



## **Bipolar Priority Setting Partnership**

### **PROTOCOL 10 September 2014**

#### **Purpose**

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

#### **Steering Group**

The bipolar disorder PSP will be led and managed by the following:

Patient and family or carer representatives:

Edmund Brooks, carer representative

Bev Thornton, service user representative and Recovery & Social Inclusion Worker, Leeds and York NHS PFT (LYPFT)

Rachel Marshall, family representative

Suzanne Hudson, Chief Executive, Bipolar UK

Margaret Edwards, Chief Executive, SANE

Diana Rose, Head of Section, Service User Research Enterprise (SURE)

Anonymous representative

Clinical representatives:

Tom Hughes, Psychiatrist, LYPFT

Mary-Jane Attenburrow, Psychiatrist, University of Oxford

Amanda Hawkins, Chair British Association for Counselling & Psychotherapy

Ian Hulatt, Royal College of Nursing Mental Health Adviser

Additional support and expertise is provided by:

Jennifer Rendell, Research Fellow, University of Oxford

Rachel Churchill, Cochrane Depression, Anxiety and Neurosis Group

Sophie Petit-Zeman, Oxford Biomedical Research Centre (BRC)

Cynthia Joyce, Chief Executive MQ

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

David Crowe, The James Lind Alliance (JLA), as Chair of the PSP

Sandra Regan, Oxford BRC JLA Project Manager/ Hub Co-ordinator

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 bipolar disorder PSP**

The James Lind Alliance (JLA) is a non-profit making initiative which was established in 2004. It brings **patients, carers, family members** and **clinicians** together to identify and prioritise the top 10 **uncertainties**, or 'unanswered questions', about e.g. the effects of treatments that they agree are most important.

This information will help ensure that those who fund health research are aware of what matters to both patients and clinicians. From 1 April 2013, the NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC) has coordinated the work of the JLA.

Tom Hughes has an interest in bipolar disorder and became aware of priority setting partnerships (PSPs) in other conditions. He approached the JLA to suggest a PSP in bipolar disorder. The JLA put him in touch with Jennifer Rendell, Rachel Churchill and Sophie Petit-Zeman. There is strong interest in bipolar disorder and in the approach of the JLA in Oxford, and Mary-Jane Attenburrow joined the group at an early stage.

## **Funding**

The bipolar disorder PSP is currently funded by the Oxford Biomedical Research Centre and Leeds and York NHS PFT. Further funding may be provided by partner organisations.

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

The aims and objectives of the bipolar disorder PSP are to:

- work with people from the above perspectives to identify uncertainties about bipolar disorder causes, diagnosis, treatment, care and prognosis
- agree by consensus a prioritised list of those uncertainties, for research
- publicise the results of the PSP and process
- take the results to research funders to be considered for funding

## **Partners**

Organisations and individuals will be invited to take part in the PSP, which represent the following groups:

- people who have personal experience of bipolar disorder
- carers or family members of people who have bipolar disorder
- medical doctors, nurses and professionals allied to medicine with clinical experience of bipolar disorder

The Steering Group will attempt to invite all organisations which can reach and advocate for these groups 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](http://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](http://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 bipolar disorder PSP and invited to attend and participate in an initial stakeholder meeting.

### **2. Initial stakeholder meeting**

The initial stakeholder meeting will have several key objectives:

- to welcome and introduce potential members of the bipolar disorder 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 Oxford "hub."

At the meeting agreement will be reached about which partners will provide funding for the PSP. 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 causes, diagnosis, treatment, care and prognosis of bipolar disorder. A period of three to six months will be given to complete this exercise, depending on the number of respondents, the profile of respondents and the range of topics identified.

The methods will be designed according to the nature and membership of each organisation, but will 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.

The Steering Group will decide how to judge the representativeness of the sample and whether measures are required to adjust for bias in the sample. Such measures may include additional efforts to reach under-represented groups or giving greater weight to uncertainties suggested by under-represented groups.

Existing sources of information about uncertainties relating to bipolar disorder which are of practical clinical importance to patients and clinicians will be searched. These can include question-answering services for patients, carers, family members and clinicians; research recommendations in systematic reviews and clinical guidelines; protocols for systematic reviews being prepared and registers of ongoing research. Other sources may include interview transcripts from the bipolar disorder module of Healthtalkonline.

The starting point for identifying sources of uncertainties and research recommendations is NHS Evidence: [www.evidence.nhs.uk](http://www.evidence.nhs.uk).

### **4. Refining questions and uncertainties**

The process of managing the data will be undertaken by a team at the University of Oxford, with input from the Cochrane Depression, Anxiety and Neurosis (CCDAN) Group editorial base at the University of Bristol and from LYPFT, and overseen by the Steering Group. The JLA will participate in this process as an observer, to ensure accountability and transparency.

The consultation process will produce “raw” unanswered questions about causes, diagnosis, treatment, care, prevention and prognosis of bipolar disorder. These raw questions will be assembled, categorised and refined by the teams at the Universities of Oxford and Bristol 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 by CCDAN, with appropriate additional staff support funded from the bipolar disorder PSP budget, to see to what extent these refined questions have, or have not, been answered by previous research. Where no systematic review is available, primary studies will be identified (including clinical trials, cohort and case-control studies as

appropriate). Where out-of-date systematic reviews are identified, searches for primary studies will be undertaken to establish the value of an updating exercise. Searches of existing research will focus on sources that are most likely to identify relevant material, including the Cochrane Database of Systematic Reviews, the Database of Abstracts of Reviews of Effectiveness (DARE), the CCDAN trials register, and the Cochrane CENTRAL trials register. Extended searches of key databases (including Medline, EMBASE, and PsycLit) will also be undertaken to identify relevant literature as appropriate. Key national guidelines (including NICE and SIGN) will also be searched for published and unpublished literature and recommendations.

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 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 PSP will keep a record of these 'answerable questions' and deal with them separately from the 'true uncertainties' considered during the research priority setting process. Steering Group members will disseminate these answerable questions, and information on the answers or where these can be found, through their own organisations' communications systems to their members and employees. Steering Group members will ask partner organisations to do the same.

Uncertainties which are not adequately addressed by previous research will be collated and entered into a bipolar disorder section within the UK Database of Uncertainties about the Effects of Treatments (UK DUETs - [www.library.nhs.uk/duets](http://www.library.nhs.uk/duets)). This will ensure that the uncertainties have been actually checked to be uncertainties. This is the responsibility of the Steering Group, which will agree the personnel and resources to carry this accountability. The Steering Group will agree how questions which are not eligible for UK DUETs (for example, questions about causes and diagnosis) will be managed and published/taken forward. .

## **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 causes, diagnosis, treatment, care and prognosis of bipolar disorder. This will be carried out by members of the Steering Group and the wider partnership that represents patients, carers, family members 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 bipolar disorder PSP will be reported to funding and research agenda setting organisations such as the NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC) and the MRC, as well as the major research funding charities and we are also keen, through the Oxford JLA hub, to see our research recommendations disseminated to industry for research funding. Steering Group members will work with researchers and funders to develop the prioritised uncertainties into clear research questions. Steering Group members will be encouraged 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. The Steering Group will keep a record of this activity and of any research activity addressing the priorities

### **Publicity**

As well as alerting funders, partners and Steering Group members will publish the findings of the bipolar disorder 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 academic paper(s), which members of the Steering group and partners will do. However, production of an academic paper will not take precedence over publicising the final results.

### **Signed by the Steering Group**

The undersigned agree to follow the bipolar disorder Priority Setting Protocol.

Mary-Jane Attenburrow Department of Psychiatry, University of Oxford

Date:

Edmund Brooks, Patient's family representative

Date:

Cynthia Joyce , MQ

Date:

Anonymous, Patient representative

Date:

Margaret Edwards, SANE

Date:

Amanda Hawkins, British Association for Counselling & Psychotherapy

Date:

Suzanne Hudson, Bipolar UK

Date:

Tom Hughes, Leeds & York Partnership NHS FT

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Rachel Marshall, Patient's family representative

Date:

Jennifer Rendell, Department of Psychiatry, University of Oxford

Date:

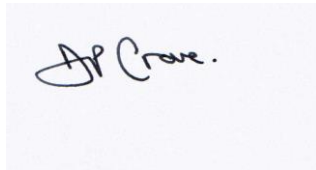
Diana Rose, The Service User Research Enterprise (SURE)

Date:

Bev Thornton, Patient & mental health support worker, Patient representative

Date:

David Crowe, The James Lind Alliance

A rectangular box containing a handwritten signature in black ink. The signature is written in a cursive style and reads "D Crowe".

Date: