



## **Prostate Cancer Priority Setting Partnership**

### **PROTOCOL June 2009**

#### **Purpose**

The purpose of this protocol is to set out the aims, objectives and commitments of the Prostate Cancer Priority Setting Partnership (PSP) and the basic roles and responsibilities of the partners therein.

#### **Steering group**

The Prostate Cancer PSP will be led and managed by the following:

- The Prostate Cancer Research Foundation
  - Lead: Emma Halls
- The Prostate Cancer Support Federation
  - Lead: Sandy Tyndale-Biscoe
- Mr. Vincent Gnanapragasam PhD FRCS FRCSEd (Urol), University Lecturer in Uro-oncology and Consultant Urological Surgeon, University of Cambridge

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

- The James Lind Alliance (JLA)
  - Lead: Lester Firkins

The steering group includes representation of patient groups and clinicians. It has also been agreed that researchers will be represented at this level, to advise on the shaping of research questions, but will not participate in the prioritisation exercise. This will ensure that the final prioritised research questions are those agreed by patients and clinicians only, in line with the JLA's mission.

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

#### **Background to the Prostate Cancer PSP**

The JLA is a project which is funded jointly by the National Institute of Health Research and the Medical Research Council. Its aim is to provide an infrastructure and process to help patients and clinicians work together to agree which 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 medical treatment.

In February 2009 the Prostate Cancer Research Foundation and the Prostate Cancer Support Federation, supported by the Prostate Cancer Charter for Action asked the JLA to work through this process with all interested organisations in prostate cancer

### **Aims and objectives of the Prostate Cancer PSP**

The aim of the Prostate Cancer PSP is to identify the unanswered questions about prostate cancer treatment from patient and clinical perspectives and then prioritise those, which both patients and clinicians agree are the most important.

The objectives of the Prostate Cancer PSP are to:

- work with patients and clinicians to identify uncertainties about the effects of prostate cancer treatments
- 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

### **Partners**

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

- men who have or have had prostate cancer
- partners of men who have or have had prostate cancer
- medical doctors, nurses and professionals allied to medicine with clinical experience of prostate cancer

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 will take responsibility for ensuring the various stakeholder groups are able to participate equally to the process.

**Organisations wishing to participate in the PSP will be required to affiliate to the JLA.** Details on the affiliation procedure can be found at [www.lindalliance.org](http://www.lindalliance.org).

### **Exclusion criteria**

Organisations which are judged by the JLA or the steering group to have conflicts or interest which may be perceived to adversely and with unacceptable bias affect those organisations' views and therefore the ultimate findings of the PSP will not be invited to participate. It is possible however that interested parties may participate in a purely observational capacity where the steering group consider it to be helpful.

## **METHODS**

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 partners, guided by the PSP's aims and objectives.

### **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, including the Prostate Cancer Charter for Action, and through the JLA's existing register of affiliates. Potential partners will be contacted and informed of the establishment and aims of the Prostate Cancer PSP and invited to attend and participate in an initial stakeholder meeting.

The JLA can draft the invitation, and an agreement should be reached as to the best organisation to distribute it.

### **Initial stakeholder meeting**

The initial stakeholder meeting will have several key objectives:

- to welcome and introduce potential members of the Prostate Cancer 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 open, inclusive and transparent mechanisms can be based for contributing to, reporting and recording the work and progress of the PSP

The administrative process for convening this meeting will be managed by the JLA in coordination with the steering group.

Following the meeting, organisations which have decided to participate in the PSP will be asked to complete a declaration of interests, including disclosing relationships with the pharmaceutical industry.

### **Identifying treatment uncertainties**

Each partner will identify a method for soliciting from its members questions and uncertainties of practical clinical importance relating to the treatment and management of prostate cancer. A period of no longer than 3 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, direct mail or email consultation, mail 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.

Suggested first choice existing sources of uncertainties for research recommendations include:

- Cochrane Database of Systematic Reviews
- NHS Evidence – cancer and kidney Annual Evidence Updates search
- BMJ Clinical Evidence
- Database of Abstracts of Reviews of Effects
- National Institute for Health Research Health Technology Assessment Programme
- NICE Guidance and the NICE Research Recommendations Database
- Scottish Intercollegiate Guidelines Network
- Relevant Royal Colleges’ guidance

### **Refining questions and uncertainties**

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 into “collated indicative questions” which are clear, addressable by research and understandable to all. Similar or duplicate questions will be combined where appropriate.

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

It is likely that there will be questions submitted which are not true uncertainties. These may give an indication of areas where knowledge or information is lacking or not being accessed. Capacity permitting, a record of questions may be maintained by the steering group, and partners can advise their membership if appropriate.

Uncertainties which are not adequately addressed by previous research will be collated and entered into a prostate cancer section within the Database of Uncertainties about the Effects of Treatments (DUETs). This will ensure that the uncertainties have been categorically checked to be uncertainties. This is the responsibility of the steering group, which will need to have agreed personnel and resources to carry this. **This is a key component of the JLA process, and the next stage of prioritisation can only proceed upon its completion.**

### **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 prostate cancer. This will be carried out by members of the steering group and the wider partnership who represent patients and clinicians.

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, whereby organisations consult their membership and ask for a top 15-20 most important uncertainties, ranked or unranked.

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. 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.

### **Findings and research**

It is anticipated that the findings of the Prostate Cancer PSP will be reported to funding and research agenda setting organisations such as the NIHR HTA Programme and the MRC, 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 Prostate Cancer PSP using both internal and external communication mechanisms. The JLA will also capture and

publicise the results, through iterative reports of the process itself. 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 precedent over publicising of the final results.

**Signed by the steering group**

The undersigned agree to follow the Prostate Cancer Priority Setting Protocol.

Emma Halls, The Prostate Cancer Research Foundation

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Date: .....

Sandy Tyndale-Biscoe, The Prostate Cancer Support Federation

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Date: .....

Mr. Vincent Gnanapragasam, University of Cambridge

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Date: .....

Lester Firkins, The James Lind Alliance

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Date: .....