Participant information letter

Development of Quality Indicators for in-hospital pharmacotherapeutic stewardship: A RAND-modified Delphi study

Dear participant,

You are asked to participate in a scientific study. Participation is voluntary. Your digital informed consent is required prior to participating.

You are asked to participate in this study because you are a member of the European Association of Clinical Pharmacology and Therapeutics (EACPT), are active in the field of prescribing and medication safety and/or selected by a colleague.

This study is conducted by Amsterdam University Medical Centers - location VU University Amsterdam (VUmc) on behalf of the Education working group of the European Association of Clinical Pharmacology and Therapeutics (EACPT). This study and study procedures have been approved by the Medical Ethics Committee of Amsterdam UMC – location VUmc and has decided that this study does not fall within Medical Research Involving Human Subjects Act (WMO) **(no. 2021.0221)**. The registration number of data collection and –processing in VUmc is **VUmc_2021-5261.**

Prior to participation, you are informed about this research. Please read this letter carefully and feel free to ask additional questions to this research to the coordinating researcher or principal investigator described in point 7.

1. Purpose of the study

The purpose of the study is to develop a set of Quality indicators (QIs). QIs are explicit statements providing measurable items and metrics for the quality of care, assessing 3 aspects of care:

- structure, reflecting the healthcare setting's organization;
- process, reflecting the delivered care to eligible patients;
- and outcome, reflecting interventions' consequences and patient outcome.

Reliable, specific and evidence-based QIs could provide a framework for appropriate in-hospital pharmacotherapeutic stewardship, that can be used as metrics for quality assessment and improvement of the in-hospital setting.

2. Expectations

This is a RAND-modified Delphi consensus study among experts in the field of prescribing, medication safety and clinical pharmacology and pharmacotherapy (CPT). The study consists of two rounds of online questionnaires, conducted through the online survey programme Castor EDC. Finally, an online consensus meeting will be held on the 29th of June 2021 during the official, online focus meeting organized by the EACPT.

In both rounds we will send an online questionnaire with statements per aspect of care (structure, process and outcome).

Round 1:

You will be asked to appraise each potential QI on a 5-point Likert scale (with 1 indicating "strongly disagree"; 2 "disagree"; 3 "neither agree nor disagree"; 4 "agree" and 5 indicating " strongly agree"), including the options 'cannot assess'. You will be enabled to comment to each potentially relevant QI, including suggestions for rephrasing and adding QIs for consideration.

Round 2:

All accepted, rephrased and newly suggested QIs will be presented in an extensive summary for final remarks. You will be asked to rate newly suggested QIs using a 5-point Likert scale (with 1 indicating "strongly disagree"; 2 "disagree"; 3 "neither agree nor disagree"; 4 "agree" and 5 indicating " strongly agree") and to express their agreement on suggested QIs with either 'yes' or 'no'.

Both rounds will take approximately 15 minutes to complete.

Online consensus meeting:

During the online consensus meeting held on the 29th of June organized by the EACPT outcomes and statements for rephrasal resulting from the surveys will be discussed with survey-participants. Participation during this meeting is voluntarily.

This research requires that we collect additional information from you. It concerns personal data as described in point 5. Please see there for further information.

3. Possible disadvantages, risks and benefits

You do not gain any (direct) benefit from participating in this study. Your participation can contribute to more safe in-hospital prescribing in Europe and it will support and harmonize measurable items and metrics for the quality of care, assessing 3 aspects of care (structure, process and outcome) of pharmacotherapeutic stewardship in the in-hospital setting in Europe to improve medication- and patienf safety.

Risks and disadvantages associated with participation are slim: we ask you for a time-investment of around 30 minutes in total.

4. Participation
Participation in this survey is entirely voluntary. If you decide to participate in the study, you can stop participating at any time during the study and without giving a reason. Your data collected in the survey will be deleted and not used in this study. If you have already signed the electronic consent form, you can announce your withdrawal via email to r.mahomedradja@amsterdamumc.nl.

5. Data processing and storing
For this study it is necessary to collect personal data. This concerns your: email address, age, gender, university affiliation, profession, number of years of clinical experience and number of years you are prescribing. The personal data will not be visible to other respondents. Furthermore, this personal data will not be linked with other research data.

All data is collected in the confidential and secure system Castor EDC (GDPR and ISO 27001 & 9001 certified). After collection, data will be stored in a separate directory on the secure server of Amsterdam UMC location VUmc that only the research team has access to. This data will be coded, meaning that every participant will have a code that is used instead of the name and other personal identifiable information. Only the researcher (Rashudy Mahomedradja) know which code is linked to which participant. At publication, all data will be fully anonymized and untraceable back to you.

If you participate in this study, you consent to data being stored for 15 years after ending the study for further analysis within context of this study. After 15 years, the data will be destroyed. When requested, we will destroy your data within 15 years after ending the study, but published or submitted data will not be retracted. Prior to using data outside the context of the current study, we will always contact you for additional consent. Upon request via e-mail you will receive an electronic copy of your own data.

For more information about your rights on data processing, you can contact Rashudy Mahomedradja via r.mahomedradja@amsterdamumc.nl or professor dr. Michiel van Agtmael via agtmael@amsterdamumc.nl. Rashudy Mahomedradja is responsible for lawful data processing. If you are dissatisfied about how we handle your privacy, you may file a complaint to our privacy officer via privacy@vumc.nl. You can also contact the Dutch Data Protection Authority (DPA) via https://autoriteitpersoonsgegevens.nl/en/contact-dutch-dpa/contact-us.

6. Compensation for participants
There will be no compensation for participating in this study.

7. Contact information
If you have any remaining questions, please contact Rashudy Mahomedradja (coordinating researcher) via r.mahomedradja@amsterdamumc.nl or professor dr. Michiel van Agtmael (principal investigator) via agtmael@amsterdamumc.nl or via +31 (0)20 444 8090.

Thank you for your time and interest in this study.

Yours sincerely,
Rashudy Mahomedradja, PharmD
Dr. Jelle Tichelaar, MD, PhD
Dr. Kim Sigaloff, MD, PhD
Prof. dr. Michiel van Agtmael, MD, PhD

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Informed consent form

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- I have read the information letter for participants. I have had the opportunity to ask additional questions. My questions have been sufficiently answered. I have had enough time to decide whether to participate or not.
- I know that participation is entirely voluntary. I am aware of my right to withdraw or end my participation from the study at any time. I do not need to justify that decision.
- I know that certain people have access to my data. These people are listed in this information letter. I am entitled to inquire and look into how my data are stored.
- I consent to my data being used in the way and for the purpose stated in the information sheet. If for any reason my data would be used for research with another objective, I will be informed and again be asked to consent.
- I consent to my data being stored for another 15 years after ending this study to permit further analysis within the context of this study.

This is a digital informed consent form, built into Castor EDC. If participants select Yes, they will be able to continue the rest of the survey. If participants select no, they will be prompted the message: "Without consent you cannot participate in this survey." And they will not be able to continue to the rest of the survey. The date and timestamp is automatically logged the moment the survey is completed. (As the survey cannot be viewed without consent, this means that consent is always given prior to completion).