PCNE WS 4 Fuengirola: Development of a COS for interventions to optimize the medication use of people discharged from hospital.

Aim:

The aim of this study is to develop a core outcome set for interventions to optimize the medication use of people discharged from hospital.

Methods:

Defining the scope

The scope for this COS was defined by an international group of experts linked to PCNE (Pharmaceutical Care Network Europe) during two consecutive consensus meetings, as to make sure that the COS would be relevant for all kind of intervention projects in this field.

Preliminary search

Before starting the development of the COS, a systematic search was performed in the COMET (Core Outcome Measures in Effectiveness Trials) database to make sure there was no existing or ongoing work on this topic. We found…

Overview of the work performed

The COS was developed using a 4-step approach, shown in Figure 1. We followed the guidelines for the development of a COS, and the project was registered on the COMET database (XXX).

A research team was set up with experts linked to PCNE and local investigators of the participating centres.

Step 1: systematic review

Purpose

The objective of the systematic review was to identify all outcomes used or planned to be used in previous and ongoing studies investigating the impact of interventions aimed to optimize the medication use of people discharged from hospital.

Search strategy

The following electronic databases were used: PubMed, Embase, Cochrane, OVID, Web of Science, Cinahl, clinicaltrials.gov.

The search string was built from terms referring to the target group (patients discharged from hospital: hospitalized, in-patient, discharge) and the type of intervention (education, counselling, medication management, new medicine service, medication review, medication reconciliation, dose adaption, self-care, motivational interviewing, shared information, shared medical records, telemonitoring,…). The search was further limited to studies focusing on medication (medication, medicine). MeSH terms or similar categories were used wherever possible.

(status: MeSH terms have been defined)

The search was limited to studies published in English during the last ten years (?).

Two reviewers independently assessed the title, abstracts, and full texts of studies resulting from the search. A third reviewer was consulted if no consensus was reached.

Result PubMed search: papers

Study selection

We considered the following study types: Clinical Trial; Comparative Study; Controlled Clinical Trial; Evaluation Studies; Meta-Analysis; Multicenter Study; Observational Study; Pragmatic Clinical Trial; Randomized Controlled Trial; Systematic Reviews.

In addition, also prospective interventional studies were considered.

The following studies were excluded:

- Studies published before 2008 (or: before 2000?)
- Qualitative studies[1]; cross-sectional studies; pilot studies
- Non-peer reviewed studies
- ~~Studies on specific diseases~~
- Studies where no outcome was reported
- Studies with no abstract available

- *Sample size lower than … (could be later on)*

Data extraction

The following data were extracted from the retrieved studies: setting (hospital setting, primary care); health care professional providing the service; type of intervention; number of patients included or intended to be recruited; mean age of the patients.

Concerning data on outcomes and outcome instruments, the following information was retained: name of the outcome (free text); primary or secondary outcome; instrument used to measure the outcome.

All data extractions on outcomes and outcome measurement instruments were performed by two independent reviewers (xx). Findings were summarized in an excel file.

Classification of outcomes into health domains and subdomains

The classification of the outcomes extracted from the studies was performed in several rounds. We first identified a list of subdomains…

Qualitative research

Purpose

A qualitative study was set up to fill the gaps in literature, and to make sure that all outcomes that matter for the population of interest are taken into account.

[1] Why not qualitative studies? Because stakeholders will be involved in the next step. Moreover: COS focuses on clinical trials.

Study design

First, the literature was searched for studies investigating the viewpoints of different groups of stakeholders related to medication use around discharge. The same search strategy as described in XX was used, but in this step we focused specifically on qualitative research.

In a next step, focus groups and semi-structured interviews were performed to complete the data from the literature. Focus groups were chosen as a method to get input from health care professionals and other stakeholders; interviews were performed to know what matters to patients, family members and carers.

Participants

Focus groups and interviews were performed in five different countries (XX,…).

In each country, one focus group was organised. A hospital was the starting point for participant sampling because of the availability of an operational structure (e.g. steering group, discharge management team) having contact with all sectors of health care (GPs, community pharmacists etc.). The following HCPs were invited to participate in each focus group: a general practitioner, a general practitioner-coordinator in a nursing home, a medical specialist (preferentially from geriatric, surgery or emergency ward), a community pharmacist, a hospital pharmacist, a ward nurse, a home care nurse, a care coordinator, and a discharge manager. The focus groups with stakeholders involved people having responsibility in professional organizations of the different disciplines or working for larger organizations in the field (care coordinators, community pharmacists, general practitioners, home nurses, hospital pharmacists, patients, medical specialists, employees of insurance companies, and representatives of the ministry of health).

In each country, also eight interviews with patients and/or family members were organized. Patient recruitment was performed in two community pharmacies or two GP practices. Patients were eligible if they had been recently discharged from the hospital (less than three months ago) and were using at least XX different medications post-discharge.

The study was approved by the local research ethics committees (XX).

Interviews

With the agreement of the physician in charge of the patient's care, the researcher informed the patient or the caregiver about the study and its objectives. Participants provided informed consent prior to the interview.

The topic guide was developed within the international research group, based on information available in the literature and previous experience. Focus of the interview was on the perception of the patient on a seamless transition, and what matters to them regarding medication use.

Interviews were recorded and transcribed verbatim.

Focus groups

Analysis

Transcripts of the interviews and focus groups were analysed using NVivo. The analysis was conducted by two independent researchers (X and Y). The analysis focused on generating a comprehensive list of outcomes that are important to patients, HCP and other stakeholders.

Consensus process

Who should be involved?

- *Head of internal medicine department*
- *Head nurse of a hospital department*
- *General manager of the hospital*
- *Main partner of the surgery*
- *Pharmacy manager*
- *Research pharmacists*

Research team

About 15 people confirmed that they are willing to work on the development of the COS over the next year.

A google docs will be used to divide the tasks. For each task, a leader will be assigned:

- Literature review:
- Qualitative research: Fabienne B
- Delphi approach: Veerle (?)

Publication policy

As a first step, the initiative will be registered on the COMET database (VF). Next, the protocol paper will be finalized and published (VF?).

For all papers (international and national), a publication policy should be developed.