

WORKING TOGETHER TO IDENTIFY RESEARCH QUESTIONS

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The James Lind Alliance (JLA) was established in 2004 to encourage patients, carers and clinicians to work together to identify healthcare research questions. This article describes the JLA working partnership on urinary incontinence that will start work this year. It is hoped that organisations representing patients, carers and clinicians will come together to identify gaps in the existing evidence that lead to uncertainty in the way incontinence is managed. The authors feel that this represents an opportunity for providers and consumers of continence services to influence the research agenda.

Key Words

Continence
Urinary incontinence
Research
Partnership working

A great deal of the research into clinical practice and NHS services that is conducted each year does not adequately address the questions and uncertainties that are of practical importance to patients, their carers and the clinicians to whom they turn for help (Chalmers, 2004; Partridge and Scadding, 2004).

Concerns are growing about this mismatch between what is researched and the information that is needed to inform everyday clinical decisions

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(Partridge and Scadding, 2004; The James Lind Alliance [JLA], 2005).

A study in the late 1990s highlighted this issue when it consulted patients, rheumatologists, physiotherapists and GPs about their interests and priorities relating to the treatment of osteoarthritis of the knee (Tallon et al, 2000). The study found that there was a considerable difference between the topics and interventions which were of most interest to the patients and clinicians, and those that had been researched. All the clinicians felt that drug therapies, especially non-steroidal anti-inflammatory drugs (NSAIDs), were over-researched. Rheumatologists thought more research was needed on appropriate indications for knee replacement and that better outcome measures should be developed. Physiotherapists felt that little research had addressed clinically relevant questions and they were particularly concerned about the absence of research into exercise-based therapies. GPs highlighted difficulties in finding good evidence about the success rates of surgical procedures and wanted more research on conservative treatments such as exercise and education. Patients were also interested in knowing more about the effectiveness of conservative therapies and of self-help and coping strategies (Tallon et al, 2000).

In recent years, concerns have been expressed that the public is losing influence over research and that it increasingly follows an agenda set by industry (Partridge and Scadding, 2004; Delaney, 2006). While the contribution to improvements in healthcare made by the pharmaceutical and medical devices industries cannot be overlooked, their interests and priorities do not necessarily reflect those of patients, carers and practising clinicians. In the last 10–15 years the number of publicly funded clinical trials has decreased and the proportion of trials that are industry funded has increased, for the most part focusing on drug-based therapies (Partridge and Scadding, 2004). The result is that research into commercially developed drug-based therapies far outweighs research into other forms of therapy.

In such an environment it is all the more important that publicly funded research addresses clinical uncertainties of practical importance to clinicians, patients and carers. 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 which affect everyday clinical practice are addressed by research. The JLA 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 (Lind, 1753). The JLA's approach is to endeavour to bring together at least one patient organisation and at least one clinical organisation from within a single clinical area to form a working partnership. The aim of a working partnership is to identify treatment uncertainties and unanswered questions that are of practical importance and to prioritise these in order to influence and inform the publicly funded research agenda. The NHS's Health Technology Assessment (NHS HTA) programme has made a commitment to prioritise the research recommendations emerging from the JLA's work and the Medical Research Council (MRC) has indicated that it will take account of priorities identified by the JLA working partnership (Database of Uncertainties about the Effects of Treatments [DUETS], 2006).

The first JLA working partnership, on asthma, is currently up and running. Other working parties that have been formed or are being planned address the clinical areas of epilepsy, diabetes and rheumatoid arthritis.

The JLA working partnership on urinary incontinence was proposed in 2006 and will begin its work in 2007. It will be dependent upon the active participation and collaboration of partner groups and it is hoped that patients, carers and clinicians will be represented whose knowledge and experience relates to the full range of urinary incontinence problems.

Three descriptions of overlapping types of urinary incontinence are included in Table 1. Individual clinicians and healthcare consumers can become involved in two ways. First, by encouraging their respective organisations to participate and second, by responding to their organisation's requests for views on topics, which at present are not sufficiently well addressed by existing research.

Methods

The process through which the working partnership plans to fulfil its objectives will involve several stages.

It will be an iterative process, with the precise methods adopted in any stage determined through consultation between the partners. The methods must be open, inclusive and transparent.

Initiation

The first stage will involve the identification of potential partner organisations. This will be done through a process of consultation with the JLA's existing register of affiliates, which includes large organisations such as the Department of Health and the RCN as well as individual clinicians and researchers, and through an internet search. Organisations that can represent and advocate for patients and carers, and clinicians involved in the management of incontinence, will be identified by the JLA. Organisations will be excluded from participation if they are considered by the JLA to have conflicts of interest that may affect the organisation's views and therefore undermine the independence of the findings of the working partnership.

It is possible that this process may miss out some organisations and one of the purposes of this article is to raise awareness of the project to ensure that all eligible organisations have an opportunity for participation.

Potential partner organisations will be invited to appoint a representative to attend an exploratory meeting. Representatives of the JLA and the

authors of this article and the working partnership protocol will be present in order to present the plans for the working partnership and to address concerns and questions. This will be a facilitation role adopted for the purposes of the meeting rather than an assumption of leadership. It is envisaged that a steering group will be formed and that all partner organisations will be involved in the planning and management of the project.

The first objective of the meeting will be to identify those organisations that will commit to the working party in the longer term as well as individuals who will act as those organisations' representatives and principal contacts. The second objective will be to establish baseline principles for inclusive and transparent reporting and recording of the work and the progress of the working partnership. The third objective will be the establishment of a steering group (Figure 1).

Consultation

The identification of unanswered questions relating to the treatment and management of urinary incontinence will be the first task for the working partnership. Each partner organisation will be asked to identify a method for soliciting members' views on uncertainties or questions regarding the treatment and management of urinary incontinence. These should be of practical clinical importance not adequately addressed

Table 1. Urinary incontinence subgroups (overlapping) defined for the purposes of the JLA working partnership	
1	Continence which is idiopathic or a symptom of a condition that is not acute and which is largely treatable in primary care (for example, stress urinary incontinence, over-active bladder; enuresis [bedwetting])
2	Incontinence resulting from acute illness or trauma. Incontinence which is iatrogenic. Incontinence resulting from conditions or diseases (whether acquired or congenital) that cause disability in addition to urinary incontinence (for example, incontinence resulting from prostate surgery, spinal cord injury, Cauda Equina syndrome, multiple sclerosis, spina bifida, certain learning disabilities)
3	Incontinence in older people, whether clinical or functional (for example, resulting from reduced mobility or dementia)

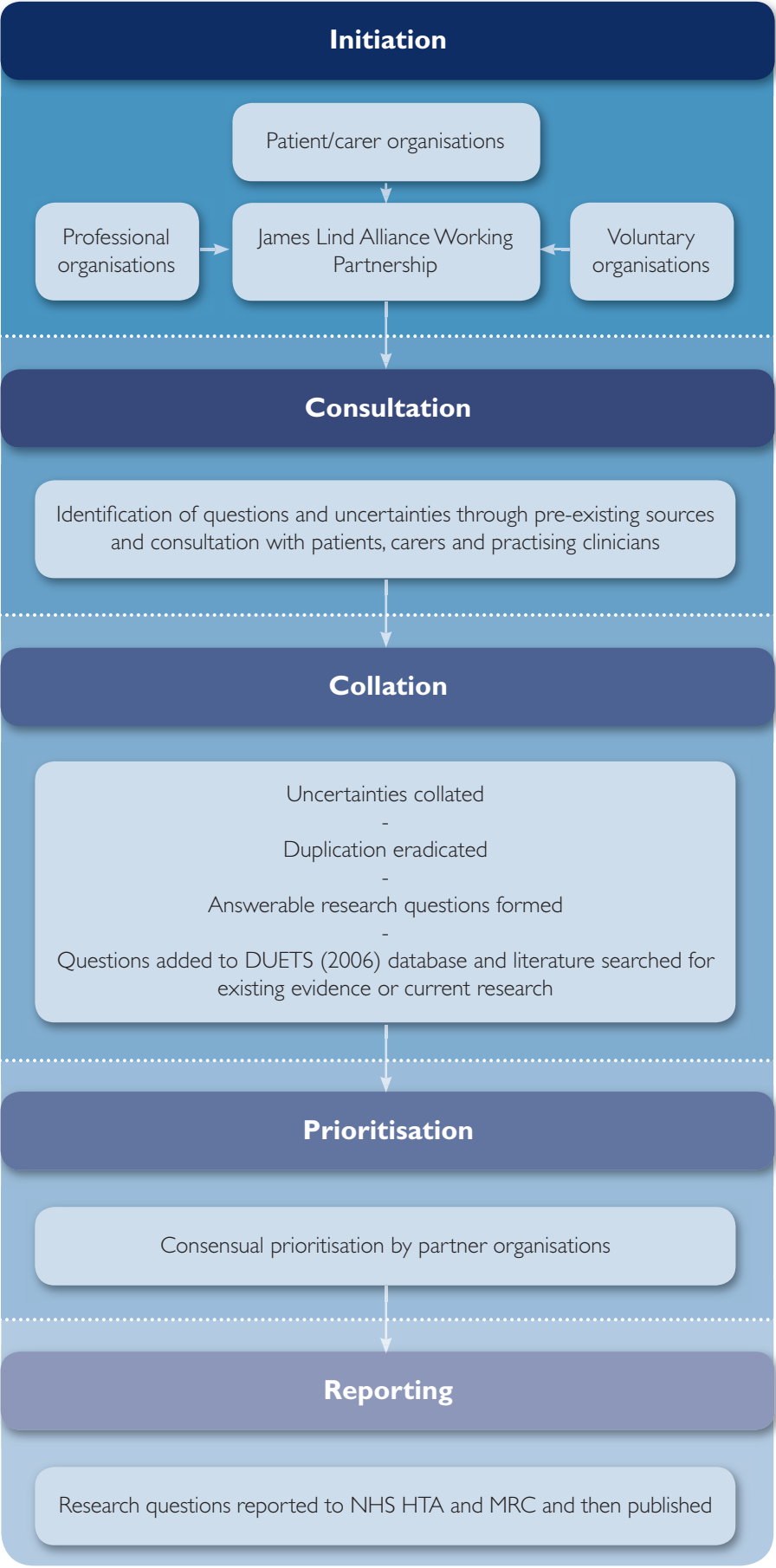


Figure 1. The process of the proposed JLA working partnership on urinary incontinence.

by existing research. The methods will be selected according to the nature and membership of each organisation and may include meetings, focus group work, mail or email consultation, and web-based consultation or questionnaires. The methods employed must be as open, transparent, inclusive and representative as possible.

In addition, existing sources will be examined for evidence regarding a lack of healthcare knowledge. For example, services that are intended to answer patients' and carers' questions such as NHS Direct, NHS Direct Online and websites run by voluntary organisations 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 Welsh ATTRACT website, which answers primary care clinicians' questions about clinical evidence. An example is the question posted by a clinician on the ATTRACT site: 'What is the incidence of urinary incontinence and faecal incontinence following external beam radiotherapy in prostate cancer?' The answer revealed a lack of robust research evidence, indicating that while some data could be found regarding post-radiotherapy incidence of urinary incontinence, little could be said that was evidence-based regarding faecal incontinence.

Another method that can be used for the identification of unanswered research questions is the examination of research recommendations – indicators of 'residual uncertainty' – contained in systematic reviews commissioned by organisations such as the National Coordinating Centre for Health Technology Assessment (NCCHTA), the Cochrane Collaboration, the Scottish Intercollegiate Guidelines Network (SIGN) and the National Institute for Health and Clinical Excellence (NICE) (Brown et al, 2006).

Collation

At the end of the consultation process (which will take from nine months to a year) the working partnership will have amassed a body of 'raw' questions and uncertainties relating to the

treatment and management of urinary incontinence. These will be assembled, categorised and refined and any similar questions and uncertainties will be combined where appropriate. The Cochrane Collaboration Incontinence Review Group will help the JLA 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.

After this process the issues that remain unanswered will be fashioned into clear and accessible questions, which can be addressed effectively by research and which will be distributed among clinicians and patients to determine if they are understandable. These will be entered into a urinary incontinence module within DUETs, an NHS system that has been established to collate and publish unanswered questions about the effects of treatments (Crowe, 2006; DUETs, 2006).

Prioritisation

The aim of the final stage of the working party process is to prioritise the identified unanswered research questions through consensus. Many methodologies exist which 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 organisations, informed by the experience and advice of the JLA.

Reporting

The final output of the JLA working partnership on urinary incontinence will be a schedule of research questions which cannot be answered by reference to the existing evidence and which have been prioritised by consensus between patients, carers and practising clinicians. It is envisaged that subsequent funding applications for studies that address questions identified and prioritised 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

then be submitted for publication in appropriate journals.

Summary

Continence is an area in which the patient's voice is not as widely heard as it is in other disease areas because of the perceived stigma (Shaw, 2001). 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 party on urinary incontinence should contact the author or the James Lind Alliance (www.lindalliance.org).

Funding and support

The costs to date of work on the development of the JLA working partnership 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, the Cochrane Collaboration Incontinence Review Group, the MRC, JLA and HSRU and the University of Aberdeen. A PhD studentship for a dependent qualitative study is funded through the University of Aberdeen by the MRC. The NHS Research and Development Programme provides infrastructure support for both the JLA and the Cochrane Incontinence Group. **CUK**

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Key Points

- ▶ Healthcare research often does not answer the questions of most importance to patients and carers.
- ▶ Concerns have been expressed that the public is losing influence over research and that it increasingly follows an agenda set by industry.
- ▶ The working partnership on urinary incontinence will enable patients, carers and clinicians to identify and prioritise gaps in the existing evidence which lead to uncertainty in the way incontinence is managed.
- ▶ The resulting list of research questions will be published and will inform the selection of topics for future research.

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