Participant information letter

The European List of Essential Medicines for Medical Education, a Modified Delphi Study

Dear,

You are asked to participate in a medical education 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 listed as a (principal) clinical pharmacology and therapeutics teacher in the European Network of Teachers in Pharmacotherapy (NOTIP). Therefore we expect you to be the most knowledgeable person at your medical school on the subjects of this survey.

This study is conducted by Amsterdam University Medical Centers, VU University Amsterdam on behalf of the Education working group of the European Association of Clinical Pharmacology and Therapeutics (EACPT). The executive researcher is Erik Donker, PhD-student at Amsterdam UMC. This study has been approved by the Ethical Review Board Committee of the Netherlands Association for Medical Education (NVMO) and the Medical Ethics Committee of Amsterdam UMC (VUmc) has decided that this study does not fall within Medical Research Involving Human Subjects Act (WMO).

Prior to participation, you are informed about this research. Please read this letter carefully and feel free to ask additional questions to the researcher.

1. Purpose of the study
The purpose of the study is to construct a list of available drugs which are standard practice to prescribe and which a European junior doctor must be able to prescribe safely and effectively without supervision. This will improve and harmonise the design of education and training in clinical pharmacology and pharmacotherapy (CP&T) in all medical curricula in Europe.

2. Expectations
This is an online Delphi consensus study among experts in the field of education in CP&T. The study consists of two parts, conducted through the online survey programme Castor EDC.
Part 1 (starting date: 13rd of September 2021):
In part 1 we will send you a list of drugs and ask you to indicate which drugs are available to prescribe in your country. Moreover, we would like to ask you to send us the email addresses of a group of experts within your university so we can invite them to participate in part 2 of the study. Please adhere to the following criteria for the selection of your expert group:

- Two experienced (≥3 years of teaching experience) teachers who are explicitly engaged in education in CP&T, of which at least one teacher is registered as a clinical pharmacologist;
- At least five medical specialists, preferably a surgeon (e.g. general surgeon); an internist (e.g. general internist, gastroenterologist, pulmonologist, cardiologist); a general practitioner; a specialist in geriatric medicine or geriatrician;
- Two recently graduated junior doctors (graduated ≤1 year ago) who have clinical patient contact.

Part 2 (starting date 18th of October 2020):
Part 2 will consists of two rounds. In both rounds we will send a list of drugs and ask you (and colleagues) to evaluate two statements per drug:

1. "In my country, it is standard practice to prescribe this drug to patients."
2. "A junior doctor must be able to prescribe this drug safely and effectively without supervision."

There is also room to note down suggestions of missing drugs. In addition, in round 2 we will ask you (as a coordinator) to indicate whether the new suggested drugs are available in your country. Both rounds will take approximately 30 minutes to complete.

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

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 prescribing of (junior) physicians in Europe and it will support and harmonize the educational programs in clinical pharmacology and pharmacotherapy in Europe. Risks and disadvantages associated with participation are slim: we ask you for a time-investment of around 90 minutes in total.

4. Participation
It is up you to decide whether or not participate in this survey. Participation is entirely voluntary. Your decision will not be shared with the other local coordinators. 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. Only data that is already send to the other participants for part 2 and/or round 2, and the actual publication cannot be retracted. If you have already signed the electronic consent form, you can announce your withdrawal via an email to e.donker@amsterdamumc.nl.
Participation of the group of experts that you have selected will also be entirely voluntary. It is not allowed to oblige your employees to participate. The decision of the experts will not be shared with you.

5. Data processing and storing

For this study it is necessary to collect personal data. This concerns your: email address, university affiliation, profession, number of years of clinical experience, number of years of teaching. The personal data will not be visible to other respondents.

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, 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 two researchers (Erik Donker and David Brinkman) knows which code is linked to which participant. At publication, all data will be fully anonymized and untraceable back to you. We will never publicize individual responses together with a name, university or country. Therefore, 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 10 years after ending the study for further analysis within context of this study. After 10 years, the data will be destroyed. When requested, we will destroy your data within 10 years after ending the study, but shared, 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. The executive researcher will always contact you for interim relevant information. 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 Erik Donker via e.donker@amsterdamumc.nl. Erik Donker 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

There will be no compensation for participating in this study, except that all participating experts will be listed as contributor to the resulting journal article.

If you have any remaining questions, please contact Erik Donker via e.donker@amsterdamumc.nl or +31 20 444 8090.

Thank you for your interest in this study.

Yours sincerely,
Erik Donker, MD
David Brinkman, MD, PhD
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De volgende tekst wordt in begin van vragenlijst geplaatst en deelnemers kunnen alleen doorgaan als ze instemmen met onderstaande tekst.

Informed consent form

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- I have read the information letter for coordinators. 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 10 years after ending this study to permit further analysis within the context of this study.
- I know that when requested, the executive researcher will destroy my data within 10 years after ending the study, but shared, published or submitted data will not be retracted.