

Stroke Priority Setting Partnership

PROTOCOL January 29 2020¹ Version 4.1²

1. Purpose of the PSP and background

The purpose of this protocol is to clearly set out the aims, objectives and commitments of the Stroke Priority Setting Partnership (PSP) in line with James Lind Alliance (JLA) principles. The Protocol is a JLA requirement and will be published on the PSP's page of the JLA website. The Steering Group will review the Protocol regularly and any updated version will be sent to the JLA.

The JLA is a non-profit making initiative, established in 2004. It brings patients, carers and clinicians together in PSPs. These PSPs identify and prioritise the evidence uncertainties, or 'unanswered questions', that they agree are the most important for research in their topic area. Traditionally PSPs have focused on uncertainties about the effects of treatments, but some PSPs have chosen to broaden their scope beyond that. The aim of a PSP is to help ensure that those who fund health research are aware of what really matters to patients, carers and clinicians. The National Institute for Health Research (NIHR – www.nihr.ac.uk) coordinates the infrastructure of the JLA to oversee the processes for PSPs, based at the NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC), University of Southampton.

The Stroke Association³ has initiated this PSP to deliver the goals of its new Corporate and Research Strategies, and following conversations with members of the stroke community over the last couple of years, for the following reasons:

- In keeping with new Corporate and Research Strategies the Stroke Association wants: all of its work to address the needs of people affected by stroke; to work in partnership with others to raise the profile of stroke research and to influence other funders to push stroke higher up their research priorities; and for all its

¹ This is a generic protocol modified with agreement from the JLA Adviser to reflect the make-up of the Stroke PSP.

² The Steering Group is responsible for ensuring any updates or amendments to the PSP plan are included in subsequent versions of the Protocol and sent to the JLA for publication on the website.

³ The Stroke Association is covering most of the costs of this PSP, as detailed in the Terms of Reference. The Cochrane Stroke Group is contributing the time of their Information Specialist in an advisory capacity.

funded research to be driven by the needs of people affected by stroke and the challenges they face;

- The results of the Life After Stroke PSP, published in 2011, will be approximately 10 years old by the time this PSP completes and publishes;
- Given the perception that the Life After Stroke PSP was Scotland only, a UK-wide PSP with a broader scope should allow priorities to be generalisable across the UK and to support researchers working in areas of unmet need e.g. prevention, pre-hospital⁴ and acute care.

2. Aims, objectives and scope of the PSP

The aim of the Stroke PSP is to identify the unanswered questions about stroke from both people affected by stroke⁵ and from the perspectives of the health and social care professionals who work with them^{6 7} and then prioritise those that stroke survivors, carers and professionals agree are the most important for research to address.

The objectives of the PSP are to:

- work with people affected by stroke and health and social care professionals to identify uncertainties about stroke in keeping with the scope outlined below;
- agree by consensus a prioritised list of those uncertainties, for research;
- publicise the results of the PSP and process;
- take the results to research funding bodies to be considered for funding.

⁴ By pre-hospital care we mean emergency care, i.e. from the onset of symptoms (e.g. recognised by application of the FAST test), ambulance care, diagnostic tests and treatment provided prior to admission to an acute ward with a known diagnosis of stroke.

⁵ By “people affected by stroke” we mean those who have had strokes (sometimes known as stroke survivors) and the family members/close friends who care for them.

⁶ Some people who take part in the PSP may have dual roles i.e. be both affected by stroke and a health or social care professional.

⁷ In keeping with the JLA’s mission, in order to contribute questions and/or take part in prioritisation activities, health or social care professionals excludes researchers without an active practice.

Initial discussions about the potential scope of the PSP were held at a meeting of interested parties in Birmingham on 25 July 2019. The initial suggestions were refined by the Steering Group via e-mail and at the first Steering Group meeting on October 24 2019, and subsequently agreed. However, the scope may be refined further⁸ as the process progresses and uncertainties are submitted.

The scope of the project should encompass:

- perspectives gathered from the four nations of the UK;
- all aspects of the stroke pathway, where this might mean the clinical pathway or the experience of people affected by stroke, and includes causes, diagnosis, prevention (primary and secondary), and care/treatment⁹ (pre-hospital, acute, post-acute, long-term and end-of-life);
- all types of stroke (i.e. ischaemic, intracerebral haemorrhage, subarachnoid haemorrhage - SAH), and transient ischaemic attack (TIA);
- questions relating to:
 - long-term impacts of holistic care, including quality of life and emotional/psychological effects;
 - stroke in association with other conditions;
 - access to services;
 - public awareness and perception of stroke;
- perspectives of those who may traditionally be less heard from e.g. the elderly, those whose first language is not English, people who live in lower income areas, those who may not have such a high level of education as others, those who live in care homes, and those who are left with communication or other difficulties following stroke.

⁸ The Steering Group would like to include questions from those under 16 who may be acting as carers e.g. for parents. The sensitivities around this are being explored. If there are no reasons to exclude this group, they will be added to the scope.

⁹ The Steering Group will define what periods of time the different stages after stroke refer to and what they encompass – for example how long is post-acute, does it incorporate rehabilitation and if so, does this incorporate inpatient and ESD?

The PSP will exclude from its scope questions:

- about stroke services and care outside of the UK;
- about childhood stroke i.e. stroke experienced by those under 16.¹⁰

The Steering Group recognises that this is a broad scope that will need managing through having more than one set of priorities and final workshop, and considering the implications for the evidence-checking stage of the process in terms of resources and parameters.

The Steering Group will take a dynamic approach to what emerges from the questions/uncertainties gathered, in order to respond as needed. This might be, for example, through shaping the subsequent stages and Final Workshops according to certain themes¹¹, identifying whether feedback needs to be provided with regard e.g. to NICE Guidelines, or identifying where a piece of educational work might be needed.

3. The Steering Group

The Steering Group includes membership of people affected by stroke and health and social care professionals¹², as individuals or representatives from a relevant group.

The Stroke PSP will be led and managed by a Steering Group involving the following representation from across the UK:

¹⁰ This is because the causes of childhood stroke can be different to adult stroke, as is the treatment pathway. In addition, a new PSP is starting in Childhood Neurology which is likely to include childhood stroke. 16 has been chosen as the lower age rather than 18 because, in Scotland, one is considered an adult at 16.

¹¹ For example, the Sight Loss and Vision PSP used the survey responses to guide the number and focus for each top 10 workshop, which were based on 12 different categories of eye condition.

¹² In some PSPs, it has been suggested that researchers are represented on the Steering Group, to advise on the shaping of research questions. However, researchers who do not also have an active practice cannot participate by contributing or prioritising questions. This is to ensure that the final prioritised research questions are those agreed by patients, carers and practising professionals only, in line with the JLA's mission.

People affected by stroke¹³ representatives, and charities that work with them:

- Ade Adebajo, Stroke Survivor (England) and Chair, INVOLVE Working Group for Diversity and Inclusion;
- Brinton Helliwell, Stroke Survivor (England) and representative of Different Strokes;
- Dianne Haley, Chest, Heart & Stroke Scotland;
- Jenny Hylands, Stroke Survivor (Northern Ireland) and Specialist Speech and Language Therapist (Aphasia);
- Sandra Edgington, partner of a stroke survivor;
- Sarah Belson, Stroke Association (PSP Lead);¹⁴
- Ruth Lyle, Stroke Survivor (Scotland).

Health and social care professional organisations/representatives^{15 16}:

- Christine Roffe, National Institute for Health Research Clinical Research Network: Stroke;
- Clare Gordon/Liz Lightbody, National Stroke Nursing Forum;
- Diederik Bulters, British Neurovascular Group;
- Eirini Kontou/ Shirley Thomas, British Psychological Society;
- Gillian Mead, Cochrane Stroke Group;
- Jennifer Crow, Royal College of Occupational Therapist Specialist Section – Neurological Practice;
- Jenny Lund, Royal College of General Practitioners;
- Jonathan Hewitt, Stroke Implementation Group, Wales;
- Marian Brady/Katie Chadd, Royal College of Speech & Language Therapists;
- Marian Brady/Alex Pollock, Nursing, Midwifery and Allied Health Professions Research Unit;

¹³ Additional members are being sought to represent the views of carers.

¹⁴ The Stroke Association recognises the need for equitable membership of the Steering Group, and therefore is limiting its own representation to the PSP Lead with support from the Project Manager. However, in order to ensure that a range of expertise and knowledge from across the Stroke Association is available to the PSP, a Staff Panel has been convened. This will meet in between Steering Group meetings, and will discuss topics appropriate to the Steering Group Agendas, in order to provide relevant views and information via the PSP Lead/Project Manager.

¹⁵ In some cases, Steering Group members may be researchers representing clinical organisations but not have an active practice themselves. Where this is the case, in keeping with previous footnotes, they cannot contribute questions or participate in prioritisation exercises.

¹⁶ Where two names are listed, the place is shared in order to manage commitment.

- Niamh Kennedy, Northern Ireland Multidisciplinary Association of Stroke Teams (NIMAST);
- Phil White, UK Neurointerventional Group;
- Rustam Al-Shahi Salman/ Nick Evans, British Association of Stroke Physicians;
- Thompson Robinson, Royal College of Physicians; & National Institute for Health Research Stroke National Specialty Group;
- Ulrike Hammerbeck/Sally Davenport, Association of Chartered Physiotherapists in Neurology.

Support members:

- James Lind Alliance Adviser and Chair of the Steering Group: Suzannah Kinsella;
- Information Specialists: Ann Daly, Clinical Librarian; Joshua Cheyne, Cochrane Stroke Group;
- Project Manager: Sandra Regan, Stroke Association.

The Steering Group will agree the resources, including time and expertise that they will be able to contribute to each stage of the process, with input and advice from the JLA.

4. Partners

Organisations and individuals will be invited to be involved with the PSP as partners. Partners are organisations or groups who will commit to supporting the PSP, promoting the process and encouraging their represented groups or members to participate. Organisations which can reach and advocate for these groups will be invited to become involved in the PSP. Partners represent the following groups:

- People affected by stroke;
- Health and social care professionals who work with stroke survivors in some capacity.

Exclusion criteria

Some organisations may be judged by the JLA or the Steering Group to have conflicts of interest. These may be perceived to potentially cause unacceptable bias as a member of the Steering Group. 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 steps through which the PSP aims to meet its objectives. The process is iterative and dependent on the active participation and contribution of different groups. The methods used in any step will be agreed through consultation between the Steering Group members, guided by the PSP's aims and objectives. More details of the method are in the Guidebook section of the JLA website at www.jla.nihr.ac.uk where examples of the work of other JLA PSPs can be seen.

An overview of the Timeline can be found at Appendix 1.

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 Stroke PSP. A list of partners, with contacts owned by Steering Group members, will be attached as Appendix 2 when agreed.

Step 2: Awareness raising

An initial meeting was held in July 2019 with a number of interested organisations and people in order to secure support and participation from among the community of people affected by stroke and the health and social care professionals who work with them. This resulted in a first draft of the scope, and the formation of the Steering Group.

With regard to ongoing awareness raising, the Stroke Association is developing a Communications/Engagement Plan for discussion by the Steering Group. This will be attached at Appendix 3 when agreed.

Step 3: Identifying evidence uncertainties

The Stroke PSP will carry out a consultation to gather uncertainties from people affected by stroke and health and social care professionals. A period of 6-12 weeks will be given to complete this exercise (which may be revised by the Steering Group if required).

The Stroke PSP recognises the need to make extra efforts to involve those affected by stroke who may traditionally have less opportunities, such as:

- black, Asian and minority ethnic (BAME) communities;
- those in lower income communities;
- people with difficulties arising from stroke, e.g. aphasia, memory or vision loss, impaired capacity;
- those who do not use computers/the internet;
- the elderly;
- people whose first language is not English;
- stroke survivors of working age.

In addition, the Steering Group recognises that General Practitioners may need extra efforts to engage with.

The Steering Group will use the following methods to reach the target groups:

- Online survey with paper copies available;
- Reaching out through colleagues who work with people affected by stroke to gather questions face-to-face in a range of situations, including at existing group meetings, and at 3/6 month reviews and clinics;
- Promotion at conferences and meetings.

The Communications/Engagement Plan (Appendix 3) will provide the necessary tools to allow consistent messaging at each stage of the process.

Existing sources of evidence uncertainties may also be searched through a Literature Review. This may include, for example, question-answering services for people affected by stroke and for health and social care professionals; research recommendations in systematic reviews and clinical guidelines; protocols for systematic reviews being prepared and registers of ongoing research; the healthtalk module on stroke; Stroke Association internal data systems. If a

Literature Review is agreed, the sources to be searched will be attached as Appendix 4.

Step 4: Refining questions and uncertainties

The consultation process will produce 'raw' questions¹⁷ and comments indicating stroke survivors', carers' and professionals' areas of uncertainty. These raw questions will be categorised and refined by the PSP Information Specialist, Ann Daly into summary questions which are clear, addressable by research, and understandable to all. Similar or duplicate questions will be combined where appropriate. Out-of-scope and 'answered' submissions will be compiled separately. The Steering Group will have oversight of this process to ensure that the raw data is being interpreted appropriately and that the summary questions are being worded in a way that is understandable to all audiences. The JLA Adviser will observe to ensure accountability and transparency.

This will result in a long list of in-scope summary questions. These are not research questions and to try and word them as such may make them too technical for a non-research audience. They will be framed as researchable questions that capture the themes and topics that people have suggested.

The summary questions will then be checked against evidence to determine whether they have already been answered by research. This will be done by the PSP Information Specialist, Ann Daly following Steering Group guidance who, in turn, will be advised by the Cochrane Information Specialist, Joshua Cheyne. The PSP will complete the JLA Question Verification Form, which clearly describes the process used to verify the uncertainty of the questions, before starting prioritisation. The Question Verification Form includes details of the types and sources of evidence used to check uncertainty. The Question Verification Form should be published on the JLA website as soon as it has been agreed to enable researchers and other stakeholders to understand how the PSP has decided that its questions are unanswered, and any limitations of this.

Questions that are not adequately addressed by previous research will be collated and recorded on a standard JLA template by the PSP Information Specialist, Ann Daly. This will show the checking undertaken to make sure that the uncertainties

¹⁷ By "raw" questions, we mean the questions as they are written by those taking part and that may not yet be written in such a way that could easily inform research.

have not already been answered. 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.

The Steering Group will also consider how it will deal with submitted questions that have been answered, and questions that are out of scope.

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 about stroke. This will involve input from people affected by stroke and health and social care professionals. The JLA encourages PSPs to involve as wide a range of people as possible, including those who did and did not contribute to the first consultation. There are usually two stages of prioritisation.

1. *Interim prioritisation* is the stage where the long list of questions is reduced to a shorter list that can be taken to the final priority setting workshop. This is aimed at a wide audience, and is done using similar methods to the first consultation. With the JLA's guidance, the Steering Group will agree the method and consider how best to reach and engage stroke survivors, carers and health and social care professionals in the process. The most highly ranked questions (usually around 25) will be taken to one or more final priority setting workshop(s)¹⁸. Where the interim prioritisation does not produce a clear ranking or cut off point, the Steering Group will decide which questions are taken forwards to the final prioritisation.
2. *The final priority setting* stage is generally a one-day workshop facilitated by the JLA. With guidance from the JLA and input from the Steering Group, up to 30 stroke survivors, carers and clinicians will be recruited to participate in a day of discussion and ranking, to determine the top 10 questions for research. All participants will declare their interests. The Steering Group will advise on any adaptations needed to ensure that the process is inclusive and accessible. The

¹⁸ In light of the results of steps 3 to 5.1, the Steering Group will decide how many Final Workshops there will be. In the case that there is more than one, it is likely that they will be in different topic areas, each with its own Top 25.

Steering Group may decide to hold more than one workshop, depending on the results of preceding stages.

6. Dissemination of results

The Steering Group will identify audiences with which it wants to engage when disseminating the results of the priority setting process, such as researchers, funders and the patient and clinical communities. They will need to determine how best to communicate the results and who will take responsibility for this. Previous PSPs' outputs have included academic papers, lay reports, infographics, conference presentations and videos for social media.

It should be noted that the priorities are not worded as research questions. The Steering Group should discuss how they will work with researchers and funders to establish how to address the priorities and to work out what the research questions are that will address the issues that people have prioritised.

The dissemination of the results of the PSP will be led by the Stroke Association, in accordance with a Dissemination Plan developed by the Steering Group. The plan will specify agreed routes such as target journals/meetings, and lay reports, and responsibilities. This plan will be attached at Appendix 5 when available, and will help to inform the level of additional budget that may be required. All Steering Group members will be authors on the paper(s) that is/are produced.

However, the Steering Group recognises the need to engage with funders as early as possible in the process, and will give this due consideration.

The JLA encourages PSPs to report back about any activities that have come about because of the PSP, including funded research. Please send any details to jla@soton.ac.uk.

7. Agreement of the Steering Group

The Stroke PSP Steering Group agreed the content and direction of this Protocol on **[insert date]**.

8. Appendices¹⁹

1. Timeline overview
2. List of Partners
3. Communication/Engagement Plan
4. Literature Review
5. Dissemination Plan

¹⁹ These will be appended as they become available.