

Influencing the research agenda: establishing and evaluating a partnership of patients, carers and clinicians to identify research priorities – a protocol

Brian Buckley¹
Adrian M Grant²
Lester Firkins³
Alexandra C Greene⁴
Jude Frankau⁴

¹ Department of General Practice, National University of Ireland, Galway and Chair of Board of Trustees, Incontact (Action on Incontinence), London

² Co-Chair, Cochrane Collaboration Steering Group and Editor, Cochrane Incontinence Review Group, University of Aberdeen

³ Medical Research Council and James Lind Alliance Development Group

⁴ Health Services Research Unit, University of Aberdeen.

Contact author:

Brian Buckley
Department of General Practice
Clinical Sciences Institute
National University of Ireland
Galway
Ireland

Tel/fax: 00353 74 9736298

bsbuckley@iol.ie

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ABSTRACT

Objective: To establish and evaluate a partnership of patients, carers and professionals in order to identify research priorities relating to the treatment and management of urinary incontinence (UI).

Background: There are mismatches between the questions being addressed by researchers and the uncertainties that are most important to patients and carers and to the practising clinicians to whom they turn for help. The James Lind Alliance (JLA) was established in 2004 to encourage consumers and clinicians to work together to identify treatment uncertainties and priorities for research.

Intervention: This paper describes plans for a working partnership of patients, carers and clinicians intended to inform the future commissioning of research on UI. The partnership aims to identify and prioritise uncertainties about the treatment and management of UI which are of practical importance and which cannot currently be answered by up-to-date systematic reviews of research evidence. A concurrent qualitative evaluation study will inform the broader debate about consumer involvement in healthcare research agenda setting.

Dividends: The project will have value on several levels: uncertainties relating to the treatment or management of UI which are currently unanswered by research evidence will be identified and prioritised; the qualitative evaluation will inform the debate about patient and carer involvement in research agenda setting and provide guidance for future JLA partnerships.

Key words:

Patient involvement
Research prioritisation
Research agenda
Urinary incontinence

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BACKGROUND

Research on the effects of therapies which has been prioritised by industry and academia often fails to address those questions and uncertainties which are of practical importance to patients and carers and the clinicians to whom they turn for help¹⁻³. In recent years the number of publicly-funded trials has decreased and the predominance of industry funded trials concerned with drug-based therapies has increased, far outweighing research into other forms of therapy^{2,3}. Concern has been expressed that the public is losing control of the research agenda and that there is a mismatch between what is researched and the information needed to inform everyday decisions when patients, carers and clinicians are considering how best to manage health problems^{3,4}.

For example, when patients, rheumatologists, physiotherapists and general practitioners (GPs) were consulted about their research priorities relevant to the treatment of osteoarthritis of the knee, a substantial mismatch was identified between their priorities and the current dominance of drug-based research. Of the published trials, 59% were on drug treatments; 89% of commercially funded trials identified were on drug treatments. Rheumatologists considered non-steroidal anti-inflammatory drugs (NSAIDs) to be over-researched, that indications for knee replacement warranted more research and that better outcome measures should be developed. Physiotherapists felt that clinically relevant questions were insufficiently addressed and were concerned about the absence of research into exercise-based therapies. General practitioners felt there was insufficient research into success rates of surgical procedures and wanted more research on conservative treatments such as exercise and education. Patients also wanted more research into surgery as well as conservative therapies and self-help and coping strategies³.

The James Lind Alliance

In recent decades the value of involving patients and carers in the planning and conduct of medical and health services research has become increasingly accepted². Whilst developing effective methods for patient and carer involvement at study level presents one set of challenges, however, quite another is presented by looking for ways to involve patients and carers in informing the wider research agenda.

The James Lind Alliance (JLA) was established in 2004 to encourage patients and clinicians to work together to identify treatment uncertainties and unanswered questions which are most important in any particular clinical area and to prioritise those in order to influence and inform the publicly funded research agenda. The Alliance is named after the 18th century Scottish naval surgeon who conducted one of the earliest reported controlled clinical trials, which compared different alleged treatments for scurvy ⁵. The NHS Health Technology Assessment (HTA) programme has made a commitment to receive the HTA recommendations for research emerging from JLA working partnerships into the HTA programme prioritisation process. Although the Medical Research Council (MRC) works in responsive mode, it, too, has indicated that it would take account of priorities identified by JLA Working Partnerships ⁶.

The JLA is endeavouring to facilitate the establishment of Working Partnerships (WP) consisting of at least one patient organisation and at least one clinical organisation that aim to identify and prioritise, by mutual consent, important uncertainties about treatment effects. The involvement of the relevant Cochrane Review Group is encouraged, to provide systematic evidence about what rigorous research has already been undertaken on a particular topic.

The process has to involve several stages. The first stages involve identifying uncertainties about the effects of treatments which cannot be answered by referring to up-to-date systematic reviews of existing research evidence ^{7, 8}, assembling them in the Database of Uncertainties about the Effects of Treatments (DUETs), and collating similar uncertainties identified in different sources to form a DUETs module. The final phase involves prioritisation of these treatment uncertainties through mutual consent between patients clinicians;⁸ publishing them, and drawing them to the attention of funding agencies.⁸

Identifying and prioritising uncertainties about the treatment and management of incontinence

The clinical area which will be considered by the Working Partnership described by this protocol is urinary incontinence (UI), defined as the “demonstrable involuntary loss of urine” ⁹. Urinary incontinence occurs at all ages and is associated with a wide variety of conditions. For some urinary incontinence is an occasional slight leakage from the bladder, for others it is a complete inability to control voiding. The prevalence of urinary incontinence is difficult to establish: the populations surveyed and definitions used across studies vary, and the problem of under-reporting is usually difficult to quantify. For example, prevalence estimates for *any* urinary incontinence

(UI) range from 5% in women over 15 years of age in Belgium¹⁰ to 69% in women over 19 years of age in Wales ¹¹. Commonly cited figures for “regular” urinary incontinence are those resulting from a 1995 Royal College of Physicians study : 8.75% of women <65, 15% of women >65, 3% of men <65 and 8.5% of men >65 ¹². More recent research resulted in higher estimates for urinary incontinence “several times a month or more often” : 8.9% of men over 40 and 20.2% of women over 40 ¹³. In addition it has been estimated that 1-2% of adults experience bedwetting, and 5-10% of 5-14 year olds are affected by bedwetting, daytime wetting or soiling ¹⁴.

Urinary incontinence can affect seriously the ability to work, travel and socialise, and adds significantly to the work of carers ¹⁵. Despite these practical implications, the problem remains largely hidden. There is little doubt that many people affected by urinary incontinence are anxious to conceal the problem and reluctant to discuss it ¹⁶⁻¹⁸. In the population as a whole, a majority of those who are incontinent do not seek professional help ¹⁹. In eight separate UK studies the average figure for those affected by incontinence who *do* seek help is only 34.3%²⁰. Research in Ireland showed that only 40% of people aged 40 or over with bladder problems have ever discussed these with a doctor or nurse,²¹ and that of people aged over 75 who were incontinent, only 44% were known to be so by their GP ²². Failure to seek help can result from embarrassment or a belief that incontinence is normal in women following childbirth or both sexes after a certain age, while poor awareness of treatment options promotes a feeling that nothing can be done, or that surgery is an inevitable result ^{16, 23}.

The JLA Working Partnership on incontinence

The JLA WP on incontinence was proposed in 2006 as an opportunity to ensure that the questions, uncertainties and priorities of patients, carers and practising clinicians affected by or treating incontinence are taken into account in the commissioning of research. This is a clinical area which is affected at all levels by the taboo which surrounds incontinence so that there is poor public and professional awareness both of the condition itself and of services and treatments available. Crucially, the stigma associated with incontinence may mean that consumers may be less likely to express their concerns and priorities relating to treatments than in other disease areas. In this sense it is an area to which a systematic method of gathering, collating and prioritising clinician and consumer views and questions is particularly appropriate.

Partners

Organisations will be invited to take part in the Working Partnership which represent the following groups: : those who are or have been incontinent, carers of people who are or have been incontinent, and medical doctors, nurses and professions allied to medicine with clinical experience of incontinence.

For the purposes of the WP process, three overlapping subgroups of people affected by incontinence have been defined:

- Those affected by incontinence that is idiopathic or which is a symptom or result of a condition or disease which is not acute and which is treatable in primary care (for example, Stress Urinary Incontinence [SUI], Over-active Bladder [OAB], Enuresis [bedwetting]).
- Those affected by incontinence resulting from acute illness or trauma or from conditions or diseases which cause wide-ranging disabilities in addition to incontinence, whether acquired or congenital (for example, as a result of prostate surgery, Spinal Cord Injury [SCI], Multiple Sclerosis [MS], Spina Bifida [SB], Cauda Equina Syndrome, certain learning disabilities).
- Elderly people affected by incontinence, whether clinical or functional (i.e. as a result of reduced mobility or dementia).

We consider it important that organisations that can reach and advocate for members of each of these subgroups should be involved in the Working Partnership.

Exclusion criteria

Organisations which are judged by JLA to have conflicts of interest which may be perceived to affect those organisations' views and therefore the ultimate findings of the WP will not be invited to participate.

METHODS

This section describes a schedule of proposed stages through which the Working Partnership aims to fulfil its objectives. The process is iterative and dependent upon 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 Working Partnership's aims and objectives.

Identification and invitation of potential partners.

Potential partner organisations are being identified through a process of peer knowledge and consultation, through the JLA's existing register of affiliates and through internet search. Potential partner organisations will be contacted and informed of the establishment and the aims of the JLA Working Partnership on incontinence and invited to attend and participate in an exploratory meeting.

Exploratory meeting.

The exploratory meeting will have several key objectives:

- To welcome and introduce the representatives of the potential partner organisations.
- To present the proposed plan for the JLA Working Partnership on Incontinence.
- To invite the representatives to discuss the project. Representatives of the JLA and the authors of this protocol will address concerns and questions.
- To identify those potential partner organisations which will commit to the Working Partnership and identify individuals who will be those organisations' representatives and the Working Partnership's principal contacts.
- To establish principles upon which open, inclusive and transparent mechanisms can be based for contributing to, reporting and recording the work and progress of the WP.

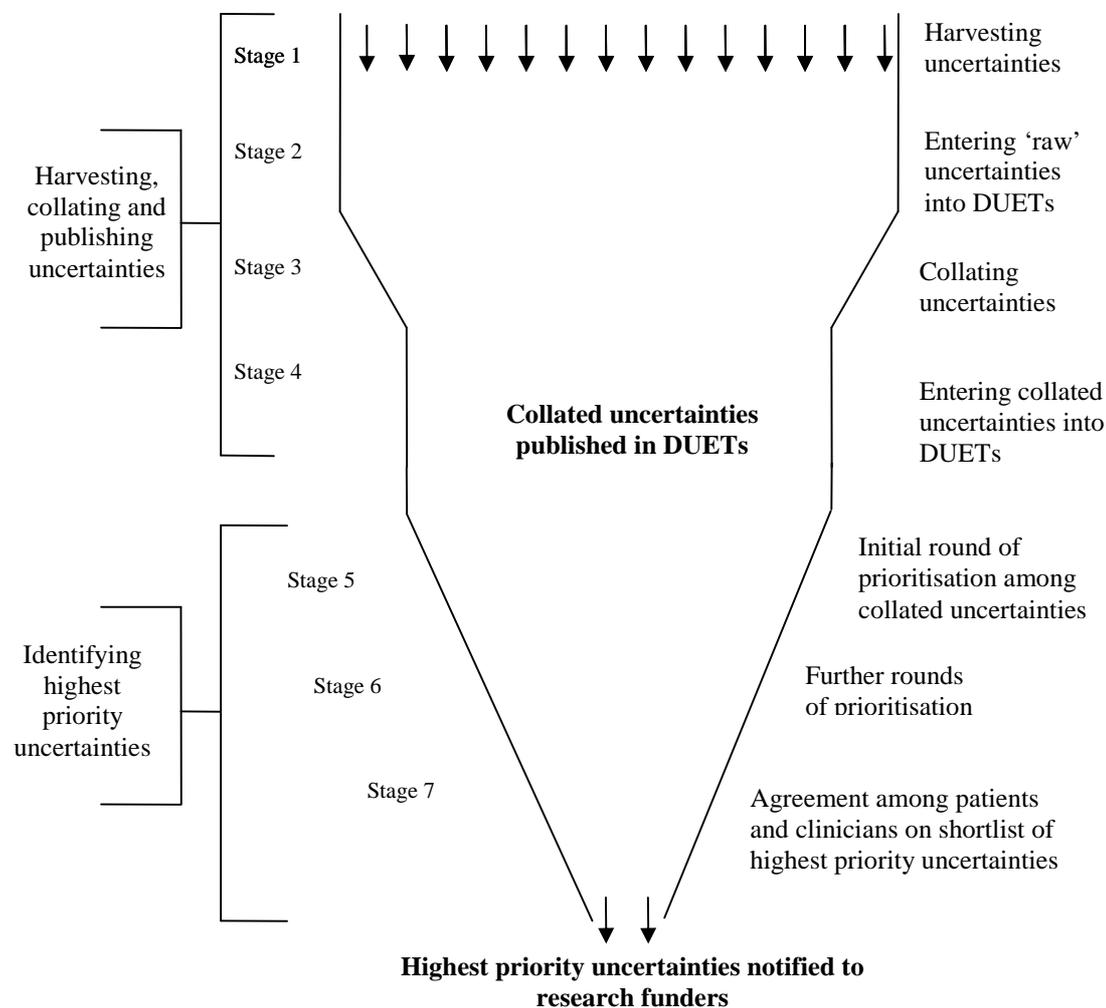
Identifying treatment uncertainties

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 incontinence.

The methods may be designed according to the nature and membership of each organisation but must be as transparent, inclusive and representative as practicable. We envisage that the methods used may include membership meetings, direct mail or email consultation, mail or web-based questionnaires, internet message boards with associated email notification, and focus group work.

Existing sources of evidence about treatment uncertainties will be examined. These include question-answering services for patients and carers (eg. NHS Direct) and for clinicians (eg. ATTRACT, which answers primary care clinicians' questions about clinical evidence)²⁴; research recommendations in systematic reviews and clinical guidelines²⁵; protocols for systematic reviews being prepared and registers of ongoing research.

Figure 1: Identifying and prioritising uncertainties about the effects of treatment:
the role of the Database of Uncertainties about the Effects of Treatments (DUETs)



Refining questions and uncertainties

These consultation processes will produce “raw” unanswered questions about the effects of treatments. These raw questions will be assembled and categorised and refined 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 searched to see to what extent if any these refined questions have been answered by previous research. The Cochrane Collaboration Incontinence Review Group will assist in this process.

Uncertainties which are not adequately answered by previous research will be collated and entered into a disease area module within the DUETS database.

Prioritisation

The aim of the final stage of the WP process is to prioritise through consensus the identified uncertainties relating to the treatment or management of incontinence through consensus.

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 ⁸: Adapted Delphi techniques; Expert Panels or Nominal Group Techniques; Consensus Development Conference; Electronic Nominal Group and Online Voting; Interactive Research Agenda Setting; Focus groups.

Findings

The findings of the JLA Working Partnership on incontinence will be reported to funding and research agenda setting organisations such as the NHS HTA Programme and the MRC and will be published.

CONCURRENT QUALITATIVE EVALUATION STUDY

Concerns have been expressed that while there has been considerable debate about the “why” of patient and carer involvement in research, the “how” has been less well reported. Unless the challenges, strengths and limitations of exploratory strategies for patient and carer involvement are adequately reported, opportunities for the development of effective and methodologically defensible strategies will be limited ²⁶.

The JLA WP on incontinence presents a valuable opportunity to incorporate a qualitative evaluation of the JLA methods. To this end a MRC funded PhD studentship based in the Health Services Research Unit at the University of Aberdeen has been established and a researcher appointed, Jude Frankau.

An evaluative approach has been identified which will be most useful both to maximise the chances to understand the process of a working partnership between clinicians and other stakeholders and in this way, to inform the development of future working partnerships. Interpretative evaluation aims to address topics of importance to the research participants, resulting in findings which provide participants with the means to evaluate their own experiences, in order to contribute to positive change ²⁷. The researcher will

study the processes of the WP and the perceptions of the participants through WP meetings and other forms of interaction and communication. The study will start from initial approaches to participants, follow the development of the Partnership as it meets to agree and prioritise research topics, culminating in the conclusion of its activities.

Questions would be addressed about factors that increase or decrease the likelihood of a successful partnership:

- How are potential participants identified and approached?
- How are partners' representatives designated?
- What form does preparation for both patients and clinicians take?
- What format do meetings take and how was this decided upon?
- What are the roles of facilitators?
- How do participants interact both within and between the partner groups?
- In what ways is consensus reached?
- What is the value of the 'product'?

Methods

This study will use qualitative methods, drawing on the theoretical frameworks of medicine and social science. The interpretive evaluation is based on a case study group with non-participant observation of the partnership facilitation between stakeholders undertaken over two years (or until the partnership ceases to function if sooner than two years)²⁸. This is supplemented by the robust combination of participant observation and face to face interviews with stakeholders (representatives of the patient groups, clinician groups, and of the JLA) which enables greater in-depth analysis of what social and cultural factors influence the successful outcome of consumer involvement in healthcare agenda setting. More specifically, participant observation is useful to allow the researcher to collect information about the interactions of participants in their 'natural environment'²⁹, such as at meetings and conferences, whilst in-depth interviews, which are similar to a 'loosely structured conversation', assist the researcher to have a deeper understanding of stakeholders' beliefs, expectations and experiences of what constitutes successful interactions in general and successful working partnerships in particular³⁰. Short qualitative questionnaires consisting of open-ended questions on similar themes to those covered by the interviews may be used when it is not practicable to undertake full-scale interviews. Documentary analysis (public leaflets and minutes) provides the opportunity to explore how the interactions between stakeholders, in addition to their personal perceptions of events, are translated into public documents³¹.

Dividend of the work

The work will be valuable at three levels. It will inform the broader debate about consumer involvement in healthcare research agenda setting; it will provide guidance for future JLA Working Partnerships; and it will enhance the relevance of future research on incontinence to patient and consumer needs.

CONCLUSIONS

The JLA Working Partnership on Urinary Incontinence offers a number of benefits. It will be primarily an opportunity for collaboration between patients, carers and clinicians with the aim of informing the research agenda of those unanswered research questions which are of most practical importance to those who seek the most effective ways to treat or manage incontinence. However, the incorporation of a concurrent qualitative evaluation study will be of additional value. It will inform the broader debate about consumer involvement in healthcare research agenda setting; it will provide guidance for future JLA Working Partnerships; and it will enhance the relevance of future research on incontinence to patient and consumer needs.

SOURCES OF FUNDING AND SUPPORT

The costs to date of work on the development of the JLA WP on incontinence have been met by the Health Service Research Unit (HSRU – funded by the Chief Scientist’s Office of Scotland), University of Aberdeen, Incontact (Action on Incontinence) and the MRC. The work of the authors is supported by the Department of General Practice, National University of Ireland, Galway (BB), the Cochrane Collaboration Incontinence Review Group (AMG), the MRC and JLA (LF) and HSRU, University of Aberdeen (ACG). The PhD studentship for the dependent qualitative study is funded through the University of Aberdeen by the MRC (JF). The NHS R&D Programme provides infrastructure support for both the JLA and the Cochrane Incontinence Group.

Ethical approval

Not needed.

Competing interests

None

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