



Faecal and urinary incontinence in frail elderly people

SBRI Healthcare NHS England competition for development contracts

June 2015



Summary

A new national Small Business Research Initiative (SBRI) Healthcare competition is being launched by NHS England in partnership with the Academic Health Science Networks (AHSN's) to find innovative new products and services. The projects will be selected primarily on their potential value to the health service and on the improved outcomes delivered for patients.

The competition is open to single companies or organisations from the private, public and third sectors, including charities. The competition will run in two phases:

- Phase 1 is intended to show the technical feasibility of the proposed concept. The development contracts placed will be for a maximum of 6 months and up to £100,000 (inc. VAT) per project
- Phase 2 contracts are intended to develop and evaluate prototypes or demonstration units from the more promising technologies in Phase 1. Only those projects that have completed Phase 1 successfully will be eligible for Phase 2.

Developments will be 100% funded and suppliers for each project will be selected by an open competition process and retain the intellectual property rights (IPR) generated from the project, with certain rights of use retained by the NHS.

The competition opens on 15th June 2015. The deadline for applications is 1200hrs on 11th August 2015.

Background

Multi-morbidity – defined as suffering two or more chronic conditions – affects patients of all ages but prevalence increases markedly with age, being present in most people aged 65 years and older¹.

The type of chronic conditions included in studies of multi-morbidity varies, making it difficult to find consistent reports of prevalence in the UK, but it is widely recognised that the number of patients with multi-morbidity is increasing – particularly as the population ages - and that those patients are likely to have complex needs for healthcare². Some of the most prevalent chronic diseases in the over 65's include:

- Cardiovascular disease - including angina, heart attack, stroke, heart murmur and arrhythmia
- Musculoskeletal - including osteoarthritis, rheumatism and osteoporosis
- Respiratory diseases - including chronic lung disease, asthma
- Diabetes
- Cancer

Multi-morbidity has a particularly significant impact on the workload for both primary and secondary care, with estimates of between 32-78% of all consultations in general practice taken up by those patients² depending on the classification of chronic diseases included in the definition of multi-morbidity.

¹ Epidemiology of multimorbidity and implications for health care, research, and medical education: a cross-sectional study - Barnett *et al*, **Lancet** 2012; 380: 37-43

² Epidemiology and impact of multi-morbidity in primary care: a retrospective cohort study – Salisbury *et al*, **British Journal of General Practice** 2011. DOI: 10.3399/bjgp11X548929

In addition to the burden on primary care, multi-morbidity has wider implications in terms of association with high mortality, reduced functional status for the patient and increased use of both in-patient and ambulatory health care¹. Almost 30% of inpatient days in the UK are used by people with three or more chronic conditions³.

The problems commonly identified and experienced by patients with multi-morbidity are numerous, diverse and commonly associated with the single-disease framework, by which modern day healthcare is delivered^{4,5}. This leads to fragmentation of care, confusion and a burden of self-responsibility on an – often increasingly frail – multi-morbid elderly patient.

Frailty is an expression of a clinical condition that implies concern about an elderly person's vulnerability and outlook; it is associated with both physical and functional decline and has been shown often to overlap with multi-morbidity⁶.

Deterioration to a state of worse frailty is more common than improvement and is strongly associated with adverse outcomes and increased rates of admission to long term care⁶.

There are several definitions of and means to measure frailty, making prevalence unclear, however, it is estimated that between a quarter and half of people older than 85 years are frail and therefore at increased risk of 'geriatric syndromes' which are manifested as a variety of health problems^{6,7}.

This competition theme of 'Multi-morbidities in the frail elderly' focuses on 3 such problems:

- Falls
- Incontinence
- Decline in functional ability

Incontinence is a significant unmet clinical need that leads to substantive effects on quality of life due to negative impact on physical and emotional health, stigmatization and social isolation. It places a huge burden on NHS resources – estimated at more than 2% of the total UK healthcare budget⁸. In the elderly, it is second only to dementia as a reason for admission to residential care.

Multiple morbidities can result in continence care being neglected in favour of more 'urgent' medical conditions, the treatment for which can in itself result in incontinence. This also leads to misconceptions as to what can be done to help older people remain continent or maintain dignity through the use of discreet products and devices. Although continence difficulties are more prevalent among the elderly, it need not be a consequence of ageing.

³ Chronic diseases: what happens when they come in multiples? – **British Journal of General Practice**, April 2007

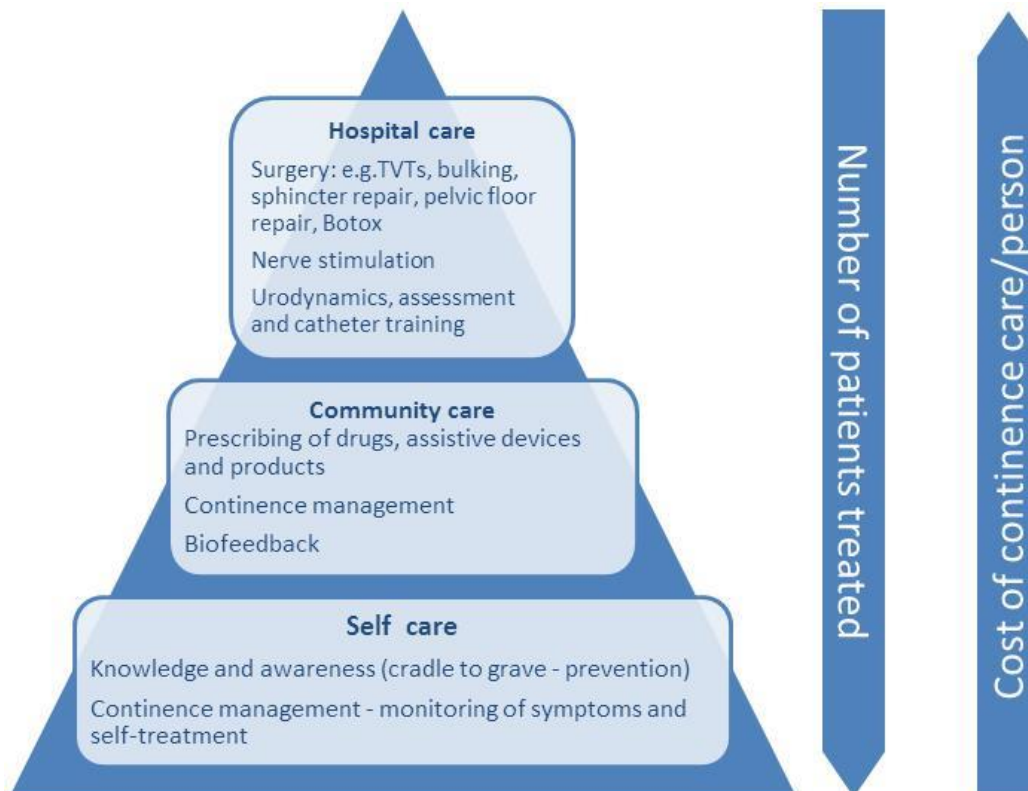
⁴ Managing patients with multimorbidity in primary care – Wallace et al, **BMJ** 2015; 350:h176
doi:10.1136/bmj.h176

⁵ Multimorbidity: Time for action rather than words - Salisbury, C, **British Journal of General Practice**, February 2013 DOI: 10.3399/bjgp13X661020

⁶ Frailty in Elderly People – Clegg et al, **The Lancet**, 2013, 381, 752-762

⁷ A randomized trial of a multicomponent home intervention to reduce functional difficulties in older adults – Gitlin et al, **JAGS**, 54: 809-816, 2006

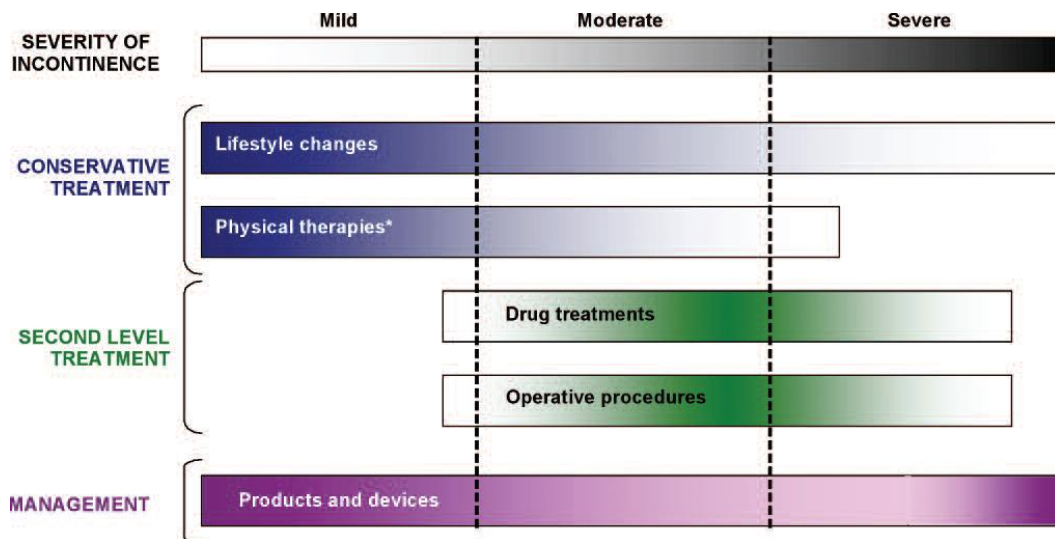
⁸ Management of faecal incontinence in adults: summary of NICE guidance – Norton et al, **BMJ** 2007; 334:1370-1



Faecal incontinence (FI) is defined as the inability to control the passage of faeces through the anus, and urinary incontinence (UI) as the involuntary loss of urine. Individuals may be affected by one or both forms. FI and UI are not a disease, they are symptoms, and often result from an underlying treatable medical condition. Many forms of faecal and urinary incontinence share a common pathophysiology and often co-exist with pelvic organ prolapse.

The exact prevalence of incontinence is difficult to determine due, in part, to inconsistencies in definition and the social stigma associated with the condition. However, the prevalence of FI is estimated to be ~10% in the adult population, with approximately a third of cases affecting persons under 40 years of age. It is estimated that 15% of those over 85 years living at home and 10% - 60% of those in residential and nursing homes experience FI.

Treatment of incontinence depends on the severity of the condition, as illustrated in the graphic below. Treatment options are often similar for FI and UI.



Reproduced with the kind permission of the Bristol Urological Institute, North Bristol NHS Trust

- Conservative treatment options are often short lived and most are not capable of restoring full continence:
 - FI options include dietary manipulation, constipating agents, enemas, pelvic floor training, bowel retraining, biofeedback therapy, continence devices and, where tolerated, rectal irrigation.
 - UI options include life-style and dietary changes, pelvic floor exercise, bladder retraining and continence devices.
- Second level treatments include neuromodulation, operative procedures and drug treatments:
 - Drug treatments:
 - FI drug treatments focus on diarrhoea or constipation
 - UI options include use of Onabotulinum toxin A, but requires surgery and can result in bladder retention requiring catheterisation for bladder emptying; it may increase risk of urinary tract infection and anticholinergics to reduce involuntary bladder contractions, but these have side-effects such as dry mouth and constipation
 - Operative procedures:
 - FI options include bulking materials, artificial sphincter, sphincter repair, endoscopic heat therapy and cell therapy (experimental); colostomy is performed as last resort
 - UI options include bulking materials, artificial sphincter, sphincter repair, tapes slings and retropubic suspension for pelvic floor reconstruction
 - Procedures are invasive, irreversible, and balance variable success rates against associated risks of additional surgical intervention or resulting untreatable, worsening symptoms, thus few opt for this treatment route

- Neuromodulation:
 - Considered first-line treatment option for adults in whom non-operative therapies have failed to alleviate symptoms⁹
 - Chronic stimulation of the sacral nerve roots using an implanted electrode and generator; requires surgery, prone to septic complications, device malfunction, erosion and migration requiring revision surgery and prone to loss of efficacy in longer term; is costly - ~£9.5K for the implant and recurring costs of £7.5K every 5-6years for battery replacement
 - Stimulation of the tibial nerve; efficacy is uncertain
- Management:
 - Those for whom surgical intervention is not, or is no longer, an option must manage their incontinence with stoma bags (FI), absorbent pads, catheters (UI) or other devices
 - Continence management devices can be problematic:
 - May be bulky, noisy or have odour, all of which creates embarrassment for the user
 - Catheters for UI increase the risk of urinary tract infections
 - Indwelling catheters for UI are prone to biofilm formation and device encrustation; leakage around the catheter can be caused by detrusor over-activity, infection, catheter obstruction, or the catheter or balloon size being too large

Challenges

Clinicians in FI and UI have put forward a range of unmet needs that could improve the care they are able to offer to patients. The list is not exhaustive and should only be used as a guideline for the sort of solutions that may be of interest.

Prevention of continence difficulties and early treatment can be important in avoiding complications in later life. However, treatment and management in the frail elderly is a prime focus for this call.

1. Prevention

Faecal and/or urinary incontinence experienced by many individuals could be prevented or symptoms reduced. Three main factors appear to influence prevention:

1. The taboo around incontinence and the tendency for it to be hidden
2. A lack of knowledge and understanding as to the causes of incontinence and what can be done to avoid it
3. A lack of tools that use human factors in their design, which enable individuals to identify their risk, motivate participation in prevention therapies and be able to monitor progress.

⁹ NICE 2007

What if we could break down the taboo surrounding incontinence by informing and educating people of all ages into the causes and how to prevent incontinence?

What if we can identify and monitor individuals who are at risk from incontinence?

Would identification and long-term monitoring of women at risk of incontinence after childbirth reduce complications later in life?

Would self-monitoring tools empower individuals to prevent pelvic floor decline?

Can we demystify and remove the stigma associated with incontinence and its treatments?

What if we had integrated, patient-centred systems that addressed pelvic floor function and health in the context of an individual's life-span?

What if technology could help individuals of all ages and abilities be motivated to undertake pelvic floor exercises on a frequent basis?

2. Diagnosis

Early, accurate diagnosis may mean cost-effective conservative treatment with symptom improvement rather than expensive invasive surgical procedures when symptoms become more severe.

What if we could accurately diagnose and treat all individuals with faecal or urinary incontinence?

What if we had non-invasive, low cost, point of care diagnostics that could be used by non-clinicians in residential care homes or individuals in their own homes?

What if diagnostic accuracy could be improved leading to more appropriate treatment outcomes?

What if we could diagnose those individuals who are most at risk of complications of continence treatment or management, such as urinary tract infection?

What if devices can be incorporated into continence management products for more accurate monitoring of incontinence and associated problems, e.g. infection or hydration

3. Treatment

There is a need for minimally invasive, reversible treatments that offer immediate symptom relief and a low morbidity profile. New materials that will not cause tissue erosion or necrosis through the lifetime of the device are critical for successful integration of any devices.

What if we could have cost-effective, reliable, long-lasting, easy to use, minimally invasive, biocompatible and safe treatments suitable for older people?

What if we had an effective non-surgical solution to stress UI symptoms, which is more effective than pelvic floor exercises, and more widely usable than surgery?

What if the physiological function of the sphincter muscle could be restored?

What if patients own cells could be used to restore sphincter

What if degenerating sphincter muscle could be re-conditioned or regenerated?

What if we had a non- or minimally-invasive treatments that could be delivered in outpatient or residential care

What if we had an implantable device that would function for extended periods without further intervention?

Could electrical stimulation for continence symptoms be made more comfortable, reliable, cheaper and easy to use?

Can the effect of Onabotulinum toxin A treatment be more predicable?

Could more 'sensitive' surgical instruments reduce risk of incontinence post radical prostatectomy?

Could improved methods of stoma formation improve surgical outcomes?

4. Management

For many patients, management of symptoms is the preferred or only option. It is essential that continence management devices are easy to use, carry a low risk of complications, are reliable and discrete. Design solutions must be user-focussed and ideally be tailored to individual needs.

What if we can offer personalised continence management that offers patient dignity and minimises the effects of social stigma?

What if absorbent products included built-in smart sensors?

What if we had an intermittent catheter that does not need lubrication and can be reused?

Can indwelling catheters be designed to resist or repel urease-producing bacteria?

What if we had a genuinely leak-free, comfortable, easy to use and aesthetically acceptable urinal for women who may be confined to a wheelchair or a bed?

What if we had urine collection bags that are discreet, safe and aesthetically acceptable?

What if we had fashionable clothing designed to make using continence aids discreet and functional?

Would accurate early patient detection of urine infection reduce need for antibiotic treatment?

What if we had novel continence management aids for symptom relief that offered patients complete confidence?

How can we improve bladder training and use of continence devices for vulnerable individuals and those with cognitive impairment?

Supporting documents

<http://www.appgcontinence.org.uk/pdfs/CommissioningGuideWEB.pdf>

<http://www.appgcontinence.org.uk/pdfs/Continence%20Care%20Services%20England%20Report%202013.pdf>

Application process

This competition is part of the Small Business Research Initiative (SBRI) programme which aims to bring novel solutions to Government departments' issues by engaging with innovative companies that would not be reached in other ways:

- It enables Government departments and public sector agencies to procure new technologies faster and with managed risk;
- It provides vital funding for a critical stage of technology development through demonstration and trial – especially for early-stage companies.

The SBRI scheme is particularly suited to small and medium-sized businesses, as the contracts are of relatively small value and operate on short timescales for Government departments.

It is an opportunity for new companies to engage a public sector customer pre-procurement. The intellectual property rights are retained by the company, with certain rights of use retained by the NHS and Department of Health.

The competition is designed to show the technical feasibility of the proposed concept, and the development contracts placed will be for a maximum of 6 months and up to £100,000 (incl. VAT) per project.

The application process is managed on behalf of NHS England by the Eastern Academic Health Science Network through its delivery agent Health Enterprise East. All applications should be made using the application forms which can be accessed through the website www.sbrihealthcare.co.uk.

Briefing events for businesses interested in finding out more about the competition will be held on the 18th June and 25th June 2015 in Birmingham and London respectively. Please check the website for confirmation of dates and venues, information on how to register and details of the categories that will be presented at each event.

Please complete your forms using the online application process and submit them by 1200hrs on the 11th August 2015.

Key dates

Competition launch	15 June 2015
Briefing events	18 & 25 June 2015
Deadline for applications	11 August 2015
Assessment	September / October 2015
Contracts awarded	November 2015
Feedback provided by	December 2015

More information

For more information on this competition, visit:

www.sbrihealthcare.co.uk

For any enquiries e-mail:

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For more information about the SBRI programme, visit:

www.innovateuk.org/SBRI