

Patient Safety in Primary Care Priority Setting Partnership

Plain English Language Protocol

Drafted 18 May 2016

Purpose

The purpose of this protocol is to set out the aims, objectives and commitments of the Patient Safety in Primary Care Priority Setting Partnership (PSP) and the basic roles and responsibilities of those taking part.

Steering Group

The Patient Safety in Primary Care PSP will be led and managed by the following:

Patient representative/s:

- Michael Molete
- Katherine Murphy (Patients Association)
- Laurence Webb

Healthcare professional representative/s:

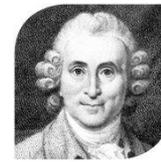
- Rose Gallagher (Royal College of Nursing)
- Barry Kinshuck (British Dental Association)
- Alison Lea (Royal College of General Practitioners)
- Janice Perkins (Pharmacy Voice)
- Margaret Watson (Royal Pharmaceutical Society)
- Claire Vaughan (Salford Clinical Commissioning Group)

The Partnership and the priority setting process will be supported and guided by:

- Richard Morley (James Lind Alliance)
- Stephen Campbell (NIHR Greater Manchester Primary Care Patient Safety Translational Research Centre)
- Siân Taylor (NIHR Greater Manchester Primary Care Patient Safety Translational Research Centre)

The Steering Group includes representation of patient/carer groups and healthcare professionals.

When will the project take place?



Start date: 31/05/2016

End date: 31/3/2017

What is the main research question?

A survey will aim to enable patients and clinicians to identify and prioritise important questions to them about primary care patient safety that have not yet been answered by research.

What is the justification for the research?

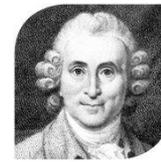
A 2011 report by the American Medical Association stated that research into primary care patient safety was far behind patient safety research in hospital care (Lorincz et al 2011). There is a need to know what methods are being used currently in primary care to measure patient safety (Vincent et al 2013). A recent literature review by Spencer and Campbell found that the majority of publications relating to primary care patient safety have been published only in the last decade. (Spencer and Campbell, 2014). For example, most research has been done in general practice and pharmacy with relatively little in dentistry.

With the majority of contacts with the NHS and other healthcare services occurring within primary care, the opportunity for patient safety incidents to occur is significant. While patient safety incidents with serious negative consequences are comparably rarer in primary care than in hospital care, the volume of avoidable risks is substantially higher because there are more than 340 million GP consultations and approximately 1 billion community prescriptions dispensed each year (HSC IC 2013) in England alone.

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. This will allow us to focus all our energy and resources on areas of research that might make a difference. 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 and then prioritise those unanswered questions that patients and clinicians agree are the most important.

Background to the Patient Safety in Primary Care PSP

The JLA is a project which is overseen by the National Institute for Health Research Evaluation, Trials and Studies Coordinating Centre (NETSCC). Its aim is to provide opportunities for patients and healthcare professionals to work together to agree what are the most important treatment uncertainties affecting their particular interest, in order to influence the prioritisation of future research in that area. The JLA defines an uncertainty as a “known unknown” – in this case relating to the effects of treatment.



Primary care includes a number of healthcare areas including general practice, pharmacy, dentistry and others working in the community.

Patient safety can be defined as the avoidance, prevention, and amelioration of adverse outcomes or injuries stemming from the processes of health care.

The NIHR Greater Manchester Primary Care Patient Safety Translational Research Centre (Greater Manchester PSTRC) has been funded to address specific issues in primary care patient safety. To understand and identify research priorities the Greater Manchester PSTRC has set up a PSP to identify instances where patients may be receiving unsafe care, in the primary care setting, and prioritising those incidents for further research.

Aims and objectives of the Patient Safety in Primary Care PSP

The aim of the Patient Safety in Primary Care PSP is to identify the unanswered questions about potential patient safety issues that may arise in a primary care setting from patient and healthcare professional perspectives and then prioritise those that patients and healthcare professionals agree are the most important.

The objectives of the Patient Safety in Primary Care PSP are to:

- work with patients and healthcare professionals to identify unanswered questions about patient safety issues in primary care
- to agree a prioritised list of those uncertainties, for research
- to publicise the results of the PSP
- to take the results to research funding bodies to be considered for funding

Partners

Organisations and individuals will be invited to take part in the PSP, from the following groups:

- people who have experienced a patient safety incident in primary care
- carers of people who have experienced a patient safety incident in primary care
- healthcare professionals with experience of a patient safety incident in primary care

It is important that all organisations which can reach and speak for these groups should be invited to become involved in the PSP. The JLA will take responsibility for ensuring the various stakeholder groups are able to contribute equally to the process unless they have a conflict of interest.

Method

This section describes what will happen during the project. The process is dependent on the active participation and contribution of different groups. The methods we shall use will be agreed through consultation between the partners, guided by the aims of the project.

1. Identification and invitation of potential partners

Potential partner organisations will be identified through finding out which organisations can talk for or represent the key services provided in primary care (general practice dentistry, pharmacy and other community providers) as well as key patient groups. Potential partners will be contacted and informed of the establishment and aims of the Patient Safety in Primary Care PSP and invited to attend and participate in an initial face-to-face stakeholder meeting.

2. Initial stakeholder meeting / awareness raising

The initial stakeholder meeting / awareness raising will have several key objectives:

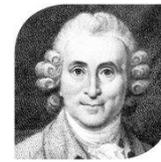
- to welcome and introduce potential members of the Patient Safety in Primary Care PSP
- to present the proposed plan and timeline for the PSP
- to initiate discussion, answer questions and address concerns
- to identify partner organisations that will commit to the PSP and identify individuals who will be those organisations' representatives and the PSP's principal contacts
- to establish a means of working that will allow for open, inclusive discussions and for people/organisations to contribute to all stages of the PSP .

The meeting will be arranged and managed by the Steering Group with input from the JLA.

3. Identifying treatment uncertainties

The Patient Safety in Primary Care PSP will ask patients, carers and healthcare professionals to find out unanswered questions in relation to patient safety in primary care.

We want as many people as possible to answer the survey. We will advertise the survey online and ask our Partners (in general practice, pharmacy, nursing, dentistry and patient groups) to advertise the survey on their own websites. We will tweet about the survey and advertise it through PSP partners, patient forums and academic conferences. No patient forums are being targeted specifically. The following are members of the PSP: 1) The Patients' Association, 2) Lesbian Gay Bisexual and Transgender Foundation, 3) Care Ambassador for GM. In addition, we expect the Tweet to be picked up by as many forums, patient and professional, as possible. The wording of the tweet is:



What are your questions about primary care (general practice, pharmacy, dentistry) patient safety?
Submit your question here: bit.ly/100XBI1 (Appendix A)

Taking part in the survey(s) will mean someone agrees to take part in the research. However, the survey will have a Patient Information Sheet (Appendix B), which will be embedded on the website where people submit questions. Participants can read before they decide to complete the survey or not.

Existing sources of information about unanswered questions will be used. These can include research ideas in academic journals and clinical guidelines. The PSP will also use information from previous projects funded by the Greater Manchester PSTRC as a source of unanswered questions.

The starting point for identifying sources of uncertainties and research ideas is NHS Evidence: www.evidence.nhs.uk.

4. Refining questions and uncertainties

The process will produce “raw” unanswered questions about primary care patient safety issues. These raw questions will be turned in to clear questions that research could answer and which are understood by all. Similar or duplicate questions will be combined where appropriate.

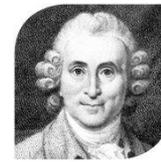
The existing research literature will be looked at to see to what extent these clear questions have, or have not, been answered by previous research.

Uncertainties, which are not adequately addressed by previous research, will be collated and recorded in a suitable format agreed by the Steering Group and JLA. This will ensure that the unanswered questions have been actually checked to be uncertainties. This is the responsibility of the Steering Group.

5. Prioritisation – interim and final stages

The aim of the final stage of the priority setting process is to prioritise through consensus the identified unanswered questions in relation to patient safety in primary care. This will be carried out by members of the Steering Group and the wider partnership that represents patients and healthcare professionals.

The interim stage, to proceed from a long list of uncertainties to a shorter list (e.g. up to 20), may be carried out over email, with organisations asked to consult their membership and choose and rank their top 10 most important uncertainties.



The final stage, to reach agreement on, for example, 10 prioritised uncertainties, is likely to be conducted in a face-to-face meeting led by the JLA.

The JLA will lead this process and ensure transparency, accountability and fairness. Participants will be expected to declare their interests in advance of this meeting.

Findings and research

It is anticipated that the findings of the Patient Safety in Primary Care PSP will be reported to funding and research agenda setting organisations such as the NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC), NIHR Central Commissioning Facility (NIHR CCF) as well as the major research funding charities. Steering Group members and partners are encouraged to develop the prioritised uncertainties into research questions, and to work to establish the research needs of those unanswered questions to use when approaching potential funders, or when allocating funding for research themselves, if applicable.

Publicity

As well as alerting funders, partners and Steering Group members are encouraged to publish the findings of the Patient Safety in Primary Care PSP, as well as the JLA. The exercise will be distinct from the production of an academic paper, which the partners are also encouraged to do. However, production of an academic paper should not take precedence over publicising of the final results.



APPENDIX A

James Lind Alliance Priority Setting Partnership on primary care patient safety

Tweet wording

We are seeking to identify patient safety research priorities for general practice, pharmacy, dentistry.

What are your questions about primary care (general practice, pharmacy, dentistry) patient safety?
Submit your question here ([bit.ly](#) url to be inserted).

**This Project Has Been Approved by the University of Manchester's Research Ethics Committee
[UREC 1: ethics/16141].**



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?

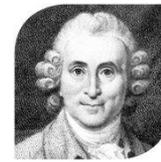
The research will be conducted by Professor Stephen Campbell, Dr Siân Taylor and Dr Rebecca Morris from the National Institute for Health Research funded Greater Manchester Primary Care Patient Safety Translational Research Centre in the Institute of Population Health at the University of Manchester, 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?

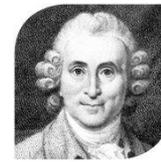
If you have any queries about the study or if you are interested in taking part then please contact the researcher(s):

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].



Appendix C: Proposed demographic questions

James Lind Alliance Priority Setting Partnership on primary care patient safety

1. The NIHR Greater Manchester PSTRC is working with the James Lind Alliance to identify and prioritise the most important issues for research in primary care patient safety. If you have important unanswered questions about patient safety in primary care please describe them below.

For more information and the participant information sheet [Read the Information Sheet](#)

We are seeking to identify priorities for research about safety in primary care. Primary care includes your GP surgery, dental surgery, pharmacy, out of hours care, walk in clinic, community or district nursing, ambulance and opticians.

Only complete this survey if you are over 16 years of age. If you are 16 or 17 years old please tick below to show that you consent to take part in this survey.

I am aged 16 or 17 and consent to take part in this survey

2. What are your questions for researchers to answer about patient safety in primary care?

If you have more than one question for researchers to answer please list all questions with numbers to clearly indicate each new question.

3. If you did not answer the question above asking you to suggest questions for researchers to answer about patient safety in primary care, is this because:

- a. you have no questions about primary care for researchers to answer
- b. you did not understand the question
- c. Other, please specify

The following questions are all optional.

4. How old are you?

- 16 to 24 years
- 25 to 34 years
- 35 to 44 years
- 45 to 54 years
- 55 to 64 years
- 65 to 74 years
- 75 and over
- Prefer not to say

5. Do you live in England, Wales, Scotland or Northern Ireland?

- Yes
- No
- Prefer not to say



If yes, please enter the first 2 letters of your postcode below

6. What is your highest level of education?

- No qualifications
- 1 to 4 GCSEs or equivalent
- 5 or more GCSEs or equivalent
- Apprenticeship
- 2 or more A levels or equivalent
- Degree level or above
- Other qualifications
- Prefer not to say
- Other, please specify

7. What is your ethnic group? Choose one option that best describes your ethnic group or background

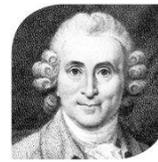
- White
- Asian or Asian British: Indian
- Asian or Asian British: Pakistani
- Asian or Asian British: Bangladeshi
- Asian or Asian British: Chinese
- Asian or Asian British: Other
- Black or Black British: African
- Black or Black British: Caribbean
- Black or Black British: Other
- White and Black Caribbean
- White and Black African
- White and Asian
- Arab
- Prefer not to say
- Other, specify (optional)

8. Do you, personally, work as a Healthcare Professional in any capacity? For example, a doctor/nurse/therapist/pharmacist/health service researcher/other NHS staff, etc. (if retired answer for your previous work)

- Yes
- No
- Don't know
- Prefer not to say

9. How do you describe your gender?

- Female
- Male
- In another way
- Prefer not to say



10. Is your gender identity the same as the gender you were given at birth?

Yes

No

Do not understand the question

Prefer not to say

11. Which best describes you?

Lesbian/Gay

Bisexual

Heterosexual/Straight

Other

Prefer not to say