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A survey of end user and health care professionals experience of discomfort as related to intermittent catheterisation

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ABSTRACT

Background and Methods: Clinical evidence around discomfort experienced at the various stages of the intermittent catheterisation (IC) journey is limited. This research aimed to gain insights into discomforts encountered at initiation of IC and when products were changed/swapped during their lifetime of use. To gather a range of viewpoints, digital questionnaires were distributed to End Users and to Health Care Professionals (HCP's) to consider how discomfort has/may be experienced and managed.

Results: The surveys were completed by ninety nine End Users and 113 HCP's. The results highlighted the variety of different ways in which discomfort may be described. For those End Users with urethral sensation, 89% stated the discomfort experienced acclimated i.e. they no longer felt the discomfort after a couple of days catheterising. Elements associated with improved experienced included End user education and how expectations were managed.

Conclusions: The findings highlight the need to ensure that all End Users receive adequate education and counselling to manage all aspects of IC not only when they start their journey of IC, but also on product switching and during their lifetime of use and that this should be tailored to their individual needs. By having a better understanding in relation to discomfort it may help HCP's to understand challenges faced, prepare End Users and set their expectations, and aid the development of more evidence-based education and training for IC users.

1. Introduction

According to the International Continence Society, Intermittent Catheterisation (IC) is defined as the drainage of the bladder or a urinary reservoir with subsequent removal of the catheter, mostly at regular intervals [1]. It is accepted as the gold standard in individuals with bladder dysfunction (neurogenic and non-neurogenic) and in the treatment of urinary retention [2]. It is also referred to as ISC or clean intermittent self-catheterisation (CISC) denoting that the patient/end user is performing the procedure rather than a caregiver.

In 2023, the global market size for urinary catheters was valued at 5.2 billion USD [3]. According to Berendsen et al. 2021, intermittent catheters make up around 60% of this global market [4]. A significant proportion of these IC users have neurogenic lower urinary tract dysfunction. A recent publication outlined the epidemiology of neurological conditions underlying urinary tract disorders and the rate of IC use in these populations [5]. They reported that 45% of those with a spinal cord injury, 8%–21% of those with multiple sclerosis, and 89%–100% of those with spina bifida are using IC.

IC can have a significant physical and/or emotional impact on patients' lives, but very little research addresses the patient's problems and challenges in everyday life [6]. HCP's are often concerned about complications or adverse events that can arise in patients performing IC, especially in the long term but patients may often be more concerned about the discomfort associated with catheterisation [2]. Literature relating to first time use of ICs and the challenges faced from a discomfort standpoint is available but there is a lack of understanding on how long the acclimatisation period may be before IC does not cause discomfort, how persistent discomfort may be managed in the

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longer term and if discomfort returns in association with changes to IC regimens such as when switching products.

A qualitative study performed to understand adults lived experiences with IC identified nine themes around individuals lived experiences and pain/discomfort was one of them [7]. They concluded that 'the challenge, and opportunity, is to learn more about what has gone right for those who have adapted and to leverage the clinical, practical, psychological, and social factors that enable individuals to integrate IC into the rhythm of their daily lives'.

This article will outline the findings of two surveys exploring End Users and HCP'S experience and beliefs of discomfort on initiation of IC and in association with product switching in established users.

2. Methods

Two surveys were developed and distributed online to two different study populations. The questionnaires were executed in Q1 and Q2 of 2023. The study protocol was submitted to the Institutional Review Board (IRB) who felt the study was exempt under 45 CFR (Code of Federal Regulations) § 46.104(d)(2), as the research was non-interventional post-market experience survey developed by Hollister Inc. Global Clinical Affairs in collaboration with Global Marketing and was available to any individual that performs IC irrespective of the brand of IC they use.

2.1. Study populations

Group 1 – End Users were recruited from the Hollister Inc. Continence Care Panel (CCP) based in the United States (US). The CCP is group of individuals with lived experience of IC who help to evaluate existing and new products and participate in related research. Participants received a Qualtrics survey link via email that described the intent of the survey and required consent for participation. The survey involved no risk to the End Users as it is a non-interventional, post-market experience insight survey. For End Users to participate in the survey, they had to be screened and meet the following requirements: complete consent to participate, speak and understand English, currently use an intermittent catheter, Male or female, and at least 18 years of age. For completing the one-time survey, End Users were compensated for their time with a $10 electronic gift card.

Group 2 - Health Care Professional were recruited from the Hollister Inc.: Key Opinion Leaders (KOL) panel, Clinical Advisory Boards (CABs) and Secure Start contacts based in the US and Europe. No compensation was provided for completion of this survey by HCP's. All the HCP's that participated had experience in neurogenic and non-neurogenic patients requiring IC.

2.2. Survey design and data management

The questionnaire for group 1 collected data on their reason for performing IC, duration and frequency of performing IC, who trained them on how to perform IC, and if they felt sensation when performing IC. It also explored the experience relating to discomfort when first trained to use IC, if they changed their IC to another brand during the lifetime of use and their overall experience related to discomfort. The questionnaire for group 2 collected data on their profession and length of time in role. It questioned how many patients feel discomfort when initiating IC and how long that lasts for, if there are specific conditions where increased discomfort is observed and how they counsel/advise patients to manage discomfort. Rationale for switching products alongside observed discomfort, timeframes for concerns were also explored.

Qualtrics is a robust survey creation tool and CCPA (California Consumer Privacy Act) compliant, and results can be viewed in reports and can be downloaded. Participants reported on their experience and all data was reported in aggregate.

2.3. Statistical methods

Survey data was reported using the frequency of responses for each survey question. The frequency of responses was reported using counts or percentages. A convenience sample of less than or greater than 100 individuals for each group was set. No statistical methodology was used to determine sample size.

3. Results

3.1. Demographics

98 End users completed the study and the majority had been performing IC for over 5 years, and most performed IC 4–6 times per day. The majority (81%) performed IC due to a neurogenic condition. End Users reported performing IC in a variety of positions. On initiation of IC, 82% reported receiving training from a HCP, others learnt by video, through product information leaflets, from family members or a medical supply company. A variety of different catheter brands were used and 78% had tried an alternative product. Table 1 shows the demographics and clinical background of the End Users surveyed.

Within group 2, 113 HCP's from Europe and the USA completed the survey. The HCP's all had experience in training and educating on IC use, and roles varied from Clinical Nurse Specialists, Urology Nurses, Rehabilitation Nurses, SCI Nurses, Nurse Practitioners and Registered General Nurses. Their area of work specialised in urology, rehabilitation hospitals and centers (SCI) and public care.

3.2. End users

Overall, 54% of end users reported having sensation in the urethra. When they were first trained on IC, 81% of those with sensation felt discomfort to which 34% attributed to an active Urinary Tract Infection (UTI) at that time. Other sensations reported included urethral pain, spasm, irritation, stinging, burning, bleeding, pain on insertion/removal and meatus irritation (Fig. 1). 44% felt discomfort for a couple of seconds to a couple of minutes, 27% reported it lasted a couple of hours to one week and 30% stated "other" and gave various reasons from the discomfort being a sensation as opposed to being a physical manifestation (Fig. 2).

The potential for discomfort occurring had been highlighted to 72% during their training by the HCP, and 89% stated the discomfort experienced/felt acclimated (i.e. they no longer felt the discomfort after a couple of days catheterising). For the 11% with ongoing discomfort, some spoke to their HCP, some switched catheters or added lubricant/anaesthetic gel whilst others worked on their technical skill. Some report that it is a persistent issue that on balance when recognising the risks and benefits that ISC can afford, they just accepted.

For those who changed/switched their brand of product only 40% had received guidance that discomfort may be experienced, and that there may be an acclimatisation period. 46% felt discomfort when they switched brand which lasted for a couple of seconds to minutes and generally resolved sooner than it had on initiation (Fig. 2).

Interestingly 0% experienced urethral or meatus irritation at the time of switching, but discomforts experienced consisted of urethral bleeding, pain on insertion and removal of IC, urethral burning, stinging, spasm, pain, difficulty passing the prostate and UTI (Fig. 1). 21% did not feel any discomfort when switching and 7% reported "other" which consisted of discomfort rarely occurring, documenting no issues and difficultly in using the product/brand which was seen as discomfort.

3.3. Health care professionals

78% of HCP's reported that it is normal for new patients to feel discomfort when trained to use IC (if they have sensation) and 80%

Table 1
End User demographics.

Question	Possible answers	Responses
Age of respondent	20–40 yrs	26
	41–60 yrs	46
	61–80 yrs	23
	81–90 yrs	3
How long using IC	< I year	2%
	1–2 years	2%
	2 to 5 years	35%
	5 years +	61%
Indication for IC	Spinal Cord Injury	52%
	Multiple Sclerosis	9%
	Spina Bifida	9%
	Other neurogenic conditions	11%
	Enlarged prostate	10%
	Cancer	1%
	Other functional conditions	8%
Position in which IC performed	Sitting on toilet	15%
	Standing in front/over toilet	20%
	Stitting in wheelchair	34%
	Sitting on side ofbed	9%
	Lying down/in bed	18%
	Other	4%
Frequency of IC	<once a day	1%
	Once a day	8%
	2–3 times a day	4%
	4–6 times a day	49%
	6–8 times a day	27%
	>8 times a day	10%
From whom or what source did you receive your training on using IC's	Nurse	54%
	Doctor/Urologist	18%
	Physiotherapist/occupational therapist	10%
	IC supplier	7%
	Information pamphlet or video	7%
	Did not receive any training	2%
	I do not remember	1%
	Other (Parents)	1%
Brand of IC product currently used	Bard	13%
	Coloplast	27%
	Convatec	8%
	Cure medical	13%
	Hollister	31%
	Wellspect	4%
	Other	4%
Used a prior IC brand to current product	Yes	78%
	No	22%
Previous brand used	Bard	31%
	Coloplast	17%
	Convatec	1%
	Cure medical	15%
	Hollister	21%
	Teleflex Inc	6%
	Wellspect	8%

reported that there was an acclimatisation process, and 96% educate their patients on the possibility of discomfort while their urethra acclimates to IC during initial training. The duration of discomfort was seen as couple of seconds to couple of minutes, with some experiencing it up to one week. When discussing duration of discomfort, 52% advised patients that it lasted a couple of seconds to a couple of minutes. Discomforts communicated to HCP's by their patients which were the most prevalent were pain on insertion and removal of IC, urethral burning, stinging and irritation. Other discomforts noted were blood in urine, urethral pain and meatus irritation.

When asked to consider specific conditions associated with increased discomfort with IC, Benign Prostatic hyperplasia (BPH), Multiple Sclerosis (MS) and Pelvic Organ Prolapse (POP) were most commonly suggested. Techniques to manage discomfort suggested by HCP's included to check for infection, changing the catheter tip (nelaton versus coudé/tiemann) consider medication; followed by reassessing patient technique, positioning or catheter features and teaching alternative techniques to help advance the catheter including coughing, deep breathing and relaxation as well as gentle pressure and insertion in increments.

When switching products, 46% of HCP's expected that End Users would experience some form of discomfort, just over half of these (53%) felt that this was acclimatisation. The most prevalent discomforts noted were pain during insertion and removal of IC, urethral burning, stinging and irritation. Other noted discomforts were blood in urine, urethral pain and meatus irritation. The duration of acclimatisation during this switching process was predominantly recorded as couple of seconds to couple of minutes, with some experiencing it from three to five days. Some HCP's noted that this is very much patient dependent. Fig. 3 demonstrates the variations of the end user and HCP perception of duration of discomfort.

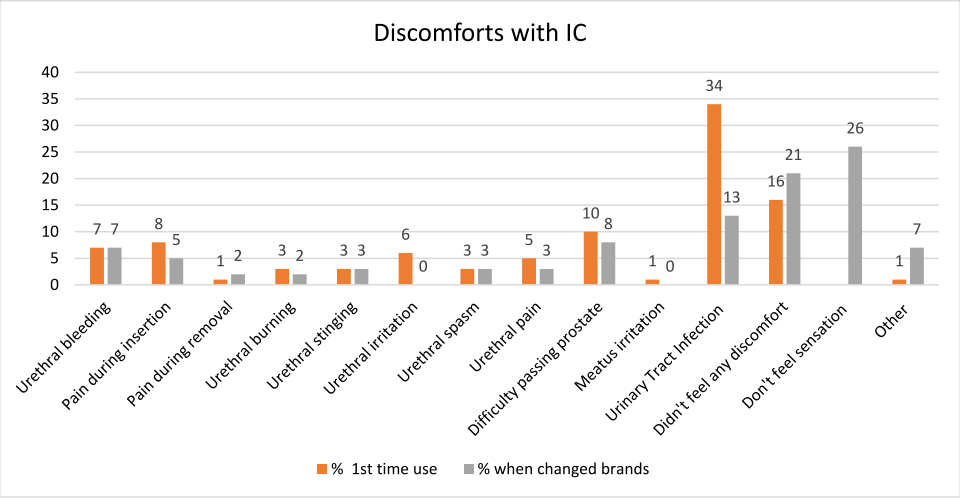

Fig. 1. comparison for discomfort experienced with initiation of IC, compared to that associated with switching products. The biggest difference was a significant reduction in discomfort in the switching group (34% vs 13%) in relation to reduction in UTI prevalence. There was little difference noted between the other discomforts at initial ISC training and when product was changed.

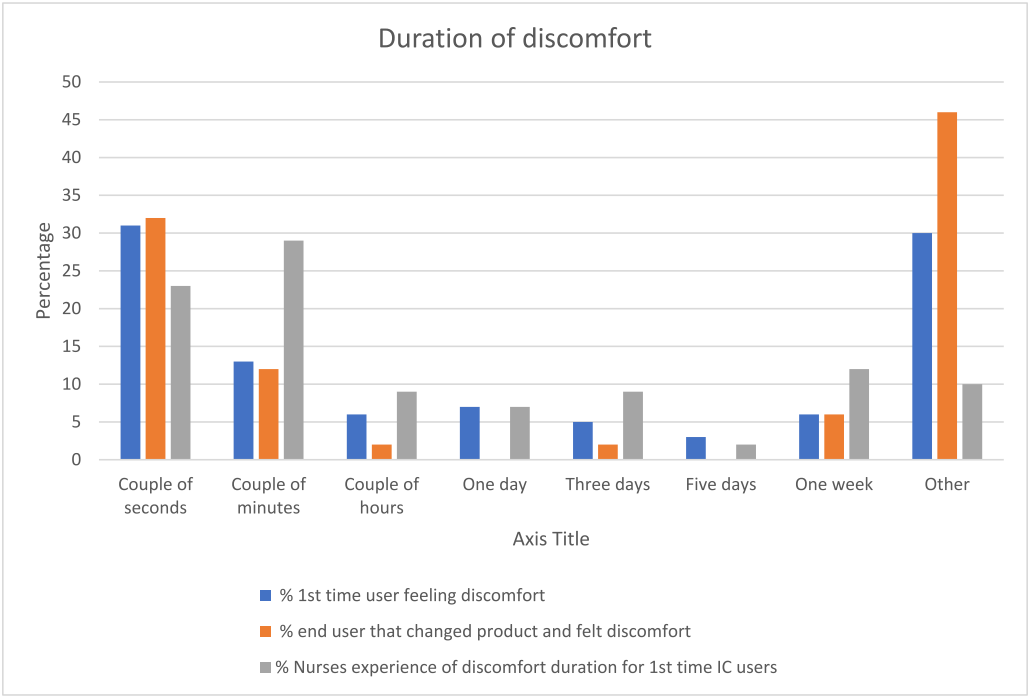

Fig. 2. Discomfort duration reported on initiation and on switching by End Users compared to HCP (nurses) experience.

3.4. Switching experience of end user and clinician

According to the End Users, the main reasons for switching were related to insurance cover, due to medical supply issues of their regular product, the need for discretion (i.e. discreet product that could be carried on the person) or prevention of recurrent UTI's. In contrast, the top reasons HCP's reported were all clinical and included experiencing discomfort beyond training period, changes in dexterity, inability to handle IC (i.e. not suitable for their condition) or due to being unable to pass the prostate.

When switching product, 60% of End Users stated that no guidance was given on the potential of feeling discomfort with the new catheter. For those who did receive advice, 40% of guidance was given by a medical supply company, 34% by a HCP, 18% did not seek guidance and 8% "Other" (which included no choice from insurance company, support group, peers and company representatives). This varies significantly from initiation of IC where guidance was predominantly from HCP's (82%) and 7% from medical supply company. Fig. 3 compares how End Users received training in IC use on initiation compared to when switching products.

4. Discussion

These surveys have provided in-depth clinical insights into End Users experience of discomfort and highlighted the variations with HCP perceptions.

4.1. Urethral sensations and terminology

The results of the survey show that a significant proportion of End Users experience discomfort when they first start to perform IC, and this

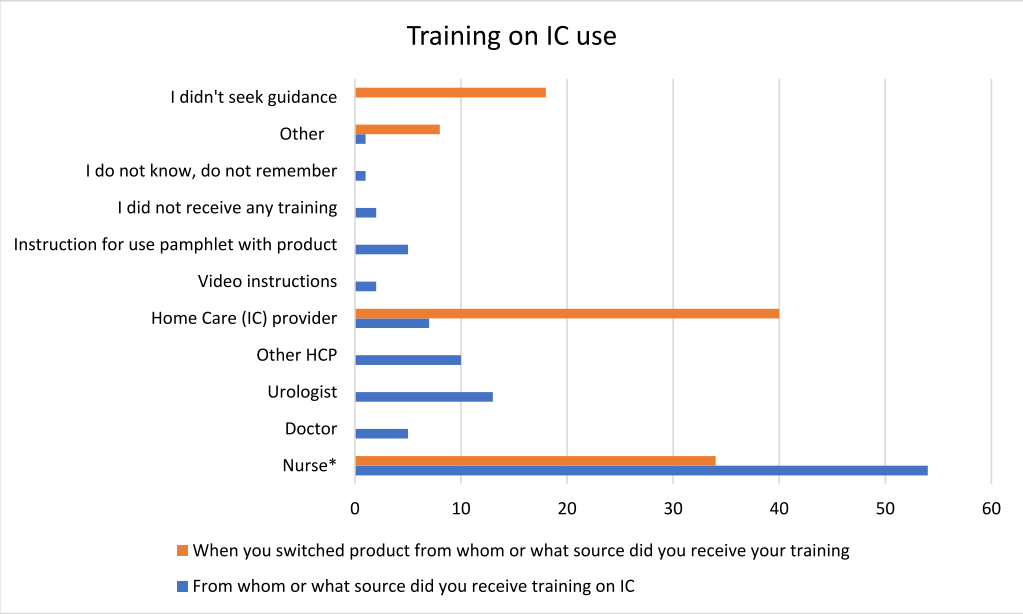

Fig. 3. Training of IC use initial vs switching.

either perceived or experienced discomfort is managed predominantly by the HCP through discussion and education in the training phase. HCP's also indicated that it is normal for first time users of IC's to feel discomfort during the training period, which is consistent with current clinical literature.

During the switching period, feelings of discomfort causes issues that are beyond the End Users normal experience and are similar to those described on initiation of IC. It could be questioned if lack of appropriate education or access to the HCP for guidance at this time may be a factor that needs to be investigated further.

The term 'discomfort' can have a lot of meanings — according to the Collins English dictionary (2023) discomfort is a painful feeling in part of your body where you have been hurt slightly or when you have been uncomfortable for a while [8]. Alternatively, discomfort is a feeling of worry caused by shame or embarrassment. There have been several reports in the literature regarding discomfort/pain during catheter insertion or removal, and as a consequence of bladder spasm or UTI, [9,10]. 34% of first time users reported discomfort attributed to a UTI and it is unclear if their symptoms are due to inflammation rather than the direct discomfort sensation caused by the catheter. Fear of pain can hinder relaxation and learning and can be reduced by appropriate training of the person carrying out the catheterisation [11]. Research has shown that patients may experience a range of reactions/emotions whilst learning IC, including embarrassment and aversion, which may not dissipate over time [12]. Future research regarding the impact of psychological and emotional aspects on discomfort is required.

Within the end user survey, multiple options to describe and define discomfort were provided including urethral bleeding, pain on insertion, pain on removal, urethral burning, urethral stinging, urethral irritation, urethral spasm, urethral pain, difficult to pass prostate, meatus irritation, urinary tract infection, other (specify) and the option for did not feel any discomfort. Interestingly, when the HCP's were asked to specify the discomfort that End Users may experience, in addition to all the terms listed above, resistance/pressure, sensitivity of the area, pain at the sphincter/prostate and psychological aspects (e.g. anxiety/being tense) were also reported.

4.2. Acclimatisation

Acclimatisation is defined as when you adjust to a new climate or situation [13] There is no clinical definition of exactly what is considered to be acclimatisation when performing IC, but the term is used by some HCP's, and is dependent on not only the physical process of IC but also with the psychological issues associated with undertaking IC especially on a long-term basis. The clinical benefits of IC over indwelling catheterisation is well documented in clinical literature. The benefits that IC's offer End Users outweighs the discomfort noted at initial training and the residual low risk of trauma and/or dissatisfaction. However, in this survey it was often considered to be in relation to no longer experiencing discomfort with IC. There is a distinct lack of literature regarding this concept even through 80% of the HCP's in this survey reported that they felt there was an acclimation period that they counselled the patients about. It was recognised that duration of acclimation varied and 26% stated that they found duration in time hard to quantify, as it was dependent upon each patient and multiple factors have to be considered.

4.3. Product switching

For end users proficient in performing IC, the majority reported they felt discomfort for a short duration of time when they switched products. The most common source of guidance sought during this time was from their medical supply company. It was noted by HCP's that the experience of switching is very much End User dependent and highly variable depending on the End Users condition, dexterity, sensation, technique, type of IC used and UTI status.

One of the most interesting observations in this study was in the different reasons for why End Users switch products. For the HCP's reasons for switching were all generally related to managing clinical challenges with IC e.g. alternative tips, managing dexterity or to improve discomfort/prevent UTI's. However, the reality for this population of End Users (who were all based in the US) is often that they have no choice in the matter and only 34% discussed switching and received advice on new products from their HCP. The decision to switch was often made by their insurance companies (and related to financial restrictions with products) or due to issues with medical supply companies or discontinuation of product. Only a small group reported positive reasons for switching e.g., more discreet product, easier to use, to reduce UTI's etc.

Anecdotally, HCP's have raised concerns regarding the practice of some medical supply companies. Whilst they report to supply a variety of products, there have been cases reported that End Users are told

that their current product is out of stock/unavailable, so are offered 'an alternative' switching them onto a similar product from a different brand without any discussion with the End Users HCP. Whilst it is acknowledged that in recent times there have been global supply issues for certain products resulting in the need to switch products, this raises potential conflicts of interest and the interplay between business and health of End Users. Variations in health care delivery systems, product availability and end user experience in other parts of the world need to be investigated to gain a wider understanding of product switching.

4.4. Educational needs

Clinical literature suggests the success of ISC requires the procedure be acceptable to the patient from the start. This, in turn, requires skilled training(including verbal explanation, practical instruction and written information [14]), support and long-term follow-up by the healthcare team. Without support, anxieties and problems can go unreported, and therefore unresolved. Additional time spent teaching and monitoring the patient has been shown to have a positive impact in the long term [15]. End User support is crucial, and HCP's should reinforce the importance of promoting patient-centred care before and after the initiation of IC.

A knowledgeable and experienced clinician with experience in IC, is an important component for successful IC teaching. Providing education for patients on awareness of problems associated with catheterisation, and the understanding of how to avoid possible complications has been shown to led to fewer complications and increased compliance with IC [16].

A scoping literature review by Quallich et al. (2023) identified research studies and guidelines examining patient/caregiver educational interventions related to IC and issues related to teaching IC [17]. They reported that current research is extremely limited and additional research is needed to support the development of patient/caregiver educational interventions and to examine their effectiveness.

Integrating IC in everyday life can be difficult. The EAUN Guidelines (2013) [18] suggest that the End Users require close ongoing support and follow-up, yet real word data such as this study indicates there is a lack of continued education during the switching process. There is a need to ensure that all End Users receive adequate education and counselling to manage all aspects of IC not only on initiation but also on product switching. It could be included as a point of information within user education material/product user guides and all HCP's and call handlers/support staff at medical supply companies should be discussing potential issues with the End Users. Given workforce challenges within health services, it could be suggested that developing expert patients/buddy systems as ongoing support may be a sustainable model to enhance education in the future.

5. Limitations

There are some limitations to this study. Firstly, all the End Users were from the US. This means that some of the reasons for switching i.e. due to insurance companies etc., may not be relevant in all other health services. Validation across other countries and health services is required to ensure the full range of clinical experience has been considered. There may also be an element of recall bias in the participants as we are asking them to remember the discomfort they experience in initiation of IC and for many this was more than five years ago. Whilst 54% of participants reported urethral sensation, we do not know what level of sensation they have and if that would impact on the findings. Unfortunately, data on age or gender of end users or information on catheter type used was not available which may impact on the interpretation of the findings.

6. Conclusions

This real world evidence survey provides an insight in end users experience of discomfort associated with IC and HCP's perception of discomfort experienced. End user and HCP responses noted "discomfort" can be recorded in many different ways, and can be physical, as well as presenting in psychological manifestations, and is a known consequence with IC.

The findings highlight the need to ensure that all End Users receive adequate education and counselling to manage all aspects of IC not only when they start their journey of IC, but also on product switching and during their lifetime of use and that this should be tailored to their individual needs. By having a better understanding in relation to discomfort and acclimatisation it may help HCP's to understand challenges faced, prepare End Users and set their expectations, and aid the development of more evidence-based education and training for IC users.

Ethics approval

The study protocol was submitted to the Institutional Review Board (IRB) who felt the study was exempt under 45 CFR (Code of Federal Regulations) 46.104(d)(2), as the research was non-interventional post-market experience survey developed by Hollister Inc. Global Clinical Affairs in collaboration with Global Marketing and was available to any individual that performs IC irrespective of the brand of IC they use.

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Declaration of competing interest

No research grant was provided for this study but the end users were compensated for their time to complete the survey with a $10 gift voucher provided by Hollister UCL.

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