



**Life after Stroke in Scotland Priority Setting Partnership  
Final Version (24<sup>th</sup> March 2010)  
PROTOCOL 2010.**

**Purpose**

The purpose of this protocol is to set out the aims, objectives and commitments of the Life after Stroke in Scotland Priority Setting Partnership (PSP) and the basic roles and responsibilities of the partners therein.

**Steering group**

The PSP will be led and managed by the following:

- Lester Firkins, JLA (Chair James Lind Alliance)(CHAIR of PSP steering group)
- Alex Pollock, DORIS (researcher)
- Katrina Brennan (clinician)
- Fiona Brodie (clinician)
- Angela McLeod (patient/carer representative)
- Kathleen Frew (patient/carer representative)

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

- The James Lind Alliance (JLA)
  - Lead: Lester Firkins
- UK DUETs
  - Lead: Mark Fenton
- DORIS
  - Lead: Alex Pollock

The steering group includes representation of patient groups and clinicians. It has also been agreed that researchers may 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 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 treatment.

This PSP was started as a result of a project funded by the Scottish Government’s National Advisory Committee for Stroke (NACS). DORIS (Database Of Research In Stroke) has been awarded 3 years funding to facilitate the establishment within Scotland, specific to stroke rehabilitation, of:

- Easy access to completed and ongoing research evidence
- Treatment uncertainties, evidence gaps and research priorities
- A collaborative and inclusive approach to research planning and activity

To meet the aim of identifying treatment uncertainties, evidence gaps and research priorities DORIS approached the JLA, and this PSP has been the result.

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

The aim of the PSP is to identify the unanswered questions about Life after Stroke in Scotland from patient and clinical perspectives and then prioritise those that patients and clinicians agree are the most important.

The sole focus of this PSP is Life after Stroke in Scotland. Life after Stroke includes all aspects of general management and rehabilitation after stroke; prevention and management of complications arising from stroke; and life after stroke (including return to work, family roles, leisure pursuits, relationships; and quality of life). For the purposes of this PSP, Life after Stroke does *not* include assessment, investigation, immediate management, or pharmacological or surgical interventions aimed at secondary prevention of stroke or TIA.

The focus of the PSP has been defined to be in line with Scottish national stroke guidelines. SIGN 64, “Management of Patients with Stroke: Rehabilitation, Prevention and Management of Complications, and Discharge Planning”, focuses on general management, rehabilitation, the prevention and management of complications and discharge planning. SIGN 108, “Management of patients with stroke or TIA: assessment, investigation, immediate management and secondary prevention”, focuses on the patient pathway from the onset of a suspected stroke and covers management of suspected stroke by non-stroke specialist practitioners, and clinical and radiological assessment.

The focus on this PSP is reflective of SIGN 64. However one distinct difference is the emphasis of SIGN 64 on the first 12 months after stroke; this PSP does not place any emphasis on any particular time point after stroke.

**The objectives of the PSP are to:**

- work with patients and clinicians to identify uncertainties about Life after Stroke in Scotland
- to agree by consensus a prioritised list of those uncertainties, for research
- to publicise the methods and results of the PSP
- 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:

- Stroke patient and carer groups throughout Scotland
- Health professionals and organisations from primary, secondary and tertiary care, responsible for delivery and management of care and services to stroke patients and carers in Scotland
- Research organisations and groups with an interest in stroke rehabilitation
- Key professional bodies and groups relevant to Life after Stroke in Scotland.

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 that, where possible, 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 of 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 able to participate in the priority setting stages. It is possible, however, that interested parties may participate in a purely observational capacity when the steering group considers it may 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, and will include the organisations listed above. Each of these organisations will be personally contacted by a member of the JLA PSP, and provided with key information relating to:

- the proposed plan for the PSP
- 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

To facilitate and assist involvement of patient and carer groups, members of the PSP will offer to attend a range of meetings of these groups and to present information about the plan and principles of the PSP.

Following this contact, 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 Life after Stroke in Scotland. 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 (but is not exhaustive):

- Cochrane Database of Systematic Reviews
- Cochrane Stroke Group specialised register of stroke trials
- NHS Evidence – stroke Annual Evidence Updates search
- Database of Abstracts of Reviews of Effects
- Scottish Intercollegiate Guidelines Network
- Royal College of Physician stroke guidelines

- NHS Quality Improvement Scotland (QIS) best practice statements on stroke care

### **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 existing knowledge or information is not being disseminated effectively. Capacity permitting, a record of questions may be maintained by the steering group, and partners can advise their memberships if appropriate.

Uncertainties which are not adequately addressed by previous research (reliable, up to date (less than 3 years) systematic reviews) will be collated and entered into an appropriate section within the UK Database of Uncertainties about the Effects of Treatments (DUETs). This will ensure that the uncertainties have been actually checked to be uncertainties. This is the responsibility of the steering group, which will need to have agreed personnel and resources to carry this accountability. 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 that represents 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 10 - 15 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 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 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 precedence over publicising of the final results.

### **Publication and authorship**

All members of the steering group should be offered the opportunity to be co-authors on any papers arising from the work of the PSP. Lead author and order of co-authors should be agreed in advance, and should reflect the contribution of the individual steering group members. The role of the supporting organisations (JLA, UK DUETs, DORIS and partner organisations) should be acknowledged in any publication.

**Signed by the steering group**

The undersigned agree to follow the Life after stroke in Scotland Priority Setting Protocol.

Lester Firkins, The James Lind Alliance

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Alex Pollock

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Katrina Brennan

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Fiona Brodie

.....Date: .....

Angela McLeod

.....Date: .....

Kathleen Frew

.....Date: .....