



Inflammatory Bowel Disease (IBD) Priority Setting Partnership

PROTOCOL 18 September 2013 [approved 15 Nov 2013]

Purpose

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

Steering Group

The IBD PSP will be led and managed by the following:

Patient representative/s:

- Crohn's and Colitis UK (CCUK)
 - Peter Canham
 - Helen Terry
- Core
 - Howard Ellison

Clinical representative/s:

- British Society of Gastroenterology (BSG)
 - Chris Probert
 - Alan Lobo
 - Julie Solomon (staff support)
- British Society of Paediatric Gastroenterology, Hepatology and Nutrition (BSPGHAN)
 - Ronald Bremner
 - Mamoun Elawad
- British Dietetic Association (BDA)
 - Miranda Lomer
 - Katie Keetarut
- Association of Coloproctology of Great Britain and Ireland (ACPGBI)
 - Justin Davies
 - Omar Faiz
- Crohn's in Childhood Research Association (CICRA)
 - Rod Mitchell
- Royal College of Nursing (RCN)
 - Karen Kemp
 - Lisa Younge
- NIHR Comprehensive Clinical Research Network Specialty Group in Gastroenterology (NIHR CCRN SGG)
 - John McLaughlin

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

- The James Lind Alliance (JLA) – Chair of the Steering Group
 - Lester Firkins OBE
- Ann Daly – information analyst

The Steering Group includes representation of patient/carer groups and clinicians¹.

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

Background to the IBD PSP

The JLA is a project which is core-funded by the National Institute of Health Research. 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.

In 2010, the BSG’s Research Committee constructed a clinical research strategy document that was designed to help direct research in gastroenterology and hepatology. The document included the research priorities that had been determined by the BSG’s six Clinical Studies Groups, which covered endoscopy, IBD, small bowel and nutrition, cancer diagnosis and prevention, neurogastroenterology and motility. In early 2011 a consultation of members was held by the BSG to ascertain further what members felt were the research priorities at the time, and these were submitted to NETSCC, with some success (and some logistical difficulties). Simultaneously a plenary meeting of the CSGs was held in London at which Lester Firkins of the JLA spoke to explain the JLA’s mission. Several of the research priorities that were submitted via the 2011 consultation were in the area of IBD, and subsequent discussions with Lester led the BSG to look into the idea of setting up a PSP in this area, with the aim of improving the logistics of determining research uncertainties in a defined area that was of interest to a large proportion of UK gastroenterologists. An awareness meeting was held in November 2012 with representatives of most organisations in the Steering Group, and an agreement was reached to proceed with an IBD PSP.

Aims and objectives of the IBD PSP

The aim of the IBD PSP is to identify the unanswered questions about IBD treatment from patient and clinical perspectives and then prioritise those that patients and clinicians agree are the most important.

The objectives of the IBD PSP are to:

- work with IBD patients, carers and clinicians to identify uncertainties about the effects of IBD treatments
- to agree by consensus a prioritised list of those uncertainties for research

¹ In some cases, it has been suggested that researchers are represented at this level, to advise on the shaping of research questions. However, researchers cannot participate in the prioritisation exercise. This is to ensure that the final prioritised research questions are those agreed by patients, carers and clinicians only, in line with the JLA’s mission.

- to translate these prioritised uncertainties into research questions which are amenable to hypothesis testing
- 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:

- adults and children who have had or who still have IBD
- carers (including parents/guardians) of people who have had or who still have IBD
- doctors, nurses and professionals allied to medicine with clinical experience of IBD

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 in order to demonstrate their commitment to the aims and values of the JLA. Details on the affiliation procedure can be found at www.lindalliance.org.

Exclusion criteria

Some organisations may be judged by the JLA or the Steering Group to have conflicts of interest. These may be perceived to adversely affect those organisations' views, causing unacceptable bias. 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.

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. More details and examples can be found at www.JLAguidebook.org.

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 and through the JLA's existing register of affiliates. Potential partners will be contacted and informed of the establishment and aims of the IBD PSP and invited to attend and participate in an initial stakeholder meeting.

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

2. Initial stakeholder meeting

The initial stakeholder meeting will have several key objectives:

- to welcome and introduce potential members of the IBD 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 an open, inclusive and transparent mechanism 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 Steering Group in coordination with the JLA.

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.

3. 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 IBD.

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, email consultation, postal 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.

The starting point for identifying sources of uncertainties and research recommendations is NHS Evidence: www.evidence.nhs.uk.

4. Refining questions and uncertainties

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. The JLA will participate in this process as an observer, to ensure accountability and transparency.

The consultation process will produce “raw” unanswered questions about the effects of treatments. These raw questions will be assembled and categorised and refined by an information specialist with PSP experience, Ann Daly, into “collated indicative questions” which are clear, addressable by research and understandable to all. Similar or duplicate questions will be combined where appropriate. The Health Research Classification Scheme (HRCS) will be used to classify the uncertainties. The Scheme is available at <http://www.hrcsonline.net/>

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

Sometimes, uncertainties are expressed that can in fact be resolved with reference to existing research evidence - ie they are "unrecognised knowns" and not uncertainties. If a question about treatment effects can be answered with existing information but this is not known, it suggests that information is not being communicated effectively to those who need it. Accordingly, the JLA recommends strongly that PSPs keep a record of these 'answerable questions' and deal with them separately from the 'true uncertainties' considered during the research priority setting process. The PSP will discuss the best way to summarise and communicate these 'answerable questions' to the broader public, probably through the publication mentioned in the Aims section above.

Uncertainties which are not adequately addressed by previous research will be collated and entered into an IBD section within the UK Database of Uncertainties about the Effects of Treatments (UK DUETs - www.library.nhs.uk/duets) by Ann Daly. 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.**

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 relating to the treatment or management of IBD. 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 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 IBD 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 IBD PSP using both internal and external communication

mechanisms. The JLA may also capture and publicise the results, through descriptive 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.

Signed by the Steering Group

The undersigned agree to follow the IBD Priority Setting Protocol.

British Society of Gastroenterology (BSG)

Name:

Signature:

Date:

Crohn's and Colitis UK (CCUK)

Name:

Signature:

Date:

The James Lind Alliance (JLA)

Name:

Signature:

Date:

British Society of Paediatric Gastroenterology, Hepatology and Nutrition (BSPGHAN)

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British Dietetic Association (BDA)

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Association of Coloproctology of Great Britain and Ireland (ACPGBI)

Name:

Signature:

Date:

Crohn's in Childhood Research Association (CICRA)

Name: Rod Mitchell

Signature:

Date:

Royal College of Nursing (RCN)

Name:

Signature:

Date:

NIHR Comprehensive Clinical Research Network Specialty Group in Gastroenterology
(NIHR CCRN SGG)

Name: John McLaughlin

Signature:

Date:

Information analysis

Name: Ann Daly

Signature:

Date: