Report on Workshop 5 at the 11th PCNE conference (Pharmaceutical Care Network Europe) in Egmond aan Zee, 6-9 February 2019

Development of a core outcome set (COS) for pharmacist-led interventions to optimize the use of oral anticoagulants (OAC) in adults

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Research team

Ten researchers from 5 countries (Australia, Germany, Malta, Switzerland, The Netherlands) formed a think tank during a 4-days workshop, and worked on the development of the above mentioned COS. One participant (SJ) is a PhD student in Leiden (The Netherlands) and will evaluate with his promotor whether he can the project to a successful conclusion within his PhD thesis.

Figure 1: Participants of the Workshop 5 of the 11th PCNE conference; participants who worked on the presented report are highlighted in green.

Background

It is challenging to define and chose valid outcomes (i.e., the "what" we measure and report in studies such as QoL, mortality, GP visits, falls, ADR, gait speed etc.) that allow to prove the added value of pharmaceutical care. In addition, the use of different outcomes makes comparing and combining data very difficult. The development of a core outcome set (COS) for specific pharmaceutical care entities has the potential to measure relevant outcomes, to reduce heterogeneity between trials, to reduce the risk of outcome reporting bias and thus, to enhance the value of evidence. The driver is whether the selected measurement (of the outcomes) is sensitive to change. Thus, the selection of the outcomes is the central element i.e., meaningful and important outcomes to all key stakeholders. The definition of COS is "*a standardised set of outcomes, with international relevance, that represents the minimum that should be measured and reported in all trials within a specific area*" [1]. The feasibility of the measurements in the local settings should be taken into account, depending whether the study is for research of for implementation into practice.

Aims

i) to develop a core outcome set (COS) for pharmacist-led interventions to optimize the use of oral anticoagulation drugs in adults, independent of the indication (prevention, treatment) and the setting (ambulatory, institutionalized care);

ii) to evaluate the utility of goal attainment scaling (GAS) as instrument to measure an outcome.

Methods

The key components of COS development will be used according to [2] (Figure 2).

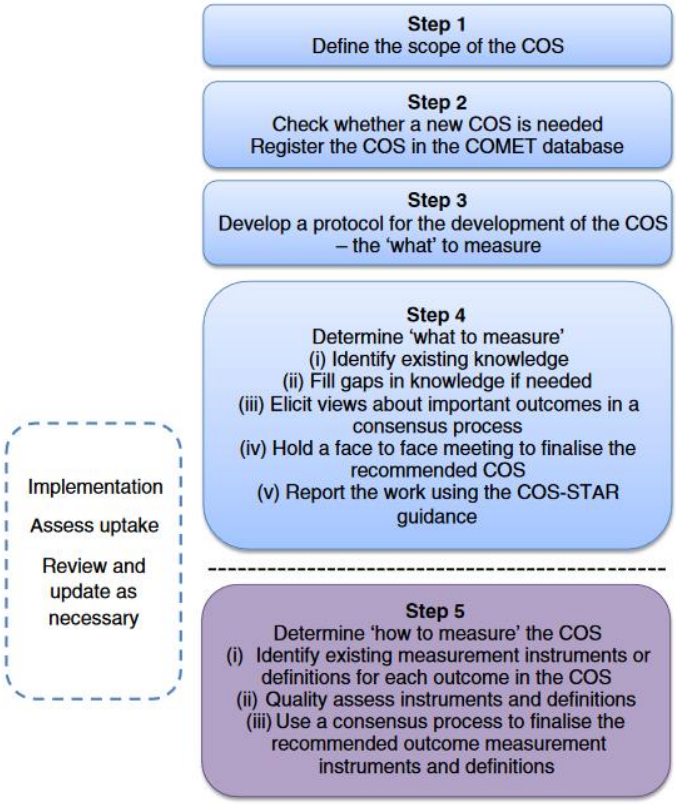

Figure 2: The core outcome set (COS) development process [2].

A. Identify existing knowledge

A1) Search in the COMET database (Core Outcome Measures in Effectiveness Trials)

A search (www.comet-initiative.org) performed 7 February 2019 showed that there is no existing or ongoing work on this topic. We obtained one hit with the search word "anticoagulation": "Trial design and reporting standards for intra-arterial cerebral thrombolysis for acute ischemic stroke", from 2003.

A2) Literature search

A fuzzy search will be performed in Pubmed, as we assumed that many studies have been performed and published, each with formulated outcomes. A preliminary search with the following concept map was performed:

	Key word 1	**AND key word 2**	**AND Key word 3**	**AND Key word 4**
OR	vitamin K antagonist	Pharmacist*	atrial fibrillation	clinical trial
OR	anticoagulation	pharmacy-led	thromboembolism	RCT
OR	NOAC		prevention	
OR			treatment	

Filters: 5 years

A3) Search in the grey literature

We propose to search the following sources of information in the following countries:
--GERMANY: ABDA, Fachgesellschaften cardiology, haematology, orthopaedic;
--AUSTRALIA: Pharmacy guildes with depository; Pharmaceutical Society PSA;
--NL: KNMP guidelines; NHG guidelines for GP;
--SWITZERLAND: ESC guidelines.

A4) Data extraction

Extraction of ECHO (economic, clinical, humanistic outcomes) from the retrieved studies will be performed, until saturation (to be defined; proposed as "3 times in a row the same outcome"). The outcomes will be listed according to the COMET taxonomy for outcome classification [3], including process outcomes. We will end up with a long list of outcomes.

A5) Brainstormed outcomes from participants

adherence to medication; bleeding; prevention of the thromboembolic event; convenience of treatment (eg, complexity); hospital admissions (number, length, re-admission); costs; treatment burden; satisfaction; QoL; use of antidote/blood transfusion; adverse drug events other than bleeding; ED visits; mortality; patients' questions/consultation/telephone boosts.

B. Stakeholders involvement

B1) Selection

Further outcomes will be obtained by interviewing the following stakeholders: patient organisation, carers, pharmacists, GPs nurses, specialists (cardiologists, haematologists), anticoagulation clinics, payers (insurance company; government; pharmaceutical company); professional associations (pharmaceutical, cardiology).

B2) Questioning

SMART questions will be developed. Because of time constraint. Focus groups will be reduced to a minimum that is, to patients. A chat platform on social media will be created with the name: #WeBloodThinners. We will ask Dr. Mehandra Patel (from the UK) for advice on dissemination.

C. Consensus process

To be developed. The participants will form the first set of panellists of the Delphi rounds. Snowball sampling was chosen as valid method to augment the number of panellists. Consensus will be defined. We will end up with an approved list of outcomes.

D. Instruments

To be developed. Instruments able to assess/measure the outcomes will be searched in PubMed. The feasibility to use the instruments in the different countries will be taken into consideration.

E. Utility of GAS

The usefulness of GAS is acknowledged as a useful approach to facilitate person-centered pharmaceutical care. However, to succesfully apply collaborative goal-setting, pharmacists need specific skills training and competency assessment. GAS is seen as a novel instrument to measure a behaviour and its change, and not a process. Thus, the targeted outcome could be in one of the following contexts: i) adherence to medication; ii) anxiety; iii) self-management of treatment.

Because GAS can only be developed together with the patient, a model GAS for any patient's complaints was developed. The corresponding pharmacy-led intervention will target patient knowledge.

- PROBLEM: insufficient knowledge about self-management of treatment; mainly side effects such as bleeding.
- GOAL: patient knows what to undertake in case of side effects such as bleeding.
- PLAN: give instructions (up to stop treatment), at the discretion of the pharmacists.
- EVALULATION: verification question such as "What do you do when you bruise?"

A lot more	Patient knows what to do when he suffers from >2 side effects	+2
A little more	Patient knows what to do when he suffers from 2 side effects	+1
Goal achieved	Patient knows what to do when he suffers from 1 side effect	0
Baseline /No change	Patient doesn't know what to do when he suffers from a side effect	-1
Get worse	Patient has wrong knowledge and suffers from side effects	-2

Table 1: Model GAS targeting a deficient knowledge on side effects with OAC.

The term “side effect” can be replaced with any complaints concerning:
--drug management (adherence, diet);
--laboratory management (self-monitoring);
--co-medication (DDI);
--fear (of anticoagulation; side effects).

Publication policy

The project should be registered on the COMET database.

References

1. Prinsen CA, Vohra S, Rose MR et al. Core Outcome Measures in Effectiveness Trials (COMET) initiative: protocol for an international Delphi study to achieve consensus on how to select outcome measurement instruments for outcomes included in a “core outcome set”. Trials 2014; 15: 247
2. Williamson PR, Altman DG, Barnes KL et al. The COMET Handbook: version 1.0. Trials 2017;18(Suppl 3):280
3. Dodd S, Clarke M, Becker L. A taxonomy has been developed for outcomes in medical research to help improve knowledge discovery. J Clin Epidemiol 2018; 96: 84-92