Putting Ostomates at the Heart of Pouch Design

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SUMMARY

Ostomy pouches are used daily by over 13,000 people in the UK each year, to collect effluent from their stomas. Although this Class I medical device has undergone a design revolution since the 1940s, ostomates' needs are still not being fully realised. Building upon knowledge and insights gained from interviewing and surveying ostomates, this paper will explore how applying key Human Factors considerations could help inform the future design of ostomy pouches and ultimately, improve the quality of life of ostomates.

KEYWORDS

Ostomates, Ostomy Pouches, Design, Human Factors, Healthcare

Introduction

Ostomates are often referred as people who have undergone surgery to create a stoma, which provides an opening at the surface of the abdomen to divert the flow of bowel or bladder effluent. This surgical intervention is conducted on 13,500 people in the UK each year and can be an acute or long term measure for a range of clinical conditions. This can vary from an illness, injury, or a problem with the digestive system, that can impact people of all ages from neonates to the elderly (Kettle 2019). A key product for ostomates are ostomy pouches which collect the stoma effluent. Simplistically, they consist of two key components; an adhesive baseplate to attach to the abdomen and a pouch to collect the effluent. Depending on the type of pouch (drainable or closed, one-piece or two piece system), ostomates may need to replace their pouch daily or up to once a week.

Since the development of commercially available rubber pouches in the 1940s (Lewis 1999), there has been a radical evolution in the design of ostomy pouches resulting in a variety of pouches available today. Despite these developments there has not been a major step change in pouch design since the 1980s, which means ostomates are still faced with product concerns and challenges because one pouch fit does not fit all. These challenges are evidenced in Quality of Life (QoL) studies which report that ostomates' QoL is impacted by skin problems due to failed skin barriers, pouching sizing systems, lack of access to support user groups and ostomy nurses (Maydick-Youngberg 2017). Therefore, this paper will explore the areas in which Human Factors considerations can be applied to help inform future design of ostomy pouches to help improve ostomates' QoL.

Applying Human Factors to pouch design

Considering that ostomy pouches are typically a Class I medical device within the EU, we wanted to explore through the lens of the Medicines and Healthcare products Regulatory Agency guidance (MHRA 2021) in relation to Human Factors considerations (users, use environment and device-user interface), and what this realistically means for ostomates.

Users

Users of ostomy pouches include a variety of people; from ostomates and lay caregivers to experienced and novice Healthcare Professionals (HCPs). With this range of users, comes various cognitive abilities (level of education, years of product experience, type of product training received and existing mental models), physical and sensory abilities (sex, age, their dexterity levels, their hearing abilities, their visual ability, and their co-morbidities) and user preference (pouch colour, pouch shape and size to match their daily actives) to take into consideration. Ultimately, how are ostomy manufacturers incorporating inclusive design principles to provide solutions for real people to help minimise their product frustrations and improve their QoL?

Use environment

Ostomy pouches can be applied and emptied by HCPs, caregivers and patients in various environments including a home setting, public setting, hospital, or community care setting. This of course introduces several variables: the room temperature (potentially impacting the adhesive properties of the baseplate), level of light (perception of design/instructions) and ambient noises (from home background noises to a hospital setting) which may impact how users interact and perceive the product, as well as their level of attention. How is the design of the pouch and instructions supporting users' needs when in various real-world environments?

Device-user interface

The user-interface of an ostomy pouch includes several touch points from the baseplate, baseplate liners, pouch material, filters, to a resealable tail (if drainable). With that comes a range of sensory experiences to consider; touch (how does the pouch material and shape feel against the body?) auditory (will the pouch materials crinkle and be easily heard by others?), sight (how does the location of their ostomy impact their ability to visually applying their pouch?) and smell (how effective are the filters in neutralising odour?). Overall, how is the design of the pouch interface supporting its ease of use and ostomate's pouch concerns?

Conclusion

It is evident that one type of ostomy pouch does not fit all ostomates. Echoing that of past research, more is needed to push the design and development of ostomy pouches into the 21st century to help alleviate ostomates' pouch concerns and unmet needs. Ultimately, we need to apply a holistic approach in the ostomy pouch design process to not only help improve product satisfaction and overall user experience, but more importantly the QoL of its users. This can only be achieved if ostomy pouch users are placed at the heart of Human Factors activities during the iterative design and development process.

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