

BMJ Open Health literacy in medication communication during hospital discharge: a qualitative study at an internal medicines ward in Norway

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ABSTRACT

Objective When discharged from hospital patients are often assumed to have sufficient health literacy (HL) to participate in their medical treatment and manage medical self-care after discharge. However, limited HL is a widespread concern and patient participation during discharge is lacking. In this study, we explore how HL influences medication communication during hospital discharge.

Design A qualitative case study, comprising unstructured observations of patient–healthcare personnel (HCP) encounters followed by semistructured interviews. Data were analysed using content analysis.

Setting An internal medicines ward at a university hospital in Norway.

Participant Fifteen patients aged 40–89 years were included close to the day of discharge.

Results The following themes describing dimensions of HL emerged: (1) access, (2) understand, (3) appraise and (4) apply. Most patients sought access to medication information from HCP, while some felt dependent on HCP to provide it. However, their abilities to understand, evaluate and make informed decisions were challenged, partly because HCPs' ability to adapt their communication to the patient's knowledgebase varied.

Conclusion The results give a broader understanding of how HL influences medication communication during hospital discharge. To consider central dimensions of HL is important to achieve optimal medication communication, as the communication only can be exercised within the frames of the patient's HL. The findings in this study support that HL should be described as a shared responsibility between the patients and HCP. Attention should be focused to the HCP's responsibility to adapt the communication to the patient's knowledgebase.

INTRODUCTION

Medication communication with the patient during hospital discharge is often insufficient, potentially causing adverse drug reactions, medication discrepancies or hospital readmission.^{1 2}

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ Combination of observations and patient interviews is a powerful approach that describes what happened from different point of views, which is a strength to this study.
- ⇒ The sample size is limited; however, the rich interview data and observations provide a high information power.
- ⇒ Participation was voluntary and a bias towards empowered and confident patients cannot be excluded.
- ⇒ This study was performed at one internal medicines ward located at one hospital and the transferability can be questioned.

According to the World Health Organization (WHO) high health literacy (HL) empowers the patient to engage in decision-making about their health, and WHO recognises HL as a 'critical determination of health'.³ However, limited HL is a widespread concern, associated with a poor ability to comply to a medical treatment, a decreased use of preventive healthcare services and higher hospitalisation rates.^{4–6} HL is an evolving concept commonly described as the skills determining the patient's ability to gain access to, understand and use information in ways that promote and maintain health.⁷ Newer definitions describes HL as a dual sided concept, where there is a shared responsibility between the patient and the healthcare personnel (HCP).^{8 9}

The focus of healthcare systems is shifting from the conventional way of practising medicine towards an ambition to involve the patient in the decision-making.^{10–12} In this shift, the healthcare systems are assuming that the patient has sufficient skills to comprehend and use health information, that is, adequate HL, and that home-dwelling patients self-manage their medications after

hospital discharge.^{11 13 14} Despite it being well known that clear and understandable communication empowers the patient, HCP frequently presents health information at an HL level higher than the patient can comprehend.^{13 15 16} Previous studies have identified the patient's engagement during hospital discharge to be lacking and home-dwelling patients are frequently reporting difficulties in medical self-management and in the understanding of health information provided from the hospital.^{17–19}

The patient is the only constant through the 'patient journey' and should be recognised as the key actor in their healthcare.²⁰ While extensive research has been made to improve hospital discharge, it is essential to understand the patient's perspective in addressing health information during and after discharge.¹⁹ By observing the hospital discharge and follow-up with patient interviews, the medication communication can be captured and described from different point of views.²¹ In this substudy, which is a part of a broader research project (see online supplemental file 1), we explore how HL influences medication communication during hospital discharge.

METHODS

Patient and public involvement

A representative from the User's Board of the Hospital Pharmacies Enterprise provided input to the study protocol (see online supplemental 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 5 years of experience from the User's Board and has a master's degree in welfare management.

The Norwegian hospital setting

The patient's right to sufficient health and medication information is anchored in Norwegian legislations. This includes the right to participate in the organisation of healthcare services, where the level of participation and information should be adapted to the patient.²²

Hospitalised patients receive their medicines from the hospital during their stay, but do not get them dispensed at discharge. Home-dwelling patients who manage their medicines themselves will normally collect their prescriptions at a pharmacy of their own choice.

Approach

This substudy was conducted using a qualitative research design, comprising unstructured observations followed by semistructured interviews.

Sampling strategy and setting

The study setting was at an internal medicines ward at a university hospital in Norway. The observers (two pharmacy students and a clinical pharmacist, authors KRB, HBL, SER) enrolled hospitalised patients into the study from September to December 2019, close to the day of

the patients planned discharge. Thereafter, the patients were observed during medication-relevant encounters with HCP, through to hospital discharge. After discharge, the patients were interviewed in their home, at a temporary sheltered unit, a café or by telephone.

Patients were included through purposive sampling. To ensure variation in demographic characteristics, eligible patients were selected, based on sociodemographics (eg, gender, age, education, ethnicity), diagnoses and assumed length of hospital stay. Eligible patients should be over 18 years old, home dwelling and expected to be discharged to their homes or a short-time nursing home department. Preterminal or cognitively impaired patients were not eligible.

Data collection

A pilot study was performed by KRB, HBL, SER, LM to ensure synchronised observations and to develop an observational form (see online supplemental file 2). In Norway, HCP at hospitals normally wears white uniforms. The observers disclosed their HCP background, but dressed to appear as 'the girl from the university', wearing a yellow t-shirt with the word 'observer' across the front, rather than HCP.²³

Data were collected Monday to Friday from 08:00 to 15:30. In addition, observations were conducted over 1 weekend to gain a wider perspective of the patient's experience. Communication involving medications were documented, along with descriptive data like environment, behaviours and the affect on patient activation. Patient's demographics, medical treatment, medical history and discharge summary were collected from the medical records. All patients were mainly observed by one of the observers, in order to maintain continuity for both parties. A second observer stepped in when necessary, for example, during lunchbreaks. The observations were audio recorded if the patient stayed in a single room and both the patient and HCP gave their consent.

The interviews were conducted by KRB or HBL within 2 weeks after discharge and were audio recorded if the patient gave their consent. Interviews were performed using an interview guide (see online supplemental file 3), containing suggestions of open-ended questions and personalised to each patient based on data from the observations.

By continuously comparing eligible patients with data from previously enrolled patients sufficient information power was strived for.²⁴ Saturation was appraised to be reached after 15 observed patients and 10 patient-interviews. Of patients approached, one declined to participate. The patients from the pilot study (n=3) were not interviewed, one patient declined to be interviewed and one patient was not reachable after discharge.

Analysis

The research teams for the analysis had different backgrounds (education and experience in the hospital setting), which provided different perspectives. For the

Table 1 Four dimensions of health literacy⁹

Access medication information	Understand medication information	Appraise medication information	Apply and use medication information
Ability to access medication information and keeping oneself updated on medical issues	Ability to understand and derive meaning to medication information	Ability to evaluate and interpret medication information	Ability to make informed decisions on medical issues

analysis presented in this article, data material from all observations and interviews was analysed. The initial step of the analysis was to inductively create codes using transcripts from the pilot study, first individually and later in multiple consensus sessions (KRB, HBL, SER, SKS, YA, LM). This resulted in a codebook used to deductively code the remaining transcripts (KRB, HBL, SER). Text from code groups involving medication communication and qualities reflecting HL was then condensed into units of meaning. Code groups were combined cross case and the identified units of meaning were clustered into themes, representing four dimensions of HL, inspired by Sørensen's model of HL, [table 1](#).⁹

The content in each theme was reduced into a condensate and modified into descriptions and interpretations in form of an analytic text and quotations. To maintain sociocultural context and ensure interpretative validity, translation into English was done after fulfilment of the analysis.

The patients are presented with age. The quotes are from observations if not specified with 'int'.

RESULTS

Fifteen patients were included in the observational study, of which 10 were interviewed after discharge. Patient demographics are presented in [table 2](#).

The median length of observations was 2 days (range 1–22 days) and the interviews varied between 33 and 87 min (median 55 min). The collected data material consisted of 295 513 words. The thematic analysis comprises four themes; access, understand, appraise and apply.

Access

All patients in this study received medication information during hospitalisation, typically when HCP handed out medicines, during ward rounds and in a written discharge summary. Nevertheless, the level of details often seemed to depend on what the patient had requested.

It appeared as most patients felt responsible to obtain sufficient medication information, by asking HCP questions. Some patients were observed to have written down their questions and thereby prepared themselves for the physician's visit. However, in the interviews, some patients expressed that they wanted specific medication information during hospitalisation but felt dependent on HCP to provide it.

The HCP explained what medicines I received and why I should take them, but very little about side-effects. It would have been nice to get a heads-up about what to expect.

60, int

In the interviews most patients informed that they had been seeking medication information through online

Table 2 Demographics for patients that participated in the study

Demographics	(n=15)
Sex	
Male	7
Female	8
Age	
Median (range)	71 (40–89)
Cause of admission	
Heart failure	3
Atrial fibrillation	2
Pyelonephritis	1
Myocardial infarction	3
Pulmonary oedema	2
Pulmonary embolism	1
Diabetes	1
Gaut	1
Haemoptysis	1
Education	
Compulsory school/unknown	5
Upper secondary school	3
University	7
Citizenship	
Norwegian	10
Other	5
Length of hospitalisation (days)	
≤5	6
6–10	4
>10	3
Unknown*	2

*The patients were transferred to another ward and the discharge was not observed.

searches, by reading patient information leaflets or by asking for medication information at the pharmacy.

I checked a lot of details with the pharmacy staff when I picked up my medicines after discharge. There is one question I always ask; is there something I should have asked you, that I haven't? It makes them think, because they are the ones with the knowledge.

58, int

Even patients who received assistance from next of kin or home care nurse expressed a need to remain some sense of control. However, it appeared as though a few elderly patients, not responsible for handling their medications after discharge, did not feel the need for medication information at the hospital.

I'm sure I received good medicines information, I just didn't bother listening to it.

71, int

HCP was occasionally observed to hand out medicines without sharing information. In these situations, the medical treatment would be unknown to the patient if the patient did not request information.

I got the medicines required, at specific times, so I just took them and thought that's the way it should be. There were no questions. I don't have any clarity of what sort of medicine it was, but it was enough information for me.

89, int

Understand

The patients showed different ways of understanding medication information, as some patients appeared simply to acknowledge it, while others strived to derive meaning from it.

I got a prescription for sleeping pills that I haven't used. I sleep better now, after I started with my heart medicine. It has slowed down my pulse, which I guess is what kept me up at night.

53, int

It was commonly found that the patients reassured that they understood the medicines information at the hospital by responding with questions or asking HCP to clarify or repeat information.

So, it's not sure my blood sugar will continue to be high when I finish this cortisone-treatment? I understand diabetes is a common side-effect.

40

However, some patients were responding with a nod or humming in what seemed to be agreement when receiving medication information, making their level of understanding unclear. During interviews, examples of patients that had struggled to understand the information were revealed.

She used a physician's-language that was hard to understand, so I was thinking: what is she actually saying now?

67, int

The patients often had difficulties in understanding their written discharge summary. Despite this, the written medication information appeared to be an information source for the majority of patients.

Like this, it says butenamid in my discharge summary, that is the same as Burinex. But it says that butenamid is for heart failure and I know Burinex is a diuretic... is it really the same then?

70, int

Appraise

The patients appraised their own ability to evaluate medication information differently. They were commonly found to evaluate their medical treatment, both during hospitalisation and after discharge.

She [the physician] said I should take this medicine at night, because my blood pressure was peaking in the morning. But I've also read a report about the medicine saying it's 50% more effective if you take it at night.

58, int

One patient evaluated HCPs' information during hospitalisation to ensure correct medical treatment and appeared to trust herself more than the HCP.

The nurse told me to take the tablet a half hour after breakfast. But I thought that was wrong, that's not what I've read. I googled it just to make sure I remembered correctly, and I did. You should take it on an empty stomach in the morning, 4–8 hours after food.

53, int

Even though the majority of the patients appeared to evaluate the medication information, the level of source criticism was found to be diverse. There appeared to be a prevalent use of online search engines, while only some claimed to use well known and trusted websites.

I don't remember what website I used... I just googled the name of the medicine and read whatever came up.

60, int

On the other hand, it appeared as some patients found their own ability to evaluate medication information to be insufficient, implying that it is the physician's responsibility.

I think... to be able to discuss anything about medicines, you have to be a doctor. I can't decide anything. I just have to trust the doctor when he says that the medicine is good for me.

48, int

Apply

Some patients appeared to strive for control of their medical treatment, while others seemed to derive security from a 'HCP know best' attitude.

Patients who appeared to seek control often expressed their medical needs and challenged HCP regarding medical issues.

I needed medicine for my enlarged prostatic gland, and I alerted the HCP about difficulties to urinate during my whole hospitalisation. I really had to push for them to act on that.

60, int

However, situations were frequently observed in which the patients did not have the opportunity to be in control of their medical treatment, as they got informed about changes in their medical treatment after the decision had been made. Some patients tried to regain the control by not accepting the medical changes presented to them.

They said I should start on blood thinning medicine, but I said no. The doctor became a bit like, huh?! They did not expect to hear that. But then I said I would do it, I have to do it, right?

53, int

A few patients who felt uncertain about their medical treatment after discharge took responsibility by contacting the hospital to get an extra assurance.

I called the hospital after discharge. It was only pills for the morning and evening in my medicine-dispenser, not for mid-day as I got in the hospital. It didn't say anything about this in my discharge summary either. I was wondering if I had been taken of it or if it was wrong that I didn't get it anymore.

67, int

Some patients had made changes to their medical treatment, without consulting HCP. One patient did not comply with the dosage of his inhalator from the discharge summary, as he stated that the information in the discharge summary was incorrect. Another patient's cause of admission was because of his intentional discontinuation of prescribed medication:

I used blood thinning medicine before, but I got side-effects and it didn't seem to have any effect on my actual problem. I stopped using it on my own initiative, which I guess was a bit stupid of me.

60, int

Some patients appeared to take a more passive position, not striving for control in their medical treatment, assuming that HCP was in charge of all decisions. An example of this is one patient who complied with her medical treatment even though she knew it included drug-drug interactions (DDIs) and did not suit her needs.

At the pharmacy they told me that the new medicine did not fit with another of my medicines. This was a Friday, I took the pills during the weekend, but when I mentioned it at my scheduled appointment with the GP on the following Monday, he called the hospital immediately.

I asked if I could take it [nitroglycerine-spray] before I went out, but the doctor said that I only should take it when I feel chest pain. Then I have to take it in public, which I think is dreadful, but I follow doctors' orders.

83, int

However, even for the more passive patients, it still seemed important to engage, for example, to make sure that the practical aspects of medication management were taken care of.

Everything is new to me, it's a bit of a fuzz. If you could fill the pill-dispenser until Thursday, the home nurse services will take care of it after that. Will you notify the pharmacy?

90

DISCUSSION

This study aimed to explore how HL influences medication communication during hospital discharge. Previous studies often focus on the individual patient's HL; how to measure it and correlate it to the patient's health outcomes and skills in health communication or health behaviour.^{5 6 25-32} The findings from our study describes HL as a shared responsibility between the patient and HCP and supports HL to be a dual sided concept, as high-quality medication communication is essential for the patient to play an active role in their medical treatment.^{8 9}

The patients in our study either took on an active or passive role in their medical treatment.^{15 33} The active patients wanted to engage in their medical treatment and appeared motivated to seek information, while passive patient appeared more dependent on the HCP making decision for them. Low and high HL levels have been connected to patient's characteristics like being passive or inactive in their approach to healthcare versus being active and feeling in control about their healthcare.³⁴

HCP did not always adapt their verbal and written communication to the patient's knowledgebase, creating a gap in the information provided and perceived. Previous studies show that HCP often overestimates the patient's HL and uses a medical jargon incomprehensible to the patient.³¹ This might indicate that the patient is expected to learn areas of expertise that are defined by the healthcare system and that HL is a concept that should not belong solely to the patient.⁸

Some patients in our study were seeking medication information online, which may indicate dissatisfaction with patient-HCP medication communication.³⁵ In addition, many patients appeared to lack awareness of relevant

and reliable websites, as search engines were often the first port of call. Previous studies problematise online health information accessible for patients, as patients may not understand or that an information overload may cause the patients to feel less empowered.^{27 35} Generally, in our study patients still valued the advice from HCP above online health information. HCP could give guidance to the patients in using quality online information sources.³⁵

The passive role of some patients in this study may be a consequence of not understanding or a fear of uncovering the knowledge gap. To accept information without question or without seeking to ensure that it meets one's needs is associated with inadequate HL.³⁴ These qualities can also be correlated with the patients' external health locus of control (EHLOC), for example, relying on that HCP know best rather than one's own capability of being in control of one's health.³⁶ An example of this is described as one patient complied to her medical treatment even though it did not suit her needs and she knew it included DDIs. However, EHLOC fosters the patients' acknowledgement of HCP's medical decisions, which can be beneficial to health and is therefore not equal to inadequate HL.³⁶ Previous studies have concluded that patients that choose to depend on HCP to make health decisions on their behalf often are capable of making informed health decisions themselves.¹⁴ The question is if the patients in our study were silent by choice or silenced due to lack of knowledge.

Patients who believe that their health is directly related to their own actions, internal health locus of control (IHLOC), are assumed to more likely engage in a healthy behaviour.³⁶ The results from this study support that this assumption is true. However, one of the patients who could be described as active, and possessing IHLOC, had discontinued life-necessary medicines on his own initiative, resulting in the current hospitalisation. This patient also struggled to understand the medication information provided from HCP. This exemplifies that IHLOC and an active patient role do not always correlate with adequate HL or healthy outcomes. Adequate HL requires more than to actively seek medication information; it is a key ability to identify when to act autonomously and when to ask HCP for guidance.^{36 37} One can argue that on this occasion the healthcare system failed to communicate understandable health information to the patient, and to assume that this patient's HL is inadequate would seem unfair.

In this study, patients were frequently observed not to have an opportunity to be in control of their medical treatment, as decisions were made in their absence. Even though a few patients argued against a decision that had been made by HCP on their behalf, the general approach appeared to be acceptance, that is, engaging in a passive patient role. Several studies suggest that a lower ambition to participate in decision-making regarding health is related to inadequate HL.^{25 28 38 39} However, similar to our observations, it is argued that patient participation rather emerges from HCP giving patients an opportunity

to participate.^{40 41} Previous studies suggest that patients adjust to the HCP's level of engagement, as low HCP engagement seems to trigger an active patient role and vice versa.¹⁵ However, studies also indicate that HCP more often take the initiative to invite passive patients to participate in medical decisions.⁴¹ This implies that the level of engagement among the patients in our study may have been affected by the HCPs' behaviour designated to increase patient activation, and not solely by their own will.⁴⁰

The combination of observations and patient interviews is a powerful approach that captures and describes what happened from different points of view, which is a strength to this study.²¹ The patient experience does not always equal the objective story. Examples of this were one patient who described a 30-min long discharge conversation that was observed to last for only 10 min.

Participation in the study was voluntary and a bias towards empowered and confident patients can therefore not be excluded. However, the vast majority of patients asked to participate gave their consent and the recruitment of a heterogeneous sample of participants is therefore considered successful. Although the sample size in this study is limited, the rich interview data and observations provide a high information power.²⁴

Interviews with patients and HCP (unpublished focus groups interviews with HCP) found that the observer did not affect the medication communication, at least not in the long run. The long observational time (4 months) at the setting, a hospital ward used to having, for example, students as observers, probably reduced potential observer effects.⁴² Furthermore, the observations were mainly conducted by one observer, who also did the interview, which helped build a relationship between the patient and the researcher. By identifying as the girl from the university rather than HCP, this relationship may have affected the patients to speak more freely in their interviews about their hospital experiences.²³

Although the research team consisted of persons with different backgrounds, all but one were women and all had a Northern-European background. To limit the effect of potential preunderstanding bias, the researchers discussed their sociocultural position and value system during the research process.

This study was performed at one internal medicines ward located at one hospital and the transferability can be questioned.

CONCLUSION

The results give a broader understanding of how HL influences medication communication during hospital discharge. To consider central dimensions of HL is important to achieve optimal medication communication, as the communication only can be exercised within the frames of the patient's HL. The findings in this study support that HL should be described as a shared responsibility between the patients and HCP. Attention should be

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Contributors SER, SKS, MM and LM conceptualised the study and developed the method. KRB, HBL and YA contributed to development of the method. KRB, SER and HBL conducted the data collection. KRB, SER, SKS, HBL, YA and LM analysed and interpreted the patient data. KRB, SER and LM wrote the original draft. YA, HBL, SKS and MM were major contributors to the writing, review and editing. LM is acting as guarantor for the overall content. All authors read and approved the final manuscript.

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Data availability statement All data relevant to the study are included in the article or uploaded as supplementary information. Duo to the sensitive nature of data in this study, patients and HCP were assured raw data would remain confidential and would not be shared.

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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

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Responsible for the research: Oslo University Hospital, Morten Mowé

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- Helene Berg Lie, Master's student in Pharmacy
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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:

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- 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

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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)

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: <input type="checkbox"/> Measurements <input type="checkbox"/> Medicines adm. <input type="checkbox"/> Ward round <input type="checkbox"/> Meal		<input type="checkbox"/> Medicines reconciliation <input type="checkbox"/> Discharge <input type="checkbox"/> Other:	Hospital environment <input type="checkbox"/> Single-bed room <input type="checkbox"/> Meal <input type="checkbox"/> Facilitation, e.g. movement, hygiene <input type="checkbox"/> Telephone/calling <input type="checkbox"/> Other:	Written information about medicines at hospital discharge <input type="checkbox"/> Distributed <input type="checkbox"/> 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). <i>Remember to describe any consequence of observer presence!</i>					

Incl.nr	Department/group	Bed	Observer (initials):	Date:	Page /
<p>Part 1: Chronological observations; Actions, quotes patient/health care personnel (e.g. questions, use of medical terms), drawing of the setting.</p> <p>Part 2: Observer interpretations, reactions, feelings, opinions (environment and communication). <i>Remember to describe any consequence of observer presence!</i></p> <p>Cont.</p>					

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-model¹

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, McElroy JC. An innovative approach to integrated medicines management. *J Eval Clin Pract.* 2007;13(5):781-8.