

APPENDIX B

James Lind Alliance Priority Setting Partnership on primary care patient safety

Cover sheet and Participant Information Sheet: Weblink version

You are being invited to take part in a research study to identify important questions about primary care patient safety that have not yet been answered by research. Before you decide, 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.

Who will conduct the research?

The research will be conducted by Professor Stephen Campbell, Dr Siân Taylor and Dr Rebecca Morris from the National Institute for Health Research funded Greater Manchester Primary Care Patient Safety Translational Research Centre in the Institute of Population Health at the University of Manchester, working in collaboration with the James Lind Alliance (JLA) and the Patient Safety in Primary Care Partnership established to support this research. The Partnership steering group is a group of clinicians, patients and charity representatives with an interest in primary care patient safety, who will help guide the research.

What is the purpose of the research?

Research into patient safety (the prevention of errors and adverse effects to patients associated with healthcare) in primary care including general practice, pharmacy, dentistry and others) is an under-researched area with the main patient safety research focusing on hospital care. There are many unanswered questions about primary care patient safety. Time and money available for research are limited, so it is important to address the research questions that matter to people – that is, patients, their families and the healthcare professionals that care for them. The aim of the primary care patient safety Priority Setting Partnership is to identify the unanswered questions about primary care patient safety from patient and clinical perspectives.

Why have I been chosen?

You have been chosen as a member of a patient forum or support group or because you have identified and accessed the website: <http://www.population-health.manchester.ac.uk/PatientSafetyPSP>

What would I be asked to do if I took part?

There are several phases to the study. *You will be asked to complete a short series of questions on an on-line form.* Paper copies will be available on request and will be sent to peoples' postal address. Those who wish to be considered for involvement in a final priority setting workshop will spend a day doing so and will be paid reasonable travel expenses - accompanied by receipts for auditing purposes. A final priority setting workshop will be attended by no more than twenty people including the Priority Setting Partners and members of the public who have indicated a wish to attend. The PSP partners will select the members of the public who will attend.

What happens to the data collected?

The survey process will produce a long list of "raw" "new" unexplored and unanswered questions about primary care patient safety, which will be turned into a shorter list (e.g. up to 20 clear questions, addressable by research using a web-based survey), whereby individuals choose and rank their top 10 most important research questions. The final stage will be conducted in a face-to-face meeting, using group discussions and plenary sessions.

How is confidentiality maintained?

All submitted survey questions will have no identifiable data on them. If you request a paper copy, you will be sent a stamped addressed envelope, which will have no patient identifiable data. Your response will be anonymous unless you wish, by implicit consent, to add your contact details so that

you have the opportunity to take in a final priority setting workshop. Contact details will be kept separate from survey responses, which will be allocated a numerical survey response number only. It will not therefore be possible to align contact details to survey responses. Contact details will be kept in a secure encrypted University computer, to which only the study researchers will have access.

What happens if I do not want to take part or if I change my mind?

You do not have to take part. Your participation is entirely voluntary.

Submitting your questions constitutes consent to participate in the study. If you decide to take part you are still able to change your mind until you have submitted your questions. As we will not be able to identify you from your responses so once you have submitted your questions they cannot be withdrawn.

Will I be paid for participating in the research?

Submitting your survey question priorities is voluntary and does not incur any expenses or payment.

What is the duration of the research?

5-10 minutes to answer the consultation survey. If you also take part in the prioritisation survey, this will take 10-20 minutes to complete. Those who wish to be involved in a final priority setting workshop will spend a day doing so. The first survey is April to July 2016, the prioritisation survey is October 2016 to February 2017 and a final priority setting workshop will be in March 2017.

Where will the research be conducted?

An online survey or a postal survey.

Will the outcomes of the research be published?

The JLA will capture and publicise the results, through descriptive reports of the process and there will be academic output(s) as well.

Who has reviewed the research project?

The project has been reviewed by the University of Manchester Research Ethics Committee.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions.

Minor complaints

If you have a minor complaint then you need to contact the researcher(s) in the first instance: stephen.campbell@manchester.ac.uk or 0161 275 7655

Formal Complaints

If you wish to make a formal complaint or if you are not satisfied with the response you have gained from the researchers in the first instance then please contact the Research Governance and Integrity Manager, Research Office, Christie Building, University of Manchester, Oxford Road, Manchester, M13 9PL, by emailing: research.complaints@manchester.ac.uk or by telephoning 0161 275 2674 or 275 2046.

What Do I Do Now?

If you have any queries about the study or if you are interested in taking part then please contact the researcher(s):

Professor Stephen Campbell: Stephen.campbell@manchester.ac.uk – 0161 275 7655

Dr Siân Taylor: Sian.Taylor-2@manchester.ac.uk - 0161 275 1871

Dr Rebecca Morris: Rebecca.Morris@manchester.ac.uk - 0161 275 0748

This Project Has Been Approved by the University of Manchester's Research Ethics Committee [UREC reference number 16141].