# Patient Safety Culture and Medication Safety in Intensive Care across Europe: Focus Group Interviews

# Participant Information Sheet

**Principal Investigator: Dr Raisa Laaksonen**

**Co-Investigators: Special Interest Group for the Investigation of Medication Errors in Intensive Care Units, European Association of Hospital Pharmacists (EAHP)**

Thank you for considering participating in this research project. Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish, as well asking us if there is anything that is not clear or if you would like more information. You can find the relevant contact details below.

Should you decide to take part keep a copy of this information sheet and your signed consent form.

**What is the purpose of the study?**

The purpose of this study is to explore the patient safety culture that exists in intensive care units as experienced by the healthcare professionals working in that setting across Europe. We are interested in knowing more about the practices that exist to promote medication safety, and to determine barriers and enablers to the implementation of medication error prevention strategies in the intensive care setting. We are hoping that the findings from these focus groups will be used to inform the development of policy recommendations to support medication safety in intensive care units.

**Who is this study for?**

Healthcare professionals (e.g. doctors, nurses and pharmacists) working in intensive care units and patient safety experts from different European countries have expertise in, and experience of, the topics explored in this study.

**Why have I been invited?**

You have been invited to take part in this study as you have been identified as being in one of the above groups of individuals.

**Do I have to take part?**

It is up to you to decide whether or not to take part. If you decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. After signing the consent form, please scan the signed consent form and email it to the Principal Investigator. If this option is not suitable for you, please inform the Principal Investigator of your intention to participate by email: you will be able to consent verbally at the start of a focus group interview, and we will audio record this. If you decide to take part you are still free to withdraw at any time, also during the focus group interview, without giving a reason, and without affecting any aspects of your employment.

**Will I get paid for taking part?**

There is no payment for taking part in the study.

**Contents**



## 1. What will happen to me if I take part?

If you agree to take part, we will ask you to participate in an online focus group interview together with other healthcare professionals working in other intensive care settings. The language used in the focus group interview will be English. The focus group interview will take place in April-May 2022. It is expected that the focus group will last up to a maximum of 90 minutes, and will take place using the Zoom online videoconferencing facility. You will also have the option of joining by telephone. In the focus group, you will be invited to discuss your thoughts on, and experiences of, patient safety culture and medication safety initiatives in the intensive care unit and how medication safety can be improved to enhance patient safety.

We will audio record the focus group interview with a voice recorder. As a back-up, we will also use the videoconferencing facility to audio and video record the focus group; the video recording will be deleted immediately after the interview, only the audio recording will be kept for transcription. Additionally, you may

turn your video camera off if you would prefer to be recorded using audio only. The audio recording will then be transcribed to provide an accurate record of the discussion. You will be identified by a participant code and not by name. This code will not be shared with anyone outside the research team.

Participation in this study is completely voluntary. There is no obligation to participate, and should you choose to do so, you can refuse to answer specific questions, or decide to withdraw from the focus group. Once the focus group has been concluded, your contribution cannot be withdrawn as the focus group will be an amalgam of voices generated from the focus group audio file, and it is not possible to delete your data.

All of the information you provide will be kept confidential. Please see the attached Data Protection Statement. Details such as the name of participants will be seen only by the Principal Investigator and will be stored in a locked filing cabinet at the Faculty of Pharmacy, University of Helsinki. All data from the focus group will immediately be transferred to an encrypted computer, stored in passcode secured files on the cloud service of the University of Helsinki and wiped from the recording device. The data will then be transcribed by a transcriber. As a participant, you will be given the opportunity to verify the accuracy and completeness of the transcript of your focus group interview if you so wish. We will also ensure that all identifying information will be removed from the transcripts. Once the focus group interviews are transcribed and verified, all audio recordings will be deleted and only the pseudonymised, coded, transcript will remain. All data will be available only to the research team. Please be aware, however, that while we can guarantee that we will maintain confidentiality, and we will ask all participants to maintain confidentiality, we cannot guarantee that group members will do the same.

All materials recorded on paper and all data recorded electronically will be securely stored for 24 months after the publication of the research, after which they will be destroyed safely.

## 2. What are the possible disadvantages and risks of taking part?

You will need to take the time to participate in the online focus group. You will also need to provide us with your name and contact details. The online videoconferencing facility, Zoom, is a licensed product of Zoom Inc., but all audio and video data are transferred only between servers located in the Nordic countries. For licensing purposes only, the names, email addresses and IP addresses of the participants will be transmitted to servers of Zoom within the European Union (EU). To maintain your confidentiality, we will adhere to the General Data Protection Regulation (GDPR) 2016 (EU), Data Protection Act 2018 (Finland) and data protection policies of the University of Helsinki. Please see the attached Data Protection Statement.

### 3. What are the possible benefits of taking part?

While there may be no immediate benefit to you from participating, we hope that the final study report and policy recommendations from this research will be of value to intensive care units across Europe whose managers may choose to utilise the findings and the developed policy to benefit their intensive care unit and hospital. You will be given the option of receiving a summary of this final study report.

### 4. What if something goes wrong?

If you have a concern about any aspect of this study, you can contact the Principal Investigator, Adjunct Professor Raisa Laaksonen via email at raisa.laaksonen@helsinki.fi. If you are still not satisfied with the response, you may contact the University of Helsinki Data Protection Officer via email at tietosuoja@helsinki.fi.

### 5. What will happen to the results of the research study?

It is anticipated that the findings of the research study will be disseminated via a number of avenues, such as through a report to the EAHP, a peer reviewed research paper and presentations at academic conferences. Additionally, summaries of the findings will be produced, targeted at relevant groups such as health care professionals working in the intensive care setting, professional bodies, and policy makers. It will not be possible to identify participants from any reports or outputs of the study.

### 6. Who is organising and funding the research?

This research is organised by the Special Interest Group (SIG) for the Investigation of Medication Errors in Intensive Care, European Association of Hospital Pharmacists (EAHP). The EAHP has received funding from BD (Becton, Dickinson and Company) for the running of the project. The research, its outcomes and decisions on recommendations delivered by this working group remain independent from this financial support. The SIG is comprised of professional clinical experts (doctors, nurses and pharmacists) and patient safety experts from different European countries.

### 7. Who has reviewed the study?

The Principal Investigator has obtained approval from the Ethical Review Board in the Humanities and Social and Behavioural Sciences, University of Helsinki (18/2022, 18.3.2022), stating that the study meets the ethical requirements set for research in the human sciences.

## 8. Contact for Further Information

If you would like further information on any aspect of the study, please do not hesitate to contact us.

Co-chairs of the SIG for the Investigation of Medication Errors in Intensive Care:
Principal Investigator, Adjunct Professor Raisa Laaksonen (raisa.laaksonen@helsinki.fi), University of Helsinki, Finland
Dr Virginia Silvari (virginia.silvari@hse.ie), Health Care Executive, Ireland

**If you agree to take part in this study, please keep a copy of this information sheet and sign the attached informed consent form.**

**Please scan the signed informed consent form and email it to the Principal Investigator Raisa Laaksonen (raisa.laaksonen@helsinki.fi). She will contact you to arrange the focus group interview.**

Thank you for your time!