



## Pancreatitis Priority Setting Partnership

PROTOCOL 2<sup>nd</sup> 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 the pancreatitis 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](http://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.

Pancreatitis is a devastating clinical condition that can either present with **acute** / sudden onset of symptoms / or recurrent acute symptoms or with **chronic** and life-long lasting symptoms. Only 40% of the general public are aware they have a pancreas and 70% don't know what it does. It is an under-represented area in the field of gastroenterology in terms of funding for research, staffing and profile. Guts UK Charity, for example is the **only** charity funding a research fellowship into pancreatitis in the UK.

Approximately 56 cases per 100,000 people suffer from **acute pancreatitis** with severe complications occurring in 25% of these patients, out of this 1 in 4 will die. For acute pancreatitis only, estimated cost of care in the UK is £200 million per year ( <https://bmjopen.bmj.com/content/6/6/e011474> 20216). There are also 12,000 admissions of **chronic pancreatitis** per annum of patients with chronic pancreatitis in the UK at an estimated cost of £55.8 million. An estimate of direct and indirect costs is at £285.3 million per year. This equates to £79,000 per person per year. <https://pubmed.ncbi.nlm.nih.gov/24661411>

NICE guidelines (<https://www.nice.org.uk/guidelines.104>) on pancreatitis were published as recently as September 2018, however there is still a huge variation of care across the UK. This PSP will have the opportunity to further influence the NICE guidelines and support their implementation. Also potentially contribute to the establishment of agreed pathways and standards for the diagnosis, management (including treatments) and support of pancreatitis and bring together the needs of patients and clinicians when addressing and prioritising funding of research in the future.

The Pancreatitis PSP is funded by **Guts UK Charity** (50%), **British Society of Gastroenterology** (25%) and **The Pancreatic Society of Great Britain and Ireland** (25%).

## 2. Aims, objectives and scope of the PSP

The scope of the pancreatitis PSP will bring together patients, carers, charities and health care professionals based in the UK and Ireland to identify and prioritise gaps in evidence in the diagnosis, treatment, management and support of patients with pancreatitis.

The objectives of the PSP are to:

- work with patients (adults and young people aged 11+), carers and health care professionals to identify uncertainties about the diagnosis, treatment, management and support for people with pancreatitis.
- 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 NICE and research commissioning bodies to be considered for funding.

### **Inclusion criteria:**

- Diagnosis, treatment, management (e.g prevention - post diagnosis, co-morbidities) and support (e.g education, advice, peer support and care) of pancreatitis.
- Patients (adults and young people aged 11+) living with pancreatitis in UK or Ireland with acute, recurrent acute and chronic.
- Carers of either patients who are currently living with pancreatitis or those who have lost a relative or friend to a diagnosis of pancreatitis in UK or Ireland
- Healthcare professionals including surgeons, consultants, allied health professionals (AHP), endoscopists working in UK and Ireland

### **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 pancreatitis PSP will be led and managed by a Steering Group involving the following:

### **Patient and carer representative/s:**

<b>Vishnu Aggarwal</b>	Patient
<b>Mark Batey</b>	Patient
<b>Kirsty Donaldson</b>	Patient
<b>David Hawkins</b>	Carer
<b>Amy Lucas</b>	Patient
<b>George Rawlins</b>	Patient
<b>Ian Scott</b>	Patient
<b>Katie Ward</b>	Carer

## Clinical representative/s:

**Dr Tassos Grammatikopoulos** – Consultant in Paediatric Hepatology & Honorary Senior Lecturer, Paediatric HPB and nutrition, BSPGHAN

**Professor Andrew Hopper** – Gastroenterology Consultant and Honorary Professor at Sheffield Teaching Hospitals and Sheffield University

**Dr John Leeds** – Consultant Gastroenterologist Pancreaticobiliary Physician, Honorary Clinical Senior Lecturer

**Dr Vikramjit Mitra** – PSP Clinical Lead, Consultant Gastroenterologist, Chair BSG Pan CRG (Chronic pancreatitis) Honorary Senior Clinical Lecturer

**Professor Damian Mole** – 1117 Chair in Surgery, MRC Senior Clinical Fellow, Honorary Consultant Liver Pancreas and Biliary Surgeon, Centre for Inflammation Research, Clinical Surgery, University of Edinburgh

**Stacey Munnely** – Advanced Nurse Practitioner, Gastroenterology + GI Medicine & surgery, Lecturer Practitioner Salford University

**Mary Phillips** – Specialist Dietitian (Hepato-pancreatico-biliary surgery), Team lead: ICU, NST and HPB Dietetics

**Professor Barbara Ryan** – Consultant Gastroenterologist, Clinical Professor of Gastroenterology, PSGBI

## Project Team

**Julie Harrington** – PSP Lead - Guts UK Charity, CEO

**Dr Vikramjit Mitra** - PSP Clinical Lead

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

**Maryrose Tarpey** - James Lind Alliance Adviser 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, groups or individuals who will commit to supporting the PSP, promoting the process and encouraging their represented groups or members to participate.

Charities and others involved in pancreatitis research or who advocate / provide support to patients and their families and friends will be invited to become involved in this PSP.

Partners represent the following groups:

- people who have had pancreatitis.
- carers of people who have had pancreatitis.
- health and social care professionals - with experience of pancreatitis.

### 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](http://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 pancreatitis 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
- to encourage participation in the process
- to initiate discussion, answer questions and address concerns.

### Step 3: Identifying evidence uncertainties

The pancreatitis PSP will carry out a consultation to gather uncertainties from patients, family/carers, charities 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 may also be searched.

### 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 pancreatitis. 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.

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. In addition, with the JLA's guidance, the Steering Group will agree the method and consider how best to reach and engage young people (aged 11+) and adult patients, carers/family 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.

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 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 will declare their interests. 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](mailto:jla@soton.ac.uk).

## **7. Agreement of the Steering Group**

The pancreatitis PSP Steering Group agreed the content and direction of this Protocol on 2<sup>nd</sup> November 2021.