DELPHI STUDY INFORMATION SHEET

We would like to invite you to take part in a Delphi consensus study. Before you decide whether or not you would like to take part, it is important for you to consider why the research is being done and what it will involve. Please read this information sheet carefully.

What is a Delphi study?

The Delphi technique seeks to obtain consensus on the opinions of experts, termed panel members, through a series of structured questionnaires. As part of the process, the responses from each round are fed back in summarised form to the participants who are then given an opportunity to respond again to the emerging data. The Delphi is therefore an iterative multi-stage process designed to combine opinion into group consensus.

What is the purpose of the study?

Current guidelines from the Royal College of Obstetricians and Gynaecologists (2010) recommend that all pregnant or postpartum women with suspected pulmonary embolism (PE) should receive diagnostic imaging. However this non-selective approach results in a low prevalence of PE among those investigated. Approximately fifty women (and foetuses in pregnant women) will be exposed to the risks of diagnostic imaging for every one diagnosed with PE who is able to benefit from diagnosis and treatment.

The DIPEP study aims to derive a clinical decision rule to guide clinicians' judgments on imaging when managing pregnant and postpartum women with suspected PE. A cohort of women will be recruited and a clinical decision rule statistically derived. The study also hopes to validate a clinical decision rule developed through expert consensus.

The purpose of this Delphi study is to identify candidate variables that should be considered for inclusion in the expert clinical decision rule. These predictors will then be discussed at separate, later, round-table consensus meeting to derive the final expert clinical decision rule. Delegates at this round table meeting will comprise the DIPEP study co-investigators.

Why have I been invited to take part?

As an established expert in this field we are keen to gain your views about which variables may be important in predicting PE in pregnant and postpartum women. Specifically, we would like to ask your views on the predictive value of a range of demographic, clinical, and pregnancy-related features. We plan to recruit 15-20 participants consisting of DIPEP principle investigators, DIPEP co-investigators and selected experts in pulmonary embolism.

What will I be asked to do if I take part?

We are inviting you to participate as a Delphi panel member. This would involve completing a brief questionnaire, rating possible predictors of PE using an online survey. It is envisaged that this should take approximately 30. You would subsequently receive a reminder of your ratings, a summary of the group's responses and a further online questionnaire to re-rate the original list of predictors. This process would continue until a group consensus is achieved or three Delphi rounds have been completed. In order to allow timely conclusion of the study we would respectfully request a response time of 1 week for completion of each round.

Who is organizing and funding the research?

This research is part of a larger Health Technology Assessment Programme funded study examining the management of pregnant and postpartum women with suspected PE: The Diagnosis of Pulmonary Embolism in Pregnancy (DIPEP) study. Further information can be accessed via the study website: https://www.sheffield.ac.uk/scharr/sections/dts/ctru/dipep

The Delphi study will be conducted by Dr Gordon Fuller, a National Institute of Health Research clinical trials fellow, and supervised by Professor Steve Goodacre, an emergency medicine consultant and clinical professor at the School of Health and Related Research, University of Sheffield.

Confidentiality

No personal information will be collected and survey responses will be collated anonymously using an identifying number known only to the participant and lead investigator. All responses received in the study will be strictly confidential, and your identity will not be divulged. Direct quotes to free-text answers may be used as part of the study report or later Delphi iterations, but these will be not be traceable back to you.

Data protection

Survey responses will be collected online using a quality-assured United Kingdom based survey company, utilising an encrypted internet server and registered with the Information Commissioner's Office. Further information is available from: <u>http://www.smart-survey.co.uk/security.</u>

Results will be downloaded to an encrypted University of Sheffield computer to allow analysis by the research team. Data will be stored for the duration of the research project only and then deleted. You have the right to access submitted information according to UK data protection laws.

Research ethics

The proposed Delphi study abides by the ethical requirements of the University of Sheffield, aiming to assure 'rigour, respect and responsibility' in the conduct of the research project. A copy of the University of Sheffield ethics committee application and decision letter is available on request. All participants will be asked to complete a consent form.

What do I do now?

Thank you for reading this information sheet and for considering taking part in this research. Please let us know whether or not you would like to take part by replying to this email. If you wish to participate we would be very grateful if you could also complete the attached consent form.

If you have any questions or concerns please do not hesitate to contact me.

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