsiderable observer-effects. Researchers with different backgrounds were involved in the analytical process, providing different perspectives (pharmacists, social scientist).

This study was performed at one internal medicines ward located at one hospital, and it is uncertain how well the study findings inform health care contexts that differ from that in which the original study was undertaken.

Conclusion

The results give a broader understanding of how patients experience medicines communication during hospital discharge. Even though elements of PCC was observed in several encounters, overall communication was not sufficiently fostering empowerment of the patient. Spending time with patients, building relations based on mutual trust seemed to be undervalued. Both patient and HCPs appears to be inculcated by the biomedical tradition, and uncertain about roles and opportunities associated with PCC. Attention to patient preferences and core elements of the PCC model should be paid from admission to empower patients in self-management of their medications.

List of abbrevations

EHLOC - External Health Locus of Control

HCPs - Health Care Personnel

IHLOC – Internal Health Locus of Control

IMM - Integrated Medicines Management

PCC - Patient centred care

Competing interests

The authors declare that they have no competing interests

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Author contributions

SER, SKS, MM, and LM conceptualized the study and developed the method.
YA, HBL and KB contributed to development of the method.
SER, HBL and KB conducted the data collection.
SER, SKS, HBL, KB, YA and LM analysed and interpreted the patient data.
SER, SKS and LM wrote the original draft.
YA, HBL, KB and MM were major contributors to the writing, review and editing.
All authors read and approved the final manuscript.

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Data statement

Due to the sensitive nature of the data in this study, patients and HCPs were assured raw data would remain confidential and would not be shared.

Supplementary files

Additional file 1. Study protocol

Additional file 2. Observational form

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Medicines communication in hospital - the patient perspective

Protocol version no. 1 – 2018-10-12

The original protocol was written in Norwegian. In this translated version, elements considered not of central importance, i.e. the introduction and summary has been deleted.

Project participants

Project leader, Co-supervisor: Morten Mowé, associate professor, Faculty of Medicine, University of Oslo (UiO) and Head of the Medical Clinic, Oslo University Hospital. E-mail: mormow@ous-hf.no

PhD-candidate, responsible study pharmacist: Stine Eidhammer Rognan

Responsible for the research: Oslo University Hospital, Morten Mowé

Responsible for the data management: Oslo University Hospital, Morten Mowé

Other project members and collaborators:

- Liv Mathiesen, Main supervisor, Associate professor, Department of Pharmacy, UiO
- Sofia Kälvemark Sporrong, Co-supervisor, associate professor, Department of Pharmacy, University of Copenhagen
- Yvonne Andersson, co-supervisor, head of research and development, Hospital Pharmacies Enterprise, South Eastern Norway
- Marianne Lea, Clinical Pharmacist, PhD-candidate
- Elin Trapnes, Clinical Pharmacist
- Anne Mette Njaastad, Senior Consultant, the Medical Clinic, Oslo University Hospital
- Berit Gallefoss Denstad, User representative, Hospital Pharmacies Enterprise, South Eastern Norway
- Helene Berg Lie, Master's student in Pharmacy
- Kajsa Bengtsson, Master's student in Pharmacy
- Kirsten Kilvik Viktil, Associate professor, Department of Pharmacy, UiOLisbeth Damlien, Clinical Pharmacist, PhD-candidate

Table of contents

Abbreviations

ATC	Anatomical Therapeutic Chemical Classification System
HF	Health Trust
IMM	Integrated Medicines Management
IMS	Internal medical ward
OUS	Oslo University Hospital
PLO	Nursing and Care
REK	Regional Committees for medical and health research ethics
TSD	Services for sensitive data
UIO	University of Oslo

Hypothesis, aims and objectives

The aims and objectives are:

- Mapping the discharge process to identify factors for success and failure towards achieving seamless and safe drug care.
- Evaluating whether patient needs regarding medicine information at hospital discharge were met.

The hypothesis is that understanding the patients' journey through the discharge process, and the patient perspectives, can help to improve the discharge transitions and reduce the gap between different care levels.

Methods

- *Study design:*
  This is a qualitative study, consisting of mostly unstructured observations with the addition of semi-structured interviews and medicines reconciliation.

- *Setting*:
  The study will be conducted at the internal medicines ward, Indremedisinsk sengepost (IMS), OUS, Ullevål and in the patient's home or nursing home, 1-2 weeks after discharge. A pilot study will be conducted during the spring 2019. Inclusion to the main study will start during the fall 2019 and continue until saturation is achieved. Estimated duration of the main study is September 2019 - January 2020.

- *Inclusion criteria:*
  Eligible patients are ≥18 years, home dwelling, have a residential address in Oslo, are responsible for their medicines administration prior to hospital admission, and expected to be discharged to their homes or a short-term nursing home department.

- *Exclusion criteria*: Pre-terminal or severe cognitively impaired patients are not eligible. Patients with planned transfer to and hence discharge from other wards.

- *Number of participants*:

  Part 1: Observational study: The data collection will continue until saturation is achieved. The recruitment of participants will be purposive. Patients of various age, ethnicity and with various diseases will be asked to participate in the study. The PhD candidate will, together with the master's students, select eligible patients. Advice will be obtained from doctors or nurses at the ward. An experienced senior researcher (SKS) will be guiding the PhD-candidate in detailing the design of the study during the pilot period, and as required during the conduct of the study.

  Part 2: Semi-structured interviews: The interviews will primarily take place at the patients' homes, 1-2 weeks after discharge. If patients are discharged to a short-term stay at a nursing home or with increased assistance from the home nursing service at home, any health care personnel will also be asked to participate in the interview, if necessary. As for the observational part, we will aim to assure the information power in the study sample, and the data collection will last until saturation is achieved.

  Inclusion of patients to the pilot study will continue until necessary background information to design the study is obtained.

- *Procedures and training*

Observations and interviews will be performed by the PhD-candidate and master students in pharmacy. The PhD-candidate is an experienced clinical pharmacist familiar with the routines at the hospital and the patient population at the ward. The master students are familiar with drugs and will be provided with relevant training in aspects of clinical work before entering the field work. For example, the Hospital Pharmacies Enterprise, South Eastern Norway has a standardized procedure for training in medicines reconciliation.

All observers will be trained in observation- and interview methods by an experienced senior researcher. The PhD-candidate is experienced with clinical communication with patients about their medicines, and has in addition completed the course FRM5905V Clinical Pharmaceutical Work Methodology, which is a part of the experience-based master programme in clinical pharmacy at the University of Oslo. The PhD-candidate will complete a course in qualitative methods during the spring of 2019. The master's students will complete relevant research preparation courses during the spring of 2019.

Representatives from the internal medicine department as well as a user representative from the user committee at the Hospital Pharmacies Enterprise, South Eastern Norway have been involved in the design and planning of the studies.

A pilot study will be carried out for the observation study and the interview study in the spring of 2019.

- *Data collection:*
  Part 1: The observational study will describe the hospital discharge process. The observations will focus on the patient and cover all events relevant for the medicines treatment, starting when the first tentative discharge date is set or 2-3 days before the tentative discharge date, continuing until the patient is discharged. Eligible patients will be purposively sampled to ensure quality and heterogeneity of the data. The assumed less complicated patient pathways (assumed short length of stay) are attempted to be included early in the study period. These patients will be followed by the observer throughout the hospital stay. The assumed most complicated courses (assumed long length of stay) will be included towards the end of the study period as the observer has gained more experience, e.g. about routines for discharge and events that are relevant to the drug treatment, and these patients are followed from 2-3 days before tentative discharge.
  During the observations, the observer will be present and identifiable, but without any role in the social setting. The observer will only be observing the patient when there are health care personnel present, and the observer will otherwise not disturb the patient. The observer will observe what happens to the patient when the patient interact with health care personnel during their hospital stay, what is said, when and how. The observer may interact with patients if it is natural in the setting, e.g. if a patient initiate a conversation in the hallway which is not about the medical treatment in the hospital. In these situations, keywords from patient conversations will be registered. See the section about content of communication below.

  Written informed consent will be obtained from:

- patients eligible for inclusion
- next of kin and/or healthcare professionals who assist the patient in medication management
- healthcare professionals at the internal medicines ward (will be obtained in advance of the study period)
- external healthcare professionals involved in the patients' medical treatment during the hospital stay (e.g. Infectious Disease Physician, Geriatric psychiatrist, orthopaedist, priest). If any of these do not consent, we will not observe their encounters with the patient

Each observer will keep her observations in field notes, including a diary of chronological events and her own reactions, feelings and opinions about what is happening to the patient. The field notes are comprised of both checklists and free text. Further details of an observational form will be developed during the pilot study. The focus in the observations may be more structured when approaching saturation of the data material is close.

Different types of data will be collected:

- Content of communication (verbal and non-verbal): Communication between patient and healthcare professionals, information or dialogue about medicines including information to the patient about his/her medical treatment. Focus will be centred on the patient and events relevant for the medical treatment.

- Descriptive data: Patient demography, description of contextual factors like behaviours, actions, activities and interactions with healthcare professionals (e.g. what happens, when and in what order, duration of conversations between patient and healthcare professionals). Sex, profession and, if relevant, discipline/specialization of the health care professionals will be registered.

The observers will transcribe the data consecutively to prevent memory bias, to make sure that all details and all reflections are registered. The observers will read each others transcripts and meet on a regular basis to debrief, discuss and hence assure the quality of the data. A pilot will be carried out during the spring of 2019, where registration forms, checklists and procedures will be developed.

Part 2: Semi-structured interviews with the patients already included in the observational study, will be conducted at the patients' homes or at the nursing home department 1-2 weeks after the hospital discharge. The interviews will be audiotaped if the patient consent to this. If the patient do not consent to audio recording, there will be taken notes during the interview. Consent is obtained for observation and for home visits using the same consent form (attached).

If the patient do not communicate in Norwegian or English, we aim to get assistance from a person who speaks the patient's native language to carry out the interview, or the interview will be carried out with the help of an interpreter. The interviews will focus on how the patients perceived the medicines information they received when they were discharged from the hospital. In the interviews, open-ended questions adapted to the individual patient will

primarily be used to explore different patient perspectives. The interview guide will contain predefined questions (see examples below) and for individual patients, keywords from the observational study will be added, for further detailed exploration.

The patient interviews will focus on:

- Which factors related to drug treatment matters the most and why
- How the discharge process was experienced
- Adherence and thoughts about the treatment that was planned when discharged from the hospital

The interviews will also consist of a medicines reconciliation that aims to capture how the patient actually use his/her medicines, misunderstandings and / or challenges experienced by the patient, and the results of the medicines reconciliation will be explored in detail in dialogue with the patient. The patients actual medicines use will be compared to the medicines list in the discharge summary and any information sent from the hospital to the home nurse services by nursing and care (Pleie og omsorgs (PLO)) – messages. If necessary, supplementary information can be provided from next of kin either participating in the interview or in a separate interview (additional consent). The medicines reconciliation will be conducted according to the Integrated Medicines Management (IMM) model adapted to the Norwegian setting.

The interview guide will be piloted during spring 2019.

- *Demographic data and measurement variables:*
  The following demographic data and measurement variables are obtained from the EPJ, electronic medicines chart and any prescription card from a multi-dose dispensing pharmacy. The data will be registered for the study population as part of the inclusion to ensure heterogeneity in the study population:
  - Age
  - Sex
  - Residential area in Oslo
  - Cause of hospital admission
  - Medicines list in the medical record at admission: Number of drugs, ATC-classification
  - Diagnoses (ICD-10): Number, type and, if relevant, year of diagnosis.
  - Date of hospital admission.
  - Date of admission to the internal medicines ward
  - Whether the patient were receiving medicines dispensed in a multi-dose package system prior to admission- Yes/No
  - Level of care in medicines management before hospital admission (independent, partial independent with some assistance from next of kin or home nurse service)
  - Whether the hospital admission was acute or planned
  - Socio- economic background, level of education
  - Ethnic background
  - Cognitive function (form to be implemented at the internal medical ward)
  - Frailty scale (form to be implemented at the internal medical ward)

  If patients do not agree to participate in the study, gender, age and possible cause will be registered (e.g. male, 50 years old, did not want to participate).

The following data will be recorded during or at the time of hospital discharge:

- Medicines reconciliation observed performed during the hospital stay
- Date of hospital discharge
- Where the patient is discharged to
- Medicines list in the discharge summary: Number of drugs, ATC-classification
- Diagnoses (ICD-10) according to the discharge summary: Number, type and, if relevant, year of diagnosis.
- Medicines dispensed in a multi-dose package system - Yes/No
- Level of care in medicines management after hospital discharge (independent, partial independent with some assistance from next of kin or home nurse service)

- *Analysis*

Part 1: Observational study.
Different types of data will be analyzed.

- The communication content of the field notes will be systematically examined by conventional inductive content analysis, which is a useful method particularly when the theory and research literature on the phenomenon being studied is limited (1). After transcribing the content word for word, it will be read repeatedly so that the observers achieve a holistic and in-depth understanding of the content. The data material will be read word by word and coded into different categories that describe the observer's perception of the content of sentences or paragraphs. In the further process, overall themes will be developed that link the categories together. The observers will collaborate in the analysis to ensure quality, i.e. that the context is understood and that important observations are not lost.
- Descriptive data: Mapping of the discharge process, what happens, when and in what order. Time-ordered displays will be developed for this purpose (2). This tool stimulates the identification of what can lead to what and why. Quantitative data such as demography and waiting time will be summarized.

Part 2: Interviews will be recorded as audio files and afterwards transcribed word by word. Analysis will be inductive with systematic text condensation and content analysis (2). In those cases where assistance are obtained from an interpreter to conduct the interview, the transcription is preferably performed by the interpreter. If the interview is conducted by a PhD student or master's student with the help of an interpreter, information from the patient passed on by the interpreter will be transcribed. Where it is the interpretation of what the patient conveys that is transcribed, efforts will be made to find an external interpreter to listen through the audio file in order to capture additional information from the patient. Such work will be remunerated on an hourly basis.

The interviewers will collaborate in the analysis to ensure quality, i.e. that the context is understood.

Furthermore, several separate analysis will be performed with data from the observational study, to identify any patterns across the interview- and observational method. Whether the

patients' need for information when discharged from hospital is satisfied and whether it leads to active patient participation based on the need, will be evaluated.

Any problems the patients face with the drug treatment (revealed by interview and medicines reconciliation) will be classified quantitatively and qualitatively, including the number of patients with discrepancies, the number of discrepancies and the type of discrepancy.

Milestones

	Dato
Completion of protocol including consent form	2018-11-12
Data Handler Agreement (Services for sensitive data – TSD) at the University of Oslo	2019-01-02
Application submitted to the Regional Committees for Medical Research Ethics - South East Norway (REC) and the privacy ombudsman at Oslo University hospital	2018-11-12
Research preparation courses and training for PhD students and master's students	Spring 2019
Piloting	Spring 2019
Inclusion to the main study	Sep. 2019 – Jan. 2020
Submission of master's theses (2 planned)	Spring 2020
Completion of data analysis	June 2020
Submission of articles (3 planned) for publication	Autumn 2020/ Spring 2021

During periods of droplet infection in the ward, inclusion may be slower. Progress in the inclusion will be reported every week to the main supervisor.

Audit and inspection

Hospital Pharmacies Enterprise, South Eastern Norway may perform internal audit of the study.

Ethics

The hypothesis is that understanding the patients' journey through the discharge process, and the patient perspectives, can help to improve the discharge transitions and reduce the gap between different care levels. Communication between patients and healthcare professionals will be observed at the hospital, and patients will then be interviewed 1-2 weeks after discharge from hospital. Before inclusion of patients in the study, they will receive written information about the project and can decide for themselves whether they want to participate or not. It will be taken into account that it may be challenging to visit all patients at home as it may be some patients who does not want to be visited, or withdraw their consent. Some patients will be included in the study even if they only want to participate in the observational study, this can help ensure the information strength of the sample. Before observing health care personnel, they will receive written information about the project and can decide for themselves whether they want to participate or not.

It is well known that information transfer during transition of care is a risk area, and there is a need for greater focus on and knowledge about patient involvement. The purpose of the study is to map the discharge process to identify factors important for achieving seamless and patient-safe treatment, as well as to evaluate whether patients' need for information when discharged from

hospital is met. It is expected that the results from the project will be useful in further development and improvement of health care services for patients.

The observer and interviewer are pharmacy students or pharmacists not affiliated to the internal medicine department on a daily basis, and not involved in the overall assessments behind decisions regarding drug treatment. The observer and interviewer will have no active role in the interdisciplinary team of health care professionals, thus participation in the study will not contribute to any risk for the participants. In case of discovering potentially serious drug-related problems at the hospital, the information will be passed on to the project manager, Morten Mowé, who will make an assessment of what to do with this information. If the interviews reveal critical discrepancies in the patient's medication management at home, this information will be passed on to the home nursing or GP. Master's students will sign a declaration of confidentiality before starting the pilot study.

Privacy and information:
Patients will be included after informed written consent, see appendix for declaration of consent. The same applies to health personnel and any relatives. The attending physician will decide whether the patients are competent to give an informed consent when the observers are in doubt. After consent has been obtained, the patient / health personnel / relatives will be registered with a study number. The code list will be stored electronically in MedInsight. The participants will receive a copy of the consent form. The signed consent forms will be kept locked up in the hospital. The participants will be free to withdraw their consent at any time, without having to give any justification for this. The registered data will be deleted if a consent is withdrawn, as long as the data has not been included in the analysis.

All collected data will be treated confidentially and identifiable data will not be taken from the hospital. Completed transcripts from the observations will be stored immediately on Services for sensitive data (TSD) at the University of Oslo. The interviews will be audiotaped and the files will be uploaded to Services for sensitive data (TSD) at the University of Oslo, immediately after the interview. Audio files will be deleted after the interviews has been analysed. De-identified electronic research data will be processed in the analysis program NVivo on TSD. See attached draft agreement between OUS and UIO. The data will be compiled as de-identified data, with one study number per patient. The code list that connects patient identity to study number will be stored electronically in MedInsight and thus secured and separated from other data. The code list will be deleted no later than 10.01.2023. The signed consent form will be kept locked up in the hospital.

An application will be sent to REC. In accordance with procedures for research at OUS, a notification will also be sent to the privacy ombudsman at OUS.

Budget

The study is funded by the Hospital Pharmacies Enterprise, South Eastern Norway.

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Appendices

Written informed consent form

- Patient version
- Health care professional version (a copy can be provided on request)

Data handler agreement for storage of sensitive data (a copy can be provided on request)

Patient - observation Medicines communication – the patient's perspective, 10.04.19, version 1

Oslo universitetssykehus

REQUEST ABOUT PARTICIPATION IN A RESERACH PROJECT

MEDICINES COMMUNICATION AT THE HOSPITAL – THE PATIENT'S PERSPECTIVE

This is a request for you to participate in a research project. The aim of the project is to understand your experiences of the discharge process at the hospital, and if you have received necessary information. The study's focus is patient safety when discharged from the hospital. We know that transfer of information between health care levels is a weak link, creating risks. There is also a need for more focus on and knowledge about patient involvement in this process. Understanding how you have experienced these processes could contribute to improved procedures and patient safety.

Patients of various age, ethnicity and with various diseases are asked to participate in the study. We will observe what happens to you when you are interacting with health care personnel during your hospital stay.

The research project is a collaboration between Oslo University Hospital and the University of Oslo. The study is conducted during the period September 2019 to the end of January 2020.

WHAT WOULD PARTICIPATING MEAN FOR YOU?

Accepting to participate in the study means that a pharmacist or a pharmacy student will observe what happens to you when you interact with health care personnel during your hospital stay, what is said, when and how. You will only be observed when there are health care personnel present, and the observer will otherwise not disturb you. The observations at the hospital will not use any extra of your time. The observers will take notes about what happens, if you are staying at a single room we might use a Dictaphone. Personal information will be retrieved to secure a broad selection of patients in the study, see below.

Personal Information

We will collect and register some information about you in this project. This information will include gender, age, city of residence, education, ethnicity, language, reason for hospital admission, date of admission, date of discharge, your illnesses, your list of medicines at admission and at discharge, whether you use a multi dose dispensing aid, whether you receive help with administering your medicines, if your admission was acute or planned, cognitive function, degree of frailty and where you are discharged to.

To be certain we have the correct information it might be necessary to retrieve information from various sources. By consenting to participate in the study you also consent that the pharmacist and the pharmacy students might:

- Retrieve necessary information from your medical record at the hospital
- Retrieve necessary information from your general practitioner, or from persons who assist you in taking your medicines (e.g. home care nurse or next of kin). This contact is achieved through phone calls or by telefax.

Patient - observation Medicines communication – the patient's perspective, 10.04.19, version 1

POSSIBLE ADVANTAGES AND DISADVANTAGES

As you will be observed in parallel with other health care personnel being with you, participating in the project will not be an extra burden to you during your hospital stay.

The results of this project are expected be useful in the development of better health care services for patients.

VOULENTARY PARTICIPATION AND THE OPPORTUNITY TO WITHDRAW YOUR CONSENT

The participation in the project is voluntary. If you wish to participate, you can sign the consent on the next page. You are free to withdraw your consent at any time and without giving any reason. Withdrawing your consent will not influence your further treatment. If you choose to withdraw you can request that the information stored about you is deleted. This would not apply when the information has been included in analyses or has been published in scientific publications. If you at a later stage wish to withdraw or have any questions about the project, you can contact PhD-student Stine Eidhammer Rognan, at +4795111337 (phone), or stinerog@student.matnat.uio.no (email).

WHAT WILL HAPPEN TO THE INFORMATION ABOUT YOU?

The information about you which are registered will only be used as described under the aim of the project. You are entitled to insight to the data registered about you. You are also entitled to correct any information that is incorrect, and you are entitled to get to know the security measures employed in the handling of the data.

Your name, birthdate or other information that can identify you is removed before handling the data. A study code can connect your information to your person through an electronic solution which only the PhD-student Stine E. Rognan, student Kajsa Bengtsson, student Helene Berg Lie and the supervisor, Liv Mathiesen can access.

All information registered will be anonymised and deleted 5 years after the end of the project at the latest.

Patient - observation Medicines communication – the patient's perspective, 10.04.19, version 1

INSURANCE

Patients in this project are covered through the law for patient protection (Pasientskadeloven).

APPROVAL

The Data protection officer has assessed and approved the project, ref no. 19/06465.

In accordance to the new law for personal information, both the responsible organisation Oslo University Hospital and project leader Morten Mowé have the responsibility to secure that the handling of your information is in accordance with the regulations. This project is legally anchored in the EU person protection legalisation, articles 6a and 9 no. 2 and your consent.

You have the right to complain to the Norwegian Data Protection Authority (Datatilsynet) about the handling of the information about you in the project.

CONTACT DETAILS

If you have any questions regarding the project you can contact Stine Eidhammer Rognan, PhD-student at the University of Oslo, phone: +4795111337, e-mail address: stinerog@student.matnat.uio.no

The data protection officer at Oslo University Hospital is Tor Åsmund Martinsen, e-mail address: toamar@ous-hf.no.

Patient - observation Medicines communication – the patient's perspective, 10.04.19, version 1

Patient - observation

Medicines communication – the patient's perspective, 10.04.19, version 1

I HEREBY CONSEBT TO PARTICIPATE IN THE PROJECT AND TO MY PERSONAL INFORMATION ARE USED IN ACCORDANCE TO THE DESCRIPTION GIVEN

Place and date

The participant's signature

The name of the participant in printed letters

Signature by deputy

As next of kin to _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ (Full name) I consent to her/his participation in the project.

Place and date

Signature next of kin

Next of kin's name in printed letters

I confirm to have provided information about the project

Place and date

Signature

Responsibility in the project

Oslo universitetssykehus

REQUEST ABOUT PARTICIPATION IN A RESERACH PROJECT

MEDICINES COMMUNICATION AT THE HOSPITAL – THE PATIENT'S PERSPECTIVE

This is a request for you to participate in a research project. The aim of the project is to understand your experiences of the discharge process at the hospital, and if you have received necessary information. The study's focus is patient safety when discharged from the hospital. We know that transfer of information between health care levels is a weak link, creating risks. There is also a need for more focus on and knowledge about patient involvement in this process. Understanding how you have experienced these processes could contribute to improved procedures and patient safety.

During your hospital stay you have participated in an observational study, please refer to a separate consent form. One to two weeks after discharge, we would like to interview you at your home.

The research project is a collaboration between Oslo University Hospital and the University of Oslo. The study is conducted during the period September 2019 to the end of January 2020.

WHAT WOULD PARTICIPATING MEAN FOR YOU?

We would like to interview you to hear your story about how you experienced the communication at the hospital and at discharge. If you accept to be interviewed, the person who performed the observation of you during you hospital stay will contact you by phone to schedule an interview at your home 1-2 weeks after discharge. The interview will last for approximately 1 hour and will be recorded.

Personal Information

We will collect and register some information about you in this project. This information will include gender, age, city of residence, education, ethnicity, language, reason for hospital admission, date of admission, date of discharge, your illnesses, your list of medicines at admission and at discharge, whether you use a multi dose dispensing aid, whether you receive help with administering your medicines, if your admission was acute or planned, cognitive function, degree of frailty and where you are discharged to.

To be certain we have the correct information it might be necessary to retrieve information from various sources. By consenting to participate in the study you also consent that the pharmacist and the pharmacy students might:

- Retrieve necessary information from your medical record at the hospital
- Retrieve necessary information from your general practitioner, or from persons who assist you in taking your medicines (e.g. home care nurse or next of kin). This contact is achieved through phone calls or by telefax.
- Contact you after 1-2 weeks to schedule the interview.

Patient - interview

Medicines communication – the patient's perspective, 10.04.19, version 1

POSSIBLE ADVANTAGES AND DISADVANTAGES

The interview which will be performed 1-2 weeks after discharge from hospital will demand that you reserve some time for it, but you will decide when it is the most convenient for you. Some might find it inconvenient to receive strangers to their home. We strive to achieve that the person who observed you at the hospital is the one that will visit you, and who you will have become acquainted with during your hospital stay.

The results of this project are expected be useful in the development of better health care services for patients.

VOULENTARY PARTICIPATION AND THE OPPORTUNITY TO WITHDRAW YOUR CONSENT

The participation in the project is voluntary. If you wish to participate, you can sign the consent on the next page. You are free to withdraw your consent at any time and without giving any reason. Withdrawing your consent will not influence your further treatment. If you choose to withdraw you can request that the information stored about you is deleted. This would not apply when the information has been included in analyses or has been published in scientific publications. If you at a later stage wish to withdraw or have any questions about the project, you can contact PhD-student Stine Eidhammer Rognan, at +4795111337 (phone), or stinerog@student.matnat.uio.no (email).

WHAT WILL HAPPEN TO THE INFORMATION ABOUT YOU?

The information about you which are registered will only be used as described under the aim of the project. You are entitled to insight to the data registered about you. You are also entitled to correct any information that is incorrect. You are also entitled to get to know the security measures employed in the handling of the data.

You name, birthdate or other identifying information is removed before handling the data. A study code can connect your information to your person through an electronic solution which only th PhD-student Stine E. Rognan, student Kajsa Bengtsson, student Helene Berg Lie and the supervisor, Liv Mathiesen can access.

All information registered will be anonymised and deleted 5 years after the end of the project at the latest..

Patient - interview

Medicines communication – the patient's perspective, 10.04.19, version 1

INSURANCE

Patients in this project are covered through the law for patient protection (Pasientskadeloven).

APPROVAL

The Data protection officer has assessed and approved the project, ref no. 19/06465.

In accordance to the new law for personal information, both the responsible organisation Oslo University Hospital and project leader Morten Mowé have the responsibility to secure that the handling of your information is in accordance with the regulations. This project is legally anchored in the EU person protection legalisation, articles 6a and 9 no. 2 and your consent.

You have the right to complain to the Norwegian Data Protection Authority (Datatilsynet) about the handling of the information about you in the project.

CONTACT DETAILS

If you have any questions regarding the project you can contact Stine Eidhammer Rognan, PhD-student at the University of Oslo, phone: +4795111337, e-mail adress: stinerog@student.matnat.uio.no

The data protection officer at Oslo University Hospital is Tor Åsmund Martinsen, e-mail adress: toamar@ous-hf.no.

Patient - interview

Medicines communication – the patient's perspective, 10.04.19, version 1

Patient - interview

Medicines communication – the patient's perspective, 10.04.19, version 1

I HEREBY CONSEBT TO PARTICIPATE IN THE PROJECT AND TO MY PERSONAL INFORMATION ARE USED IN ACCORDANCE TO THE DESCRIPTION GIVEN

Place and date

The participant's signature

The name of the participant in printed letters

Signature by deputy

As next of kin to _ (Full name) I consent to her/his participation in the project.

Place and date

Signature next of kin

Next of kin's name in printed letters

I confirm to have provided information about the project

Place and date

Signature

Responsibility in the project

Protocol Amendment No. 1

Medicines communication in hospital - the patient perspective

A study approved by the Privacy Ombudsman, Oslo University Hospital

Reference number 2019/6465

Protocol Amendment No. 1

Date: 2019-13-04

The Protocol Amendment involves

A specification has been added under the heading 'exclusion criteria' in the method section. The wording of one of the exclusion criteria has changed from

«Pre-terminal or severe cognitively impaired patients are not eligible», to:

«Pre-terminal, severe cognitively impaired or **patients with acute confusion** are not eligible**, as it is considered unethical to observe them**».

The head of information safety, Oslo University Hospital, has approved the use of IPad devices for registration of data in the observational study, referring to mail correspondence 2019-05-04.

Observational data will be registered as text in web forms 'nettskjema' and handwritten documents as well as audio files on Services for sensitive data (TSD) at the University of Oslo. The following IPad applications will be used:

- 'Nettskjema': Document scanner (photos of handwritten documents can be uploaded as attachments in web forms delivering directly to TSD).
- 'Nettskjema': Dictaphone (audio files can be uploaded as attachments in web forms delivering directly to TSD). A dictaphone can be used when a patient has a single room (updated consent form, see next section)
- 'Nettskjema': Registration forms.

Everything else on the devices will be locked down for security reasons.

Updated consent form

When a patient has a single room, a dictaphone can be used, information leaflets for patients and healthcare professionals have been updated with information about this.

The patient consent form have been changed from one form to two forms: The first form is for the observational study and the second form is for the interview.

Protocol Amendment No. 2

Medicines communication in hospital - the patient perspective

A study approved by the Privacy Ombudsman, Oslo University Hospital

Reference number 2019/6465

Protocol Amendment No. 2

Date: 2019-24-09

The Protocol Amendment involves

In consultation with and after request from internal medicines ward, Indremedisinsk sengepost (IMS), the following exclusion criteria have been removed:

«Patients with planned transfer to and hence discharge from other wards»

This because we consider the aims and objectives challenging to answer otherwise. Many patients are transferred from IMS to other wards. The second aim and objective has the following wording: «Evaluating whether patient needs regarding medicine information at hospital discharge were met».

As long as neither the patient nor the health care personnel withdraw their consent, the observations can continue at an other ward until the patient is discharged from the hospital.

Protocol Amendment No. 3

Medicines communication in hospital - the patient perspective

A study approved by the Privacy Ombudsman, Oslo University Hospital

Reference number 2019/6465

Protocol Amendment No. 3

Date: 2019-12-10

The Protocol Amendment involves

Alternative method for semi-structured interview:

If the patient pathway is complicated, with a long length of stay including transfer from the internal medicine ward (IMS) to another ward at Oslo University Hospital (see Protocol Amendment No. 2), the first part of the semi-structured interview can be carried out while the patient is still in the hospital. The rationale behind this is that the longer time before an interview, the more biased the patients memory, hence the patients will remember more from the stay at IMS if the interview is rescheduled and moved back in time.

Part 1 of the semi-structured interview mainly explores the patient perspective on medicines communication during the stay at IMS. Written informed consent to the interview will be obtained from the patient and the interview will preferably takes place within visiting hours at the ward where the patient is admitted.

Part 2 of the semi-structured interview focuses on compliance to the planned medicines treatment, including medicines reconciliation, and this part of the interview will still be carried out in the patient's home environment or possibly in a nursing home 1-2 weeks after the patient is discharged from the hospital.

A new version of the information letter and consent form for the semi-structured interviews (part 1 and part 2) has been prepared.

Appendix 1. Observational form

Incl.nr	Department/group	Bed	Observer (initials):	Date:	Page /
Relevant information electronic patient/medical record (E.g. new medicine, changed dose/adm.form/dosage/ time, discontinued. Changed patient condition, etc.)					
Start observation:		**End observation:**			**Tentative discharge date:**
Encounter - type: ☐ Measurements ☐ Medicines adm. ☐ Ward round ☐ Meal ☐ Medicines reconciliation ☐ Discharge ☐ Other:		**Hospital environment** ☐ Single-bed room ☐ Meal ☐ Facilitation, e.g. movement, hygiene ☐ Telephone/calling ☐ Other:	**Written information about medicines at hospital discharge** ☐ Distributed ☐ Reviewed jointly		**Health care personnel (oral and written consent)** Prof. title, incl.nr, ♂/♀
Part 1: Chronological observations; Actions, quotes patient/health care personnel (e.g. questions, use of medical terms), drawing of the setting. **Part 2:** Observer interpretations, reactions, feelings, opinions (environment and communication). Remember to describe any consequence of observer presence!					

Incl.nr	Department/group	Bed	Observer (initials):	Date:	Page /

Part 1: Chronological observations; Actions, quotes patient/health care personnel (e.g. questions, use of medical terms), drawing of the setting.
Part 2: Observer interpretations, reactions, feelings, opinions (environment and communication). Remember to describe any consequence of observer presence!

Cont.

21 Items from the Standards for Reporting Qualitative

Research (**SRQR**) that the Authors Consider Essential for Complete, Transparent

Reporting of Qualitative Research

No.	Item	Description	Section of the manuscript which reports the information that meets the criteria of the checklist
1.	Title	Concise description of the nature and topic of the study. Identifying the study as qualitative or indicating the approach (e.g., ethnography, grounded theory) or data collection methods (e.g., interview, focus group) is recommended.	Title page
2.	Abstract	Summary of key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results, and conclusions.	Page 2
3.	Problem Formulation	Description and significance of the problem/phenomenon studied; review of relevant theory and empirical work; problem statement.	Introduction, page 3
4.	Purpose or research question	Purpose of the study and specific objectives or questions.	Aim, page 4
5.	Qualitative approach and research paradigm	Qualitative approach (e.g., ethnography, grounded theory, case study, phenomenology, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g., post-positivist, constructivist/interpretivist) is also recommended; rationale.	Approach, page 5
6.	Researcher characteristics and reflexivity	Researchers' characteristics that may influence the research, including personal attributes, qualifications/experience, relationship with participants, assumptions, and/or presuppositions; potential or actual interaction between	Data collection, page 6 Discussion, page 16

		researchers' characteristics and the research questions, approach, methods, results and/or transferability.	
7.	Context	Setting/site and salient contextual factors; rationale.	Setting, page 5
8.	Sampling strategy	How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g., sampling saturation); rationale.	Sampling strategy, page 5 Data collection, page 6 Analysis, page 6-7
9.	Ethical issues pertaining to human subjects	Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues.	Data collection, page 6
10.	Data collection methods	Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources/methods, and modification of procedures in response to evolving study findings; rationale.	Setting and sampling strategy, page 5 Data collection, page 6 Analysis, page 6-7
11.	Data collection instruments and technologies	Description of instruments (e.g., interview guides, questionnaires) and devices (e.g., audio recorders) used for data collection; if/how the instrument(s) changed over the course of the study.	Data collection, page 6 Setting and sampling strategy, page 5 Appendix 1 Observational form A copy of the interview guide can be provided on request
12.	Units of study	Number and relevant characteristics of participants, documents, or events included in the study; level of participation.	Analysis, page 6-7 Table 1 Table 2
13.	Data processing	Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding and anonymization / de-identification of excerpts.	Data collection, page 6 Analysis, page 6-7

14.	Data analysis	Process by which inferences, themes, etc. were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale.	Analysis, page 6-7
15.	Techniques to enhance trustworthiness	Techniques to enhance trustworthiness and credibility of data analysis,(e.g., member checking, triangulation, audit trail); rationale.	Analysis, page 6-7 Discussion, page 16
16.:	Synthesis and interpretation	Main findings (e.g., interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory.	Results, page 7-14 Discussion, page 15-17 Conclusion, page 17
17.	Links to empirical data	Evidence (e.g., quotes, field notes, text excerpts, photographs) to substantiate analytic findings.	Results, page 7-14
18.	Integration with prior work, implications, transferability, and contribution(s) to the field	Short summary of main findings, explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application/generalizability; identification of unique contribution(s) to scholarship in a discipline or field.	Discussion, page 15-17
19.	Limitations	Trustworthiness and limitations of findings	Discussion, page 15-17
20.	Conflicts of interest	Potential sources of influence or perceived influence on study conduct and conclusions; how these were managed.	Discussion, page 15-17
21.	Funding	Sources of funding and other support; role of funders in data collection, interpretation, and reporting.	Page 17

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Empowering the patient? Medication communication during hospital discharge: A qualitative study at an internal medicines ward in Norway.

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Empowering the patient? Medication communication during hospital discharge: A qualitative study at an internal medicines ward in Norway.

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Abstract

Objective

Effective communication and patient empowerment before hospital discharge is an important step to ensure medication safety. Patients discharged from hospital are often expected to assume self-management, frequently without health care personnel (HCPs) having ensured patients' knowledge, motivation and/or skills. In this sub-study, of a larger study, we explore how the patients experience medication communication in encounters with HCPs, and how patients are empowered at hospital discharge.

Design

This was a qualitative case study. Data collection was done through qualitative observations of patient-HCP encounters, semi-structured interviews with patients and drug reconciliation. Data was analysed using content analysis.

Setting

An internal medicines ward at a university hospital in Norway.

Participants

Nine patients aged 49-90 years were included close to the day of discharge.

Results

The analysis revealed the following themes: 1) Patient centred care (PCC) which included 'understanding and involvement in the patient-as-person', 'establishment of a therapeutic alliance', 'sharing power and responsibility', and 2) Biomedical (conventional) care including sub-themes 'HCPs in power and control' and 'optimising medical outcomes, following guidelines'. Even though

elements of PCC was observed in several encounters, overall communication was not sufficiently fostering empowerment of the patient. Spending time with patients, building relations based on mutual trust seemed to be undervalued.

Conclusions

The results give a broader understanding of how patients experience medication communication during hospital discharge. Both patients and HCPs appear to be inculcated by the biomedical tradition, and uncertain about roles and opportunities associated with PCC. Attention should be paid to patient preferences and core elements of the PCC model should be paid from their admission to discharge, to empower patients in self-management of their medications.

Article summary

Strengths and limitations of this study

- We combined real time observations and patient interviews, which is a powerful approach to understand and describe what happened.
- The sample size is limited, however as the analysis had a specific aim, full observations and rich interview data, the information power is high.
- Patients were mostly unperturbed by the presence of the observer, arguing inconsiderable observer-effects.
- The researchers' sociocultural positions and values might have affected the results, although persons with different backgrounds were involved.
- The study was performed at one internal medicines ward located at one hospital, and its transferability can be questioned.

Key words

Patient empowerment, patient centred care, hospital discharge, patient perspectives, medication communication, observational study, Norway

Word count

4828

Introduction

Effective communication and patient empowerment before hospital discharge is an important step to ensure medication safety (1-4). Patients discharged from hospital are often expected to assume self-management, frequently without health care personnel (HCPs) having ensured patients' knowledge, motivation and/or skills (5-10).

Over the last decades, healthcare systems have shifted focus from the conventional (biomedical) way of practising medicine to an ambition to become involved in the full range of difficulties patients experience (biopsychosocial model, Patient Centred Care), thus covering a larger picture than the purely biological factors (7, 8). In this shift, patients are expected to move from the traditional, passive role, towards being more involved and participate in planning and decision making regarding their health and treatment (7).

In this study, we defined medication communication in accordance with Ozavci et al (3), i.e. as the verbal and non-verbal exchange and understanding of information about the treatment, focusing on medications, between patients, the patient's next of kin, and any HCP attending to the patient.

Patient empowerment has been described as the purpose in the Patient Centred Care (PCC)-framework (11). Patient empowerment is the philosophy of HCPs seeing the patient as an equal, acknowledging them as experts in their own lives (8, 12). Patient empowerment and collaboration between patients and HCPs has been implemented in laws and health care reforms in many countries, including Norway (2, 13-16). However, progress towards improving post-discharge health outcomes has been slow and the efficacy of interventions is currently indefinite (2). PCC focus on dialogues, HCPs listening to and supporting the patients, building the 'therapeutic alliance' between them and patient-as-persons with the patient as an equal party in decision making (4, 8, 17). Patients generally desire a PCC approach, being encouraged to mediate communication, HCPs recognizing their preferred level of engagement and supporting their self-management after discharge (15). Also highly valued by patients is HCPs' `humaneness' (e.g. warmth, respect and empathy), being given sufficient information and time, being treated as individuals, as well as the establishment of mutual trust (8).

According to PCC, HCPs empowering patients is essential not least at hospital discharge. Over the last decade, a number of studies have explored the patient perspective of hospital discharge by interviews (18-27), observation (28), combination of interviews and observation (29-35) and metasummaries (15, 36, 37).

Although there is extensive research on patient empowerment, PCC and related concepts at discharge, it is often viewed from other perspectives than solely the patient's (38). Patient values and perceptions must be appraised to a substantial degree, in order to make evidence-based healthcare services supporting patient empowerment in medication management after hospital discharge (38, 39).

In this sub-study, which is part of a larger study (40), we explore how the patients experiences medication communication in all encounters with all kinds of HCPs that could potentially include medication communication, and how patients are empowered at hospital discharge.

Methodology

Patient and public involvement

A representative from the User's Board at the Hospital Pharmacies Enterprise, gave input on the study protocol (see Additional file 1), and ensured that the information sheet to be handed out and explained to the patients provided a good summary of what the participants needed to know before signing the consent form. The user representative has more than five years of experience from the User's Board and has a master degree in welfare management.

The Norwegian hospital context

Patients admitted to hospitals in Norway receive all their medications from the hospital during their stay but medications are not dispensed at discharge. Home dwelling patients who are responsible for handling their medications will normally have to go to a pharmacy of their own choice and initiative to collect their prescribed medications after discharge.

Approach

This study uses a qualitative research design, consisting of mostly unstructured observations with the addition of semi-structured interviews and medication reconciliation. During the observations, the observer was present and identifiable, but without any role in the social setting (41). Criteria for reporting qualitative research, see Additional file 2 (42), were followed to guide this research.

Setting and sampling strategy

The study setting was at an internal medicines ward at a university hospital in Norway. After discharge, patients were interviewed. The interviews took place in the patient's home, at a short-term nursing home department, a café or by telephone 1-2 weeks after discharge.

Inclusion of patients took place from September to December 2019, Monday to Sunday during regular daytime working hours, close to the day of their planned discharge. Thereafter the patients were followed during HCPs encounters through to hospital discharge. Of 16 patients approached, one declined to participate.

The sampling method was purposive. Patients of various age, ethnicity, estimated length of stay, and with different diagnoses were approached. Patients eligible for inclusion should be ≥ 18 years, home dwelling, responsible for their medication administration prior to hospital admission, and expected to be discharged to their homes, or a short-term nursing home department. Pre-terminal or cognitively impaired patients were not eligible. The eligibility of a patient was assessed based on information from the patient's record and discussed within the research team. Advice was sought from HCPs at the ward when needed, before the patient was approached.

Data collection

Patients and HCPs were approached at the hospital by one of the observers (authors KB, HBL, SER, all female), and written informed consent was obtained prior to enrolment. The patients were approached in their room, provided both verbal and written information about the study and offered time to read the information, before they decided on whether they would consent to participate. The observers disclosed their HCP background to the patients i.e. two pharmacy students and one pharmacist. However, during the observations they dressed to appear more as "the girl from university" than HCPs dressed in white (43, 44).

Relevant information from the observations were documented in a form, developed and piloted, comprising three patients (see Additional file 3). The observations were mostly unstructured and had a patient-oriented focus on the content in the medication communication and contextual factors,

actions, activities and interactions with HCPs. All encounters with HCPs potentially involved in medication communication were observed.

The interviews after discharge were conducted by KB and HBL, and were audio-recorded if the patients consented. An interview guide (see Additional file 4) comprising a list of items and probing questions guided the interviewer. The guide included questions on experiences of the hospital stay, discharge and the period post-discharge, focusing on medication information and the patient's beliefs about medicines. Also included were specific questions based on the observations of the individual patient. In conjunction with the interview, a medication reconciliation was conducted according to the Integrated Medicines Management (IMM) model adapted to the Norwegian setting (45).

De-identified data were immediately stored on a protected area for sensitive data at the university. The observations were audiotaped, if the patient had a single room and if patients and HCPs had consented. Patients gave an additional informed consent to the interview, which was audiotaped.

Ethics Approval

The Regional Ethics Committee assessed the study and found no ethical approval necessary. The study was approved by the Privacy Ombudsman and the Hospital Investigational Review Board March 08 2019, reference number 2019/6465. A gift (value of 150 NOK – 13 € or 14 USD) was given to the patients participating in the interviews.

Authors' preunderstanding

Researchers with different backgrounds were involved, providing different perspectives. SER is a clinical pharmacist and PhD student within clinical pharmacy. KB and HBL were at the time pharmacy students in their final year (master). SKS is a social scientist, holding a PhD in social medicine, and working within social pharmacy. YA is a medical scientist with a PhD in medical research. She is currently working as head of research at the Hospital Pharmacies Enterprise. MM is the head of the Medical Clinic at the study hospital. He is a specialist in internal medicine, digestive medicine and geriatric medicine. LM is a pharmacist with a PhD in pharmacology, currently working within clinical pharmacy at the university. The authors had from none to extensive experience with qualitative methods.

As seen above, the research team consisted of persons with different backgrounds (education, experience of the hospital setting). However, all but one, were female, and all had a Northern-

European background. The researchers were aware of how their sociocultural positions and value systems might have affected the results and discussed this during the research process.

Analysis

Criteria for inclusion in the analysis for this sub-study were the presence of data from observations at the day of discharge and interviews after discharge. This resulted in the inclusion of nine patients.

Data were transcribed consecutively to prevent memory bias. All transcribed data were analysed in Norwegian, using conventional content analysis (46). The first part of the analysis was inductive; codes were derived directly from the first transcripts and a codebook consisting of codes theoretically relevant to the research question was developed in a one-day consensus session (KB, HBL, SER, SKS, YA, LM). Transcripts were read, and codes suggested by all six analysers individually. These preliminary codes were put on post-its on the wall. First individually and then together, the post-its were merged (if describing the same), put into groups, or added (if new codes came up during discussions) (46). Several one-day consensus sessions (including more transcripts), were held, in which the experience from the coding was discussed, and codes slightly changed. All transcripts were imported to the NVivo qualitative data analysis software (47) (by KB, HBL, SER), during this part of the process new codes were added to the codebook. A last revision of the coding was made using the final codebook. All coding made by one person was audited by the others. The first author (SER) condensed text from selected code-groups into units of meaning, focusing on how the patients experienced the medication communication in encounters with HCPs at the hospital, and how they were empowered at hospital discharge. Furthermore, the code groups were combined cross case and clustered into the two main themes, patient centred care (PCC, biopsychosocial, empowerment) and the biomedical framework (non-empowerment), searching for similarities, differences and connections (48). The content was reduced into a condensate and quotes were selected that seemed to best reflect the themes. In order to keep interpretations as close to the sociocultural context as possible and ensure interpretative validity, translation into English (condensate and quotes) was done by three of the authors (SER, LM, SKS) after fulfilment of the analysis. Finally, the translation was discussed with a native English speaking person.

Saturation was considered reached after constantly comparing experiences and responses of the participants, and appraising richness and depth of the data, during the sampling period (49). After 15 observed patients, we concluded we had reached saturation. Of the 15 patients in the main study, 6

were excluded for this sub-study analysis as they lacked the interview (n=2), observations on the day of discharge (n=1) or both (n=3).

The patients are presented as pseudonyms. Quotes are from observations if not specified with 'int' for interview.

Results

The result section is covering the result of the thematic analysis of observations and interview data consisting of two parts; patient centred care (PCC, empowerment) and the biomedical framework (non-empowerment). Table 1 contains information about themes and subthemes.

Table 1 Overview of themes and subthemes.

PCC: Real interest in the patient
- Understanding and involvement in the patient-as-person
- Establishment of a therapeutic alliance
- Sharing power and responsibility
Staying with the biomedical model
- HCPs in power and control
- Optimising medical outcomes, following guidelines

Nine patients were observed and interviewed, demographics and other quantitative data are presented in table 2 and table 3.

Table 2 Demographics of the patients.

Demographics	(*n* = 9)
Sex	
Male, ♂	4
Female, ♀	5
Age, median (range)	71 (49-90)
Education	
Compulsory school/unknown	2
Upper secondary school	4
University	3

Length of hospital stay in days, median (range)	5 (4-18)
Observed days before discharge, median (range)	2 (1-6)
Main diagnoses according to discharge summary	
Atrial fibrillation	2
Pulmonary embolism	2
Pyelonephritis	1
Pulmonary oedema	1
Myocardial infarction	1
Gout	1
Heart failure	1
Citizenship	
Norwegian	8
Other	1

Table 3 Details regarding the semi structured interviews 1-2 weeks after discharge

Duration in minutes, median (range)	55 (33-87)
Location	
Home	4
Temporary sheltered unit	1
Café	3
Telephone	1

PCC: Real interest in the whole patient

When looking at HCPs' behaviour reflecting regarding real interest in the whole patient, essential elements of PCC were observed in several encounters. This could be HCPs listening to and getting to know the person behind "the patient", making an effort to acknowledge patients as experts in their own lives and supporting patients in decision-making (8, 11).

Understanding and involvement in the patient-as-person

HCPs often asked patients about their general condition, sometimes asking patients to prepare questions in advance of the encounter. Some HCPs sat down and listened actively, inviting patients to share what they had on their minds. When patients expressed complex problems, they experienced that HCPs acted on these, e.g. they were offered consultations with a psychologist or social worker.

Doctor: Do you think of something more you are wondering about? Think through or note it down, later today we can go through the medicines together.

Establishment of a therapeutic alliance

Alliances were built when HCPs recognized the patients-as-person, used their names, and included them as partners using the plural form "we". HCPs could remember what had been important during the hospital stay, e.g. they commented on how the patient's condition had changed to the better and they showed real interest in the further follow-up. Some of the HCPs acknowledged the patient's previous experience and knowledge. Sometimes, HCPs could remember details about the patient's children, jobs and private life, which seemed to have a stimulating impact on the dialogue.

Doctor: That's definitely a good idea, we will do that.

Nurse: Here are the medicines you are familiar with. Do you want us to go through them together?

HCPs seemed honest and most often kept their promises, like getting back to the patient if they had said they would. Some patients experienced continuity in the follow-up and experienced that HCPs informed them about what was going to happen next, and sometimes who would come to visit when.

Nurse: We'll see you in a while for the doctor's visit.

Nurse: We'll be back at 11 o'clock to take your blood pressure.

Doctor: I'll finish up the papers and the discharge summary and then we can have a little talk around 3 o' clock.

There were a couple of friendly faces that used to come in quite often and I think that helped because you could ask them the questions and they would get to know why you are asking and not wasting their time. John (♂, 58, int)

Sharing power and responsibility

Most of the HCPs seemed to have a focus on sharing information and increasing both the patients' and their knowledge. Some of the HCPs recognized patients' information-seeking behaviour, e.g. patients who appeared to desire a certain sense of control in medication management were provided with complete information covering all drug names and doses. HCPs also asked specific questions about patients' experiences with medications, and patients were sometimes given the opportunity to influence decisions. HCPs involved the patient's next of kin when required by the patient, and respected patients expressing not wanting to take on any responsibility in the decision-making.

When one of the patients agreed that the previous, non-compliant use of medications could have contributed to the hospital admittance, this patient experienced strong urge from HCPs not to quit medications after discharge. HCPs explained why medications were important, and made efforts to find good solutions, e.g. when the patient expressed reluctance to take one of the medications, the HCP changed to another and both parties became satisfied.

I was fussing about the drug combination. Which my body or my stomach is not very fond of. I had to push them before they took my problems seriously, but I argued it through, and got a new medicine. We decided to do that jointly. They explained why I'm getting it, the side effects and that it would take some time.

Edvin (♂, 61, int)

One of the patients experienced getting timely motivation and preparation for self-management.

I was quite surprised that they wanted me to do the injections myself right from the beginning. They mentioned it, the second day, "do you want to do it yourself"

and I looked at it and thought "I have never given an injection in my whole life" [laughs].

John (♂, 58, int)

The HCPs seemed to focus on providing patients with everything they needed, and sometimes they asked if the patients felt safe about the decision of being discharged. Some of the physicians sat down with the patients while they went through a customized written discharge summary together. One physician made sure that the patient had his glasses so that they both could read. HCPs summed up and repeated information, either to answer questions the patients had or on their own initiative.

Doctor: Are you still ok with syringes or do you want to have tablets instead?

Doctor: You have a huge list of medicines. The changes in medicines are marked in bold. Did you understand what was new? Take care of the sheet and show it to the home care nurse.

Some patients who experienced elements of the PCC-model pointed out in the interviews that more time with and continuity among HCPs and timing of information were specific areas for improvement.

I'd quite like to know why they stopped that one medicine. My suspicion may be early on we did have a discussion, and I was not fully conscious.

John (♂, 58, int)

Staying with the biomedical model

HCPs complied with the biomedical model when they appeared not to show real interest in the patient-as-person or building alliances, treating the patient only based on biomedical parameters like measurements and evidence-based therapy guidelines. Less interest in the patient was observed when HCPs interrupted the patients while speaking, or when they talked to each other without including the patients.

Nurses and nurse assistants thought they knew everything. I didn't like their personality. I didn't bother to discuss with them, but when I heard what they said I thought this is some nonsense.

Sigrid (♀, 71, int)

HCPs in power and control

Generally, HCPs were in power and control over the process at the ward. Most often, HCPs told the patients what to expect, e.g. practical planning of the day. However, sometimes the patients were given promises that were not kept, e.g. a nurse saying "I will come back to take a new blood pressure", but then not coming back. Sometimes the discharge was delayed, without the patient being informed in a timely manner.

Generally, I had to wait for medicines to be delivered to me in the morning, because it was up to the doctors to decide which ones I should have.

Heidi (♀, 53, int)

Most frequently, the patients were informed about changes in their medications after the decision had been made, and they were not invited into any discussion about options. Some of the HCPs did not seem eager to inform the patients about medications, although they had opportunities, e.g. when they were administering them. The nurses often talked about other things while handing out the medications, e.g. practical planning of the day. Some patients experienced that the medication, name and dose were unknown when asked to swallow it.

Nurse: Here are your medicines. Do you want a glass of water or a slice of bread?

The level of detail in the given information was varying and often depending on the patient's request. The HCPs were sometimes unspecific in their communication about medications and in the interviews patients expressed that this made them uncertain as to when the responsibility for administration were transferred back to them after hospital discharge.

It says butenamid in the discharge summary, is that the same as burinex? And "against heart failure", isn't it a diuretic? Diuretic because of heart failure would have been more precise.

Alfred (♂, 80, int)

I don't think we ever clarified whether I should be using that medicine (…) on the letter telling me what I need [reading the generic name]. That's the same?

John (♂, 58, int)

One patient experienced how HCPs seemed surprised when she resisted the changes she was presented with.

They said I should start with a new medicine. I said, no I don't want to. And then the nurse, no the doctor was like… what? They probably didn't expect to hear me saying that.

Heidi (♀, 53, int)

Some patients on the other hand seemed to derive security from the 'HCP knows best' perspective. One of the patients ('Synnøve', Table 4) told about how she was made aware of an error in the hospital doctor's prescription, and how she obeyed the doctor even though she was aware that it was associated with a risk. She trusted her GP to solve the problem.

Table 4 "Synnøve".

I did not have any expectations to the staff. They were nice and dazzling everyone so it was nothing, it was perfectly fine (…) The doctor had finished the papers and when the nurse gave me the discharge summary I could leave the hospital whenever I wanted. It was listed which medicines I should use and which was new. The only thing that was a bit strange was that the doctor had prescribed a new medicine for… I think it was blood clot, and it did not fit with another medicine that I had used from before. And when I got to the pharmacy to collect my prescriptions, she told me "they don't go together". This was a Friday, I let it take its course during the weekend. I had an appointment scheduled with the GP on the following Monday. When I mentioned this, he immediately called the hospital and they replaced the new medicine with another one that was a better fit.

Synnøve (♀, 84, int)

Optimising medical outcomes, following guidelines

When HCPs informed the patients about why they were given medical treatment, they often explained by referring to biomedical parameters. HCPs focused on optimising the medical treatment, following standardised evidence-based therapy guidelines e.g. for cardiac failure, with less focus on increasing the patients understanding or preparing them for self-management. Some of the patients could not recall why they were using their medications, or why some medications had been discontinued at the hospital. HCPs primary focus seemed linked to how the treatment affected the outcomes, not necessary listening to the patient's needs. One patient experienced that while the hospital doctors adhered to the biomedical model, the GP had a more patient oriented approach, and thus they provided different recommendations.

Nurse: You start on a new medicine today; it is more gentle to the kidneys.

Doctor: The ACE inhibitor is very beneficial for the future of the heart, and you have good reasons to use a beta-blocker to prevent the development of heart failure. Diuretics can be adjusted more as needed.

The side effects are a bit troublesome. We [the GP and I] decided earlier to take it out because it was causing my dizziness. At the hospital, they thought I should continue with lisinopril because of the heart having a little too low capacity. But do you have to go dizzy all the time because you have to think about your heart? It gets a bit… tiring so now we [the GP and I] have reduced to every other day. Alfred (♂, 80, int)

Discussion

This study aimed to explore and understand how the patient experiences the medications communication during hospital discharge and how they are empowered through it. Previous studies often melded perspectives of HCPs, patients and next of kin, and limited the observations to the discharge conversation only (28-35). We aimed to capture patient experiences through comprehensive observations covering all encounters presumably involving medication communication, including the discharge conversation, in combination with interviews. Even though

elements of PCC were observed in several encounters, overall communication was not sufficiently fostering empowerment of the patient. Spending time with patients, building relations based on mutual trust seemed to be undervalued.

PCC was observed when HCPs were listening to, recognizing and empowering patients in decision-making and self-management. This is known to encourage patients' medication communication and understanding (15). However, HCPs did not systematically tailor the communication to fill the competence gap between themselves and the patients. The patients were sometimes interrupted despite it being well known that interrupting the patient's `voice of the lifeworld', HCPs `voice of medicine' effectively strips away the personal meaning of the illness (8).

High quality communication is known to foster patient empowerment, hence promoting positive health behaviour, e.g. adherence to medications (9). Empowerment is related to competence and abilities, i.e. high self-efficacy is required to overrule a physician's prescription or knowing when and how to seek medical advice or support (6, 10, 16). One patient in our study, 'Synnøve' (Table 4), was informed about a potential drug-drug interaction at the pharmacy after discharge, that could have led to a reduced effect of the medicine initiated at the hospital. Information seemed not to alter this patient's adherence to her medical treatment. Adherence is known to be positively associated with 'HCP's knows best', and Doctor Health Locus of Control (6). However, attempts to empower patients when they are stressed and focused on returning home, may increase uncertainty and thereby possibly negatively affect empowerment, and reduce adherence (6, 12, 15, 50-53).

During the interviews, patients mostly expressed gratitude and satisfaction when asked what opportunities they had for patient participation. Differing patient expectations may explain why some of the patients were positively surprised when experiencing PCC, while others responded negatively with the biomedical model. A long tradition with the 'biomedical model' may have disabled resourceful patients, who always had been led by powerful HCPs, from taking advantage of their own knowledge. Patients willing to be led by powerful HCPs have an external health locus of control (EHLOC) (6). One patient in our study had an internal health locus of control (IHLOC), i.e. a high degree of self-efficacy. However, his cause of hospital admission was probably related to intentional non-adherence to medications, and as this example highlights, IHLOC and a high degree of self-efficacy is no guarantee for possessing a satisfactory amount of knowledge to take on the required responsibility of making wise decisions (6). Sometimes, it is hard to evaluate the patient's cognitive abilities, and perceived lack of insight because of cognitive limitations can be a barrier to HCPs practicing PCC (10, 54).

In our first sub-study, we found that the (same) patients were mostly proactive, able to be involved and seemed motivated to seek instructions from HCPs. However, some patients chose not to ask all questions they had, and it was evident that patients would have benefited from more information to understand the discharge process (40). The degree to which patients are capable of participation is often dependent upon how well informed they are (38). Patients taking on different roles, or HCPs prejudices, could have influenced HCPs to deliver either the PCC or the biomedical model (15, 55-57). It has been shown that less than 20 % of the variability in patient preferences can be explained by situational and demographic characteristics; e.g. illness or low degree of education can decrease the desire to be involved, whereas age can both increase and decrease it (58). It is important that HCPs review their prejudices because thinking of a patient as for example 'vulnerable', powerless and without agency, may lead to paternalism and incorrect estimation of the patient's capabilities (9, 10, 32, 50, 59, 60).

Building therapeutic alliances, an important concept of PCC, comprises more than HCPs recognizing that a friendly and sympathetic demeanour may increase patient adherence to treatment (8). To safeguard patient autonomy it is important to build relationships between oneself as HCP and the patient, based on mutual trust (8, 50, 61, 62). However, organisational staffing pressure and handover between clinical shifts are barriers in order to build such alliances during hospitalisation (9).

According to the biomedical framework, the value of time spent with patients is recognized but not offered great priority (8). To further develop PCC, HCPs need to embrace dialogues with patients, negotiating about decisional responsibility, with adjustment for capacity, e.g. the 'sick role' (13, 25). HCPs should share more of their knowledge and power; empowering patients implies acknowledging the person's agency in control of outcomes. Improving several aspects of patients' knowledge and self-confidence and how communication is provided is crucial to empowering patients in the management of medications after discharge. From a patient perspective, HCPs listening more actively could be a good way to inaugurate PCC (1, 63, 64).

A strength of the study is the combination of real time observations and patient interviews, which is a powerful approach to understand and describe what happened. What patients told, did not always equal what was observed, e.g. one patient talking about a 30-minute-long discharge conversation that actually lasted for 10 minutes. Because the whole process from hospital admission to hospital discharge was not observed, all encounters supporting self-management were most certainly not observed, however the interviews made sure that the patient perspective was not lost.

A heterogeneous sample of participants were included; however, a bias towards more empowered and confident patients, which could impact saturation, cannot be excluded. Saturation was perceived for the main study, comprising data from 15 patients. Some patients were excluded from this specific analysis as they were not interviewed and/or not observed on the day of discharge. Reasons for such lack of data were that participants withdrew their consent for the interview, or that they were moved to another ward before discharge. The nine patients included in this sub-study did not differ from those excluded by any visible character, like age or sex. As this analysis had a specific aim, full observations and rich interview data, the information power is high although the number of patients is limited (65).

Interviews with patients and HCPs (unpublished focus group interviews with HCPs) found that they were mostly unperturbed by the presence of the observer, arguing inconsiderable observer-effects. One reason stated for this was that they were used to having student observers present at the ward.

This study was performed at one internal medicines ward located at one university hospital, and it is uncertain how well the study findings inform health care contexts that differ from this context.

Conclusion

The results give a broader understanding of how patients experience medications communication during hospital discharge. Both patients and HCPs appears to be inculcated by the biomedical tradition, and uncertain about roles and opportunities associated with PCC. Attention should be paid to patient preferences and core elements of the PCC model from their admission to discharge, to empower patients in self-management of their medications.

List of abbreviations

EHLOC - External Health Locus of Control

HCPs - Health Care Personnel

IHLOC – Internal Health Locus of Control

IMM - Integrated Medicines Management

PCC - Patient centred care

Competing interests

The authors declare that they have no competing interests

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Author contributions

SER, SKS, MM, and LM conceptualized the study and developed the method.
YA, HBL and KB contributed to development of the method.
SER, HBL and KB conducted the data collection.
SER, SKS, HBL, KB, YA and LM analysed and interpreted the patient data.
SER, SKS and LM wrote the original draft.
YA, HBL, KB and MM were major contributors to the writing, review and editing.
All authors read and approved the final manuscript.

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Data statement

Due to the sensitive nature of the data in this study, patients and HCPs were assured raw data would remain confidential and would not be shared.

Supplementary files

Additional file 1. Study protocol

Additional file 2. Observational form

Additional file 3: Interview guide

Additional file 4: SRQR

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Medicines communication in hospital - the patient perspective

Protocol version no. 1 – 2018-10-12

The original protocol was written in Norwegian. In this translated version, elements considered not of central importance, i.e. the introduction and summary has been deleted.

Project participants

Project leader, Co-supervisor: Morten Mowé, associate professor, Faculty of Medicine, University of Oslo (UiO) and Head of the Medical Clinic, Oslo University Hospital. E-mail: mormow@ous-hf.no

PhD-candidate, responsible study pharmacist: Stine Eidhammer Rognan

Responsible for the research: Oslo University Hospital, Morten Mowé

Responsible for the data management: Oslo University Hospital, Morten Mowé

Other project members and collaborators:

- Liv Mathiesen, Main supervisor, Associate professor, Department of Pharmacy, UiO
- Sofia Kälvemark Sporrong, Co-supervisor, associate professor, Department of Pharmacy, University of Copenhagen
- Yvonne Andersson, co-supervisor, head of research and development, Hospital Pharmacies Enterprise, South Eastern Norway
- Marianne Lea, Clinical Pharmacist, PhD-candidate
- Elin Trapnes, Clinical Pharmacist
- Anne Mette Njaastad, Senior Consultant, the Medical Clinic, Oslo University Hospital
- Berit Gallefoss Denstad, User representative, Hospital Pharmacies Enterprise, South Eastern Norway
- Helene Berg Lie, Master's student in Pharmacy
- Kajsa Bengtsson, Master's student in Pharmacy
- Kirsten Kilvik Viktil, Associate professor, Department of Pharmacy, UiOLisbeth Damlien, Clinical Pharmacist, PhD-candidate

Table of contents

Abbreviations

ATC	Anatomical Therapeutic Chemical Classification System
HF	Health Trust
IMM	Integrated Medicines Management
IMS	Internal medical ward
OUS	Oslo University Hospital
PLO	Nursing and Care
REK	Regional Committees for medical and health research ethics
TSD	Services for sensitive data
UIO	University of Oslo

Hypothesis, aims and objectives

The aims and objectives are:

- Mapping the discharge process to identify factors for success and failure towards achieving seamless and safe drug care.
- Evaluating whether patient needs regarding medicine information at hospital discharge were met.

The hypothesis is that understanding the patients' journey through the discharge process, and the patient perspectives, can help to improve the discharge transitions and reduce the gap between different care levels.

Methods

- *Study design:*
  This is a qualitative study, consisting of mostly unstructured observations with the addition of semi-structured interviews and medicines reconciliation.

- *Setting*:
  The study will be conducted at the internal medicines ward, Indremedisinsk sengepost (IMS), OUS, Ullevål and in the patient's home or nursing home, 1-2 weeks after discharge. A pilot study will be conducted during the spring 2019. Inclusion to the main study will start during the fall 2019 and continue until saturation is achieved. Estimated duration of the main study is September 2019 - January 2020.

- *Inclusion criteria:*
  Eligible patients are ≥18 years, home dwelling, have a residential address in Oslo, are responsible for their medicines administration prior to hospital admission, and expected to be discharged to their homes or a short-term nursing home department.

- *Exclusion criteria*: Pre-terminal or severe cognitively impaired patients are not eligible. Patients with planned transfer to and hence discharge from other wards.

- *Number of participants*:

  Part 1: Observational study: The data collection will continue until saturation is achieved. The recruitment of participants will be purposive. Patients of various age, ethnicity and with various diseases will be asked to participate in the study. The PhD candidate will, together with the master's students, select eligible patients. Advice will be obtained from doctors or nurses at the ward. An experienced senior researcher (SKS) will be guiding the PhD-candidate in detailing the design of the study during the pilot period, and as required during the conduct of the study.

  Part 2: Semi-structured interviews: The interviews will primarily take place at the patients' homes, 1-2 weeks after discharge. If patients are discharged to a short-term stay at a nursing home or with increased assistance from the home nursing service at home, any health care personnel will also be asked to participate in the interview, if necessary. As for the observational part, we will aim to assure the information power in the study sample, and the data collection will last until saturation is achieved.

  Inclusion of patients to the pilot study will continue until necessary background information to design the study is obtained.

- *Procedures and training*

Observations and interviews will be performed by the PhD-candidate and master students in pharmacy. The PhD-candidate is an experienced clinical pharmacist familiar with the routines at the hospital and the patient population at the ward. The master students are familiar with drugs and will be provided with relevant training in aspects of clinical work before entering the field work. For example, the Hospital Pharmacies Enterprise, South Eastern Norway has a standardized procedure for training in medicines reconciliation.

All observers will be trained in observation- and interview methods by an experienced senior researcher. The PhD-candidate is experienced with clinical communication with patients about their medicines, and has in addition completed the course FRM5905V Clinical Pharmaceutical Work Methodology, which is a part of the experience-based master programme in clinical pharmacy at the University of Oslo. The PhD-candidate will complete a course in qualitative methods during the spring of 2019. The master's students will complete relevant research preparation courses during the spring of 2019.

Representatives from the internal medicine department as well as a user representative from the user committee at the Hospital Pharmacies Enterprise, South Eastern Norway have been involved in the design and planning of the studies.

A pilot study will be carried out for the observation study and the interview study in the spring of 2019.

- *Data collection:*
  Part 1: The observational study will describe the hospital discharge process. The observations will focus on the patient and cover all events relevant for the medicines treatment, starting when the first tentative discharge date is set or 2-3 days before the tentative discharge date, continuing until the patient is discharged. Eligible patients will be purposively sampled to ensure quality and heterogeneity of the data. The assumed less complicated patient pathways (assumed short length of stay) are attempted to be included early in the study period. These patients will be followed by the observer throughout the hospital stay. The assumed most complicated courses (assumed long length of stay) will be included towards the end of the study period as the observer has gained more experience, e.g. about routines for discharge and events that are relevant to the drug treatment, and these patients are followed from 2-3 days before tentative discharge.
  During the observations, the observer will be present and identifiable, but without any role in the social setting. The observer will only be observing the patient when there are health care personnel present, and the observer will otherwise not disturb the patient. The observer will observe what happens to the patient when the patient interact with health care personnel during their hospital stay, what is said, when and how. The observer may interact with patients if it is natural in the setting, e.g. if a patient initiate a conversation in the hallway which is not about the medical treatment in the hospital. In these situations, keywords from patient conversations will be registered. See the section about content of communication below.

  Written informed consent will be obtained from:

- patients eligible for inclusion
- next of kin and/or healthcare professionals who assist the patient in medication management
- healthcare professionals at the internal medicines ward (will be obtained in advance of the study period)
- external healthcare professionals involved in the patients' medical treatment during the hospital stay (e.g. Infectious Disease Physician, Geriatric psychiatrist, orthopaedist, priest). If any of these do not consent, we will not observe their encounters with the patient

Each observer will keep her observations in field notes, including a diary of chronological events and her own reactions, feelings and opinions about what is happening to the patient. The field notes are comprised of both checklists and free text. Further details of an observational form will be developed during the pilot study. The focus in the observations may be more structured when approaching saturation of the data material is close.

Different types of data will be collected:

- Content of communication (verbal and non-verbal): Communication between patient and healthcare professionals, information or dialogue about medicines including information to the patient about his/her medical treatment. Focus will be centred on the patient and events relevant for the medical treatment.

- Descriptive data: Patient demography, description of contextual factors like behaviours, actions, activities and interactions with healthcare professionals (e.g. what happens, when and in what order, duration of conversations between patient and healthcare professionals). Sex, profession and, if relevant, discipline/specialization of the health care professionals will be registered.

The observers will transcribe the data consecutively to prevent memory bias, to make sure that all details and all reflections are registered. The observers will read each others transcripts and meet on a regular basis to debrief, discuss and hence assure the quality of the data. A pilot will be carried out during the spring of 2019, where registration forms, checklists and procedures will be developed.

Part 2: Semi-structured interviews with the patients already included in the observational study, will be conducted at the patients' homes or at the nursing home department 1-2 weeks after the hospital discharge. The interviews will be audiotaped if the patient consent to this. If the patient do not consent to audio recording, there will be taken notes during the interview. Consent is obtained for observation and for home visits using the same consent form (attached).

If the patient do not communicate in Norwegian or English, we aim to get assistance from a person who speaks the patient's native language to carry out the interview, or the interview will be carried out with the help of an interpreter. The interviews will focus on how the patients perceived the medicines information they received when they were discharged from the hospital. In the interviews, open-ended questions adapted to the individual patient will

primarily be used to explore different patient perspectives. The interview guide will contain predefined questions (see examples below) and for individual patients, keywords from the observational study will be added, for further detailed exploration.

The patient interviews will focus on:

- Which factors related to drug treatment matters the most and why
- How the discharge process was experienced
- Adherence and thoughts about the treatment that was planned when discharged from the hospital

The interviews will also consist of a medicines reconciliation that aims to capture how the patient actually use his/her medicines, misunderstandings and / or challenges experienced by the patient, and the results of the medicines reconciliation will be explored in detail in dialogue with the patient. The patients actual medicines use will be compared to the medicines list in the discharge summary and any information sent from the hospital to the home nurse services by nursing and care (Pleie og omsorgs (PLO)) – messages. If necessary, supplementary information can be provided from next of kin either participating in the interview or in a separate interview (additional consent). The medicines reconciliation will be conducted according to the Integrated Medicines Management (IMM) model adapted to the Norwegian setting.

The interview guide will be piloted during spring 2019.

- *Demographic data and measurement variables:*
  The following demographic data and measurement variables are obtained from the EPJ, electronic medicines chart and any prescription card from a multi-dose dispensing pharmacy. The data will be registered for the study population as part of the inclusion to ensure heterogeneity in the study population:
  - Age
  - Sex
  - Residential area in Oslo
  - Cause of hospital admission
  - Medicines list in the medical record at admission: Number of drugs, ATC-classification
  - Diagnoses (ICD-10): Number, type and, if relevant, year of diagnosis.
  - Date of hospital admission.
  - Date of admission to the internal medicines ward
  - Whether the patient were receiving medicines dispensed in a multi-dose package system prior to admission- Yes/No
  - Level of care in medicines management before hospital admission (independent, partial independent with some assistance from next of kin or home nurse service)
  - Whether the hospital admission was acute or planned
  - Socio- economic background, level of education
  - Ethnic background
  - Cognitive function (form to be implemented at the internal medical ward)
  - Frailty scale (form to be implemented at the internal medical ward)

  If patients do not agree to participate in the study, gender, age and possible cause will be registered (e.g. male, 50 years old, did not want to participate).

The following data will be recorded during or at the time of hospital discharge:

- Medicines reconciliation observed performed during the hospital stay
- Date of hospital discharge
- Where the patient is discharged to
- Medicines list in the discharge summary: Number of drugs, ATC-classification
- Diagnoses (ICD-10) according to the discharge summary: Number, type and, if relevant, year of diagnosis.
- Medicines dispensed in a multi-dose package system - Yes/No
- Level of care in medicines management after hospital discharge (independent, partial independent with some assistance from next of kin or home nurse service)

- *Analysis*

Part 1: Observational study.
Different types of data will be analyzed.

- The communication content of the field notes will be systematically examined by conventional inductive content analysis, which is a useful method particularly when the theory and research literature on the phenomenon being studied is limited (1). After transcribing the content word for word, it will be read repeatedly so that the observers achieve a holistic and in-depth understanding of the content. The data material will be read word by word and coded into different categories that describe the observer's perception of the content of sentences or paragraphs. In the further process, overall themes will be developed that link the categories together. The observers will collaborate in the analysis to ensure quality, i.e. that the context is understood and that important observations are not lost.
- Descriptive data: Mapping of the discharge process, what happens, when and in what order. Time-ordered displays will be developed for this purpose (2). This tool stimulates the identification of what can lead to what and why. Quantitative data such as demography and waiting time will be summarized.

Part 2: Interviews will be recorded as audio files and afterwards transcribed word by word. Analysis will be inductive with systematic text condensation and content analysis (2). In those cases where assistance are obtained from an interpreter to conduct the interview, the transcription is preferably performed by the interpreter. If the interview is conducted by a PhD student or master's student with the help of an interpreter, information from the patient passed on by the interpreter will be transcribed. Where it is the interpretation of what the patient conveys that is transcribed, efforts will be made to find an external interpreter to listen through the audio file in order to capture additional information from the patient. Such work will be remunerated on an hourly basis.

The interviewers will collaborate in the analysis to ensure quality, i.e. that the context is understood.

Furthermore, several separate analysis will be performed with data from the observational study, to identify any patterns across the interview- and observational method. Whether the

patients' need for information when discharged from hospital is satisfied and whether it leads to active patient participation based on the need, will be evaluated.

Any problems the patients face with the drug treatment (revealed by interview and medicines reconciliation) will be classified quantitatively and qualitatively, including the number of patients with discrepancies, the number of discrepancies and the type of discrepancy.

Milestones

	Dato
Completion of protocol including consent form	2018-11-12
Data Handler Agreement (Services for sensitive data – TSD) at the University of Oslo	2019-01-02
Application submitted to the Regional Committees for Medical Research Ethics - South East Norway (REC) and the privacy ombudsman at Oslo University hospital	2018-11-12
Research preparation courses and training for PhD students and master's students	Spring 2019
Piloting	Spring 2019
Inclusion to the main study	Sep. 2019 – Jan. 2020
Submission of master's theses (2 planned)	Spring 2020
Completion of data analysis	June 2020
Submission of articles (3 planned) for publication	Autumn 2020/ Spring 2021

During periods of droplet infection in the ward, inclusion may be slower. Progress in the inclusion will be reported every week to the main supervisor.

Audit and inspection

Hospital Pharmacies Enterprise, South Eastern Norway may perform internal audit of the study.

Ethics

The hypothesis is that understanding the patients' journey through the discharge process, and the patient perspectives, can help to improve the discharge transitions and reduce the gap between different care levels. Communication between patients and healthcare professionals will be observed at the hospital, and patients will then be interviewed 1-2 weeks after discharge from hospital. Before inclusion of patients in the study, they will receive written information about the project and can decide for themselves whether they want to participate or not. It will be taken into account that it may be challenging to visit all patients at home as it may be some patients who does not want to be visited, or withdraw their consent. Some patients will be included in the study even if they only want to participate in the observational study, this can help ensure the information strength of the sample. Before observing health care personnel, they will receive written information about the project and can decide for themselves whether they want to participate or not.

It is well known that information transfer during transition of care is a risk area, and there is a need for greater focus on and knowledge about patient involvement. The purpose of the study is to map the discharge process to identify factors important for achieving seamless and patient-safe treatment, as well as to evaluate whether patients' need for information when discharged from

hospital is met. It is expected that the results from the project will be useful in further development and improvement of health care services for patients.

The observer and interviewer are pharmacy students or pharmacists not affiliated to the internal medicine department on a daily basis, and not involved in the overall assessments behind decisions regarding drug treatment. The observer and interviewer will have no active role in the interdisciplinary team of health care professionals, thus participation in the study will not contribute to any risk for the participants. In case of discovering potentially serious drug-related problems at the hospital, the information will be passed on to the project manager, Morten Mowé, who will make an assessment of what to do with this information. If the interviews reveal critical discrepancies in the patient's medication management at home, this information will be passed on to the home nursing or GP. Master's students will sign a declaration of confidentiality before starting the pilot study.

Privacy and information:
Patients will be included after informed written consent, see appendix for declaration of consent. The same applies to health personnel and any relatives. The attending physician will decide whether the patients are competent to give an informed consent when the observers are in doubt. After consent has been obtained, the patient / health personnel / relatives will be registered with a study number. The code list will be stored electronically in MedInsight. The participants will receive a copy of the consent form. The signed consent forms will be kept locked up in the hospital. The participants will be free to withdraw their consent at any time, without having to give any justification for this. The registered data will be deleted if a consent is withdrawn, as long as the data has not been included in the analysis.

All collected data will be treated confidentially and identifiable data will not be taken from the hospital. Completed transcripts from the observations will be stored immediately on Services for sensitive data (TSD) at the University of Oslo. The interviews will be audiotaped and the files will be uploaded to Services for sensitive data (TSD) at the University of Oslo, immediately after the interview. Audio files will be deleted after the interviews has been analysed. De-identified electronic research data will be processed in the analysis program NVivo on TSD. See attached draft agreement between OUS and UIO. The data will be compiled as de-identified data, with one study number per patient. The code list that connects patient identity to study number will be stored electronically in MedInsight and thus secured and separated from other data. The code list will be deleted no later than 10.01.2023. The signed consent form will be kept locked up in the hospital.

An application will be sent to REC. In accordance with procedures for research at OUS, a notification will also be sent to the privacy ombudsman at OUS.

Budget

The study is funded by the Hospital Pharmacies Enterprise, South Eastern Norway.

References

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Appendices

Written informed consent form

- Patient version
- Health care professional version (a copy can be provided on request)

Data handler agreement for storage of sensitive data (a copy can be provided on request)

Additional file 2

21 Items from the Standards for Reporting Qualitative Research (**SRQR**) - Essential for Complete, Transparent Reporting of Qualitative Research (1).

No.	Item	Description	Section of the manuscript which reports the information that meets the criteria of the checklist
1.	Title	Concise description of the nature and topic of the study. Identifying the study as qualitative or indicating the approach (e.g., ethnography, grounded theory) or data collection methods (e.g., interview, focus group) is recommended.	Title page
2.	Abstract	Summary of key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results, and conclusions.	Page 2
3.	Problem Formulation	Description and significance of the problem/phenomenon studied; review of relevant theory and empirical work; problem statement.	Introduction, page 3
4.	Purpose or research question	Purpose of the study and specific objectives or questions.	Aim, page 4
5.	Qualitative approach and research paradigm	Qualitative approach (e.g., ethnography, grounded theory, case study, phenomenology, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g., post-positivist, constructivist/interpretivist) is also recommended; rationale.	Approach, page 5
6.	Researcher characteristics and reflexivity	Researchers' characteristics that may influence the research, including personal attributes, qualifications/experience, relationship with participants, assumptions, and/or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results and/or transferability.	Data collection, page 6 Authors preunderstanding, page 7

7.	Context	Setting/site and salient contextual factors; rationale.	Setting, page 5
8.	Sampling strategy	How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g., sampling saturation); rationale.	Sampling strategy, page 5 Data collection, page 6 Analysis, page 6-7
9.	Ethical issues pertaining to human subjects	Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues.	Data collection, page 6
10.	Data collection methods	Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources/methods, and modification of procedures in response to evolving study findings; rationale.	Setting and sampling strategy, page 5 Data collection, page 6 Analysis, page 6-7
11.	Data collection instruments and technologies	Description of instruments (e.g., interview guides, questionnaires) and devices (e.g., audio recorders) used for data collection; if/how the instrument(s) changed over the course of the study.	Data collection, page 6 Setting and sampling strategy, page 5 Additonal file 3 Observational form Additional file 4 Interview guide
12.	Units of study	Number and relevant characteristics of participants, documents, or events included in the study; level of participation.	Setting and sampling strategy, page 5 Analysis, page 6-7 Results, Table 1, Table 2, page 8
13.	Data processing	Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding and anonymization / de-identification of excerpts.	Data collection, page 6 Analysis, page 6-7
14.	Data analysis	Process by which inferences, themes, etc. were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or	Authors preunderstanding, page 7 Analysis, page 6-7

		approach; rationale.	
15.	Techniques to enhance trustworthiness	Techniques to enhance trustworthiness and credibility of data analysis,(e.g., member checking, triangulation, audit trail); rationale.	Setting and sampling strategy, page 5 Data collection, page 6 Authors preunderstanding, page 7 Analysis, page 6-7 Discussion, page 16
16.:	Synthesis and interpretation	Main findings (e.g., interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory.	Results, page 7-14 Discussion, page 15-17 Conclusion, page 17
17.	Links to empirical data	Evidence (e.g., quotes, field notes, text excerpts, photographs) to substantiate analytic findings.	Results, page 7-14
18.	Integration with prior work, implications, transferability, and contribution(s) to the field	Short summary of main findings, explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application/generalizability; identification of unique contribution(s) to scholarship in a discipline or field.	Discussion, page 15-17
19.	Limitations	Trustworthiness and limitations of findings	Discussion, page 15-17
20.	Conflicts of interest	Potential sources of influence or perceived influence on study conduct and conclusions; how these were managed.	Discussion, page 15-17
21.	Funding	Sources of funding and other support; role of funders in data collection, interpretation, and reporting.	Page 17

1. O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. Standards for Reporting Qualitative Research: A Synthesis of Recommendations. Academic Medicine. 2014;89(9):1245-51.

Additional file 4

Interview guide

Introduction

- Repetition of aim of study, voluntary participation and the opportunity to withdraw of consent. Audiotaping.
- Estimated time frame of the interview, breaks

Experiences of the hospital stay, discharge and the period post-discharge

- How did you experience the information at the hospital?
  - Did you receive information continuously regarding treatment/medicines?
  - How was the communication between you and the healthcare professionals?
  - How involved were you in making decisions?
  - What was good/not good?

- How did you experience being observed?

- How did you experience the hospital discharge?
  - What kind of information did you get?
    - Did you review/read written information together with health professionals?
    - Were some information only provided as oral information?
  - In what extent did you find the information sufficient?

- How did you experience the information about medicines at the hospital?
  - What information did you get about new medicines ?
  - Who provided you with information?
  - When did you start taking your new medications? Why not?

- Beliefs about medicines
  - What was the most important aspect related to the drug treatment at the hospital?
  - What are your thoughts about medicines in general? What does medicines mean to you? Positive/negative (e.g. side effects, addiction) experiences of medicines?
  - What effect(s) did you expect of the medicines, and what effect(s) have you experienced?

- How have you been after hospital discharge?
  - Did you feel ready for discharge?
  - What challenges did you experience, if any?
  - What is the plan further (e.g. medical treatment)?

Medicines reconciliation conducted according to the IMM-model[1]

End of interview

- Something more to add?
- Opportunity to stay in touch, e.g. to add or request more information.
- Thank you so much for your time

1: *Scullin C, Scott MG, Hogg A, McElnay JC. An innovative approach to integrated medicines management. J Eval Clin Pract. 2007;13(5):781-8.*

Additional file 4

Interview guide

Introduction

- ☐ Repetition of aim of study, voluntary participation and the opportunity to withdraw of consent. Audiotaping.
- ☐ Estimated time frame of the interview, breaks

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Medicines reconciliation conducted according to the IMM-model[1]

End of interview

- ☐ Something more to add?
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1: *Scullin C, Scott MG, Hogg A, McElnay JC. An innovative approach to integrated medicines management. J Eval Clin Pract. 2007;13(5):781-8.*