

Research priorities for continence care and urogenital health: URGENT recommendations

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Abstract: The Nursing, Midwifery and Allied Health Professions Research Unit (NMAHP RU) is funded by the Chief Scientist Office of the Scottish Government Health Directorates, and is co-hosted by Glasgow Caledonian University and the University of Stirling. A key component of its focus is supporting evidence-based healthcare by undertaking research on issues related to urogenital disorders in males and females, including pelvic organ prolapse, lower urinary tract symptoms (LUTS) and sexual dysfunction. These areas have been understudied and robust research is lacking. Yet they are frequently identified by clinicians, researchers, patients and carers as significantly impacting the quality of life of those affected. In consideration of the lack of evidence, and in a quest for researchable topics for subsequent years, the Urogenital Disorders programme of NMAHP RU hosted an expert group of clinicians and researchers to help establish a

research agenda and priorities for funding. The following report describes the process and the outcomes from the group's deliberations, with reflections from an international perspective.

Research priorities for continence care and urogenital health: URGENT recommendations

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Abstract

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Introduction

The Nursing, Midwifery and Allied Health Professions Research Unit (NMAHP RU) is funded by the Chief Scientist Office of the Scottish Government Health Directorates, and is co-hosted by Glasgow Caledonian University and the University of Stirling. A key component of its focus is supporting evidence-based healthcare by undertaking research on issues related to urogenital disorders in males and females, including pelvic organ prolapse, lower urinary tract symptoms (LUTS) and sexual dysfunction. These areas have been understudied and robust research is lacking. Yet they are frequently identified by clinicians, researchers, patients and caregivers as significantly impacting the quality of life of those affected. In consideration of the lack of evidence, and in a quest for researchable topics for subsequent years, the Urogenital Disorders program of NMAHP RU hosted an expert group of clinicians and researchers to help establish a research agenda and priorities for funding. The following report describes the process and the outcomes from the group's deliberations, with reflections from an international perspective.

Establishing research goals

Experts in continence product evaluation, pelvic floor muscle therapy, LUTS in adults, and sexuality from the fields of nursing, physiotherapy, medicine, counseling, health services research and consumer involvement in research were invited to join and attend an introductory meeting of the Urogenital Research Group for Nursing and the Therapies (URGENT) (Box 1). In preparation for the meeting, selected experts were asked to prepare a short presentation based on a comprehensive review of the literature on an assigned topic. This included a discussion of what is known and what needs to be known in terms of research evidence on the topic, and a list of questions which could shape future research. Each topic had a maximum of four 10 minute presentations. The four broad topic areas were:

1. conservative management of pelvic organ prolapse;
2. conservative management of LUTS;
3. conservative management of sexual dysfunction, and;
4. consumer involvement in research programs.

The criteria used by the group to establish research priorities were informed by the research policy of NMAHP RU, which has an emphasis on clinical rather than bench research. The group considered the strength of evidence, personal impact of the problem, current known research occurring in the field, and the existence of measurable and clinically relevant outcome measures. At the end of each topic session, small group discussions took place which considered the ranking of the potential ideas for further research.

A modified Delphi consensus-building approach was used to identify and prioritize research questions within each of the topic areas. At the end of all presentations, further ranking of all the questions was undertaken and each small group presented their rationale for the choice of the key areas for further study (Table 1). Discussion occurred on potential partnerships with other disciplines and funding opportunities. The following report highlights the prioritized questions, summarizing the associated research evidence and the research recommendations made.

Pelvic Organ Prolapse: What is known

Pelvic organ prolapse (POP) is the descent from the normal anatomical position of some part of the female pelvic organs, due to herniation through deficient pelvic fascia, or weaknesses or deficiencies in the ligaments or muscles which should support the pelvic organs. Vaginal delivery and chronic increases in intra-abdominal pressure (chronic constipation, obesity, chronic coughing and repetitive heavy lifting) are thought to be the main risk factors for prolapse. Symptoms associated with prolapse include a sensation of something coming down in the vagina, LUTS, bowel and sexual dysfunction, and abdominal pain and back ache. The condition is common: 40 to 50% of all women over 40 years of age are likely to have some degree of prolapse.^{1,2} The main conservative treatment options are: physical therapy such as pelvic floor muscle training (PFMT), insertion of mechanical device (e.g. vaginal pessary) and lifestyle changes such as losing weight or reducing constipation.

Pelvic floor muscle training for prolapse

Referral of women with prolapse for physiotherapy has become common in many centers. The recently updated Cochrane review on this topic³ found some weak evidence in favor of PFMT, particularly for women with anterior prolapse, but the trials were small⁴ or of poor quality⁵, making the conclusions tentative at best.

In one feasibility study⁶, 47 women with prolapse of stage I or II were randomized to either a PFMT intervention or to a control group. The intervention group had significantly greater reductions in prolapse stage and were significantly more likely to say their prolapse had improved since the start of the study. Follow-up was only 6 months and durability of the results is not known.

A general issue regarding PFMT is the lack of agreement as to the optimum regimen. The Cochrane reviews^{7,8}, which found PFMT in women with stress urinary incontinence to be effective, could not identify an optimum training regimen. Over the last 10 years the theories of pelvic floor function have changed. It is now widely accepted that the pelvic floor muscles do not work in isolation, and that other muscles, in particular transverses abdominus, also play a key role.^{9,10} However, Bø and Sherburn¹¹ argue that exercises should be specific to the pelvic floor muscles as this produces the optimum training effect. Further research is required to identify an optimum training regimen for the pelvic floor muscles. This research also needs to include developing improved techniques such as the use of dynamic ultrasound, to identify these muscles accurately and to be able to assess their function.

Vaginal pessaries for prolapse

A wide array of support and space-occupying pessaries is available in the USA. In many areas of the UK, only the ring pessary (support) and the shelf pessary (space-occupying) are readily available. There are few published data on the use of pessaries for the treatment of prolapse and there is no consensus on optimal pessary management, including frequency of change and use of antiseptics or estrogen creams. Pessary success rates are reported to be between 9 and 73% depending on the definition of success and the duration of follow-up (1 week to 3 years).¹²⁻¹⁹ Severity of prolapse was not found to predict pessary success in any of the studies. The retrospective design in some of these studies, variation in pessaries used and patient selection make it difficult to compare results. Some researchers found that women with previous prolapse surgery, previous hysterectomy or pre-existing stress urinary incontinence were less likely to have success with pessary treatment.^{15,16,18,19} Clemons et al. were unable to demonstrate a significant association between past prolapse surgery and pessary failure but did find that those with shorter vaginas and wider introitus were more likely to fail.¹² Hanson et al. reported that women on hormone replacement therapy (HRT) were more likely to succeed with pessaries but half of the women studied suffered predominantly with urinary incontinence rather than pelvic

organ prolapse.¹⁴ There is some evidence that spontaneous regression of prolapse may occur around the menopause or with the use of vaginal pessaries.²⁰⁻²²

Pelvic Organ Prolapse: Recommendations for research

PFMT

- A rigorous, adequately-powered randomized controlled trial of pelvic floor muscle training is needed. Two such trials are now underway: one in the UK²³ and one in Norway.²⁴
- Investigation of the role of pelvic floor exercises in conjunction with surgery, and mechanical devices is needed.
- Studies are required to identify the optimum pelvic floor muscle training regimen to guide practice and standardize protocols.

Pessaries

- Studies are needed to evaluate the optimal pessary-fitting protocol, the types and numbers of pessaries to try, change protocols, and whether topical HRT improves outcomes.
- A comprehensive survey is needed to establish the types of pessaries readily available in different regions in the UK and in different care settings (i.e. primary, secondary and tertiary units) and the rationale for choice of type.

Lower Urinary Tract Symptoms (LUTS): what is known

LUTS are common and affect people of all ages. Considering urinary incontinence alone, information available from the Department of Health suggests that 5% to 14% of women and 3% of men aged 25 to 44 years who live at home suffer from this condition.²⁵ For those living in institutions, the prevalence is estimated to be far higher (33% in residential homes, 67% in nursing homes and upwards of 50% in care of the elderly/elderly mental health wards.)²⁵

Long Term Indwelling Catheterization

One management strategy for intractable LUTS is an indwelling catheter. Indwelling urinary catheterization carries a known risk of urinary tract infection (UTI). Silver alloy catheters are coated with silver ions, which inhibit biofilm formation, and are claimed to reduce UTIs. There is some evidence that using silver coated indwelling catheters in hospitalized adults delays the

onset of catheter acquired UTI in the short-term, and that a role exists for these products in intensive care settings where compromised health status could be negatively affected by the development of a UTI²⁶⁻²⁸. What is not understood is whether there is a role for silver alloy catheters for selected patients who have a long term indwelling catheter.

'Trial without Catheter'

A 'trial without catheter' (TWOC) is a common procedure of removing a catheter and assessing whether the individual is fully emptying their bladder prior to permanent removal. Generally, the criteria for a successful TWOC are good control of voiding, passing adequate volumes of urine, and a low post void residual. Some centers advocate saline instillation prior to removing the catheter but this practice has not been evaluated in a manner that enables clinicians to develop evidence-based policies. Current evidence is limited to two small trials comparing both methods (saline infusion and no saline infusion) in the postoperative urology patient.²⁹⁻³⁰ The results suggest that the infusion method is safe and simple and can help in the assessment of voiding and increasing readiness for discharge. In addition to this, Kleeman et al's study of voiding efficiency after urogynecological surgery, found that by calculating post void residual after saline instillation, voiding efficiency could be predicted in 93% of patients who voided >50% of the amount inserted and in 100% of patients who voided >68%.³¹

LUTS: Recommendations for further research

- Research is required which explores long term use of indwelling silver alloy catheters, and includes outcomes such as symptomatic UTI with pyuria, adverse effects, development of antibiotic resistance and economic implications.
- A large randomized controlled trial is needed of the practice of instillation of normal saline into the bladder prior to removal and trial of voiding, to assess impact on predicting voiding efficiency and to evaluate time, cost and patient satisfaction.

Sexual dysfunction: What is known

Sexual function plays an important part in a person's overall health and well-being. Sexual dysfunction therefore can have a profound effect on quality of life. The factors contributing to

sexual problems are many: physical or mental illness, surgery, medication side effects. A combination of physical and psychological causes is common.

Male sexual dysfunction

About 20-30% of adult men may have at least one manifest of sexual dysfunction³². Male sexual dysfunction includes problems with erection, ejaculation, orgasmic sensation and sexual drive. Erectile dysfunction was defined by a National Institutes of Health Consensus Development Conference as “the inability to achieve an erection sufficient for satisfactory sexual performance (for both partners)”. The prevalence of erectile dysfunction is however unknown. Aytac et al have estimated that 152 million men worldwide were suffering from erectile dysfunction in 1995, a figure projected to rise to 322 million by 2025.³³ Conservative treatment options for erectile dysfunction include vacuum devices, pelvic floor exercises, counseling and sex therapy and lifestyle modifications used alone or in combination with medical treatments. In one trial comparing the effectiveness of pelvic floor muscle exercises, manometric biofeedback and lifestyle changes for erectile dysfunction with lifestyle changes only 40% of men in the pelvic floor muscle exercises group attained normal erectile function, 35% improved, and 26% failed to improve.³⁴ These results compared favorably with the results from one trial for men of similar etiology using sildenafil (Viagra).³⁵

Female sexual dysfunction

About 40-45% of women are affected by sexual dysfunction.³² Dyspareunia, vaginismus, orgasmic dysfunction, disorders of desire and sexual arousal problems are the main female sexual dysfunctions. Specific treatments for these disorders include Masters and Johnson’s sensate focus exercises, relaxation, pelvic floor exercises and instruction in the use of vaginal dilators. Clinical practice suggests such treatments are most effective when delivered in conjunction with psychotherapy interventions. There is limited evidence however of the efficacy of some of these approaches. In particular, there is a paucity of evidence for: the effectiveness of treatments for vaginismus³⁶ and vulvodynia; the benefits to women of using both medical and behavioral interventions for dyspareunia; or the effectiveness of pelvic floor exercises for most female sexual dysfunctions.

Sexual dysfunction: Recommendations for research

Male

- Rather than the focus being on the organic deficit, research should be holistic and should consider the broader effects of the problem and its treatment e.g. on relationships, family, employment and social interaction.
- A large multi-centered randomized controlled trial is warranted into the effectiveness of clinic-taught pelvic floor exercises for men with erectile dysfunction.
- Research is needed into partner issues, in particular how erectile dysfunction affects partners.

Female

- Trials are needed into the effects of individual and integrated treatment options for vaginismus and vulvodynia. It is crucial that such studies have a control group, are randomized and use recognized objective outcome measures.
- Large multi-centered randomized controlled trials are needed to fully investigate the role of pelvic floor muscle training, which is costly in terms of therapist time, for the treatment of many female sexual dysfunctions (e.g. anorgasmia, vaginismus).
- For women with post operative dyspareunia, studies are needed to explore how to balance the immediate physical side effects of surgery with longer term sexual dysfunction.

Consumer involvement in the planning and conduct of health care research: what is known

There are ethical reasons for involving consumers in the planning and conduct of health care research: consumers are certainly stakeholders in health care and, as taxpayers, are also funders. There are also practical benefits: with experience of the conditions and services affecting them, consumers can identify outcomes of importance, inform the design of research procedures and materials, and identify the information and support needs of potential research participants³⁷.

Involving consumers in research in a constructive and effective way is not simple, however. The appropriateness of sources must be considered: consumer perspectives constitute a complex spectrum, ranging from experiences relating to conditions or treatments expressed by individuals, to priorities relating to services expressed by society as a whole. While it might be appropriate for one or two consumers to assist in the development of materials for a study, in many other contexts more representative views are required and consideration must be given to undeclared agenda and conflicts of interest. The methods used for gathering consumer views and factoring

them into the research process also need careful consideration as does the stage of the research process at which consumer involvement is most effective.

The potential of consumer involvement in research to improve its effectiveness and ability to answer questions of importance to both consumers and practitioners is considerable. However, to date there has been greater emphasis on the “why” of consumer involvement than the “how”, so that researchers often must develop consumer involvement policies from scratch. The resultant danger is that consumer involvement may lessen the methodological integrity of research and ultimately the authority of the evidence base.

Consumer involvement in the planning and conduct of health care research:

Recommendations for research

- A body of evidence relating to consumer involvement in research should be developed.
- Appropriate and effective methods of consumer involvement may be identified study by study, but unless they are reported, there is little opportunity for the methodology of consumer involvement to be developed.
- It is essential that the strengths and limitations of methods of consumer involvement in research activities to date be reported and published.

Commentary

The purpose of the research consensus day was to identify areas of practice in urogenital health requiring further investigation and to prioritize questions for clinical research. Questions concerning practice dominated - a focus that reflected the group composition of predominantly clinicians. For example, pragmatic questions comparing silver alloy indwelling catheters versus non silver in long term care were raised, but challenges on implementing current evidence or obtaining meaningful outcome measures required more mutual discussion and would be a topic for further research seminars.

The day ended with people energized and excited about research opportunities. All in attendance agreed on the necessity for more time together as a group to consider the real issues in evidence based practice, including clinicians attempting to utilize evidence and researchers trying to find the evidence to inform practice. Further questions need debating. Is the continuing quest for

more evidence a misapplication of research energies? Do gaps in the evidence base which are most important to clinicians and patients alike remain unidentified? Is it more important to explore the reasons why current evidence is not initiated into practice than to keep adding to a pool of information which is not applied? A good example concerns the use of intermittent catheterization (IC) by community dwelling individuals. Based on the current supporting evidence, the North American experience involves IC as a typically clean procedure with reused PVC catheters that are washed by the user with soap and water and air-dried. However, in Europe, stricter protocols are adhered to and many patients use single use hydrophilic catheters. Is one method better? What does the published research suggest? In what context are the decisions made for either technique? Who influences the decision making to use one product over another? A recent systematic review suggests there is no significant difference between products but concludes, frustratingly, with the statement that further well-designed randomized controlled trials are necessary.^{38,39}

In clinical research, important findings are slow to reach the practitioners and even slower to effect change. A key example is the treatment of asymptomatic bacteriuria in patients with long-term indwelling catheters. Although routine urine cultures are no longer part of care (based on the evidence that all patients with indwelling catheters will be colonized after 30 days of catheterization), there remain many who are tested and as a result treated with antibiotics for vague issues such as odor, leaking around the catheter, urethral discharge or meatal irritation. These are common catheter-related problems and despite the knowledge that antibiotics are rarely effective in providing relief for them, urinalyses are done and patients are unnecessarily treated. The knowledge about best practice in catheter care exists. Unfortunately the knowledge is not well applied, resulting in practice that is less than optimum and not evidence-based (and costly!). According to Jeremy Grimshaw and colleagues⁴⁰ knowledge may be the least of the issues affecting evidence based practice. He argues that lack of knowledge forms less of a barrier to evidence-based practice than institutional resistance from within organizational settings, peer group attitudes among professionals, uncritical educational norms, and poorly informed consumer-generated patient demand.

How do researchers and clinicians overcome the lack of research utilization? It has long been realized that the traditional dissemination practice by researchers of publishing and presenting findings at peer reviewed conferences does little to change practice. Yet Universities reward faculty for these endeavors rather than reward them for work at the clinical level where the

research findings should have more direct relevance. Do researchers have a duty to be more involved in the direct clinical dissemination of their work? Is one research study enough to change practice or should more replication trials be conducted to support or refute the findings of the original study? And might more replications serve to put research into clinical practice itself? Replication studies may pose challenges for researchers if funding bodies prefer to support new and original research; strong arguments may be necessary to convince funders that replication studies are required to support the evidence base. New research grows out of well-conducted replication as a result of which more questions are certain to arise.

Another consideration is that a mismatch exists in many areas between the questions that are addressed by clinical and health services research and the questions which practicing clinicians and health care consumers need answered⁴¹. If research resources are to be used effectively it is important that they are directed at the many uncertainties about treatment and management which are of practical, day-to-day clinical importance but which cannot currently be answered by up-to-date research evidence. The work of groups such as URGENT and of organizations such as The James Lind Alliance, which helps clinicians and patients to work together to identify and prioritize important gaps in the evidence base, is of importance in addressing this issue.

A key agreement among participants centered on the necessity for "*further research*" in all areas of conservative management of urinary incontinence or urogenital problems. This gathering of experts and researchers facilitated some important debates on issues of clinical concern. All participants left the day with a sense that opportunities were just beginning for further critical studies which would enhance clinical decision-making. Outstanding questions for further exploration were raised and the researchers in the group were challenged to implement some of the studies. However the researchers were also left with a task of major proportions: reviewing the current evidence, writing research proposals, and applying for funding in the highly competitive market. Moreover, underlying theoretical assumptions related to research questions deserve much deeper consideration.

In conclusion, the group raised many more questions than answers for researchers and clinicians alike. Such energizing discussion should go far to encourage thoughtful consideration of practice patterns, to help healthcare professionals see research findings as related to the real clinical world where practice does not change rapidly (for good reason in many cases), and to assist in planning further strategic meetings at which research utilization is addressed in a spirit of critical question

and possibility. Further meetings of the group should include deeper exploration of these key issues.

Key points:

The URGENT Workshop identified some key research recommendations in several clinical areas.

The need for clinicians and patients from different areas within continence care and urogenital health to work together to identify barriers to improved evidence based practice was underlined.

Some key questions relating to evidence based practice in continence care and urogenital health need to be carefully considered:

- why is some robust research evidence not factored into clinical practice?
- what questions of everyday clinical importance to clinicians and patients alike remain unanswered by research?
- why is the same evidence base interpreted differently in separate regions of the world?
- is institutional resistance, clinician conservatism, and poorly informed patient pressure more serious barriers to evidence-based medicine than a paucity of evidence?

Box 1. Members of the Urogenital Research Group for Nursing and the Therapies

Name	Position	Facility
Dr Nadia Ali	SPR Gynecology	Hope Hospital, Manchester
Dr Brian Buckley	Chairman	Incontact
Mrs Libby Coats	Psychosexual Therapist	Sandyford Initiative, Glasgow
Prof Grace Dorey	Professor of Physiotherapy (Urology)	University of West of England, Bristol
Dr Mandy Fader	Reader in Nursing	University of Southampton
Dr Cathryn Glazener	Senior Clinical Research Fellow	Health Services Research Unit, Aberdeen
Ms Narelle Gregor	Research Facilitator	Western General Hospital, Edinburgh
Dr Suzanne Hagen	Program Leader, Urogenital Disorders	NMAHP Research Unit
Ms Julia Herbert	Specialist Continence Physiotherapist	Ellesmere Physiotherapy Clinic, Manchester
Mr Brian McGlynn	Specialist Nurse Urology/Oncology	Ayr Hospital
Ms Michelle McGradie	Nurse Practitioner	Western General Hospital, Edinburgh
Ms Susanne McPhee	Continence Sister	Ayr Hospital
Prof Katherine Moore	Professor & Associate Dean Graduate Studies Faculty of Nursing	University of Alberta, Canada
Prof Kate Niven	Director	NMAHP Research Unit
Mr Derek Rutherford	Specialist Urology Nurse - Sexual Medicine	Ayr Hospital
Ms Lesley Sinclair	Research Fellow, Urogenital Disorders	NMAHP Research Unit
Ms Diane Stark	Superintendent Physiotherapist	Southern General Hospital, Glasgow
Ms Katie Taylor	Clinical Nurse Specialist	Liverpool Women's Hospital

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Table 1 Research questions identified

Conservative management of pelvic organ prolapse
Scoping exercise to discover why there is a limited choice of pessaries in the UK.
Who should manage pessaries, GPs or practice nurses?
Comparison of pessary only versus pessary and PFMT?
Does the teaching of PFMT prior to surgery reduce the risk of further prolapse and the need for further prolapse surgery?
Conservative management of urinary problems
Which catheters for IC do individuals prefer? Why?
What are the costs and benefits of using silver alloy catheters (changed every 4 weeks) versus silicone catheters (changed every 4 weeks) versus hydrogel catheters (changed every 4 weeks)?
Which are the best continence products to use?
Comparison of patient satisfaction in the use of pads versus PFMT versus surgery for the treatment of incontinence?
Comparison of transverse abdominal exercise and PFMT versus PFMT only for incontinence?
What is the definitive regime for PFMT for incontinence? (i.e. how many PFME must be done each day?)
Should males and females practice PFMT from puberty onwards? If so what is the impact on later life?
Conservative management of sexual dysfunction
How effective is PFMT in the treatment of sexual dysfunction? (<i>i.e. for arousal dysfunction, for vaginismus, for vulvodynia, for ejaculatory function?</i>)
Is there a role for collaborative practice between psychotherapists and physiotherapists (PFMT) for the treatment of orgasmic dysfunction?
Evidence for vaginal dilation and/ or counselling in the treatment of vaginismus?