Continence technologies whitepaper: Informing new engineering science research

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Abstract

Advances in healthcare technology for continence have historically been limited compared to other areas of medicine, reflecting the complexities of the condition and social stigma which act as a barrier to participation. This whitepaper has been developed to inspire and direct the engineering science community towards research opportunities that exist for continence technologies that address unmet needs in diagnosis, treatment and long-term management. Our aim is to pinpoint key challenges and highlight related research opportunities for novel technological advances. To do so, we draw on experience and expertise from academics, clinicians, patients and patient groups linked to continence healthcare. This is presented in four areas of consideration: the clinical pathway, patient perspective, research challenges and effective innovation. In each we introduce seminal research, background information and demonstrative case-studies, before discussing their relevance to engineering science researchers who are interested in approaching this overlooked but vital area of healthcare.

KEY WORDS

Mechatronics in Medicine, Continence, Biomedical Devices, Medical Technologies, Incontinence

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Introduction

Incontinence is a highly prominent world-wide healthcare challenge, having a major impact on quality of life for millions of people, demanding increasing levels of resource from healthcare systems and resulting in profound socio-economic consequences. Incontinence does not represent a disease, rather a symptomatic condition with a complex and varied etiology. It can be summarised by an inability to control the passage of faeces through the anus (faecal incontinence - FI) or the involuntary leakage of urine (urinary incontinence - UI). Longstanding social stigma means that incontinence is frequently under-reported however best estimates suggest that between 3-15% of community dwelling adults experience FI (1) while for UI this increases to 24% (men) and 53% (women) (2,3), the latter figure highlighting strong causative links between incontinence and childbirth. While the prevalence of incontinence increases with age (1), this condition is not limited to the elderly and a significant proportion (0.8–7.8%) of children and young adults are also affected (4).

Many clinical challenges persist in the management and treatment of FI and UI. Applied research from the engineering sciences has significant potential to directly address these challenges and thus improve healthcare provision and quality of life. Unfortunately, despite the potential health and economic gains, there has been a paucity of technological innovation compared with major advances in other areas of healthcare for conditions of similar prevalence. This might reflect the social stigma often associated with incontinence, which not only affects patients, but can also act as a deterrent to engagement by researchers in clinical, industry and academic settings. However, it is increasingly recognised that there is a need to accelerate innovation and that this can be driven by research (5). Importantly, this is not limited to the development of new technology, but extends to exploring ways to improve existing systems.

Figure 1 illustrates the key technologies and associated research linked to continence technologies. A steady and significant rise in research output is evident over the last 30 years. While this trend may be exaggerated by a more general increase in publication opportunity, it demonstrates that innovation is active within this clinical area and reflects market demands linked to an aging population (6). However, the challenge remains to ensure that this research is translated into sustainable outputs that will deliver real-world patient benefit. This is exemplified by the absorbent pads/pants used to manage fluid discharge which historically were home-made re-usable cotton pads until fluff was introduced in the nineteenth century to improve absorbency. Commercially available disposable products appeared in the 1920s and were in widespread use by the 1940s (7). From 1980 the absorbent pad market was revolutionised with the introduction of super-absorbent polymers which could safely hold far higher volumes of fluid thus dramatically improving the performance of products (8).

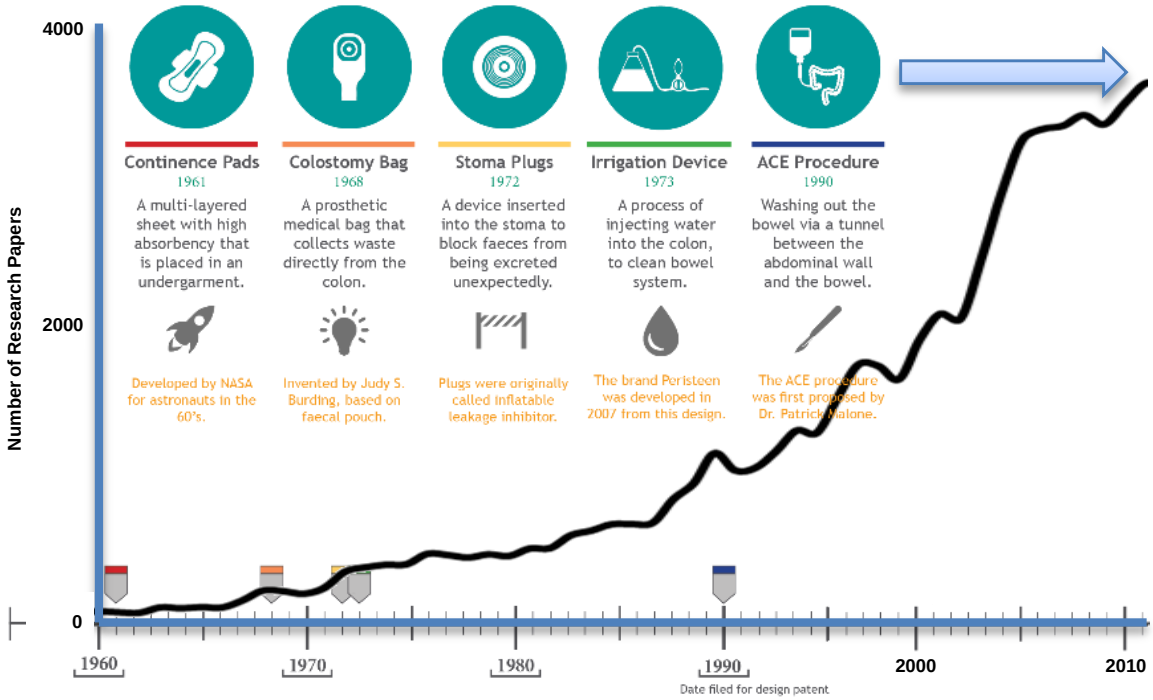

Figure 1. A timeline showing the introduction of key continence technologies and research activity in the area. (Source: Scopus)

This whitepaper has been developed to inspire and direct engineering-based research towards continence technologies, addressing improvements in diagnosis, treatment and management. Our aim is to highlight key clinical challenges, and patient needs, that incontinence brings and to share related opportunities for novel engineering science to address these areas. To do so, we draw on research, communication and case-studies from academics, clinicians, patients, incontinence charities, industry partners and funding bodies. The paper is organised into four sections; **The Clinical Context** presents key clinical aspects of healthcare for continence and significant co-morbidities, **The Patient Perspective** describes the associated needs of people who live with incontinence and thereafter **Research Challenges** identifies key technological challenges and opportunities that must be addressed to transform continence health care. Finally, **Effective Innovation** guides researchers on responsible practices to develop and translate research in this socially sensitive and clinically critical area.

The Clinical Context

Incontinence is the lack of controlled release of urine or faeces. The root cause of these events can often be multifactorial and complex to determine. Waste products are stored in the body prior to emptying, urine in the bladder and faeces in the rectum. In order to evacuate these compartments the waste material is passed through controlled openings called sphincters. Sphincters are muscles controlled by either somatic or autonomic nerves (voluntary or involuntary) and are opened in a healthy evacuation when sufficient pressure in the storage compartment leads to the sensation of 'urge'. A failure or reduction in the effectiveness of these processes can lead to varying severities of incontinence (9). Failures can be grouped into structural issues with the sphincters or supporting musculature (e.g. obstetric tearing or surgical trauma), damage to the nerves (e.g. neuropathy and surgical trauma) and cognitive issues (e.g. dementia).

Incontinence Healthcare

Clinical intervention for incontinence is a complex process involving a large number of possible 'pathways' and different healthcare professionals, a reflection that this is a symptomatic condition with a wide array of co-morbidities and causative factors (10). In broad terms, the role of healthcare professionals, and related technological needs, can be categorised into those of assessment, intervention and management, and training.

Assessment

Assessment is essential to allow correct identification and diagnosis of conditions and subsequently to inform management and intervention. Assessment methods are often intrusive and traumatic for the person involved. Typical features of assessment are unnatural positioning and social discomfort for the patient, which may compromise the validity of test results. Assessments can be subjective, requiring skilled interpretation to interpret images or readings in relation to the patient's history and presentation (Figure 2). Furthermore, it remains challenging to combine outcomes from different modes of assessment to get a comprehensive evaluation of an individual's condition and function (11,12). For example FI may be dependent on a number of physiological mechanisms so investigation requires linking evacuation defaecography which highlights pelvic floor dynamics and structural alterations, with manometry which measures pressure in the anorectum to assess the muscular contraction and relaxation of the anal sphincters (13).

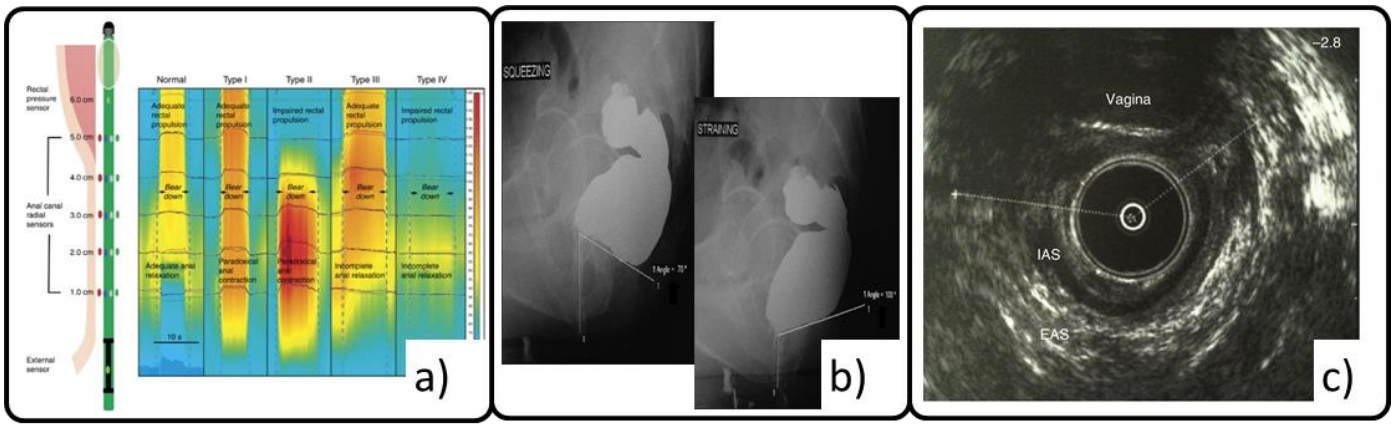

Figure 2. Outputs from key clinical tools used to assess and diagnose FI a) high resolution anorectal manometry shows the pressure distribution along the anal canal (14) b) evacuation defaecography shows movement of anatomical structures and anorectal angle change during defecation, helping to highlight abnormalities (15) and c) endoanal ultrasonography provides cross-sectional views of the anal canal enabling identification of muscle and soft tissue defects (16).

Intervention and management

Following assessment, treatment options vary depending on physical health, age, mobility, and the presence of confounding factors. In general NICE guidance for UI and FI recommends starting with conservative approaches before committing to more invasive options, as shown in Figure 3 (17–19). The aim is to achieve the best functional outcome for the patient while minimising potentially unnecessary risk or trauma such as surgery under general anaesthetic. Time is typically not a critical factor in terms of the condition changing and this gives opportunity to explore more conservative interventions. Predicting which treatment strategies will be effective and for how long is often difficult so the exploration of intervention and management options is crucial but it can be a long and frustrating process for the patient.

Management and treatment of incontinence are often treated as different topics but in reality they lie at different ends of the same intervention ‘spectrum’. Management is generally used to describe long-term activity to promote continence by performing a regular action (20) and for some, where surgical treatment is not an option, it will become a life-long commitment. Common management includes daily use of continence pads, self-catheterisation or transanal irrigation to minimise the functional impact of incontinence (17,21).

In cases where the opportunity for surgical intervention exists, choice in this area is limited. Options include repair of damaged sphincter tissue, use of mesh and tape to support the pelvic floor and associated structures, sacral nerve stimulation and implantation of ‘neosphincters’ to augment function of the biological sphincters (22–25).

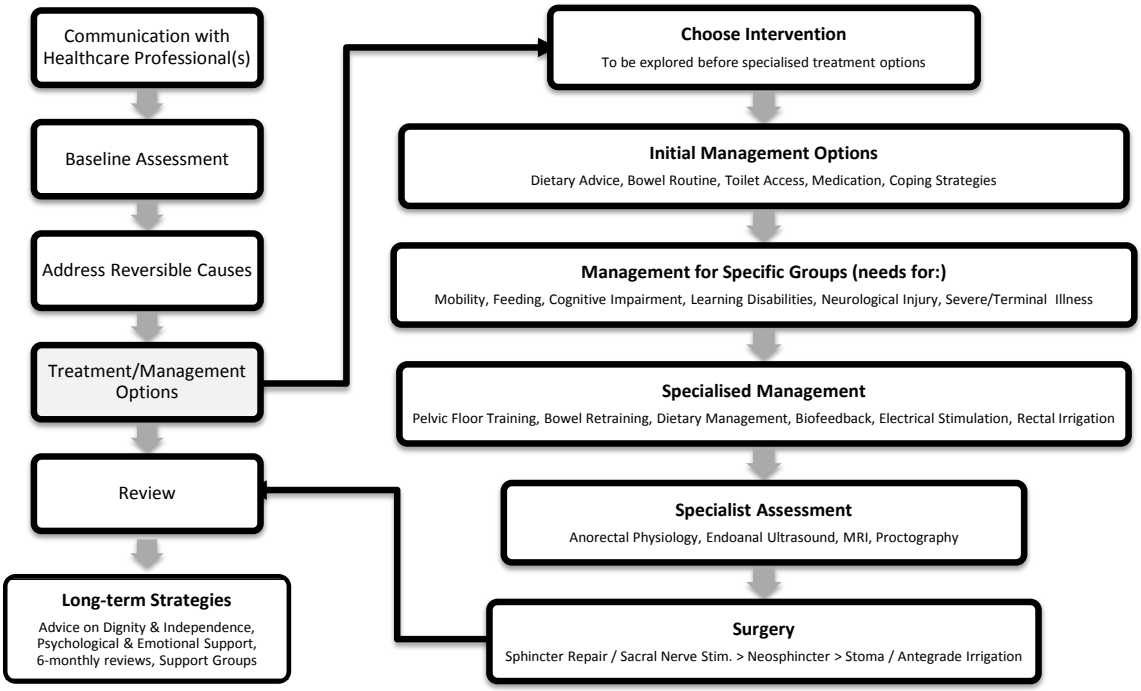

Figure 3. A summary of NICE Guidance on the treatment pathway for faecal incontinence in adults (19).

Multi-Morbidity

By 2050 the global population of older persons is projected to be more than double its size from that at 2015, reaching nearly 9.8 billion. As a combined result of both demographic and epidemiological changes, many people are now living with more than one long term disease as well as the symptoms and consequences of specific conditions - a complex scenario broadly referred to as multi-morbidity. Multi morbidity can affect people across the life course, but the prevalence is much higher in older age group. 65% of people aged 65-84 years and 82% of people aged at least 85 years are affected with those over 85 having on average over 7 or more conditions (26).

Dementia draws attention to the complex challenges of addressing multi morbidity. Over 1 million people in the UK have dementia, and 135 million are projected to have dementia worldwide by 2050. People with dementia have among the highest levels of multi-morbidiity of any long term disorder (27). As the population ages the prevalence of dementia and incontinence is increasing, as are the number of people living at home with both these conditions (28). Incontinence is common in people with severe dementia and those approaching the end of life and is a powerful predictor of admission to long term care facilities. Over 50% of people living in UK care homes have dementia and incontinence (29).

Urinary incontinence is a common symptom of Parkinson's disease (PD), as the brain's control of the sphincter is disturbed and the bladder becomes overactive and wants to empty even when there is just a small amount of urine present, resulting in urgency, frequency, incontinence and repeated night-time urination. Further research is needed on

devices and techniques to best manage incontinence in people with conditions like dementia and Parkinson's and to develop appropriate care pathways for these populations.

Clinical Pathways

When new technologies are developed they need to fit both into patient's life, and into existing clinical pathways, if they are to be successfully adopted. A new technology must offer benefits when compared to existing practices. This may be by improving diagnosis/treatment or management, or it may be equivalent to existing practice but save time or reduce cost. New technologies that require users to be trained or learn complex activities, or require significant behaviour change or upfront costs, can find adoption into practice difficult.

Innovation in bladder diaries is an example of how technology can be designed with clinical pathways in mind to improve healthcare and reduce cost. An electronic bladder diary system has been developed with guidance from patients and GPs to provide a digital alternative which meets patient needs and fits with clinical practice (30). Existing bladder diaries are paper based, non-intuitive, and require calculations to be performed by the GP, and as a result the collected information may be incomplete and/or inaccurate or not used to full effect. By performing functions such as automating data collection, storage and analysis, this digital system helps reduce GP workload and enables patient adherence to be monitored remotely. These systems must ensure that they are accessible and can accommodate different age groups, and those with visual or physical impairments (e.g. limited manual dexterity). Further research is required to fully investigate these factors. However, if successful the information collected can help inform treatment, which may include prescribing lifestyle changes, medication, requesting samples for further diagnosis, or referring the patient on for assessment by a specialist.

Key points:

- **Current assessment methods can be invasive and often traumatic, and evaluation across different modes of assessment is challenging.**
- **Management of incontinence can be a lifelong commitment and there is an increasing need to consider multi-morbidities.**
- **New technologies must offer benefits over existing practices and be user friendly.**

The Patient Perspective

Considering the clinical implications alone neglects the intense psychological impact of incontinence (particularly FI) and its powerful effect on an individual's wellbeing, health and life. This section considers key needs from a patient perspective, combining research literature with personal accounts from people with incontinence, illustrated in Figure 4, to highlight their relevance and impact on everyday life.

Enhancing Self-Confidence

Self-esteem is often significantly impacted by the social stigma associated with incontinence (29), so building a strong foundation of self-confidence is crucial. Studies on the prevalence of incontinence suggest that many people living with incontinence suffer in silence rather than looking for help (31). Key factors which influence people's self-esteem are the unpredictability associated with continence, a need to feel 'normal' and having sufficient knowledge to empower decision making.

Addressing the complicated, erratic and unpredictable nature of incontinence is one of the greatest worries for individuals who do venture out in public and creates an overwhelming feeling that life is out of control. In an effort to take charge of their condition it leads people to restrict diet, become preoccupied with access to toilet facilities and significantly limit what they do (32,33). To feel normal people instinctively want to hide their incontinence and many individuals relate the profound distress experienced as a result of accidents. It is critical that technology can help meet these demands, with a form, function and performance which causes minimum disruption and can be relied upon. FI episodes are consistently reported as being the most difficult and degrading but although many people find anal plugs useful, their performance is limited so that in the context of a major episode they fail. One further example is the 'rustling' noise made by stoma bags as they move whichis frequently a cause of complaint even though it is secondary to their main function as a containment system. Another recurring topic is smell and odour. Currently no products exist which give people confidence to believe they don't smell even when the incontinence is contained and there is clear opportunity for technologies which reinvent how smell is detected and controlled (34,35).

Better understanding of what causes incontinence and how it can be managed or treated empowers people to have the confidence to make decisions regarding the treatment choices available and, where appropriate, challenge what is offered to them, rather than 'make do' with treatments that are not best suited for them. (36–39). Lack of, or inaccurate, detailed information about the treatments available for their condition can result in people settling for coping alone, believing that the medical help offered is not individually tailored to their unique case. Recent initiatives like the web-based "Continence Product Advisor" have started to address this by placing evidenced information on continence care into the public domain in an accessible form (40) but there is also a need for personalised advice to give people the confidence to try, and to persist, with the medical solutions being offered (41–45). This is particularly relevant for

long-term interventions like pelvic floor retraining in which improvements are likely to be incremental, so effective information feedback is vital to promote engagement.

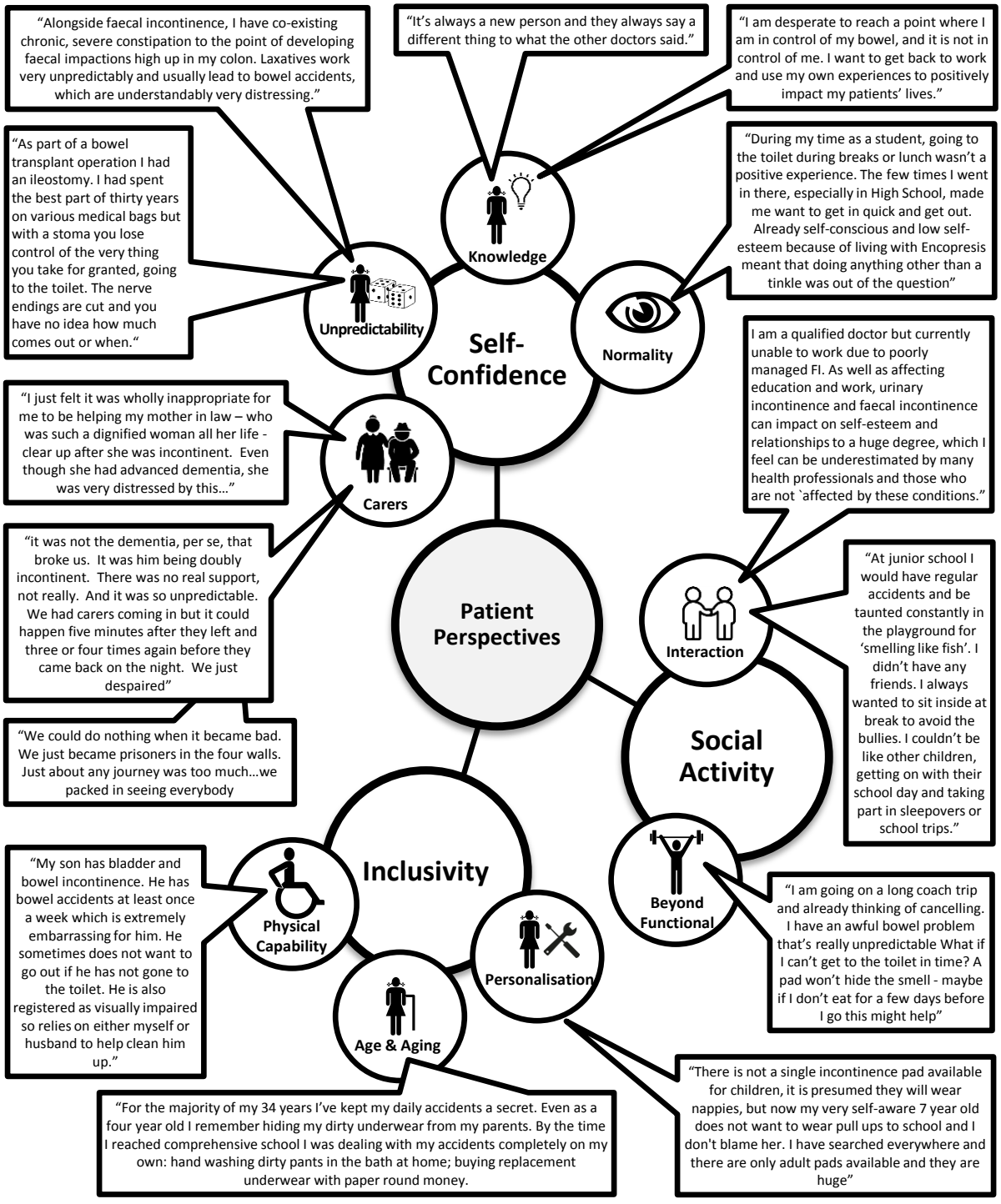

Figure 4. The Patient Perspective: personal experiences relayed by users of continence technology. Sources: IMPRESS Network[1], NIHR Devices for Dignity[2], ERIC UK[3], BBUK[4], VOICE North[5].

Supporting Social Activities

Active participation in social activity is key to maintaining good quality of life. These activities enable people to maintain, rather than shy away from, social contact and to pursue life-enhancing experiences. The challenges posed by incontinence in this area can be difficult to assess but their importance should not be overlooked (46).

Social interaction is a common challenge for those affected. There is a need for security in daily social contact to help individuals interact fully in school, at work and through leisure pursuits rather than avoiding these activities, and the associated social interaction, due to their condition (47). Equally, the emotional and physical consequences of incontinence can disrupt sexual function and/or behavior, placing strain on intimate relationships (48,49).

Technology should not stop at allowing people to 'get by' with their condition, but should also aspire to facilitate popular life-enhancing experiences such as sport and travel. It needs to empower individuals to pursue the hobbies they enjoy, unrepressed by their condition and without fear of embarrassing incidents (50,51).

Raising Inclusivity

The diversity of people affected by incontinence creates a variety of individual needs but continence technologies have traditionally been designed to serve a far more limited population. Adopting inclusive, adaptable design practices would help to bring benefit to a far broader range of those affected by incontinence.

Age, and aging are factors with particular resonance for incontinence because the physiological mechanisms associated with continence change as part of the natural ageing process. There is a consequent need for technology which can help improve quality of life for people of all ages across the life course. A key issue for users of every day management products such as pads is the need for a new direction towards a product that can adapt, or be adapted, to personal size and shape. The options available to people could be improved by introducing a comprehensive range of age appropriate or age adaptive solutions. Personalisation must include often overlooked users such as children beyond toilet training age for whom there is a huge deficit in provision, or dementia sufferers requiring products which can adapt to diminishing mental function (52–55).

[1] www.impress-network.com
[2] www.devicesfordignity.org.uk
[3] https://www.eric.org.uk/
[4] www.bladderandboweluk.co.uk/
[5] www.voicenorth.org/

There is also much scope to improve the provision for people with physical impairment which often co-exist with incontinence such as age related arthritis and visual impairment, spinal injury or Multiple Sclerosis. Technology has the capability to break down barriers to self-management that currently exist for people with a physical impairment, enabling people to perform daily toileting routines autonomously and thereby maintain independence.(56,57).

Caring for someone living with long term conditions can be challenging, with continence problems having the greatest impact. New designs need to be mindful of the profound effect incontinence has on carers and those living with people affected by it (58). The experience is often stressful, physically demanding and can inhibit employment (55). In many cases carers and family members could often benefit from greater inclusion, training in areas such as changing catheters and washing the person safely, and involvement in decision making (59).

Key Points:

- **New technology must address the need for normality and personal confidence – mininising lifestyle and ensuring reliable 'failsafe' performance**
- **Smell is unchartered. There is opportunity to address how smell is detected and/or controlled.**
- **There is a real need for personalisation inclusivity in design for all ages, those with physical and mental impairment and multi-morbidities**

The Research Challenge

For continence technologies, the research challenge encompasses a wide range of underpinning knowledge and technology. Here we highlight and discuss key engineering and physical science challenges which include both the development of new understanding and technology, *and* the translation of extant technology to this often overlooked field (60). Addressing these challenges has the potential to bring forth disruptive changes or to bring incremental improvements in overlooked areas. In turn this will help bring short and long-term benefits to the diagnosis, treatment and management of continence to profoundly improve the lives of sufferers.

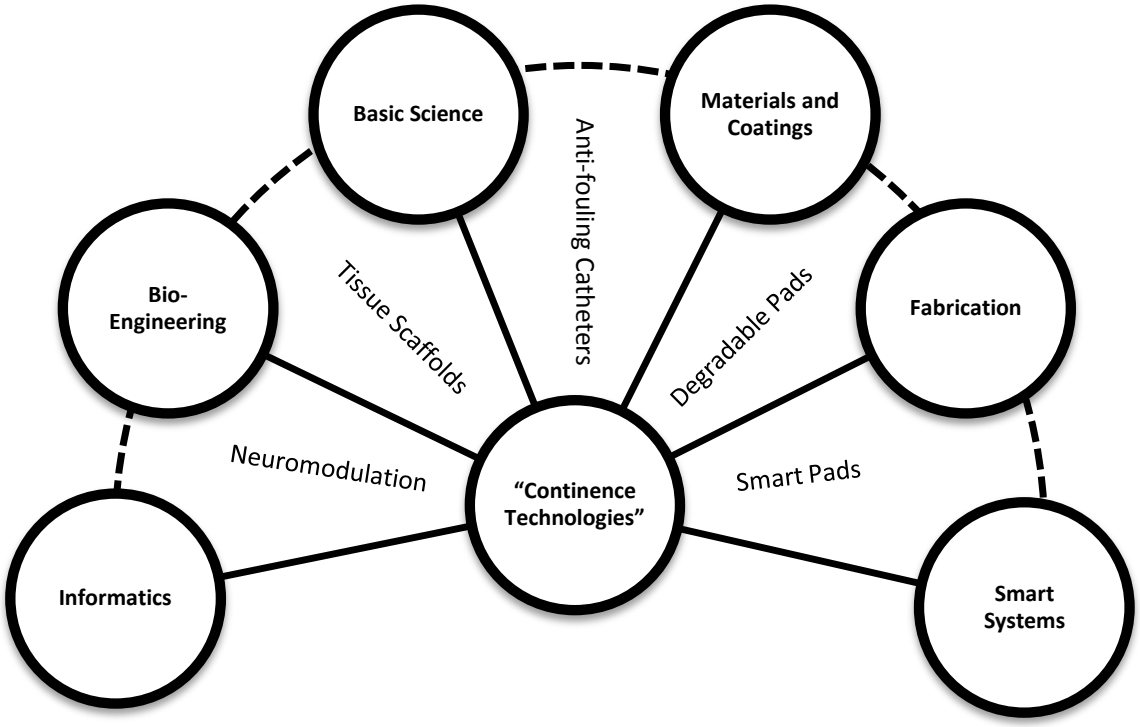

Figure 5. A summary of key research fields of relevance to continence healthcare and associated opportunities for technological advances

Basic Science

Interdisciplinary basic science research, combining materials science, mechanical and chemical engineering with biology, including biochemistry, cell biology, molecular biology and neuromuscular physiology, is essential in achieving better continence healthcare.

Improved understanding of the pathophysiology underlying the onset of incontinence is essential, firstly to bring clarity to what can be considered part of the 'normal' ageing process and secondly to understand the impact of ageing on progression of the condition (61). In addition, research needs to take into account the differences in anatomy between the sexes, in particular to better define the changes which occur with pregnancy, childbirth and during the postpartum period (62). These advances have the potential to

inform preventative measures, by identifying 'at-risk' populations and intervening appropriately, as exemplified by efforts to use stem-cell injections as a therapeutic intervention immediately after childbirth to accelerate the healing process (63).

The use of new imaging techniques combined with basic science will be instrumental in improving assessment of incontinence by providing a better picture of how the complex physiological mechanisms operate and are effected over time. For example, near infra-red spectroscopy (NIRS) can reveal the hemodynamics of musculature while open MRI can reveal its 3D structure, thereby helping to quantify the functional performance of the pelvic floor (64). In tandem, it is important to note how new imaging techniques can act to reduce the invasiveness of clinical assessment and diagnosis which is currently cited as an invasive and unpleasant experience (often leading to poor compliance).

Research exploring the neuromuscular action of the bladder and bowel has transformed our understanding of how these structures are actively controlled, featuring complex feedback systems which respond to a range of physical stimuli (65). However, more research is required to advance neuromuscular science and inform technologies such as neuromodulation which has brought life-changing improvement in continence for many patients despite a lack of understanding on its specific functional mechanisms. This will also enable clinicians to better identify patients in which these interventions are likely to be successful, avoiding unnecessary and costly trial evaluations (24).

Materials and Coatings

The advent of new materials and coatings has produced incremental benefits for continence. Notable examples include the emergence of disposable stoma bags and more recently pants and pads with super-absorbent properties. A variety materials are now available that directly interact with tissues in the body to provide support, deliver active ingredients, or provide guidance of new tissue growth. This includes synthetic materials and biologically-derived materials that may be permanent implants or dissolve over time. Synthetic polymers (e.g. polypropylene, polyethylene, PET, ePTFE have been widely used for pads, catheters, surgical meshes, and stoma bags (66–68). Materials have been used to augment anatomical structures, for example polyacrylamide hydrogels used as a bulking agent to treat urinary incontinence in women (69)). Other materials can support cell attachment, proliferation, and differentiation. Flexibility in the manufacture and processing of these materials allows for the ability to tailor their chemistry and rates of biodegradation (70). The application of materials science is not restricted only to polymers. Metals have also been used in devices for load bearing applications. For example, artificial sphincters which utilise titanium and iron-based materials for structural and actuation functionality (71). Although over the years significant progress has been made in the design of novel material formulations, multiple challenges remain. Among these, the most critical are acute and chronic foreign body responses, the risk of infection, and the presence of inappropriate mechanical properties.

Over the past decade efforts have been made to optimise catheter surfaces in an attempt to reduce the occurrence of urinary tract infection and encrustation (72,73). Organic and

inorganic materials have been mooted as potential methods of reducing bio-film formation and increasing lubricity. Hydrogel coatings (i.e. networks of crosslinked polymer chains in an aqueous solvent) are available and effective in reducing bio-film formation, trauma and encrustation due to their hydrophilic nature (74,75). However pain during insertion, erosion of mucosal and uro-epithelial layers, encrustation and infection is still common with catheters. There is opportunity to continue advancing this field; a wide range of polymer-based systems exist commercially, whilst many more are being actively developed by researchers. These range from simple hydrogel coatings to complex gel chemistries containing active and passive antibacterial and antifouling additives. Without doubt, a functional catheter-biology interface is key if successful intermittent and indwelling catheterisation is to be achieved.

Fabrication

In developing new technology it is beneficial to work with a range of specialists that have the ability to address different aspects of the product design-cycle as early as possible. Valuable contributors might include clinical engineering departments within hospitals, departments within universities such as engineering, chemistry, design or computing, design consultancies, and potential future licensees for the technology under development. Rapid prototyping has made the product design and development process more accessible to individuals with new ideas they would like to test (76). Careful product design can make the difference between a new item of technology being accepted, tolerated or rejected by end users. For instance, users of continence products continue to seek alternatives to bulky and non-washable, non-flushable continence pads. A well-managed product design process encompasses user interfaces, production methods and capabilities, planning for potential medical technology regulations, and may involve many iterations. These aspects are all in addition to the underlying function of the technology and may help the technology to meet usability engineering requirements for regulatory compliance.

Further difficulties can arise when trying to upscale production of tested technologies into medium or large scale, as these cannot usually be produced within hospital or university facilities. Additionally, high cost-per-item sums may be appropriate when costed into a research proposal, but cannot usually be carried through to scaled-up production. It is therefore instructive to seek manufacturing expertise early in the development cycle, as manufacturers will be able to advise on potential costs-saving production methods, and can provide crucial advice on what is (or is not) feasible at scale.

Smart Systems

Smart systems describe the application of sensing and/or actuation technology to transform previously ‘passive’ devices into ‘active’ systems with the capacity to monitor and react to the environment. Key challenges of applying such technology to incontinence are the challenging working environment (including contact with human tissue, reactive fluids and movement), delivering cost-effective solutions (e.g. is it feasible to instrument a disposable/single-use product) and biocompatibility/bio-

integration (e.g. to avoid aggravation of sensitive tissues). However, research advances in fields including materials, electronics and communications can help overcome these challenges to bring innovative new technology for assessment, treatment and long-term management of incontinence. For example, researchers have developed a 'smart diaper' by embedding a moisture sensing Radio-Frequency Identification Tag (RFID) tag into the absorbent pad so that its absorbent capacity can be determined (77,78). The combination of technology is important since RFID provides a low cost solution (suited for disposable pants) in a biocompatible form which can be monitored wirelessly and remotely (e.g. via a smart phone) without obtrusive connective wires. This has particular relevance in care home settings, making it both quicker and more efficient for nursing staff to monitor their patients and ensure they receive optimum care. Another form of sensing with the potential to be transformative is a wearable odour sensing system with the ability to detect, with high sensitivity, the presence of smells associated with incontinence (79). Using a similar approach to smart pants/pads, real-time feedback is provided wirelessly to a smartphone device, in this case informing the wearer about relevant odour levels. This illustrates the capacity of technology to address common personal anxieties associated with incontinence such as 'smell' and 'normality'. There is opportunity for further innovation in the combined use of different sensing modalities and implantable sensors for long-term monitoring (80). This is highlighted by early research into implantable sensors to monitor attributes of the bladder like pressure, volume and contraction (81–83). The use of actuators is less developed but recent research highlights their promise to address and transform areas where no solution exists, particularly in faecal incontinence. Key examples include a smart biomimetic sphincter using electro-active-polymers (EAPs) (84) and a novel artificial sphincter using active pressure control to prevent tissue erosion (85).

Informatics

Informatics is a growing field in healthcare, used to explore how clinical interventions affect the patient perspectives of self-confidence, social activities, inclusivity; as well as its impact on clinical practice. Its growth has been catalysed by advances in digital and cloud technologies, notably the ubiquity of mobile devices which can be used for data gathering, storage and analysis of healthcare data, often termed 'MHealth' (86).

There has been limited application of informatic and MHealth technology to address healthcare for continence, yet this represents an area in which huge gains could be made for patient benefit. A mobile app developed to guide self-treatment of stress urinary incontinence (e.g. through pelvic floor exercise regimes, dietary and lifestyle advice) has demonstrated the ability to bring clinical relevant improvements and furthermore bring cost benefits to healthcare providers (87,88). Other research demonstrates that these technologies can be scaled to provide comprehensive healthcare support which is tailored to different populations through specialised apps (e.g. to support self-catheterisation and bowel management) together with facilities for interaction with clinicians and monitoring adherence to self-care regimens (89).

The main challenge for informatics is developing robust evidence. This is currently hindered by the lack of published studies as there is a relatively small population to sample from combined with the difficulty of breaking through the intimate nature and social taboos associated with continence. For example, current studies use a variety of data collection methods from case notes to Skype or other online calls. Whilst this may provide researchers with effective data collection tools, it is difficult to standardise the results/outcomes from such research, and the method has the potential to introduce bias when interpreting results. Advances in informatics need to consider the impact of having clear measurements of success and/or clinical outcomes. Patients need to be able to provide their clinicians with critical information that will enhance their self-confidence, and clinicians need to be able to interpret this information using tools and resources to standardise the quality of information coming through (90).

BioEngineering

Biomedical engineering, encompassing tissue engineering and regenerative medicine, hold significant promise for the treatment of incontinence. Applications of this technology are already undergoing clinical testing for incontinence and a plethora of other approaches within this field are on the horizon.

Cell therapy of sphincter tissue offers an exciting opportunity to repair and recover function. Studies using autologous cells, such as myoblasts (muscle precursor cells), explanted from other sites and transplanted into sphincter muscle, have demonstrated this is technically feasible and safe (91,92). This application of cell therapy has been studied extensively for UI, with evidence of new, functional muscle following cell delivery (93). Challenges remain in harvesting appropriate cells and delivering them to the target site, an area which remains a focus of current research (94,95).
An alternative approach to cell therapy is the use of three-dimensional bioengineered muscle constructs. These are being developed as replacements for damaged or degenerated sphincter muscle. The constructs exhibit physiological functionality and also provide a useful tool for studying complex physiological mechanisms underlying sphincter malfunction (96,97). Pre-clinical research has demonstrated the feasibility of surgically implanting the bioengineered construct into rodent and rabbit models of FI (98–101). However, the practicality of scaling-up bioengineered constructs to a size applicable to humans (102), complete with innervation, vascularization and cell viability, remains untested. Before translating to humans, new approaches for retaining the mechanical properties and function of the sphincter complex will be needed, along with robust and stable large animal models of incontinence for testing the efficacy of the bioengineered constructs.

In addition to replacing dysfunctional sphincter muscle, it might also be possible to condition injured or degenerated muscle to improve continence. Cells convert mechanical stimuli into intracellular biomolecular signaling via mechanotransduction. Healthy muscle undergoes hypertrophy in response to mechanical loading and stretching. Muscle found in the sphincters that control bladder and bowel function are likely to respond in a similar manner if given an appropriate stimulus. Innovative engineering-based

technology capable of delivering mechanical strain to these muscles could provide the environmental cues necessary for stimulating therapeutic benefits. One approach envisaged might be the use of magnetic actuation to deliver mechanical strain, similar to that described for other cell types (103). Non-invasive technologies, such as actuation at a distance using magnetic force, to recondition sphincter muscle would be particularly beneficial, especially if it could provide new treatments and assistive technologies for rehabilitation at home.

Key Points:

- **Advances in basic science are required to inform existing and new healthcare interventions (from cell therapy and tissue engineering to neuro-stimulation)**

- **New materials, fabrication and manufacturing approaches can be applied to improve product performance, choice and achieving environmentally friendly products (e.g. biodegradable pads).**

- **Through user-centred design, extant technology and engineering science could be translated to great impact (e.g. adapting smart systems and informatics technology used in diabetes care to inform continence management).**

Effective Innovation

Developing continence technologies is inherently an applied and multidisciplinary area. The concept of 'translating' research from 'bench to bedside' is now well recognised and has received particular attention in the pharmaceutical industry, where numerous models have been developed to guide the process of translation and commercialisation toward clinical benefit (104). The process is less well defined for non-pharmaceutical technology and involves different mechanisms, procedures and regulatory requirements. However, common themes are apparent, in particular the need to combine basic and applied science, have close involvement of end-users (or 'stake-holders') and to have a well-defined (and funded) route from early-stage lab research toward commercial product and clinical utility (105). This section considers some of the key factors involved in the technology translation process, highlighting that it is not sufficient to have good technology alone to bring about patient benefit.

Industry Engagement

Industry engagement is vital to research as it enables the transfer of knowledge from the academic and clinical communities into commercial applications/products. In order to maximise the returns on industry engagement, it is important to find the right industry partner. This involves identifying an opportunity or problem that industry could address if it had access to the knowledge from academic and clinical communities. In general, universities tend to be best placed at providing access to researchers and the coordination of agreements, IP and delivery conditions, with the NHS having access to clinicians, clinical engineers, device regulatory expertise, and patient network (these functions are coordinated through the NIHR Office for Clinical Research Infrastructure). This helps partners to build trust in the collaboration which will contribute to adapting the knowledge to fit the specific needs of the business processes and markets.

Regulation and Approval

In the UK, regulation of medical products is overseen by the MHRA (Medicines and Healthcare products Regulatory Agency[6]) who grant medicinal licenses to manufacturers and monitor the CE marking process for medical devices. The complexity in navigating the regulatory framework to bring a product to market is dependent on the type of product and the risk classification. In general, if the intended function of the product is not achieved through pharmaceutical means, but by physical intervention, then the product is classified as a medical device and is regulated by EU directives and regulations. The risk classification depends on a range of factors and is important to determine as higher risk products require greater premarket evidence for approval to be granted. For the highest risk category a clinical trial is mandatory. The European Commission provides detailed guidance (MEDDEVs[7]) on all aspects of the medical device regulatory process.

The importance of understanding the regulatory process is underlined by the surgical mesh kits introduced to provide pelvic floor support. Commercial drivers saw the product

[6] www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency
[7] http://ec.europa.eu/growth/sectors/medical-devices/guidance_en

pushed through clinical evaluation and it received less stringent regulatory scrutiny than it should, eventually receiving FDA approval and widespread use throughout the USA. Unfortunately, the product had significant flaws, resulting in high rates of erosion, infection and failure; devastating for those people involved and with wider impact on this area of healthcare as a whole (106).

User Engagement and Public Awareness

Many people living with UI and/or FI are reluctant to talk about their condition in public. Therefore engaging them to be directly involved in developing new technology might require a different approach to conventional modes of research. Patient and public involvement in research is increasingly expected, if not required, by research funding bodies and provides the valuable but often overlooked patient perspective of new technology. An example of this is a questionnaire survey, conducted to gain opinion regarding a biomedical engineering approach to prevent or treat post-obstetric incontinence (107). It is therefore imperative that research encompasses the perspective of the end user (both patients and healthcare professionals) so that new technology addresses real needs or shortfalls in provision, and that it's mode of operation is acceptable to users and can integrate into effective clinical practice.

Patient-representing charities can be a valuable source of patient input and patient volunteers, and charities, are increasingly working together around clinical issues to create force for change. In 2016 ten charities and health organisations, and the priority setting organisation James Lind Alliance, formed a Priority Setting Partnership (PSP). The group met with patients, carers, researchers, and healthcare professionals to discuss and explore continence; the output of this PSP includes a series of needs and recommendations for addressing incontinence research and development of solutions. Recommendations include a need to address the lack of health economic evidence for incontinence interventions, the awareness of researchers of the need to include patients and carers in the development of interventions that affect them, and improving access to training and education for patients and carers to self-manage and share expertise.

Due to the high level of stigma associated with incontinence there is a particular need to be sensitive to upholding the level of privacy and confidentiality required by each individual participant. This may vary widely from person to person and research methodology should be designed appropriately in this respect. As for all research involving patient involvement, projects should be amenable to the needs of patients. Best practice for public and patient involvement is constantly evolving, and groups such as NIHR INVOLVE can be approached for guidance.

Socio-Economic

Many people still see incontinence as an inevitable part of ageing, which, combined with the taboo around it, means they don’t engage with health services or feel comfortable pushing for the most appropriate treatments if their treatment isn’t adequate.

It is crucial that Health Economic factors are considered when developing technology for incontinence. In today’s society, healthcare systems are increasingly resource limited and

those with incontinence may need to financially support their own care if products are not available through the NHS. Accordingly it is important that technology is developed to be cost effective and appropriate to as large an audience as possible.

IP management:

Intellectual Property (IP) is the concept which enables the ownership of ideas and concepts which have practical applications and commercial potential. It is important to secure the services of an IP specialist/expert as continence patients and carers can be a source of these new ideas and concepts. The identification of the actual IP is very important and the services of an IP specialist are key at this stage. Once the IP has been identified, steps must be taken to protect it and this involves exploring the different levels of legal protection available. The protection of IP is done via a set of agreements involving all parties that have access to these ideas and concepts. While most are familiar with the concept of third party agreements, employees or those close to the innovation also need to understand their responsibilities and it is important that opportunities for IP awareness training are made available. In the UK, the Academic Health Science Networks, Medipex and Medilink are all organisations offering a variety of training and educational opportunities to support responsible innovation in this area.

Key Points:

- **Engagement with industry at an early stage is vital for effective translation of research to commercial products**
- **Patient engagement is critical but in this field requires an approach sensitive to individual needs for privacy.**
- **Health Economic factors are important and should be careful considered alongside re-useable and disposable aspects of designs.**

Discussion

Current delivery of continence healthcare is skewed toward secondary and acute care settings, a reflection of current clinical pathways (see Figure 3) and the severity of conditions with which many patients present. However, this places a huge resource burden on the healthcare system and arguably results in a sub-optimal experience for many patients. In response, advisory groups and policy makers are advocating a move toward community-based healthcare for incontinence in which assessment, diagnosis and intervention can be deployed in small-clinic or home settings. Technology can, and should, play a key role in supporting this movement, for example driving improvements in less invasive and more precise assessment, providing m-Health systems to inform self-management and advancing basic-science to support cell therapies for both prevention and 'cure'.

A key theme in continence healthcare is personal empowerment and inclusivity which is closely coupled with provision of choice. The UK market is now dominated by disposable versions of previously re-usable incontinence products such as pads, pants and catheters. While these represent technological advances (e.g. in materials) they have also limited personal choice. Re-usable products (e.g. bed pads, swimwear and underwear) remain an important part of continence management and some people, whether for economy or preference, still use 'homemade' systems such as terry toweling squares (either alone or in conjunction with a disposable) to manage very heavy incontinence (108). This highlights that availability of choice is strongly governed by the diversity of products manufactured by industry and that this can often be adversely affected by commercial factors (e.g. consolidating product/size ranges to boost economies of scale) and regulatory aspects (e.g. promotion of single-use medical products).

A move to increased use of technology by patients and carers, particularly in non-supervised settings, brings the potential pitfall of misuse, which may compromise the assessment or intervention. Therefore it is imperative to adopt user-centered design principles to understand, define and meet user needs and environmental constraints. The nature of incontinence means this is non-trivial task, since patient needs are diverse, span a broad age range and are often confounded by co-morbidities, as summarised in Figure 4. However, it also presents an opportunity in which technology can be used to help deliver personalised interventions that can be customised to better meet patient need, for example 'smart' systems which alert the user of a need to change their pad. This links to common requests from patients that they wish to proactively manage their own condition, rather than being overly reliant on healthcare services.

The personal and societal challenges associated with incontinence can often be severely life-limiting, impacting profoundly on activities of daily living and limiting social interaction. Perhaps as a consequence, the expectations for technology are often focused on enabling that person to cope with a minimum set of activities, for example maintaining continence for sufficiently long to enable them to go shopping or use public transport. For many people this is a valuable achievement, however others aspire to expand their lifestyle activities, for example taking up new sports or leisure activities, and

require technology which can cater to these demands. This might manifest in products such as stoma bags capable of supporting high levels of physical activity, or intermittent catheters with surface treatments enabling safe re-use to facilitate travel. Ultimately, there is the potential, and patient need, for technology which empowers the individual.

Perhaps the key motivation of engineers and scientists working in this domain is to bring benefit to patients through application of their technology. It should be recognised that the route of translating technology 'from bench to bedside' is challenging and time-consuming. Adopting an effective innovation strategy could be considered as important as the technology itself. Many excellent technologies fail due to aspects of commercialisation revealed by health-economic analysis, IP due diligence and regulatory investigations. Furthermore, the inherent 'inertia' in healthcare systems mean that introducing a new technology requires a compelling Cost-Benefit argument. Existing pathways, as illustrated in Figure 3, will not readily change unless the technology provides significant benefit that outweighs the difficulty and cost of changing that pathway. While these considerations could be viewed as a barrier to innovation, in actuality they are a necessary part of medical technology development and there are an increasing number of funding streams and organisations dedicated to supporting these processes. With such significant clinical challenges and compelling unmet patient needs, now is a critical time for scientists and engineers to apply their research expertise to improve healthcare for continence.

Conclusions

This paper has considered key factors involved in healthcare technology for continence care, spanning the clinical context, patient perspective, research challenges and how this can be implemented through effective innovation. At the heart of any research in this area is the need for a clear definition and understanding of what we mean by 'incontinence', how it manifests and how it interacts with other conditions. In contrast to many other medical conditions, these aspects are not well defined for incontinence and as such a key contribution is to improve our understanding of this complex, diverse and symptomatic condition through advances in basic sciences. Equally, many of the clinical challenges and research opportunities associated with incontinence could be approached through adoption of existing knowledge, methodology and technology being applied to other clinical conditions. Multidisciplinary research underpinning this activity will undoubtedly strengthen medical technology in this neglected area.

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