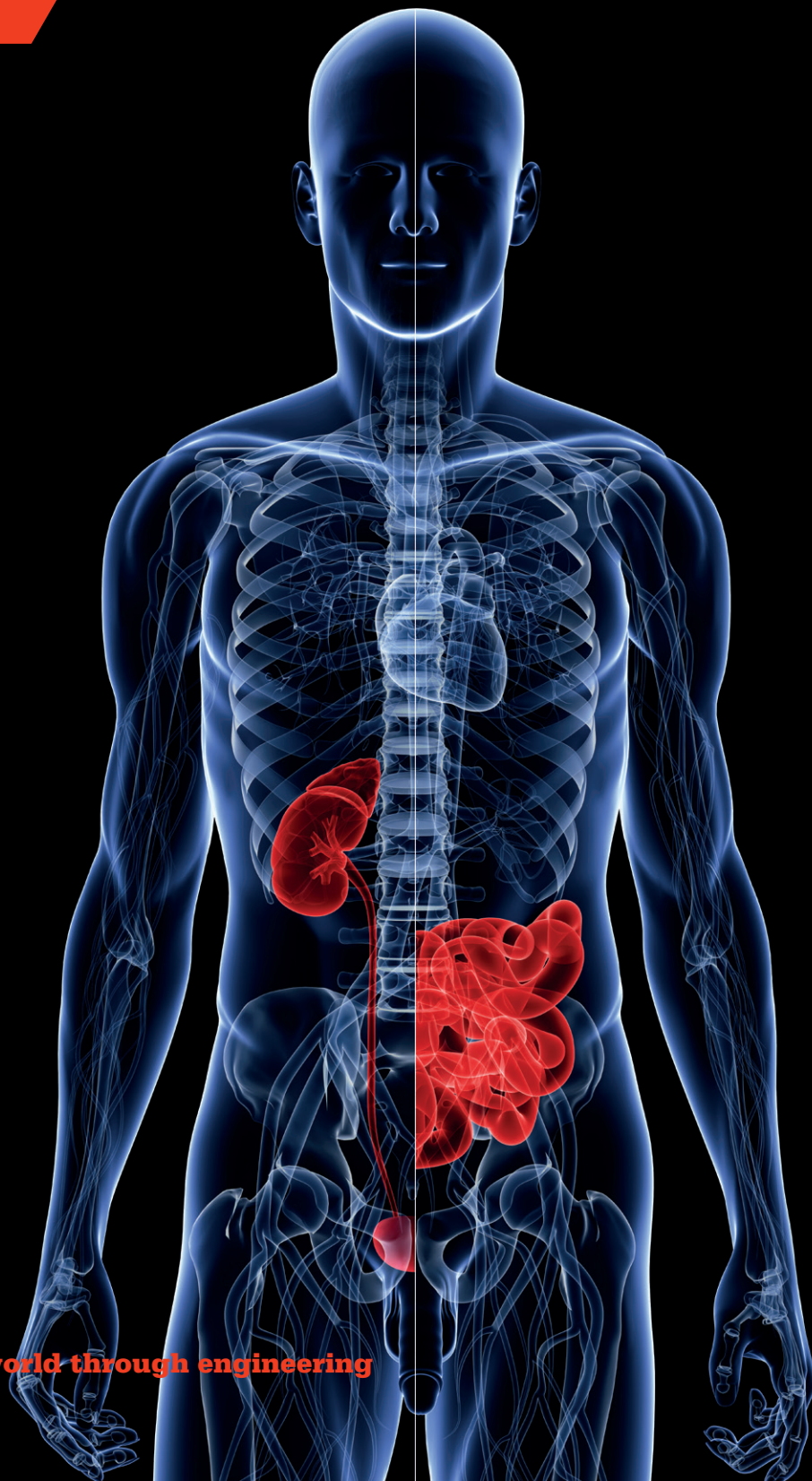


INCONTINENCE: ENGINEERING INNOVATION TO ENHANCE QUALITY OF LIFE.

Institution of
**MECHANICAL
ENGINEERS**



Improving the world through engineering

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Incontinence affects nearly one in three people at some point in their life, but still there is little public awareness of the scale of the problem and it remains largely overlooked by Government policy.

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This case study has been produced in the context of the Institution's strategic themes of education, energy, environment, healthcare, manufacturing, transport and its vision of 'Improving the world through engineering'.

Cover image

Split 3D image showing kidney and bladder (left) and intestine (right).

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Introduction

Incontinence is a common, if rarely discussed, condition. It will affect nearly one in three people at some point in their life, but still there is little public awareness of the scale of the problem and it remains largely overlooked by Government policy. Current healthcare technology for incontinence is inadequate and lacks innovation, translation and commercialisation, despite profound clinical and societal needs. The condition burdens the NHS with annual healthcare costs of over £2bn per year^[1]. It is a major cause of admission to care homes, yet society continues to shy away from discussing its impact or how it could be better addressed.

There is a clear need, voiced by patients and healthcare services alike, for new and improved products to help assess, manage and treat the condition. Despite incontinence cutting across society, our fundamental disposition is to avoid thinking about non-life-threatening unpleasant facts, thus limiting the impetus for making improvements. Consequently, unlike other areas of healthcare (eg cardiovascular disease and cancer treatment), technological advances that would provide a step-change in bowel and bladder healthcare have not materialised. There is, therefore, a critical need for technological innovation in this area, to enable healthcare systems to deliver sustainable, cost-effective care for incontinence that will result in improved quality of life.

Without a change to the policies surrounding the introduction and evaluation of healthcare technology innovation the situation is likely to deteriorate, not least because of the ageing population and comorbidities, such as dementia and Parkinson's disease, that often contribute to the onset of incontinence.

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The physical and psychological impact of incontinence often have a profound impact on self-esteem and self-confidence.



What is Incontinence?

Continence relies on appropriate function of neural, muscular and anatomical features that enable controlled storage and timely disposal of urine or faeces. Dysfunction of these features can arise from a wide range of acquired or congenital conditions.

Over 20 million people in the UK have some form of incontinence, defined as the lack of controlled release of urine or faeces. In the UK, bladder control problems affect more than 14 million adults and bowel control problems affect about 6.5 million adults. While both conditions are more prevalent in adults, particularly the elderly (up to 24% of women and 15% of men over the age of 65 suffer with urinary incontinence), more than 900,000 children have bladder and/or bowel dysfunction. While not life-threatening, incontinence is a significant unmet clinical need and major public health concern.

Incontinence can be physically, emotionally and socially debilitating. These factors are often overlooked because the condition is not life-threatening, yet their combined effect can profoundly reduce quality of life for affected individuals, family, friends and carers. The physical and psychological impact of incontinence often have a profound impact on self-esteem and self-confidence, limiting the ability (or willingness) of an individual to socialise, travel or enter employment; for example because they fear limited access to toilet facilities, 'having an accident' while in public or appearing 'abnormal'. This limits independence, both financially (with many reliant on family for care and financial support) and socially (reducing opportunities for interaction and creating a sense of isolation which affects mental/emotional health).

The Cost of Incontinence

Nationally, incontinence has a significant impact on the UK economy, both in terms of the costs due to lost productivity, direct healthcare spend and associated long-term care costs. Adult incontinence is estimated at about 2% of the total healthcare budget of the UK. This figure does not reflect the cost of ill health, depression and social isolation that often arise from bladder and bowel incontinence.

Incontinence places significant costs on the individual. The private cost of incontinence products is estimated to be £750m per year in the UK. According to Government figures, some families spend up to £100 a week on incontinence products, which are not accessible through the health service or via local authority social care provision^[2]. The Education and Resources for Improving Childhood Continence (ERIC), has campaigned for many years for better availability of continence pads for children, for which schools get no tax exemption.

These growing costs are in part due to an over-reliance on disposable management products, for example absorbent pads and catheters, which must often be purchased by the individual to meet their particular needs^[3]. This is reinforced by the current mode of healthcare, which is predominantly delivered through acute care settings (eg hospitals) or nursing homes, and places a major burden on the resources available^[4].

The Institution supports other continence organisations in calling for Government to address the issue of VAT on all continence products, including accessories; the financial benefit to our healthcare system and to society far outweighs the loss of revenue to the Government in continence product tax.

Severe Secondary Effects of Incontinence

- Dermatitis & skin infection
- Depression & mental health issues
- Ulcers
- Urinary infections
- Risk of falls and fractures due to night-time incontinence

Raising Public Awareness

Given the prevalence and impact across society, it is perhaps surprising that incontinence is rarely discussed, particularly in public forums or the media. Instead, it remains shrouded in social stigma. This has propagated ignorance or avoidance of addressing the challenges associated with the condition by Government, healthcare, industry, academia and wider society.

Key to addressing this situation is raising awareness through education, publicly accessible information and healthcare training. This must include important aspects, such as risk factors, preventative measures, associations with age and ageing, and crucially the taboo surrounding incontinence. While this must cater for a broad audience, it must also do so using innovative approaches that are culturally, age and context appropriate, for example provision of specific advice for children with bowel or bladder conditions and their parents. Public discussion of incontinence would help to dispel myths and promote preventative lifestyle measures such as pelvic floor training with the potential to save millions in healthcare costs alone.

Charitable groups such as Bladder and Bowel UK work to represent the patient voice, which can often provide compelling examples to inspire and inform others. However, recently a number of celebrities have discussed their experiences of urinary incontinence after pregnancy, bringing significant positive attention to the issue^[5]. The Institution believes that there are opportunities for the Department of Health to destigmatise the condition, by building on these examples through public awareness programmes that cover all aspects of incontinence.

Changing Care Practices

The need for awareness and understanding also extends to healthcare professionals, due to the complexities of incontinence, and the lack of specialist training provided on a general basis. Despite the Government's 2015 commitment to address inconsistencies in continence provision in the UK^[6], many healthcare professionals feel inadequately qualified to identify, assess and treat the condition. This often concerns those working in areas critical to incontinence including maternity care and GP services, who are likely to be the first point of contact for many people with the condition.

Variations continue to be endemic throughout the NHS as the guidance and framework protocols do not always lend themselves to consistent practices. Unless those processes are adequately monitored and substantial data recorded, continuous improvements in quality will continue to fall below the expectations of the patient. Government must ensure that specialist training is provided to NHS staff working with patients likely to be experiencing, or at risk from, incontinence issues.

NHS: Improving Technology Uptake

Advances in knowledge and insights into incontinence are yielding significant opportunities for new technology that may redress rising healthcare costs. The NHS is one of the largest healthcare systems in the world and therefore offers a unique platform for developing, implementing and evaluating new incontinence technology.

Provision of high-quality comprehensive continence services within the healthcare system is recognised as essential, but introduction of new and innovative technology is hampered by complex and burdensome regulation. As a result, many people affected by continence problems could be either better treated or better managed. In particular, there is a recognised need for technology to support the delivery of community-based healthcare for incontinence, reducing the current reliance on high-cost acute care delivery^[7].

Low uptake and appraisal of new technology also result from the lack of information being exchanged between healthcare professionals, end-users, and innovators of new technology, especially in terms of what technology is needed and what could be made available. Effective communication between stakeholders is essential for advancing our understanding of the condition and developing novel technology. Greater alignment is needed between scientists (from academia and industry) and healthcare professionals dealing with continence problems in the NHS. At a practical level, access to clinical and healthcare provider expertise is an invaluable resource for companies requiring collaboration to assess new technology during development. At a policy level, input from healthcare professionals is crucial when taking forward discussions on scientific opportunities, technology trends and the need for funding initiatives.

Commissioners procuring continence services need to have greater freedom to access technical innovations that offer cost-effective technology and improved quality of life for persons affected by continence problems. The Institution recommends implementing a proportionate, cost-benefit procurement framework that actively encourages research and innovation towards patient benefit.

Healthcare professionals need adequate tools to assess, identify and report where gaps in continence technologies need bridging. The current frameworks for care provision do not encourage or provide sufficient opportunity for identification and evaluation of new technology, that could lead to patient benefit and ultimately deliver healthcare cost savings through provision and procurement of cost-effective products.

The Institution recommends the creation of a Continence Technology lead within every general hospital and PCT, which would help increase opportunity for identification and evaluation of new continence technology, and in doing so facilitate industry to develop technology to support community-based incontinence healthcare.

Engineers: Driving Innovation

Despite the scale of the healthcare challenge presented by incontinence, and the clear need for innovation voiced by patients and clinicians, there is a critical lack of engineers engaged in the area. This is in stark contrast to other areas of healthcare such as cancer or cardiology, which have wider mass-media appeal, greater public awareness and none of the taboo associated with incontinence. This marginalisation of incontinence extends beyond social stigma to act as a barrier to professional conduct.

There is huge potential to bring significant patient benefit, driven by engineering, to address key challenges that have persisted for decades. These include the rise of catheter-associated urinary tract infections (CAUTIs), skin ulcers and the need for more detailed, less invasive modes of assessment. Focused application of interdisciplinary engineering science could help to better understand the fundamental mechanisms which lead to incontinence (eg through biochemistry, molecular biology and physiology) and so lead to improvements in healthcare provision, informing promising new treatments such as neuromodulation, which works well for many people, although the exact mechanisms are not well understood.

Further opportunities exist for the translation of existing knowledge and technology from allied medical engineering disciplines.

- MRI imaging techniques developed for cancer diagnosis could help bring less invasive assessment of the pelvic floor.
- Materials and coating technology are instrumental in developing the next generation of atraumatic catheters.
- Tissue engineering from other physiological systems is informing techniques to repair damaged pelvic floor musculature.
- Smart systems and informatics, increasingly used in long-term conditions such as diabetes, have real relevance to inform management of incontinence.

In short, much of the requisite knowledge, expertise and technology exists, but needs engagement from the engineering community to translate it into incontinence healthcare.

Central to this is a need to raise awareness, both of the condition itself, and the associated healthcare needs and opportunities. Education, particularly targeting biomedical engineers within university environments, could help ensure increased and sustained interest in this subject, helping create a more vibrant research community in this critically overlooked area of healthcare.

The Institution recommends that the engineering community accept a societal responsibility to educate and steer their members towards addressing the challenges associated with incontinence, and supports this through constructive educational events, targeted funding calls and research support, to help translate technologies for clinical use and patient benefit.

Industry: Responding to Patient Need

The level of enthusiasm that exists in the academic research community for innovation, particularly at Technology Readiness Levels 1–4, has been demonstrated recently by the IMPRESS network^[8], with areas covered including:

- nerve stimulation
- smart sphincters
- sensing capsules and bio-engineering

These activities have been driven primarily by academics and healthcare providers, often in response to challenges raised by people affected by continence problems. For technology at this level of development to move forward to the next stage, access to focused partnership funding initiatives that finance R&D would help capitalise on these opportunities.

However, there is a paucity and apparent lack of enthusiasm within industry for research and development aimed at addressing the challenges associated with continence problems. This is surprising given the size of the market opportunities that exist and the UK's strong engineering standing. A well-defined, engineering-based stakeholder community, focused on promoting advancement of continence technology could yield significant economic gains. The community model would need to be impartial, independent, and draw on collaboration through sharing expertise, skills and resources to create an environment that supports innovation. Incentives for this could exist via funding structures that support companies working in other sectors to engage in more R&D, or encourage the establishment of new companies developing innovative incontinence-based technology. Opportunities for advancing academic-derived technology within industry could be further supported by the creation of standardised academic research frameworks, that facilitate flexible industry partnerships through mutually beneficial exchange of ideas and handling of intellectual property.

The Institution recommends the creation of a forum for industry, academia, the NHS, governmental bodies, trade associations and research funders that will promote interaction between these groups to identify and address opportunities that exist for continence problems, and the provision of focused funding initiatives through the Research Council.

Government: Shaping Innovation Policy & Funding

Unlike diseases such as cancer, diabetes or HIV, incontinence is not considered to be a life-threatening disorder, and as a result has seen limited research funding over the last 30 years. While many areas of biomedical science share a growth in the engagement of engineers to push forward the exploitation of emerging technologies, it is often the case that the nature of continence issues prevents research leaders seeing the potential for innovation in this area.

The Government's recent Life Sciences Industrial Strategy^[9] seeks to create "an environment that encourages companies to start and grow, building on strengths across the UK, including expansion of manufacturing in the sector" and states "it is essential to create incentives for longer-term investment that will help new biopharmaceutical and medtech companies to emerge with products".

In order for industry to take up the challenge of addressing incontinence, the Government must incentivise an industry-linked drive for continence technology. The Institution recommends that Government implements the new Industrial Strategy framework. It must put in place a direct funding programme via the Research Council and Innovate UK, that will encourage medtech companies to enter the continence product market and to partner with academia and relevant charities to create a self-sustaining community of SMEs.

Recommendations

To enhance the impact of healthcare technology for incontinence, the Institution of Mechanical Engineers recommends:

1. The NHS establishes a cost-benefit procurement framework to recognise overall savings from increased use of incontinence devices.
2. The engineering community builds on initiatives like IMPRESS to establish incontinence treatment as a sector within the new Life Sciences Industrial Strategy.
3. The Government removes VAT from incontinence products to make their use, and hence their benefits, more widespread.
4. The Department of Health develops a public awareness programme to destigmatise all aspects of incontinence.
5. The NHS create a Continence Technology lead within every general hospital and PCT, which would help increase opportunity for identification and evaluation of new continence technology.
6. A forum for industry, academia, the NHS, governmental bodies, trade associations and research funders be created that promotes interaction, identifies opportunities and creates focus for funding incontinence initiatives/ research.

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Contributors

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