

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.

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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

1. Hsieh H-F, Shannon SE. Three Approaches to Qualitative Content Analysis. *Qualitative health research*. 2005;15(9):1277-88.
2. Malterud K. *Kvalitative metoder i medisinsk forskning - en innføring*. Oslo: Universitetsforlaget; 2011.

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)