PB-PG-1207-15081 – NIHR Research for Patient Benefit Programme – Final report

Project title: The development of a decision tool to improve the management of urinary incontinence in women in the community

Authors: Professor Dawn Dowding - University of Leeds
Professor Francine Cheater - Glasgow Caledonian University
Professor Joanne Booth - Glasgow Caledonian University
Professor Ian Watt - Hull York Medical School/University of York
Mrs Rosemary Horseman - North Yorkshire and York Primary Care Trust
Professor John Martin Bland - University of York
Professor David Torgerson - University of York
Mrs Anne Siddle - Leeds Community Healthcare

Plain language summary

Background

Urinary Incontinence (UI) affects about 15% of the general population and is more common in women. It is a condition that can cause a great deal of distress to sufferers, and costs the NHS about £563 million a year. Whilst there are different types of UI, each with its own way of being treated, many women with urinary incontinence currently don't seem to be getting the best treatment for their condition. The aim of this study was to design and develop a decision tool to help health care professionals identify which type of UI people have more effectively, with the aim of improving management of the condition.

Findings

In the first stage of the study we developed three different versions of the tool based on existing research evidence. We carried out interviews with groups of health care professionals who work in the community (General Practitioners, Practice Nurses and Community (district) Nurses). We asked them to discuss how they currently assess and manage UI in women, and also got them to evaluate the different versions of the tool. At the end of this stage of the study we had a decision tool that health care professonals thought they could use when treating a woman with UI.

In the second stage of the study we developed 25 fictional descriptions of women with different bladder symptoms and asked doctors and nurses to use the tool to say how they would treat the women. We then examined what they decided to identify whether or not the tool helped health care professionals agree on what treatment would be appropriate, and whether or not it improved their ability to identify the type of incontinence. We found that health care professionals who used the tool were more likely to identify the type of UI correctly than professionals who did not use the tool.

In the third stage of the study we tested the tool in real General Practice settings, to see whether or not it was useful to health care professionals in practice and what effect it may have on the type of care that women with UI receive. We found that it was used mainly by practice nurses, who felt that it helped to improve the care that women received.

Conclusions

The tool that has been developed in this study has the potential to help health care professionals assess and manage UI in women in community settings more effectively. It could be translated into an electronic tool for all community practitioners to access.

Keywords
Urinary incontinence, evidence based practice, clinical decision tool, decision algorithm, primary care.

Summary of research findings

Background

Urinary incontinence (UI), defined as 'the complaint of any involuntary leakage of urine' is a common symptom and represents a major public health concern. Evidence suggests that most UI symptoms in women are treatable or can be ameliorated in primary care settings by conservative measures such as lifestyle advice and behavioural strategies. However, adherence to guidance is very variable and women are frequently referred to secondary care without an adequate trial of these interventions.

Identifying the type of incontinence that a woman may have is based on a judgement. Judgement processes commonly involve the integration of information from a variety of sources, which are then evaluated to reach a conclusion; in this case evaluating information about the characteristics of a woman's urinary symptoms, to identify what type of UI (stress, urgency, mixed, functional and overflow) is the most probable. On the basis of this judgement a decision would be taken regarding what treatment to recommend. Using formal, structured tools to assist with the judgement process may reduce the likelihood of errors, as they encourage clinicians to focus on relevant information in a consistent fashion. Decision tools to assist primary/community health care clinicians in diagnosing the type of UI and that are accurate, acceptable and cost-effective to use in practice do not currently exist.

Aims and Objectives

The aim of this study was to develop and validate a decision tool to assist health care practitioners identify the type of urinary incontinence (UI) experienced by women living in the community, leading to improved management of a woman's UI.
It addressed the following research questions:
Does the use of a decision tool to assist with the assessment and management of UI in women in the community:
i) Increase the accuracy with which health care practitioners identify the type of UI a woman is experiencing?
ii) Improve the appropriateness of subsequent management of a woman's UI?
iii) Lead to better outcomes for women such as improved quality of life and amelioration of urinary symptoms?

The study had the following research objectives:
1. To develop an evidence based decision tool to assist health practitioners working in primary care/community to identify the type of UI experienced by women and appropriate management strategies for the woman's UI.
2. To test the decision tool for reliability and validity with practitioners working in primary care/community who treat women with UI.

3. To carry out a feasibility study to assess the acceptability of the tool in clinical practice, and the feasibility of carrying out any further research studies.

Methods
The study was in three stages;

Stage 1: Development of the decision tool.
Prototypes for possible decision tools were developed with the assistance of two continence specialists, based on evidence based guidance and systematic review evidence. The content and format of the tools were then evaluated using focus groups and in-depth interviews with 52 primary and community health care professionals (6 GPs; 3 practice nurses; 38 community nurses, 3 health care assistants) whose role includes the assessment and management of women with symptoms of urinary incontinence. Interviews and focus groups were audio-recorded and transcribed. Transcripts were analysed using the 'Framework' approach, based on a series of sequential steps: familiarisation with the data; thematic analysis to develop the coding scheme; systematic coding and charting of data to develop a coding matrix; mapping and interpretation of the data in order to explore relationships between the codes.

Stage 2: Testing of the tool for reliability and validity
The decision tool derived from stage 1 was then tested for reliability and validity using 25 clinical scenarios portraying cases of women with symptoms of urinary incontinence. The scenarios were evaluated for face validity by continence specialist nurses. Health care practitioners who consented to take part in the study were randomised either to receive or not receive the decision tool; they were then asked to record their decisions about assessment and management for each of 17 cases presented to them in the first round of testing. Four weeks later, each participant was sent a second set of 17 cases (including 9 repeat cases to test for intra-rater reliability).

Stage 3: Feasibility study
Two General Practices consented to take part in the feasibility study. In each practice GPs and practice nurses were trained to use the decision tool. In each practice, 600 women who met the inclusion criteria (over 18 years and not pregnant), stratified by age, were sent information about the study and asked to contact the research team if they had symptoms of UI. They were then sent them further information and a consent form. Patients were asked to make an appointment with a relevant practitioner, who then used the decision tool during the consultation to assess and manage their UI. Outcome data for impact of UI symptoms and quality of life were collected from all patients using the ICIQ-SF and IQoL and EQ-5D questionnaires. Interviews were carried out with health care professionals and patients to evaluate the acceptability of the tool in practice.

Key Findings
1. Four main themes were identified from the focus group data, relating to patient reporting of UI symptoms to clinicians and patterns of referral, health care professionals' perceptions about adequacy of their knowledge and training to assess and manage UI symptoms in women, implementation of (NICE) clinical guidance and health care professionals' perceptions regarding the need for a decision tool.

Current care pathways in the UK mean that the first port of call for most women with incontinence will be their GP or practice nurse/ nurse practitioner. Despite this most practice nurses and GPs highlighted their lack of up to date knowledge in this area. None of the study participants, mentioned having seen, or used, the NICE 'Quick Reference Guide', none of the practice nurses or GPs reported using validated instruments to assess UI symptom severity and impact on quality of life and most were unaware of the existence of these tools. All groups of practitioners welcomed an easy to use tool that could assist them with the process of assessing and managing UI. The tool developed on the basis of the focus group interviews was a one page decision algorithm.

2. 94 health care professionals were sent copies of the scenarios for completion; 30 GPs; 44 Community Nurses; 20 Practice Nurses. Thirty-one completed sets of scenarios were returned in the first round of testing (12 GPs, 12 Community Nurses, 7 Practice Nurses) and another 24 completed sets at the second round (11 GPs, 10 Community Nurses, 3 Practice Nurses), providing 24 sets for intra-rater reliablity analysis. Participants using the tool had a higher level of agreement and identified the type of UI more accurately (Kappa range without tool 0.2-0.65; with tool 0.69-0.84).

3. 1200 patients were included in the mail out; 236 returned a 'decline' form, mainly because they did not have UI symptoms; 58 women contacted the research team, of whom 15 were eligible and assessed by a health care professional. All GPs and practice nurses in both practices were trained in the use of the decision tool, but practice nurses carried out the consultations. Training comprised a 45 minute long session and a pack with information for every individual member of staff. Interviews with practice nurses suggested the tool was a useful guide to taking a relevant history/increasing confidence in managing UI symptoms. The ICIQ-Short Form was new to all HCPs in the study; they appreciated its comprehensiveness and brevity and the direct link to the related website. Nurses reported bladder diaries were often incomplete and difficult to interpret. They commented that the decision tool would need to be supplemented by written material relating to pelvic floor muscle and bladder training (sourced by links to websites). The need for the tool to be electronically available was strongly emphasised.
HCP's decisions: women's symptoms were accurately categorised according to UI symptoms; recommended treatments (mainly PFMT) / referrals were appropriate.
Patient completion rates for ICIQ-SF, EQFD and IQoL were high, with some attrition over time
Overall feasibility: the decision tool functioned well in practice; feedback suggested participants would find an electronic version more user friendly.

Findings from 10 patient interviews indicated the ICIQ-SF was seen as quick and easy to complete, and the bladder diary inconvenient; patients found leaflets on PFMT and bladder training useful.

Expected Impact
The tool developed and tested in this study has the potential to improve the assessment and management of UI in women in community settings. It has been shown to be useful for GPs and practice nurses who highlighted their lack of education and training in the management of UI in women. It also has the potential to be transferred into electronic format and added to

existing EHR systems in primary care; where it can be available to all health care staff for the initial assessment and management of UI in women.
Conclusions
This study has developed and tested a decision tool for the initial assessment and management of UI in women in the community. It has produced a tool that practitioners find easy to use, with minimal training, that is acceptable in practice and improves the accuracy of identification of the type of UI. The feasibility study identified that it would be practical to test the tool further in GP practice settings. Further evaluation of the tool with other areas of community nursing practice (who proved difficult to recruit to this study) and using it in electronic format, would be beneficial.

Patient and public involvement
We identified a group of service users who expressed a willingness to participate in the study through existing continence services. We have met with this group at various points throughout the project to gain their views on the content and format of the decision tool. The group also commented on the content and presentation of the 'patient pictures' representated in the clinical scenarios in stage 2 of the study. Their input and advice was used to design the pilot tools for the focus groups in stage 1, and in the content of scenarios for stage 2. The group were also asked to evaluate the symptom questionnaires used to assess patient outcomes during the feasibility study for 'user-friendliness'.

Input of service users has been extremely useful during the conduct of this study, and ensured that at all stages our process used tools that patients found easy to use and understand.

The next stage of our work with the user group is to discuss the findings of the feasibility study with them, and ask their advice regarding dissemination of the tool to relevant user groups. We will also contact the Bowel and Bladder Foundation, to ask for their input into further dissemination of the tool.

Part of our planned trajectory is to further develop the tool in an electronic format (with links to information such as guidance on bladder training, UI symptom scores online). We would then plan to evaluate the implementation of the tool in practice, in a larger study, using the lessons learned from our feasibility study. The user group will be involved in all of these developments, with one member of the group potentially being a co-applicant on further grant applications.

Data sharing statement
See link
[https://www.nihr.ac.uk/documents/nihr-position-on-the-sharing-of-research-data/12253] for the NIHR position of the sharing of research data. The NIHR strongly supports the sharing of data in the most appropriate way, to help deliver research that maximises benefits to patients and the wider public, the health and care system and which contributes to economic growth in the UK. All requests for data should be directed to the award holder and managed by the award holder.

Disclaimer

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This project was carried out between May 2009 and October 2011. This final report has not been peer-reviewed. The report was examined by the Programme Director at the time of submission to assess completeness against the stated aims.