624

Buckley B[1], Grant A[2], Tincello D[3], Wagg A[4], Firkins L[5]
1. *National University of Ireland, Galway,* ***2.*** *University of Aberdeen, Scotland,* ***3.*** *Unversity of Leicester, England,* ***4.*** *University of London,* ***5.*** *James Lind Alliance, Oxford, England*

IMPORTANT GAPS IN THE EVIDENCE: PATIENTS AND CLINICIANS WORKING TOGETHER TO IDENTIFY AND PRIORITIZE UNANSWERED RESEARCH QUESTIONS IN URINARY INCONTINENCE

Hypothesis / aims of study. Much is heard about clinical and cost effectiveness in health care, but less is heard about research effectiveness. Yet research may be failing both clinicians and patients by neglecting gaps in the evidence base which are of everyday importance (1). In any clinical area, clinicians, carers and patients often must make decisions about treatments or management strategies without the benefit of good quality critaically appraised research evidence about their effectiveness. This is as true of urinary incontinence (UI) as it is of any other field (2).

Questions about the effectiveness of treatments or management strategies which cannot be answered by referral to up to date reviews of existing research evidence can be referred to as “clinical uncertainties”. This Priority Setting Partnership on Urinary Incontinence was an initiative in the United Kingdom which aimed to help patients and practicing clinicians to work together to identify and then to prioritize clinical uncertainties of everyday and practical importance relating to UI. The ultimate aims of the work were several:

- to identify important gaps in the evidence base affecting treatment of UI
- to promote clinically useful research in UI
- to inform research funding policy
- to develop a methodology for effective clinician and patient partnership in prioritization work.

Study design, materials and methods. UK clinician and patient organisations whose remit included UI were identified and invited to participate. Participating organisations were required to ask their members to identify clinical uncertainties which were of most concern to them – gaps in existing evidence that regularly affected their ability to make decisions about treatment or management options relating to UI. Unanswered research questions were also identified in the research recommendations of systematic reviews and clinical guidelines. The examples of clinical uncertainty gathered in these ways were collated, excluded, refined and combined as appropriate.

The resulting list was prioritized in two phases: first, participating organisations were asked to identify a shortlist through consultation with their membership; second, at a workshop of patient and clinician organisation representatives, nominal group techniques were employed to reach a consensus on a “top ten” list of important clinical uncertainties. Prioritized uncertainties were verifed by searching to ensure no up-to-date systematic reviews had been published which answered the questions.

For transparency and to promote maximum engagement, the protocol and the progress of the Priority Setting Partnership were published online and in a number of journals as the work progressed (3). The final prioritized list of clinical uncertainties will be published and reported to funding agencies with the dual aims of acting as a catalyst for research design and funding applications and of informing funding decisions.

Results. Thirty organisations were identified as potential partners and invited to participate in the Priority Setting Partnership; 8 patient and 13 clinician organisations agreed to participate. These included both large organisations such as Royal Colleges and national patient charities and small organisations such as patient and clinicians groups with very specific clinical interests. These organisations consultated with their memberships and as a result 417 submissions were received which contained questions which were perceived to be clinical uncertainties. A further 131 unanswered questions were identified in Research Recommendations. Collation, refining and combining resulted in a list of 226 uncertainties (79 came from patients; 37 from clinicians; 6 from patients & clinicians; 2 from patients and research recommendations; 102 from research recommendations alone). The first prioritization phase identified a shortlist of 29 questions; the second phase prioritized 10 uncertainties (5 originally submitted by clinicians, 4 by patients and 1 from research recommendations).

The “top ten” prioritized clinical uncertainties included: identification of optimal pelvic floor muscle exercise protocols; identification of family practitioner training needs; optimal treatment and management startegies for ‘mixed’ stress and urge incontinence, neurogenic bladder dysfunctions, frequency and urgency in adults and daytime urinary incontinence in children; whether single-use intermittent catheters offer clinical benefits over re-usables; whether urodynamic studies always result in more effective decisions about surgery; and specific surgical questions about failed tension free vaginal tapes and suburethral tapes for women with pelvic organ prolapse and stress urinary incontinence. Applications for funding to conduct primary research or undertake systematic reviews which can help to address the gaps in evidence are already in preparation.

Interpretation of results. The final list reflects evidence needs associated with a wide range of UI questions. Every prioritized uncertainty relates to surgical and medical treatment uncertainties and management strategies which can have profound affect on the quality of life and rehabilitation of those affected by UI and yet about which little evidence exists.

There exist gaps in the evidence relating to interventions which are widely used yet not thoroughly understood: for example, pelvic floor muscle training is widely recommended as a treatment in many UI scenarios, yet uncertainty remains with regards to which UI types it can treat best and which are the most effective exercise protocols in terms of outcomes, patient adherence and

sustainability. Other identified areas of uncertainty relate to questions which address access to care: training for family practitioners in UI was extremely highly placed, which probably reflects concerns that, while the majority of those affected by UI who seek help do so from their family physician, these very clinicians may not be sufficiently trained to diagnose, treat and refer appropriately. Still others relate to very specific medical or surgical uncertainties: for example, suburethral tapes are a common operation for urodynamic stress incontinence in women, yet for the 10% of women whose operation fails, there are no robust comparative data to guide the decision making between medical or surgical treatment, and about whether an abdominal procedure such as colposuspension or repeat suburethral tape insertion is the correct thing to do.

Concluding message: This partnership demonstrated that clinicians and patients can work together effectively and that unanswered research questions of every day importance can be identified and prioritized through consultation and consensus.

The ten prioritized areas of clinical uncertainty reflect the heterogeneity of the patient group affected by incontinence and the wide range of treatment and management strategies available. They also reflect the uncertainty which is associated with commonly recommended treatment and management options.

It is hoped that the work will lead to the design and funding of research which seeks to answer areas of clinical uncertainty regarded as important by clinicians and patients alike.

References

1. Chalmers I Confronting therapeutic ignorance: tackling uncertainties about the effects of treatments will help to protect patients. British Medical Journal 2008; 337:a841
2. Buckley B, Grant AM What is the most effective management of neurogenic bladder dysfunction? British Medical Journal 2009;338:b659
3. Buckley B, Grant AM, Firkins L, Greene AC, Frankau J. Working together to identify research questions. Continence 2007 ; 1 (1); 76-81

Specify source of funding or grant	**The costs of the Priority Setting Partnership on Urinary Incontinence have been met in part by the James Lind Alliance, whose funding is provided by the Medical Research Council and the Department of Health. Data handling and processing and some travel have been funded by a grant from the Cochrane Collaboration. The consultation processes have been supported by the partner organisations. The authors have been supported by their academic institutions and the Cochrane Collaboration grant.**
Is this a clinical trial?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**No**
This study did not require eithics committee approval because	**This was not a study of treatments or management strategies. No patients and no patients' medical data were involved in the research. All participants took part of their own free will.**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**