

James Lind Alliance Priority Setting Partnership in

Kidney Transplantation

PROTOCOL

Version 1.4 – 12th June 2014

Purpose

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

Steering Group

The Kidney Transplant PSP will be led and managed by the following:

Patient representatives:

- British Kidney Patient Association (BKPA)
 - *Fiona Loud*
- National Kidney Federation (NKF)
 - *Angela Beale*

Clinical representatives:

- Centre for Evidence in Transplantation (CET)
 - *Simon Knight*
 - *Peter Morris*
- The Renal Association (RA)
 - *Graham Lipkin*
- British Transplantation Society (BTS)
 - *Rachel Hilton*
- British Renal Society (BRS)
 - *Simon Ball*

Charitable organisations:

- Kidney Research UK (KRUK)
 - *Lorna Marson*
 - *Keith Hodkinson*

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

- The James Lind Alliance (JLA)
 - *Leanne Metcalf*
- The Oxford Biomedical Research Centre (BRC)
 - *Hilary Cullen (Administrative support)*

The Steering Group includes representation of patient/carer groups and clinicians. 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 Kidney Transplantation PSP

The JLA is a project that is overseen by the National Institute for Health Research Evaluation, Trials and Studies Coordinating Centre (NETSCC). 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.

Sir Peter Morris established the Centre for Evidence in Transplantation in 2005, with the aim of providing a source of high quality evidence based information on all aspects of solid organ transplantation. As part of our work on evidence-based transplant surgery and transplant clinical trials, we were interested in identifying the most important questions, to both clinicians and patients, that should be brought forward for future research. We were introduced to the JLA approach following discussion with the NETSCC, and are fortunate that the Oxford Biomedical Research Centre have agreed to fund a PSP in Kidney Transplantation.

Aims and objectives of the Kidney Transplant PSP

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

The objectives of the Kidney Transplantation PSP are to:

- Work with patients and clinicians to identify uncertainties about kidney transplantation
- 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

Scope

The Kidney Transplantation PSP aims to consider all stages of the transplant process, including:

- Access to the waiting list and pre-transplant assessment
- The transplant procedure itself
- Post-transplant care in the short and long-term
- Management of the failed transplant and issues surrounding retransplantation
- Living-donor transplantation

Scope will include both adult and paediatric patients and their carers and clinicians.

In order to maintain the focus of the process, we will be excluding:

- Management of end-stage renal failure other than transplantation
- Donor selection and management (other than living donors)
- Issues specific to combined organ transplants

Partners

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

- Adults and children active on the waiting list for a kidney transplant and their carers/parents
- Adults and children who have previously received a kidney transplant and their carers/parents, even if this transplant has failed
- People who have donated a kidney as a living donor
- Medical doctors, nurses and professionals allied to medicine with clinical experience of kidney transplantation

It is important that all organisations that 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 contribute equally to the process.

Organisations wishing to participate in the PSP will be asked 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 at 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 Kidney Transplant PSP and invited to attend and participate in an initial stakeholder meeting.

The Steering Group should draft the invitation, and an agreement should be reached as to the best organisation to distribute it.

2. Initial stakeholder meeting / awareness raising ¹

The initial stakeholder meeting / awareness raising will have several key objectives:

- To welcome and introduce potential members of the kidney transplant 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 with input from the JLA.

3. Identifying treatment uncertainties

Each partner will be asked to promote to its members an online survey asking for topics of practical clinical importance relating to kidney transplantation. A period of 6 weeks will be given to complete this exercise.

The methods used to promote the survey 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 promotion, 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 diagnosis and the effects of treatments. These raw questions will be assembled and categorised and refined by staff at the Centre for Evidence in Transplantation into “collated indicative questions” which are clear, addressable by research and understandable to all. Similar or duplicate questions will be combined where appropriate.

¹ PSPs will need to raise awareness of their proposed activity among their patient and clinician communities, in order to secure support and participation. Depending on budget this may be done by way of a face to face meeting, or there may be other mechanisms by which the process can be launched.

The existing literature will be researched by CET staff 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 – i.e. 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.

Uncertainties that are not adequately addressed by previous research will be collated and prepared for entry into a kidney transplantation section within the UK Database of Uncertainties about the Effects of Treatments (UK DUETs - www.library.nhs.uk/duets) by the CET. 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. The data should be entered into UK DUETs on completion of the priority setting exercise, in order to ensure any updates or changes to the data have been incorporated beforehand.

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 kidney transplantation. Members of the Steering Group and the wider partnership that represents patients and clinicians will carry this out.

The interim stage, to proceed from a long list of uncertainties to a shorter list (e.g. up to 20), will be carried out by means of an online survey, whereby organisations consult their membership and choose and rank their top 10 most important uncertainties.

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. Participants will be expected to declare their interests in advance of this meeting.

Findings and research

It is anticipated that the findings of the kidney transplantation PSP will be reported to funding and research agenda setting organisations such as the NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC), which includes the 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 kidney transplantation 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.