sagentia innovation

WHITEPAPER

Empathetic medical design: Disrupting established medical device thinking

Our Design Director, Carl Hewett, advocates user perspectives as a foundational element of healthcare innovation. In this article, he spotlights urinary catheters and considers how empathetic design can make a positive difference in health outcomes.

In the medical industry, understanding user needs is fundamental to obtaining successful outcomes and can unlock differentiation and patient access. Yet, this aspect of Front-End Innovation can often be lost in competition with many other influencing voices, such as those from a commercial, regulatory, manufacturing and payer viewpoint, the list goes on.

So how can we find and act on the opportunities that the user perspective presents? How then do we combine these with other development drivers and requirements such as the move from hospital to home, net zero goals, digitisation, and reimbursement matters?

Our Value Proposition Matrix, which can be found on our website: sagentiainnovation.com/insights/value-proposition-matrix, details how user, concept, and market perspectives can be harnessed to drive successful innovation. Here, we drill down into the user aspect of this, focusing on urinary self-catheters to illustrate the concept.

Carl Hewett
Design Director

A static foundation

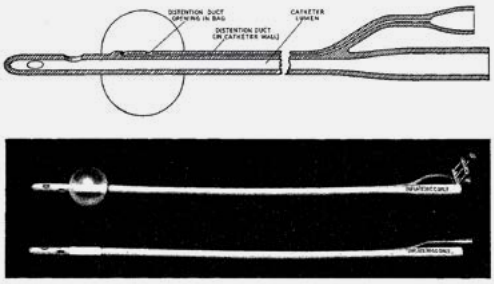
Worldwide, over 100 million urinary catheters are being used annually.

It's 85 years since the Foley urinary catheter – a flexible tube which passes through the urethra and into the bladder – was first introduced. It's a simple yet effective solution to help people void urine when they find it difficult to urinate naturally. It was the descendent of an intervention that dates back as far as ancient Egyptian treatment of urinary retention by means of transurethral bronze tubes, reeds, straws and curled-up palm leaves.[1]

A modern-day Foley catheter is functionally comparable to these early origins, and largely unchanged from Dr Frederic Foley's 1936 patent. It's commonly used in a post-surgical setting with a semi-permanent attachment via the inflatable balloon. In recent decades, the emergence of intermittent self-catheters has enabled self-care at home. Whilst greater patient freedom outside of a hospital use setting is of obvious value, these devices have remained largely unchanged. Many people report physical pain and psychological issues with long term use.

Worldwide, over 100 million urinary catheters are being used annually.[2] Unfortunately, Catheter Associated Urinary Tract Infections (CAUTI's) are one of the most common healthcare associated infections.[2] It would seem that an innovation overhaul of self-catheters is long overdue, and by placing user perspectives at the heart of design, innovation teams could create better solutions for end users' physical and mental health.

Looking more broadly, there are many medical devices and technologies in a similar situation that have been established yet unchanged with no major improvements for some time. Procedures such as colostomy care, wound care, and dialysis would also see value in a more empathetic approach.



A modern-day foley catheter is largely unchanged from the initial 1936 patent[3]

Human-centred design

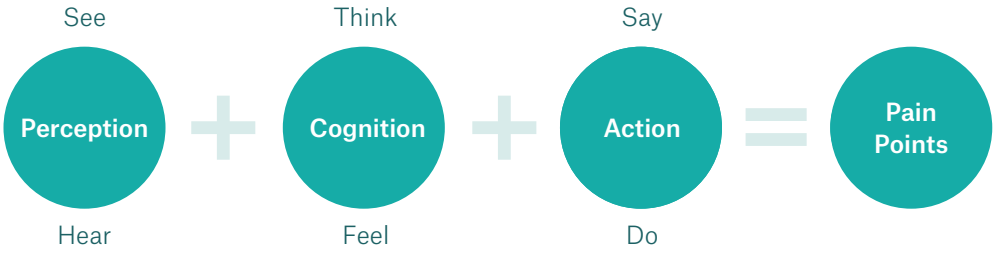
Most medical conditions, like this catheter example, have a multitude of issues that go together with them, which need to be explored and understood to gain the required perspective for success.

Human-centred design of self-catheters should begin with an understanding of the underlying reasons for use. Many long-term users have conditions such as multiple sclerosis or spinal injuries which compromise their lower body function. In extreme cases, they may also have issues with dexterity or an inability to grasp and clasp with their hands, making self-care difficult. Users often lack the necessary sensation to void their bladder naturally, which may mean they can't sense pain.

Since CAUTI's are a common side effect of catheter use, the inability to feel pain is a serious risk factor, and infections can escalate, leading to the prescription of antibiotics, and could result in sepsis.

Taking enough time to elicit deep insights from people who live with catheters is a crucial part of the innovation journey. A strong innovation team has the ability to objectively view pain points and articulate 'Jobs To Be Done' so that the right hypotheses can be created.

Ethnographical research is a great way to capture this insight, and generally, we should look to combine perspectives of perception, cognition, and action to contextualise pain points.



How to overcome embarrassment

Catheter use is an extremely personal topic that people may struggle to discuss, and this is a typical barrier that can cause more sensitive products to miss the mark. It's difficult to empathise if you are not able to explore and share context, so techniques can be adapted for maximum discretion. For instance, instead of holding interviews, tailored discovery kits that combine example products and guided situational questions, can be sent to participants to capture information on product use and allow users to record journal entries.

It's a useful approach that could have value across a variety of medical situations that create end user embarrassment, such as point-of-care diagnostics sample collection for urine, STI swab or stools.

That said, many users are willing to share their experiences, and it must not be forgotten that there is a wealth of secondary research available through communities, blogs and existing literature. For the study covered in Nursing Times, authors Suman Prinjha and Alison Chapple conducted in-depth interviews with 36 catheter users aged 22 to 96 years[4]. They reported that:

"People wanted a new design that would reduce complications, promote independence and be more discreet. Users who lacked dexterity hoped a new design would allow them to empty the drainage bag themselves, and a few wanted a device they could change themselves."[4]

Additional comments related to how people felt about "having a bag of urine strapped to the leg". They wanted a more discreet catheter or one that stored urine inside the body. Others stressed the importance of reducing the risk of complications such as UTIs, blockages, leaking and trauma or soreness around the catheter site. Many found catheter use had a negative impact on their sex life, partly due to self-image, and felt that this was overlooked by healthcare professionals.

Clearly, user experiences of urinary catheters present a host of unmet physical and psychological needs that could stimulate innovation surrounding physical design.

Humanising technology and solutions via insights that extend innovation opportunities beyond core device function is a useful mindset. Depicting journey maps of device usage in the context of a user's routine or product lifecycle affords innovation teams the ability to articulate Jobs To Be Done and hypothesise solutions linked to areas such as product ordering, use, disposal, or touch points that may overlap with catheter use.

If we can reason that "users wish to have a visually discreet catheter to avoid embarrassment", imagine a catheter that is engineered in a way that resembles the aesthetic of a mascara pen. In a situation where outside observers may see the contents of a user's purse, a person's condition is less overt. Additionally, consideration of unbranded secondary packaging when an order is delivered to a work location would have perceived value.

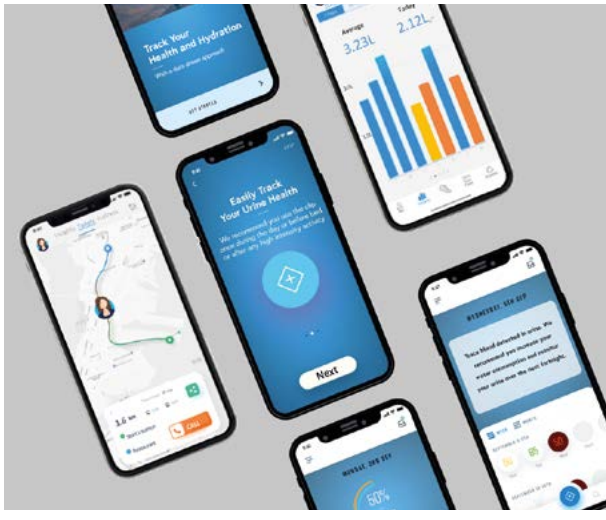
Other human-centric enablers might also take advantage of emerging digital trends, new technology or encompass factors such as sustainability.

Spot the catheter - discretion is key for more sensitive devices

Tapping into the digital ecosystem

With an understanding of the user, and well-articulated Jobs To Be Done, one might hypothesise that 'users wish to have a greater sense of freedom and control, as well as reducing the risk of infection'. Digital technologies offer ways to improve the entire user journey, from ordering and delivery to use/reuse and disposal of catheters. For instance, sensor technology might pave the way for solutions such as 'bladder full' alerts, triggering smarter management of catheter routines, rather than simply emptying bags, or changing devices at set intervals. This could be combined with a smart ecosystem holding information about wheelchair accessible public restrooms to improve users' confidence about visiting new places independently.

The value add is a better managed and maintained routine that will likely deliver benefits in terms of reduced infection risk. This thinking could of course be applied to a range of other single-use medical devices, or indeed larger treatment devices that are being moved out of the hospital setting.



Companion apps providing better continence management

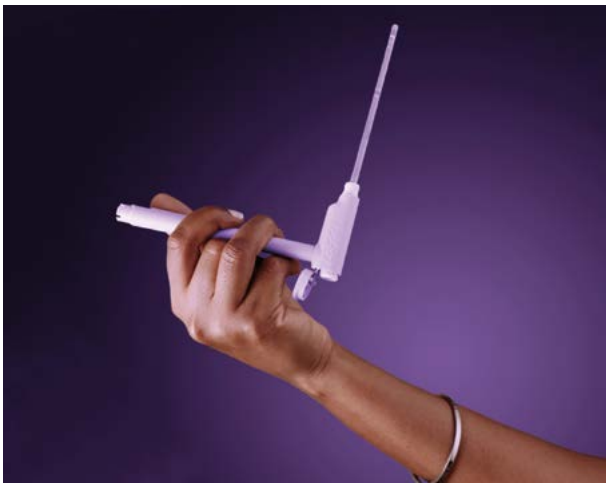
The sustainability question

A US review 'Urinary Catheter Coating Modifications: The Race against Catheter-Associated Infections', claims that an estimated 100 million urinary catheters are sold worldwide each year[5]. That's a lot of single-use plastic tubes. Besides this, catheters are generally wet-lubricated and require airtight, sterile packaging involving various polymer-aluminium layers.

When end-users have limited choice to treat conditions using products perceived as non-sustainable, it adds another layer to the already complex psychology of catheter and other medical device use. As responsible designers, we must ensure this is factored into the equation.

The priority of medical devices is always patient safety, so catheters aren't currently affected by the plastic taxes introduced in some markets. Nevertheless, today's innovation professionals should be looking towards the primary/secondary packaging as well as the end product, asking, 'can we make this more sustainable?'

A Life-Cycle Analysis (LCA) is a useful way to appraise the overt and more hidden contributors to sustainability and to target product embodiments that are reusable, have a recyclable composition, or negate the need for lubrication and multilayer packaging. All these could have a significant impact on user satisfaction and healthcare sustainability. **Wellspect** LoFric[6] is an example of a sustainably accredited design that minimises the need for primary packaging. It's a good example of sustainable design paired with a usability need, as the primary packing is repurposed as an attachable catheter handle to aid location and catheter insertion.



Wellspect LoFric Elle[6] – sustainable thinking

Reimbursement impact

While sustainable and human-centric considerations are valid, they can't be viewed in isolation. Catheters are high volume, cost-sensitive products where reimbursement rules govern patient access and product payment. In the US, the Centers for Medicare and Medicaid Services (CMS) exert tight control over catheter categories. To be eligible for "no-touch" or "sterile" or "closed system" kit, the patient must have experienced two physician-documented UTIs within the period of a year. Without this pre-approval, first time users are forced down the route of cheaper straight or curved tip catheters that are more prone to non-sterile use.

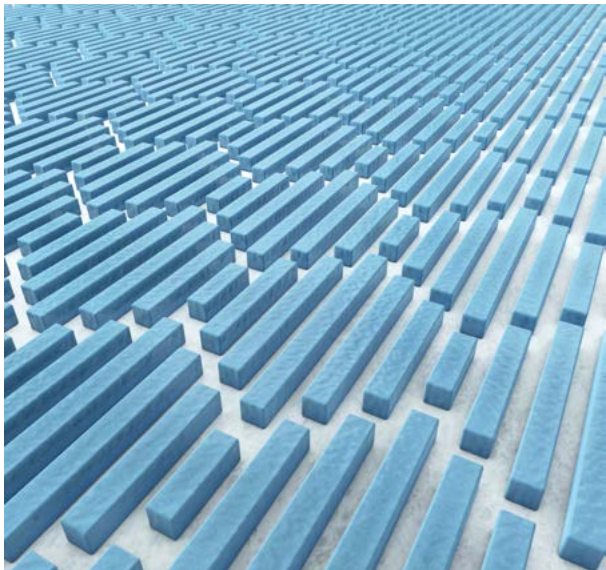
This issue is explored in a report by the MedStar Health Research Institute, 'Intermittent Catheter Reimbursement in the United States: The Experience of Nine Stakeholders Through the Lens of Actor Network Theory'[8]. In-depth interviews with catheter users revealed core pain points experienced by those who are not eligible for catheter types perceived as more usable and safer. The responses also highlighted reimbursement frameworks' low level of empathy for the catheter use experience of women:

"Men can urinate into a urinal. Women have to go into the stall. It doesn't matter if they washed their hands before they got onto the toilet, they have touched everything in the place...by giving them closed bags – even if they have to go into a stall – it just eliminates a lot of the germs."

The problem is rooted in insurance providers' stipulation of maximum allowable dollar amounts for the reimbursement of specific medical items. This is frustrating for patients when items with beneficial features are inaccessible or require them to supplement the cost via co-pay.

Understanding these limitations can stimulate the innovation of concepts that make higher value devices more cost-effective. For instance, part of the cost associated with 'coated' hydrophilic catheters is the need for a lubricant and multilayer packaging. Considering alternative materials could help mitigate this. For instance, a recent article by the Department of Biological Sciences, University of Notre Dame highlights surface topography modifications inspired by sharkskin that claim to reduce friction and bacteria adhesion. Could this offer a route to a dry catheter with frictionless insertion and antibacterial properties?

Coloplast is a great example of a pioneer challenging reimbursement classifications and patient access. Its introduction of the SpeediCath standard is a case in point. The novel casework design enables more sterile and discreet use with a device that's accessible under the "straight" tip A4351 reimbursement code. Examples like this illustrate how established norms can be overcome by considering factors like empathy and the reimbursement environment, resulting in a better user experience.



Sharkskin functional surfaces could challenge reimbursement classifications

Empathy provides wider design considerations

Identifying and understanding all stakeholders is key. Buying and prescribing circles are complex – healthcare professionals often select the product, and someone else pays for it. Often, companies providing the product are well placed to talk to these stakeholders but may not spend enough time understanding the actual user (the patient).

The user perspective has equal footing alongside technology and market perspectives and is a critical element of successful product design. While it's sometimes beneficial to consider these perspectives independently, it's important to understand the overlap between them and recognise that the user perspective can provide the "why" to technical development decisions.

Ethnographical research is a powerful tool and should be combined with secondary research sources which offer a complimentary richness and diversity of user types and opinions, some of which are pre-validated.

Future articles will explore the ways technology and market perspectives can inform innovation. In the meantime, our Value Proposition Matrix, which outlines the user-technology-market concept, is available here:

sagentiainnovation.com/insights/value-proposition-matrix

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