BROKEN BONES IN OLDER PEOPLE
(Musculoskeletal Injury: fragility fracture of the lower limb and pelvis)
Priority Setting Partnership

PROTOCOL 09th December 2016[1]

1. Purpose of the PSP and background

The purpose of this protocol is to set out the aims, objectives and commitments of the BROKEN BONES IN OLDER PEOPLE Priority Setting Partnership (PSP) and the basic roles and responsibilities of the partners therein. It is recommended that the Protocol is reviewed by the Steering Group and updated on at least a quarterly basis.

The James Lind Alliance (JLA) is a non-profit making initiative, established in 2004. It brings patients, carers and clinicians together in Priority Setting Partnerships (PSPs). These partnerships identify and prioritise uncertainties, or 'unanswered questions', about the effects of treatments that they agree are the most important. The aim of this is to help ensure that those who fund health research are aware of what really matters to both patients and clinicians. The National Institute for Health Research (NIHR – www.nihr.ac.uk) funds the infrastructure of the JLA to oversee the processes for priority setting partnerships, based at the NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC), University of Southampton.

There are approximately 5 million lower limb fragility fractures in the world each year, and many of these injuries are associated with long-term disability and even death. For example, 25% of patients with a hip fracture will die within one year of their injury. Over 200,000 patients suffer a lower limb fragility fracture in the UK every year; a figure which is projected to rise rapidly as the population gets older.

Lower limb fragility fractures are also very expensive to treat. The cost is estimated at 2% of the total healthcare burden in established market economies such as the UK – that's around £3 billion each year.

Patients with fragility fractures of the lower limb are a well-defined group, almost all of whom require treatment at a hospital. Fragility fractures often occur in older people with osteoporosis (brittle bones) and usually happen after low-energy trauma such as a fall from standing height. Many of the patients affected are frail with several other ongoing medical problems.

Although different patients may break different lower limb bones, they all have several features in common; the broken bone is painful, they often require surgery followed by lengthy periods of rehabilitation and all patients have problems with mobility after their injury. Patients with lower limb fragility fractures often find that they are not able to do the same independent day to day tasks that they could do before their injury.

[1] This is a generic protocol which should be updated to include the names and details of the Steering Group members. The document may be modified with agreement from the JLA to reflect the make-up of different PSPs and the organisations driving them.

2. Aims and objectives of the BROKEN BONES IN OLDER PEOPLE PSP

The aim of the PSP is to identify the unanswered questions about lower limb (including pelvis, legs and feet) fragility fractures in patients over 60 years of age from patient and clinical perspectives and then prioritise those that patients and clinicians agree are the most important. These questions can relate to any aspect of living with, caring for, or treating these injuries, such as pain relief, nutrition, rehabilitation, surgery, anaesthesia, information (for patients and carers) and the emotional impact of fragility fractures. These questions can relate to any setting where patients with fragility fractures are treated (community and hospital settings, inpatient and outpatient care), the treatment itself, or to problems that patients and relatives encounter in living with the consequences of fragility fracture. This PSP will not cover questions connected to prevention of fragility fractures.

The objectives of the BROKEN BONES IN OLDER PEOPLE PSP are to:

- work with patients and clinicians to identify uncertainties about the effects of BROKEN BONES IN OLDER PEOPLE
- to agree by consensus a prioritised list of those uncertainties, for research
- to publicise the results of the PSP and process
- to take the results to research commissioning bodies to be considered for funding

3. The Steering Group

The BROKEN BONES IN OLDER PEOPLE PSP will be led and managed by the following:
Patient representative/s:

- Alwin McGibbon - University/User Teaching and Research Action Partnership (UNTRAP)
- Jenny Gould – Public and Patient Involvement Member
- Philip Bell – Welsh Arthritis Research Network
- Richard Grant – UNTRAP, NIHR Collaboration for Leadership in Applied Heath Research and Care West Midlands Patient & Public Involvement (CLAHRC WM PPI)

Clinical representative/s:

- Professor Matthew Costa – Oxford Trauma, University of Oxford
- Mr Xavier Griffin – Cochrane Bone, Joint & Muscle Trauma
- Dr Rebecca Kearney – Association of Trauma and Orthopaedic Chartered Physiotherapists (ATOCP)
- Dr Mark Baxter – British Geriatric Society English National Council member of the trauma audit and research network
- Dr Stuart White – The Association of Anaesthetists of Great Britain and Ireland (AAGBI)
- Mr Tim Chesser – Falls & Fragility Fracture Audit Project (FFFAP, NHFD), British Orthopaedic Association (BOA), Orthopaedic Trauma Society (OTS)

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

- Catherine White – The James Lind Alliance (JLA)

The Steering Group includes representation of patient/carer groups and clinicians[2].

The Steering Group will agree the resources, including time and expertise that they will be able to contribute to each stage of the process. The JLA will advise on this.

4. The wider Partners

Organisations and individuals will be invited to be involved with the PSP as partners. Partners are groups or individuals who will commit to supporting the PSP by disseminating the PSP survey and helping the PSP to gather questions and uncertainties of practical clinical importance relating to the treatment and management of the health problem in question. Partners represent the following groups:

- people who have had lower limb fragility fractures
- carers of people who have had lower limb fragility fractures
- medical doctors, nurses and professionals allied to medicine with clinical experience of lower limb fragility fractures.

It is important that all organisations which can reach and advocate for these groups should be invited to become involved in the PSP. The JLA Adviser will take responsibility for ensuring the various stakeholder groups are able to contribute equally to the process.

Exclusion criteria
Some organisations may be judged by the JLA or the Steering Group to have conflicts of interest. These may be perceived to adversely affect those organisations' views, causing unacceptable bias. As this is likely to affect the ultimate findings of the PSP, those organisations will not be invited to participate. It is possible, however, that interested parties may participate in a purely observational capacity when the Steering Group considers it may be helpful.

5. The methods the PSP will use

This section describes a schedule of proposed stages through which the PSP aims to fulfil its objectives. The process is iterative and dependent on the active participation and contribution of different groups. The methods adopted in any stage will be agreed through consultation between the Steering Group members, guided by the PSP's aims and objectives. More details can be found in the Guidebook section of the JLA website at www.jla.nihr.ac.uk where examples of the work of other JLA PSPs can also be seen.

Step 1: Identification and invitation of potential partners
Potential partner organisations will be identified through a process of peer knowledge and consultation, through the Steering Group members' networks. Potential partners will be contacted and informed of the establishment and aims of the BROKEN BONES IN OLDER PEOPLE PSP and may be invited to attend and participate in an initial stakeholder meeting if this is being arranged.

[2] In some cases, it has been suggested that researchers are represented at this level, to advise on the shaping of research questions. However, researchers cannot participate in the prioritisation exercise. This is to ensure that the final prioritised research questions are those agreed by patients, carers and clinicians only, in line with the JLA's mission.

Step 2: Initial stakeholder meeting / awareness raising[3]

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

- to welcome and introduce potential members of the BROKEN BONES IN OLDER PEOPLE PSP
- to present the proposed plan for the PSP
- to initiate discussion, answer questions and address concerns
- to identify those potential partner organisations which will commit to the PSP and identify individuals who will be those organisations' representatives and the PSP's principal contacts
- to establish principles upon which an open, inclusive and transparent mechanism can be based for contributing to, reporting and recording the work and progress of the PSP.

Step 3: Identifying uncertainties

Each partner will identify a method for soliciting from its members questions and uncertainties of practical clinical importance relating to lower limb fragility fractures. A period of 6 months will be given to complete this exercise.

The methods may be designed according to the nature and membership of each organisation, but must be as transparent, inclusive and representative as practicable. Methods may include membership meetings, email consultation, postal or web-based questionnaires, internet message boards and focus group work.

Existing sources of information about treatment uncertainties for patients and clinicians will be searched. These can include question-answering services for patients and carers and for clinicians; research recommendations in systematic reviews and clinical guidelines; protocols for systematic reviews being prepared and registers of ongoing research.

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

Step 4: Refining questions and uncertainties

The Steering Group will need to have agreed exactly who will be responsible for this stage – the JLA can advise on the amount of time likely to be required for its execution. The JLA will participate in this process as an observer, to ensure accountability and transparency.

The consultation process will produce "raw" unanswered questions about diagnosis and the effects of treatments. These raw questions will be assembled and categorised and refined by the Information Specialist into "collated indicative questions" which are clear, addressable by research and understandable to all. Similar or duplicate questions will be combined where appropriate.

Systematic reviews and guidelines will be identified and checked by the Information Specialist to see to what extent these refined questions have, or have not, been answered by previous research. Sometimes, uncertainties are expressed that can in fact be resolved with reference to existing research evidence - ie they are "unrecognised knowns" and not uncertainties. If a question about treatment effects can be answered with existing information but this is not known, it suggests that information is not being communicated effectively to those who need it. Accordingly, the JLA recommends strongly that PSPs keep a record of these 'answerable

[3] PSPs will need to raise awareness of their proposed activity among their patient and clinician communities, in order to secure support and participation. Depending on budget this may be done by way of a face-to-face meeting, or there may be other mechanisms by which the process can be launched.

questions' and deal with them separately from the 'true uncertainties' considered during the research priority setting process.[4]

Uncertainties which are not adequately addressed by previous research will be collated and recorded on a template supplied by the JLA) by the Information Specialist. This will demonstrate the checking undertaken to make sure that the uncertainties have not already been answered. This is the responsibility of the Steering Group, which will need to have agreed personnel and resources to carry this accountability. The data should be submitted to the JLA for publication on its website on completion of the priority setting exercise, taking into account any changes made at the final workshop, in order to ensure that PSP results are publicly available.

Step 5: Prioritisation – interim and final stages

The aim of the final stage of the priority setting process is to prioritise through consensus the identified uncertainties relating to the treatment or management of lower limb fragility fractures. This will be carried out by members of the Steering Group and the wider partnership that represents patients and clinicians.

- The interim stage, to proceed from a long list of uncertainties to a shorter list to be discussed at the final priority setting workshop (e.g. up to 30), may be carried out over email or online, whereby organisations consult their membership and choose and rank their top 10 most important uncertainties. There are examples of how other PSPs have achieved this at www.jla.nihr.ac.uk in the Key Documents of the Anaesthesia and Perioperative Care PSP section and the Childhood Disability PSP section.

- The final stage, to reach, for example, 10 prioritised uncertainties, is likely to be conducted in a face-to-face meeting, using group discussions and plenary sessions.

- The methods used for this prioritisation process will be determined by consultation with the partner organisations and with the advice of the JLA Adviser. Methods which have been identified as potentially useful in this process include: adapted Delphi techniques; expert panels or nominal group techniques; consensus development conference; electronic nominal group and online voting; interactive research agenda setting and focus groups.

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

6. Dissemination of findings and research

Findings and research

It is anticipated that the findings of the BROKEN BONES IN OLDER PEOPLE PSP will be reported to funding and research agenda setting organisations such as the NIHR and the major research funding charities. Steering Group members and partners are expected 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.[5]

Publicity

As well as alerting funders, partners and Steering Group members are encouraged to publish the findings of the BROKEN BONES IN OLDER PEOPLE PSP using both internal and external communication mechanisms. The Steering Group may capture and publicise the results through descriptive reports of the process itself in Plain English. This 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.

[4] Steering Group members should insert information on how they intend to do this.
[5] Add further detail here about how and where the priorities will be developed and researched.

7. Agreement of the Steering Group

Agreed by BROKEN BONES IN OLDER PEOPLE PSP Steering Group members on 13th February 2017.