James Lind Alliance
Priority Setting Partnerships

GUTS UK!

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BRITISH SOCIETY OF GASTROENTEROLOGY

Irritable Bowel Syndrome (IBS) Priority Setting Partnership

PROTOCOL November 2021

1. Purpose of the PSP and background

The purpose of this protocol is to clearly set out the aims, objectives and commitments of Irritable Bowel Syndrome (IBS) 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.

Irritable bowel syndrome is a disorder of the gut brain interaction (DGBI) with symptoms of abdominal pain and altered bowel habit of diarrhoea, constipation, or alternating stool type. Other symptoms are bloating and/or distension, straining, urgency, feeling of incomplete evacuation and mucus in faeces. People with IBS can also experience back and bladder pain, which may aid diagnosis (NICE CG61)

The cause of IBS is unclear for most patients though in approximately 10% the symptoms appear after a gastrointestinal infection commonly known as post infection IBS. The diagnosis is more frequent in women than men in the UK with most people being diagnosed between the ages of 20 and 40 years.

IBS is a chronic long-term condition and 1 in 20 people are reporting IBS in the UK. Most patients with IBS are managed in primary care, but IBS is also frequently seen in Gastroenterology hospital clinics. Cost to the NHS is estimated to be up to £200 million per annum (Canavan et al 2014), the costs to society can be significantly higher with patients twice as likely to take sick leave, 12% stopping working altogether, and significant impact on mental wellbeing, confidence, enjoyment of life with some housebound because of symptoms.

European Union research funding does not appear to be distributed fairly according to gastrointestinal disease prevalence. There is a disparity between the number of people living with IBS and the level of allocated funding for clinical research. Despite IBS being one of the most frequently diagnosed gastrointestinal conditions it received less than 0.2% of the gastrointestinal research contributions to date under the European Horizon 2020 Framework (Törnblom et al, 2018).

The IBS PSP is **funded** by Guts UK Charity (50%) and the British Society of Gastroenterology (50%)

2. Aims, objectives and scope of the PSP

The aim of the Irritable Bowel Syndrome (IBS) PSP is to identify and prioritise the unanswered questions about the diagnosis, treatment and care of people (16 years+) with IBS from patients, carers, charities and health care professionals based in the UK.

The objectives of the PSP are to:

- work with people affected by IBS (patients (16 years+) and carers) and health care professionals to identify uncertainties about the diagnosis, treatment, and care of IBS
- 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.

Inclusion criteria:

- Diagnosis, treatment, and care of people with IBS
- People (16 years+) with IBS in the UK
- Carers/ family members of people with IBS (16 years+) living in the UK
- Healthcare professionals and others treating or supporting people with IBS in the UK

Exclusion criteria:

- It is recognised that international participants may respond to the surveys in which case their priorities will be separated and shared with their relevant overseas groups.

3. The Steering Group

The Steering Group includes membership of patients and carers and clinicians as individuals or representatives from a relevant group.

The IBS PSP will be led and managed by a Steering Group involving the following:

Patient and carer representative/s:

David Greenwood	Patient
Pauline Hunt	Patient
Ilkin Kasmani	Patient
Lesley Kirkpatrick	Patient
Abbey Scofield-Marlowe	Patient
Peter Setter	Carer
Margaret Anne Surginor	Patient

Clinical representative/s:

Dr Christopher Black – Locum Consultant Gastroenterologist, Leeds Teaching Hospitals NHS Trust

Dr Maura Corsetti – Clinical Associate Professor in Gastroenterology University of Nottingham

Professor Hazel Everitt - Professor of Primary Care Research, Primary Care Research Centre, Faculty of Medicine, University of Southampton

Professor Alexander Ford - Professor of Gastroenterology and Honorary Consultant Gastroenterologist, Leeds Institute of Medical Research at St James's, University of Leeds

Yvonne McKenzie – Specialist Dietitian in Gastrointestinal Nutrition and lead IBS Dietitian for the Gastroenterology Specialist Group of the British Dietetic Association.

Professor Rona Moss-Morris – Professor of Psychology as Applied to Medicine and Head of Psychology, at Institute of Psychiatry, Psychology and Neuroscience, King's College London

Sr Chris Pollard – Clinical Nurse Specialist in IBS

Project Team:

Julie Thompson – PSP Lead – Guts UK Charity, Information Manager

Professor Alexander Ford – PSP Clinical Lead

Helen West – PSP Coordinator – Guts UK Charity, Public Patient Involvement and Engagement Officer

Maryrose Tarpey – James Lind Alliance Advisor and Chair of the Steering Group

Kristina Staley – Information Specialist

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 who have IBS
- carers of people who have IBS
- health and social care professionals - with experience of IBS
- Charities and other organisations that provide support to people with IBS, their families and friends.

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.

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 IBS PSP.

Step 2: Awareness raising

PSPs will need to raise awareness of their proposed activity among their patient, carer and clinician communities, in order to secure support and participation. Depending on budget, this may be done by a face-to-face meeting, or there may be other ways in which the process can be launched, e.g. via social media. It may be carried out as part of steps 1 and/or 3. The Steering Group should advise on when to do this. Awareness raising has several key objectives:

- to present the proposed plan for the PSP

- to generate support for the process from patients/ carers, clinicians, researchers, and research funders

- to encourage participation in the process from a variety of different partners including charities and other organisations for both clinician and patient led groups.

- to initiate discussion, answer questions and address concerns.

Step 3: Identifying evidence uncertainties

The IBS PSP will carry out a consultation to gather uncertainties from patients, carers and clinicians. A period of 12-18 months will be given to complete this exercise (which may be revised by the Steering Group if required).

Existing sources of evidence uncertainties will be searched, for example the British Society of Gastroenterology IBS guidelines, the British Dietetic Association IBS and Diet guidelines and NICE CG 61.

Step 4: Refining questions and uncertainties

The consultation process will produce ‘raw’ questions and comments indicating patients’, carers’, and clinicians’ areas of uncertainty. These raw questions will be categorised and refined by Kristina Staley Information Specialist 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 Kristina Staley Information Specialist. 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 Kristina Staley Information Specialist. This will show the checking undertaken to make sure that the uncertainties 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 IBS. This will involve input from patients, carers and clinicians. 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 patients, carers and clinicians in the process. The most highly ranked questions (around 25) will be taken to a final priority setting workshop. 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 either held in person or online. With guidance from the JLA and input from the Steering Group, up to 30 patients, 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 and observers will declare their interests including any steering group members who will be attending. The Steering Group will advise on any adaptations needed to ensure that the process is inclusive and accessible.

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 Guts UK Charity.

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 IBS PSP Steering Group agreed the content and direction of this Protocol on 18th November 2021