

## CLINICAL PAPER

# Prioritizing incontinence research: patients, carers and clinicians working together

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### Abstract

There is a mismatch in many areas between the questions that are being addressed by clinical and health services research, and those that practising clinicians and healthcare consumers need answered. The James Lind Alliance Working Partnership on Urinary Incontinence started its work in 2007. Its aim is to help patients, carers and clinicians work together to identify and prioritize questions about urinary incontinence that are of practical, everyday importance, but that cannot be answered by referring to existing research evidence. The recommendations of the Working Partnership will be reported to the National Health Service Health Technology Assessment programme and the Medical Research Council, and then published. This is a valuable and innovative opportunity for providers and consumers of continence care to work together to influence the research agenda.

*Keywords:* carers, clinicians, patients, urinary incontinence.

### Introduction

Concerns have been expressed that much of the clinical research conducted each year does not address the questions about treatments that are of practical importance to patients, their carers and the clinicians to whom they turn for help (Chalmers 2004; Partridge & Scadding 2004).

For example, in the late 1990s, patients, rheumatologists, physiotherapists and general practitioners were consulted about their interests and priorities in relation to the treatment of osteoarthritis of the knee. Physiotherapists felt that little research had addressed clinically relevant questions and they were particularly concerned about the absence of research into exercise-based

therapies. General practitioners highlighted difficulties finding good evidence about the success rates of surgical procedures, and wanted more research on conservative treatments such as exercise and education. Rheumatologists thought that more research was needed on appropriate indications for knee replacement and that better outcome measures should be developed. Patients were interested in knowing more about the effectiveness of conservative therapies, and of self-help and coping strategies. All groups felt that drug-based therapies had been over-researched.

Subsequently, the researchers searched the literature for published research evidence relating to the treatment of the condition. The study found that there was a considerable mismatch between what had been researched, and

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the information that the clinicians and patients felt was needed to inform everyday treatment decisions. For example, of all the published randomized controlled trials on the subject, only 5% considered physiotherapy and exercise, 3% surgery, and 3% patient education, behavioural change, self-help and coping strategies; 83% were of drug-based therapies (Tallon *et al.* 2000).

It has been suggested that the public is losing control of the research agenda and that it is increasingly set by industry (Partridge & Scadding 2004; Delaney 2006). Of course, the contribution to improvements in healthcare made by research that is prioritized and funded by the pharmaceutical and medical devices industries cannot be overlooked, but their interests and priorities do not necessarily reflect those of patients, carers and practising clinicians.

In the past 10–15 years, the numbers of publicly funded clinical trials have decreased while the proportion of the most frequently cited trials that are industry funded has increased (Partridge & Scadding 2004; Patsopoulos *et al.* 2006). This being the case, it is all the more important that publicly funded research addresses clinical uncertainties of practical importance to clinicians and consumers.

The present article outlines the aims and work to date of the James Lind Alliance (JLA) Working Partnership on Urinary Incontinence (UI), which aims to identify and then prioritize significant unanswered research questions within one important area of healthcare in order to inform the research agenda. It updates a previous article in the journal *Continence UK* describing the project and the protocol that was published online at <[www.lindalliance.org](http://www.lindalliance.org)> (Buckley *et al.* 2007a, b).

### **The James Lind Alliance Working Partnership on Urinary Incontinence**

The JLA was established in 2004 with the aim of encouraging patients and practising clinicians to work together to try to ensure that the uncertainties that affect everyday clinical practice are addressed by research. The Alliance is named after the eighteenth-century Scottish naval surgeon who conducted one of the earliest reported controlled clinical trials, which compared different alleged treatments for scurvy (Lind 1753).

The JLA's approach is to endeavour to bring together at least one patient organization and at least one clinical organization from within

a single clinical area to form a Working Partnership. The aim of a Working Partnership is to identify 'treatment uncertainties' that are of day-to-day clinical importance, and to prioritize these in order to influence and inform the publicly funded research agenda. 'Treatment uncertainties' might be defined as 'questions about the effectiveness of treatments which cannot be adequately answered by existing research evidence'. The National Health Service (NHS) Health Technology Assessment (HTA) programme has made a commitment to receive the recommendations for research emerging from the JLA's work into the HTA programme prioritization process, and the Medical Research Council (MRC) has indicated that it will take account of priorities identified by JLA Working Partnerships.

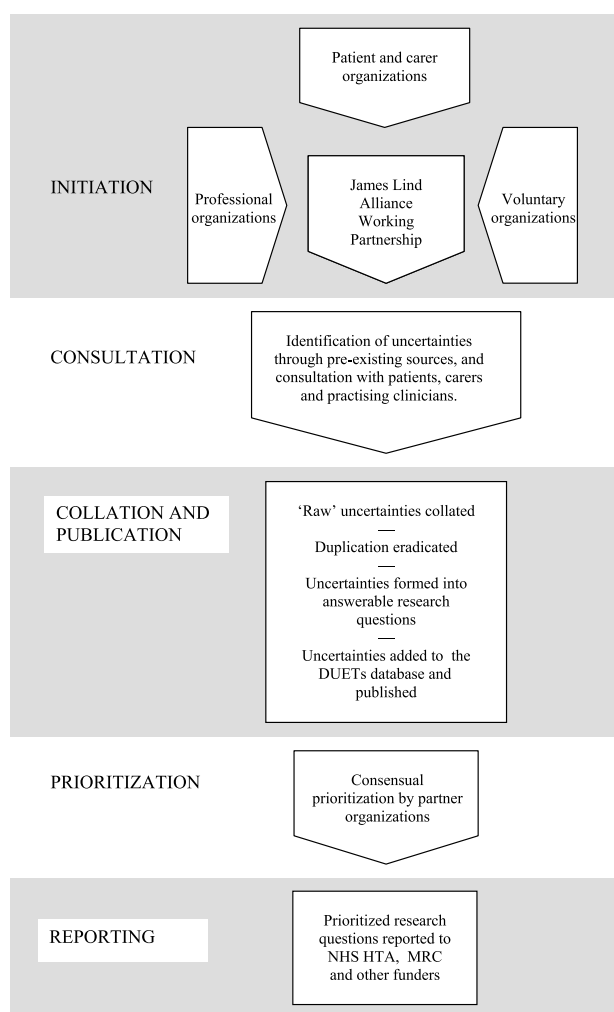
The JLA Working Partnership on UI was proposed in 2006 as a way of identifying and prioritizing treatment uncertainties relating to UI that are of importance to patients, carers and clinicians. It began its work in 2007 with the active participation and collaboration of patient and healthcare professional groups.

### **Materials and methods**

The process through which the Working Partnership aimed to fulfil its objectives was published in full on the JLA website at the start of the project and has been described in the literature (Buckley *et al.* 2007a, b). The Working Partnership was intended to be an iterative process, with the precise methods adopted at any stage determined through consultation between the partners. Thus, it is valuable at this stage to be able to describe the process and evolution of the project to date, including changes from the published protocol, and reflect on learning that has taken place in order to inform future similar Working Partnerships. Importantly, it was decided at the outset that the methods must be open, inclusive and transparent.

The stages through which the Working Partnership would achieve its aims were identified as (these stages are represented graphically in Fig. 1):

- (1) *Initiation* – during which potential partnership organizations would be identified, contacted and recruited where possible.
- (2) *Consultation* – during which the participating organizations would gather the views of their membership or constituents about



**Figure 1.** Flow chart showing the stages through which the Working Partnership would achieve its aims: (DUETs) Database of Uncertainties of the Effects of Treatments; (NHS HTA) National Health Service Health Technology Assessment; and (MRC) Medical Research Council.

treatment uncertainties of day-to-day clinical importance.

- (3) *Collation* – during which the Working Partnership would gather, categorize, refine, and where appropriate, combine these reported treatment uncertainties; and during which questions would be discarded that were determined to be answerable by existing evidence and the uncertainties remaining published in the Database of Uncertainties of the Effects of Treatments (DUETs).
- (4) *Prioritization* – during which the remaining treatment uncertainties would be prioritized by consensus of the participating organizations.
- (5) *Reporting* – during which the final prioritized list of treatment uncertainties relating to UI would be reported to the NHS HTA programme and the MRC.

## Initiation

The first stage involved the identification of potential partner organizations through a process of peer knowledge and consultation, through the JLA's existing register of affiliates, and through an Internet search. Organizations were identified that could advocate for patients who are or have been incontinent, and their carers, as well as clinicians involved in the treatment or management of incontinence. It had been intended that organizations would have been excluded from participation if they were considered to have conflicts of interest that might affect their views and, therefore, undermine the independence of the ultimate findings of the Working Partnership, but this did not prove to be necessary.

It was considered important that all 30 identified organizations should have an opportunity to participate. These included: large national charities whose aims included a possible interest in incontinence; smaller patient- or carer-focused charities with a specific remit that involved incontinence; Royal Colleges whose members' work involves the treatment of incontinence; and other professional organizations with a remit including incontinence. Potential partner organizations were sent information about the Working Partnership, where possible through a known contact person, and invited to appoint a representative to attend an exploratory meeting at which the planned project was discussed.

This meeting took place at the secretariat of the JLA in Oxford and was attended by 18 people, including representatives of patient-and-carer and professional organizations, and of the JLA. Some organizations expressed their interest in participating in the Working Partnership, but were unable to attend. Following the exploratory meeting and subsequent follow-up mailings, 18 organizations were identified that intended to participate fully in the Working Partnership. These included six patient organizations, two patient and professional organizations, and 10 healthcare professional organizations.

Through e-mail and teleconferencing, four Action Groups were agreed: a 'Steering Group' to oversee and drive the progress of the partnership; a 'Harvesting Group' to develop and drive the process of gathering uncertainties from the membership of professional and patient organizations; a 'Communications Group', which would oversee communications to and between the organizations; and a 'Prioritizing

Group', which would develop and oversee the process of categorizing and prioritizing identified uncertainties.

## Consultation

The identification and collation of treatment uncertainties relating to UI is the first substantive task for the Working Partnership, and at the time of writing (November 2007), this process is starting. The original protocol determined that each partner organization would identify a method for 'harvesting' its members' views on treatment uncertainties that suited its own membership and infrastructure. However, it was felt by many participants at the exploratory meeting and at subsequent teleconferences that this approach might result in both duplication of effort and inconsistent data collection. Therefore, it was decided that the Working Partnership's 'Harvesting Group' would develop a simple standard questionnaire.

The questionnaire that was developed includes clear information about the Working Partnership's aims and about what a 'treatment uncertainty' is. By answering three subsequent questions, respondents will be able to report to the Working Partnership the uncertainty that has affected their own treatment or their decisions about treatment of others: (1) the basic bladder problem must be identified; (2) the precise information should be identified that would have helped to inform their treatment choice, but which they were unable to find; and (3) an indication should be given of where respondents looked for the information they needed. Two examples are provided to help respondents to complete the questionnaire, one intended to illustrate a possible patient's answer and one a clinician's response (Box 1).

Using a standard questionnaire has allowed the Working Partnership to determine the format in which the uncertainties are submitted so that the unanswered research question is clear. The questionnaire also includes a consent form and fields for responders to include their contact details if they would like to know more about the project, or if they wish to be informed if good evidence is identified by the Working Partnership that addresses their uncertainty.

Guidance notes are included with the questionnaire on how it might be distributed by partnership organizations. The methods for distribution may include postal distribution,

**Box 1.** Two examples provided to help respondents to complete the questionnaire: examples 1 and 2 are intended to illustrate a possible patient's response and a clinician's response, respectively

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**For each uncertainty that has affected your healthcare choices, please answer the three questions. Here are some examples of the way you could answer them:**

### *Example 1*

**What is the basic bladder problem?**

Bedwetting in an 8-year-old child.

**What information would have helped you to decide about treatment?**

Which is most effective for stopping the bedwetting: a bedwetting alarm or desmopressin tablets, or both?

**Where have you looked for the information you wanted to help you decide?**

I have asked my doctor and phoned a patient organization, but none knew for sure.

### *Example 2*

**What is the basic bladder problem?**

Urinary incontinence in an adult male following prostate surgery.

**What information would have helped you to decide about treatment?**

Do pelvic floor exercises help men with incontinence after prostate surgery?

**Where have you looked for the information you wanted to help you decide?**

I have consulted the Cochrane Library, but it seems that up-to-date systematic reviews have revealed continuing uncertainties about treatment effects.

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inclusion in organization publications, websites, or distribution by e-mail or at meetings.

In addition to the harvesting of treatment uncertainties by participating organizations, existing sources will be examined for evidence regarding uncertainty in healthcare. This process will provide an opportunity to identify uncertainties in areas of UI that may have been under-represented in the responses to the questionnaire. For example, websites run by voluntary organizations and patient/carer groups usually maintain records of the questions they have been asked. Similar services for clinicians will also be considered, such as the National Library for Health's Primary Care Question and Answer Service and the Welsh ATTRACT website, which also answers primary care clinicians' questions about clinical evidence.

Another method for the identification of unanswered research questions is the examination of research recommendations – indicators of 'residual uncertainty' – contained in systematic reviews commissioned by organizations such as the National Coordinating Centre for Health



Technology Assessment, the Cochrane Collaboration, the Scottish Intercollegiate Guidelines Network and the National Institute for Health and Clinical Excellence (Brown *et al.* 2006). Uncertainties are also identified in registered protocols for ongoing systematic reviews and clinical trials.

## Collation

At the end of these consultation and search processes, the Working Partnership will have amassed a body of 'raw' treatment uncertainties relating to UI. These will be assembled, categorized and refined, and similar questions and uncertainties will be combined where appropriate. The Cochrane Collaboration Incontinence Review Group will help the Working Partnership to search systematic reviews and other existing literature to see to what extent, if any, these refined questions have been answered by previous research.

Treatment uncertainties that remain unanswered will then be entered into a UI module and published through DUETs (Crowe 2006).

## Prioritization

The aim of the final stage of the Working Partnership process is to prioritize the identified unanswered research questions through consensus. Many methodologies exist that may be of use in this process, ranging from adapted Delphi techniques to focus group work (Crowe 2006). The method finally chosen will be determined by consultation with the partner organizations, informed by the experience and advice of the JLA. Importantly, the prioritization of the most important uncertainties identified by the working partnership will be achieved through consensus of patients, carers and clinicians.

## Reporting

The important final output of the JLA Working Partnership on UI will be a list of uncertainties that cannot be answered by reference to the existing evidence, and that have been prioritized by consensus between patients, carers and practising clinicians. It is envisaged that subsequent funding applications for studies that address questions identified and prioritized in this way will be at a considerable advantage. The

findings of the Working Partnership will be reported to the NHS HTA Programme and the MRC, both of which are supportive of the JLA's work, and will be published so that they are available to other funding bodies.

## Summary

The proposed JLA Working Partnership on UI presents a valuable opportunity for clinicians and consumers to work together to achieve three main objectives:

- to identify uncertainties in the treatment of UI that are of day-to-day importance to patients and carers, and to the clinicians to whom they turn for help, and yet which cannot be answered by existing systematic reviews of research evidence;
- to prioritize these uncertainties, and report these priorities to bodies involved in the governance and funding of research; and
- to influence the research agenda in this way.

Although not all the organizations invited to participate have chosen to do so, it is felt that the range of organizations that are participating represent an adequate balance of patient and carer organizations and professional ones, and it is hoped that uncertainties relating to the whole spectrum of incontinence will be gathered.

Continence is an area in which the consumer voice is not as widely heard as it is in other disease areas because, in raising their voices, consumers declare that they are affected by a condition that is surrounded by stigma. In this sense, continence is a disease area to which the JLA process is especially suited, enabling as it does consumers and clinicians to collaborate systematically and constructively without the need for exposure.

Those wishing to know more about the JLA Working Partnership on UI should contact the first author (B.B.).

## Sources of funding and support

The costs to date of work on the development of the JLA Working Partnership on UI have been met by the Health Service Research Unit (HSRU – funded by the Chief Scientist's Office of Scotland), the 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 (B.B.), the

Cochrane Collaboration Incontinence Review Group (A.M.G.), the MRC and JLA (L.F.), and the HSRU, University of Aberdeen (A.C.G.). A PhD studentship for a dependent qualitative study is funded through the University of Aberdeen by the MRC (J.F.). The NHS R&D Programme provides infrastructure support for the Cochrane Incontinence Group. Core funding for the JLA is provided by the MRC and the Department of Health. The JLA Working Partnership on UI has received a grant from the Cochrane Collaboration's Prioritization Fund.

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