This is the authors' final version, post peer-review, of an article published in *Journal of Clinical Epidemiology* 2013;66(5):483-499. The definitive version is available from www.sciencedirect.com

Case study: a patient-clinician collaboration that identified and prioritized evidence gaps and stimulated research development.

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Word count:
Abstract: 200
Main text: 3451

ABSTRACT

Objective

To assess the effect of a research prioritization partnership that aimed to influence the research agenda relating to urinary incontinence.

Study design and setting

Research often neglects important gaps in existing evidence so that decisions must be made about treatments without reliable evidence of their effectiveness. In 2007-9 a UK partnership of 8 patient and 13 clinician organizations identified and prioritized gaps in the evidence that affect everyday decisions about treatment of urinary incontinence. The top ten prioritized research questions were published and reported to research funders in 2009.

A year later, new research or funding applications relating to the prioritized topics were identified through reviews of research databases and consultation with funding organizations, elements of the research community and organizations that participated in the partnership.

Results

Since dissemination of the prioritized topics, five studies are known to have been funded, three in development; five new systematic reviews are under way, one is being updated; five questions are under consideration by a national research commissioning body.

Conclusion

The partnership successfully developed and employed a methodology

for identification and prioritization of research needs through patient-clinician consensus. Prioritization through consensus can be effective in informing the development of clinically useful research.

Key words

- Patient and public involvement
- Research prioritization
- Urinary incontinence
- Lower urinary tract symptoms
- Pelvic floor muscle training
- Urethral catheter

Running title

- Stimulating research activity by prioritizing need

BACKGROUND

Despite its huge volume and scope, much of health care research is not targeted well, so that important gaps in the existing evidence base are neglected. In every clinical area there are commonly asked questions that remain unanswered by research. As a result clinicians and patients must make decisions about treatments without reliable evidence about their effectiveness. The James Lind Alliance (JLA) is an initiative that encourages patients and clinicians to work together in health research. One approach used is partnerships of patient and clinician organizations that work together to identify and prioritize the most pressing research needs in a particular clinical area.

The JLA Priority Setting Partnership (PSP) on urinary incontinence (UI) was a partnership of twenty-one UK patient and clinician organizations that identified and then prioritized gaps in the evidence that affect everyday clinical decisions relating to the treatment of urinary incontinence. The partnership was originally proposed in 2007 by representatives of a UK charity, the Bladder and Bowel Foundation, and the Cochrane Incontinence Review Group. It completed its work in 2009.

When the JLA PSP on urinary incontinence began, few projects of its kind had been completed. Mapping studies that have examined

research prioritization exercises internationally found that only a handful of projects had featured clinicians and patients working together to identify specific research questions(1, 2). Thus a methodology had to be developed that would be systematic and transparent and at the same time flexible and inclusive, so that all the potential stakeholder organizations with an interest in the area could become involved. The methods devised have been widely reported elsewhere and hence are described only in brief below(3-9).

The principal output of the JLA PSP on urinary incontinence was a list of ten research questions that were identified as priority issues by clinicians and patients working together. This report considers the impact that the work of the JLA PSP on urinary incontinence, and the dissemination of that list of ten prioritized research questions have had on research activities.

METHODS

The methods of the JLA PSP on UI

In brief, the process involved five phases. In the first phase, 30 UK clinician and patient organizations whose area of interest included urinary incontinence were identified through web searches and peer consultation, and invited to participate. Eight patient and thirteen

clinician groups participated, including both large organizations such as royal colleges and national patient charities, and small organizations with specific clinical interests.

In the second phase, participating organizations asked their members to identify questions about the treatment of urinary incontinence for which no evidence-base was available, regularly affecting their ability to make treatment decisions. An issue was considered "uncertain" if no up to date systematic review of research evidence provided reliable guidance as to the best treatment. Subsequently 417 individual submissions were received. In addition, a further 131 unanswered research questions were identified from the recommendations of systematic reviews and clinical guidelines.

The third phase involved collating and refining these questions: similar questions were combined while in some cases multiple questions were derived from a single submission; some were excluded because a systematic review that addressed them was identified; each was re-written in PICO format (population, intervention, comparator, outcome)(10). The final database contained 226 uncertainties: 79 came from patients; 37 from clinicians; six from both patients and clinicians; two from both patients and research recommendations; and 102 from research recommendations alone.

In the fourth phase a two-stage strategy was employed to identify and prioritize, through consensus of clinician and patients representatives, a "top ten" unanswered research questions relating to urinary incontinence. First, each participating organization shortlisted 10 questions from the database through consultation with their membership. These shortlists were then combined to produce a combined penultimate shortlist of 29. Second, at a workshop of patient and clinician organization representatives, nominal group techniques were used to reach a consensus on a ranked list of ten important clinical uncertainties. Prioritized uncertainties were verified by searching to ensure no up to date systematic reviews had been published that answered the questions. Of the top 10, five were originally submitted by clinicians, four by patients and one came from research recommendations.

The fifth phase focused on disseminating the findings of the PSP with the dual aims of acting as a catalyst for research design and funding applications and of informing funding decisions. The final prioritized list was published in *Neurourology and Urodynamics*, the journal of the International Continence Society(8) and presented at meetings and conferences nationally and internationally, including the annual conference of the National Institute of Health and Clinical Excellence and the Cochrane Colloquium(11).

The final list was also reported to the National Institute for Health Research's Evaluation, Trials and Studies Coordinating Centre, which considers research questions for subsequent calls for Health Technology Assessment (HTA) programme research funding applications. Topics submitted to the HTA programme enter a further selection process and, if prioritized, a commissioning brief is advertised and the research community is alerted by emails and through the HTA website. The prioritized topics were also reported to the International Consultation on Incontinence Research Society and the Pelvic Floor Clinical Studies Group for consideration by the international incontinence research community(12).

Assessing the impact of the JLA PSP on urinary incontinence

In late 2010, nearly a year after the dissemination of the PSP's findings, information has been collected about the effect the work has had on research activity. Funding agencies and sections of the research community and organizations that were connected with the PSP have been consulted to identify new research in development that relates to the work of the PSP. In addition, databases of trials and funded research have been searched. Investigators and relevant organization representatives have been contacted to establish which identified

research activities have been at least in part prompted by the activity of the JLA PSP on urinary incontinence.

RESULTS

For each of the prioritized questions in turn, information is presented about research that is known be in development or for which funding applications have been made.

Prioritized question 1: *What are the optimal pelvic floor muscle training protocols (frequency and duration of therapy) for the treatment of different patterns of urinary incontinence?*

Pelvic floor muscle training is widely recommended and practiced as a treatment in many urinary incontinence scenarios, and yet there is considerable uncertainty with regards to which types of urinary incontinence it can treat best and which are the most effective and acceptable exercise protocols(13, 14). A UK-centred international consortium of researchers is developing a research programme aimed at first identifying and then testing regimens of pelvic floor muscle training, involving different intensities and behavioural strategies, for the optimal treatment of female urinary incontinence. The question has been accepted into the HTA programme selection process so that a related commissioning brief may be developed. Both these processes will take into account the results of a recently completed systematic

review and economic modelling of non-surgical treatments for the condition(15). A Cochrane Systematic Review entitled "One type of pelvic floor muscle training versus another for urinary incontinence in women" is being updated.

Prioritized question 2: *Can guidance or training for general practitioners on appropriate pathways of care improve the management of patients with urinary incontinence?*

Research to determine whether training for GPs about urinary incontinence pathways of care was extremely highly placed particularly by patient groups, perhaps because whilst the majority of those affected by urinary incontinence who seek help do so from their GP, there are concerns that GPs may not be sufficiently trained to diagnose, treat and refer appropriately[9] [25] [26]. This question was transferred from the HTA programme to the Service Delivery Organization (SDO) programme for consideration but there are no reports of it being developed further so far.

Prioritized question 3: *What is best practice for the treatment of combined stress urinary incontinence and detrusor overactivity?*

The question was combined in the HTA programme selection process with '*A well-designed high quality RCT is needed to investigate the effectiveness of pelvic floor muscle training (PFMT) versus intensive pelvic floor muscle training (IPFMT) to treat combined stress and*

urgency urinary incontinence.' A Cochrane Systematic Review entitled "Combined conservative interventions for urge and stress, or mixed urinary incontinence in adults" is under way. Research is in development that will consider the treatment of mixed urinary incontinence. The Pelvic Floor Clinical Studies Group has awarded a grant to develop a project studying surgical management of stress incontinence in women with mixed urinary incontinence.

Prioritized question 4: *What catheter regimens are most effective in preventing urinary tract infections in patients using intermittent self-catheterisation for the management of a neurogenic bladder? What is the effectiveness and safety of prophylactic versus symptomatic antibiotic therapy in patients with neurogenic bladder dysfunction using intermittent self-catheterisation?*

The management of bladder dysfunction resulting from neurogenic disease or trauma is of crucial importance to rehabilitation and quality of life and yet Cochrane Systematic Reviews in this area have found little evidence to inform best practice(16). Two questions have been combined in this priority as they both address the same issue. A major concern in bladder management in this context is the preservation of upper urinary tract health and avoidance of renal damage. Catheterization is performed to prevent renal damage resulting from hyronephrosis as well as to achieve social continence, but itself can increase the risk of urinary tract infection, another renal damage risk

factor. Various catheter regimens and prophylactic use of antibiotocs have been considered to have potential in preventing such infections. The first of these combined questions has been referred to the External Devices and Physical Therapies Panel within the HTA programme topic selection process. The second will be considered by the Pharmaceuticals Panel. A prospective study that will explore the experience of people with multiple sclerosis who use intermittent catheterisation and reasons for cessation has been funded by the Multiple Sclerosis Society.

Prioritized question 5: *Which treatment is most effective for the reduction of urinary frequency and urgency?*

Urinary urgency and frequency, the symptoms of overactive bladder, are frequently found concomitantly and the question of which treatment is most effective is a pressing one. Yet few studies have compared behavioural therapy with common anticholinergics, while there are no industry-independent comparisons of the numerous anticholinergics available to assess efficacy and cost effectiveness. A systematic review has highlighted unresolved questions(17). As of late 2010, no new research activity has been identified. Comparison of anticholinergic drugs, bladder training or a combination of both for combined frequency and urgency has been accepted into the HTA programme selection process.

Prioritized question 6: *Is urodynamic testing prior to surgery for urinary incontinence associated with better continence rates and quality of life, than surgery indicated without such testing?*

Although used widely, the effectiveness of urodynamic testing in informing choice of surgery for incontinence is far from clear, as highlighted by recent NICE recommendations (18). Following an application which resulted from the PSP's work, the NIHR HTA Programme has approved funding for a large multicentre pilot study to assess the feasibility of a future randomised controlled trial.

Prioritized question 7: *What is best practice for the management of stress urinary incontinence following failed tension free vaginal tape surgery?*

Suburethral tapes are the commonest operation for urodynamic stress incontinence in women. But it is not clear what is best for the 10% of women whose operation fails. Options include medical and surgical treatment. Specific questions include: whether an abdominal procedure (eg. colposuspension) is more effective than a repeat suburethral tape insertion; and whether the failed tape should be excised. There are no robust comparative data to inform decision-making. A new Cochrane Systematic Review entitled "Treatment of urinary incontinence after failed minimally invasive sling surgery in women" is under way.

Prioritized question 8: *What are the most effective treatments of daytime urinary incontinence in children?*

While there is extensive evidence to guide the management of night-time bed wetting in children, this is not true for childhood daytime incontinence (19-24). A Cochrane Systematic Review entitled "Treatments for daytime urinary incontinence in children" is under way. Researchers are also developing a paediatric patient-reported outcome measure for urinary incontinence. Finally, a UK study has been funded comparing treatments for daytime UI in children.

Prioritized question 9: *Are disposable catheters more or less acceptable than reusable catheters, in terms of effective bladder management, patient experience and urinary tract infections?*

Whilst single-use catheters have been widely promoted and accepted in the UK for intermittent self-catheterisation, their clinical effectiveness compared with re-usable catheters is unclear. Thus patients are rarely offered re-usable catheters although they may prefer them for environmental reasons and ease of storage. In addition, in the absence of evidence of clinical effectiveness, the very significant difference in costs to health care systems would appear unjustified(25). The topic has been referred to the External Devices and Physical Therapies Panel in the HTA programme's selection process. A programme of research entitled "Improving choice and cost-

effectiveness for people using intermittent catheterisation" is in development by an international collaboration of researchers.

Prioritized question 10: *In women with prolapse and stress urinary incontinence, should suburethral tapes be inserted at the same time as repairing the prolapse?*

When a woman in whom SUI is pre-existing is undergoing prolapse repair surgery, should a continence procedure such as suburethral tapes should be performed at the same time (26, 27)? There is little in the way of evidence to help patients and clinicians to make the decision. Two new Cochrane Systematic Reviews are under way with support from the UK's Cochrane Incentive Scheme that will specifically address whether women with prolapse and UI should have a concomitant UI procedure with prolapse surgery and whether women without urinary incontinence should undergo a subsequent prophylactic urinary incontinence procedure.

Discussion and conclusions

The breadth of urinary incontinence as a clinical area was reflected in the wide range of evidence needs included in the final list. Each prioritized question related to uncertainties about treatment and management strategies that have profound effects on quality of life

and rehabilitation of those affected by urinary incontinence, and yet little evidence exists to guide practice.

In order to identify new research activity in the wake of the JLA PSP on urinary incontinence, this report has relied upon searching of research databases and consultation with sections of the research community, organizations that were connected with the PSP and with the funding bodies. Consultation identified a good deal of research activity related to the work of the PSP. Research databases revealed no further activity. Other research may be in preparation or under way that has not been identified: funding applications are often confidential; research databases publish only approved funding or research that is under way; and the time taken in the preparation and consideration of applications means that there is a delay in publication. The absence of published or citable sources must affect the degree to which the outcomes described in this report might be considered "robust" by health research standards. In addition, academic confidentiality has necessarily affected the potential to identify research activities included in this report.

As with other activity that takes place in broad and complex environments, such as health promotion interventions, measuring the precise impact of a PSP is challenging: it is difficult to be sure what activities are the direct result of the work and which may have

occurred anyway. Only activities known to have resulted at least in part as a result of the work of the JLA PSP on urinary incontinence have been included in this report. It must be borne in mind that this work is UK based: many aspects of the work, including the prioritization process, the research priorities identified and the relevant research funding mechanisms may not be applicable or relevant in many other regions. The issue of prioritization at an international level is an important one that deserves further attention.

Despite the difficulties in assessing the impact of the work, the JLA PSP on urinary incontinence would appear to have had considerable impact as a catalyst for research activity. Five studies are known to have been funded and several more are in development, addressing six of the ten priorities. Arguably, an up to date systematic review should underpin research developed to address all the priorities. A number of Cochrane systematic reviews have been initiated or are being updated. Some are known to have been in direct response to the PSP work, while the others are happening in the context of the Cochrane review group that was integrally involved with the PSP so that it is likely to have had some influence, if indirect. Whilst the potential value of systematic reviews to patients and clinicians seeking answers to treatment questions is undoubted, reviews often find no evidence or inconclusive evidence and so are of little direct assistance. In a 2010 survey, 9% of all published Cochrane Reviews

found no trials at all eligible for inclusion(28). A great many more were inconclusive. However, although these "empty" or inconclusive reviews are of little assistance to patients or clinicians, they can be useful in refining research questions and stimulating new research.

Several of the topics are under consideration by the UK's major funding agency for research commissioning calls. This process is complex, and the PSP has been unable to maintain influence with regards to the progress of the topics. Concerns have been expressed to the body that the specific questions identified and prioritized by patient and clinician consensus might be altered by the body's own topic prioritization process. The topics have also been recognized by two academic groups that have an interest in incontinence research so that they will be considered by the international research community. For only one of the ten prioritized questions has no specific related activity been identified.

Although the PSP appears to have been effective, there are aspects of the work that need to be considered. One is the degree to which those involved in the PSP are instrumental in driving any impact on subsequent research activity. Research groups were excluded from the topic submission and prioritization process because it was felt that there would be conflicts of interest. However, there exists an overlap between clinicians and patient organization representatives and

researchers so that individual researchers were involved in the PSP. In the months following the PSP most research developments involved those that took part in the PSP so that there was concern about the breadth of impact; however, the impact appears to have spread, as more recently research has emerged in development or under way that involves nobody involved in PSP. Thus the perception that the impact was restricted initially to those with direct involvement may have been accurate, or it may have been an effect of the confidential nature of research development. Whether there is harm or benefit associated with an initial influence of those involved in the PSP is uncertain and may be an issue worth further consideration. The JLA PSP on urinary incontinence endeavoured to ensure wide dissemination of its work to researchers not involved. For all researchers developing funding applications, a peer-reviewed publication disseminating the results of prioritization work provides a valuable reference.

Another aspect that may warrant consideration is how to maintain the impact of the work in the future. Although this will be assisted by the publication of new systematic reviews with research recommendations, it is questionable if this will be sufficient.

Another factor for consideration is that some of the questions prioritized were very broad in their scope. As a result it may have been hard for researchers to be clear about the most appropriate research response.

As with research recommendations generally, future PSPs should perhaps generate more specific and carefully constructed research questions(29). That said, whereas concise research questions may suit the research establishment, the approach might not facilitate greater patient inclusion in research prioritization. Work in New Zealand that involved citizens' juries comprising women with urinary incontinence and looked at their research priorities reported patient interests in broad questions about quality of life, day-to-day management and costs, service delivery and access to services. The one question prioritized by both the JLA PSP on UI and the New Zealand work was one that related to education and training for GPs. The New Zealand participants were dismissive of commonly used research outcomes such as pad tests and bladder diaries, considering them unrealistic and likely to lack validity(30).

In conclusion, the PSP successfully developed and employed a methodology for identification and prioritization of research needs by patient-clinician consensus and appears to have been effective in informing the development of clinically useful research. Work is needed to further develop practical and valid methods for prioritization of research topics that involve both patients and clinicians both on national and international levels.

Acknowledgements

Thanks are due to the patients and clinicians who submitted uncertainties; all the participating organizations and their representatives; Mark Fenton of DUETs; Sally Crowe of Crowe Associates; Patricia Atkinson of JLA; Ron Marsh; the Cochrane Incontinence Review Group; Jude Frankau and Alexandra Greene; Katherine Cowan.

Sources of funding and support

The costs of the JLA PSP on UI were supported in part by a grant from the Cochrane Collaboration's Prioritization Fund and by the JLA, whose core funding is provided by the MRC and the Department of Health. The consultation processes were supported by the partner organizations. The authors have been supported by their respective academic institutions.

Disclaimer

The views contained in the paper are those of the authors and are necessarily shared by the funders or the participating organizations.

Conflicts of interest

BSB is an editor and author with the Cochrane Incontinence Group and a grantholder on studies funded by the Health Research Board of Ireland and by the NIHR HTA programme. He is a voluntary member of the Board of Trustees of the Bladder & Bowel Foundation.

AMG was Coordinating editor of the Cochrane Incontinence Group until December 2007 and holds NIHR grants evaluating treatments of UI. He is Director of the NIHR Programme Grants for Applied Research Programme.

CMAG is a Joint Coordinating Editor of the Cochrane Incontinence Review Group and an Investigator on studies funded by the NIHR HTA programme and WellBeing of Women.

Table 1: Identified research activity associated with the James Lind Alliance Priority Setting Partnership on Urinary Incontinence.				
Prioritized topic	Research in development	Research funded	New or updated review	In HTA process
1. Pelvic floor training	yes		Updated	yes
2. GP training or guidance				
3. Mixed stress & urge UI	yes	yes	New	yes
4. Neurogenic bladder management		yes		yes
5. Mixed frequency & urgency				yes
6. Effectiveness of urodynamics		yes		
7. Failed tape surgery			New	
8. Daytime UI in children		yes x 2	New	
9. Disposable/reusable catheters	yes			yes
10. Concomitant SUI & prolapse surgery			New (x 2)	

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