

## **Towards the development of the Psychosocial Impact of Assistive Devices Scale for Continence (C-PIADS)**

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### **Abstract**

**BACKGROUND:** Current outcome measures for continence management devices do not adequately address psychosocial impact. The PIADS is an assessment tool that has been shown to reliably predict the adoption and use of assistive technology devices, but it is not widely used for continence devices.

**OBJECTIVE:** To explore whether the PIADS requires modification to address the particular needs of continence device users and to inform any subsequent item development.

**METHODS:** The study used interpretive methods in which qualitative information from semi-structured interviews was combined with the findings from cognitive interviews for questionnaire pre-testing. A total of 40 participants in UK and Canada were interviewed.

**RESULTS:** Few participants had difficulty in understanding or relating to the majority of PIADS items. Several items were not considered relevant to continence and some areas for potential new items were uncovered. Embarrassment and concealment of urinary incontinence from others were common topics.

**CONCLUSIONS:** The PIADS appears to fundamentally address many, but not all, of the important psychosocial concerns of adults who have continence difficulties. A version for continence, the C-PIADS, will require modification of the PIADS and is likely to contain some new items.

**Key words:** Continence, incontinence, PIADS, measurement, patient perspective.

## 1. Background

Continence difficulties (CD) pose a problem for millions of people of varying ages worldwide. CD are generally defined by the presentation of symptoms of urgency to void (urge), leakage when coughing, laughing or with exercise (stress), both urge and stress (mixed) and voiding difficulties. Causes vary and include functional difficulties (e.g. impaired mobility), neurological disease, childbirth injuries, birth defects, spinal injury, factors associated with ageing (e.g. menopause, prostate enlargement), or can be iatrogenic.

Treatment of the underlying condition and management of symptoms forms the basis of care.

Continence symptoms can be ameliorated with pelvic floor rehabilitation, drugs, or surgical intervention. There are also many different assistive technology devices (ATDs) used to aid continence management. In the US and Canada, ATDs are defined as 'any item, piece of equipment, or product system, whether acquired commercially, modified, or customized, that is used to increase, maintain or improve functional capabilities of individuals with disabilities' (1). In the UK, the definition has been simplified to 'any product or service designed to enable independence for disabled and older people' (2).

The most commonly used ATD for the management of CD is the absorbent pad or diaper. Other products include pessaries, vaginal inserts, penile clamps, male and female urinals and male external catheters. These may be single use or re-usable. Implantable devices such as artificial urinary sphincters and slings are used to provide structural support to the pelvic floor and thus reduce urine leakage. Urinary catheters are used primarily to empty the bladder when voiding is compromised, but are also used to manage urine leakage in some patients. Devices for electrical stimulation of the sacral or posterior tibial nerve may be employed to assist in the management of incontinence, and biofeedback devices that promote or stimulate pelvic floor contractions are used to help restore continence. Evidently, there are many devices to help manage continence in adults; however, the psychosocial impact on the user has not been well established, primarily due to the lack of a suitable validated instrument (3).

Clinical assessment of treatment outcomes has been shown to underestimate the degree of impact perceived by patients, and to focus on clinical issues, which can be of lesser importance to patients than social or psychological issues (4;5). Patient self-completed questionnaires or patient reported

outcome measures (PROMs) provide a method for the standardised collection of data on symptom impact and treatment benefit from a patient perspective. In essence, this is an objective assessment of the patient's subjective experience of incontinence (6).

CD can have an important impact on psychological and social functioning. The World Health Organization's International Classification of Functioning is a useful framework for conceptualizing quality of life that puts emphasis on psychosocial influences. By 'psychosocial', we refer to both factors within the person and factors attributable to the environment that affect the psychological adjustment to health conditions of individuals who have CD. Internal factors, which include independence, personal control, self-efficacy, and self-acceptance, are the core dimensions of psychological well-being. We are concerned with the challenges these individuals encounter as they interact with their social environment. This includes measuring how they perceive their continence management technologies as environmental facilitators. We consider unrestricted and facilitated participation in human life to be essential in the technology user's definition of quality of life outcomes. However, the numerous effects of CD on a person's psychological and social well-being make it challenging to measure the impact of a particular ATD. CD has been associated with elevated levels of stress and feelings of powerlessness as well as isolation and depression (7). It also serves as a formidable barrier to engaging in activities of daily living (8).

There are several well-researched and fully validated instruments which are designed principally to assess the health-related quality of life impact of incontinence symptoms (9). Historically, the emphasis on quality of life (QoL) tools relating to incontinence has largely been one of focus on symptom reduction. Symptom reduction is a valid measure for judging the efficacy of a drug to reduce urgency incontinence (for example), but it is not useful for evaluating ATDs used to manage symptoms of unchanging severity. Moreover, QoL tools have not been used consistently or extensively in device effectiveness research and their validity for evaluating the psychosocial impact of assistive devices is unknown.

To achieve this in a standardised, objective and measurable fashion, specifically designed tools are required. One such tool, a 26-item self-report questionnaire called the Psychosocial Impact of Assistive Devices Scale (PIADS) (10,11), originally developed for the English and French speaking populations of Canada, is now available in many international linguistic and cultural translations. Scores on the PIADS are summarized in three quality of life subscales: Competence (reflecting

perceived functional capability, independence and performance); Adaptability (reflecting inclination or motivation to participate socially and take risks); and Self-esteem (reflecting self-confidence, self-esteem, and emotional well-being). The PIADS may be used to obtain a pre-device use baseline and/or to obtain post device use assessments of device impact. The timing of these assessments depends on the judgment of the assessor about the coincidence of assessment with an important phase of use, such as early adoption or longer-term impact. The PIADS is a fully validated assessment tool that has been shown to reliably predict the adoption and use of ATDs (13-15). Other ATD assessment tools are designed to aid the selection of an ATD (e.g. Matching Person and Technology Assessment) rather than assess its impact, or tend to be ATD specific.

The purpose of this study was to scope the need for and contribute towards the development of a measure for the psychosocial impact of continence management technologies. The strategy chosen was to investigate use of the PIADS with continence technology users. We aimed to discover which PIADS items were relevant to individuals with CD and whether new items were required to adequately assess the psychosocial impact of continence technology. Currently, it is not possible to adequately evaluate continence devices from the patient's perspective in clinical practice. The new tool, when fully developed and validated, will be known as the C-PIADS (Continence-PIADS). It will enable accurate assessment and ongoing monitoring of the introduction, or alteration of, assistive devices, which is essential for standardised practice and robust patient care. The provision of such a tool will enable patient-centred evaluation of new and existing technologies and will facilitate the establishment of a robust evidence base on which to establish treatment decisions for individuals with CD and for guidance at a population level.

## **2. Method**

The study used interpretive methods in which qualitative information from semi-structured interviews was combined with the findings from cognitive interviews for questionnaire pre-testing to inform the development of a new questionnaire.

### **2.1 Participants**

All participants provided written informed consent prior to enrolment in the study, which was approved by the Research Ethics Boards of the Bruyère Research Institute and the University of Ottawa in

Canada, and the Southmead Research Ethics Committee in the UK. A purposive sampling strategy was employed in order to recruit individuals that could provide information rich interviews. In Ottawa, participants were recruited based on recommendation by physio- and occupational-therapists from Ottawa hospitals and community care access centres, whereas in Bristol participants were recruited from Southmead Hospital, Urology Outpatient's Department and a community-based continence clinic. In Ottawa, 9 participants (M= 1; F= 8) were recruited. The average age was 80 years (range: 63-86 years). In Bristol, 31 individuals, (M= 8; F= 23) were recruited. The average age was 56 years (range: 17–87 years). All interviewees self-reported CD – bladder and/or bowel - and use of ATDs to manage continence symptoms. All but one of the participants at the Ottawa site used absorbent products to manage their CD; at the Bristol site, 25 participants used pads (three were in addition to other continence devices), six used intermittent catheters (ISC), two used Foley (indwelling) catheters and one had an artificial sphincter (Table 1).

All participants had consulted a health care professional (HCP) about their continence concerns prior to participating in the study, and were approached to enter the study via their HCP. Participants had incontinence symptoms for a wide variety of reasons including prostate cancer, urethral stretch, overactive bladder, spina bifida. Although we know that attitudes to continence and the management of continence symptoms is related to a number of personal and environmental (both health and social) factors, this pilot study did not attempt to correlate or explain these outside of the PIADS.

## **2.2 Data collection**

Semi-structured, face-to-face, interviews, lasting between 10 and 30 minutes, were conducted with individuals in a safe and confidential environment, such as their own home or in a private room. The interviewer in the UK was an experienced continence nurse and qualitative researcher; the interviewer in Canada was an experienced qualitative researcher in the field of disability and stigma. Questions included: *What technologies (i.e. devices and strategies) are used for continence management? What daily difficulties are encountered with continence management? What is the impact on daily life and significant other people? What are the most liked and disliked features of the technologies being used? What barriers are there to obtaining desired continence management solutions?* The objective was to provide opportunities for interviewees to spontaneously (i.e. *without* reference to PIADS) identify important concerns and issues that should be considered for developing a version of the

PIADS for continence technologies. Face-to-face interviews were audio-taped with permission from participants.

All participants at the Ottawa site and 20 of the 31 participants at the Bristol site were also asked to complete the PIADS in paper format, while considering their currently-used primary continence device or product. This took between 5 and 10 minutes to complete. Participants were asked to comment on the suitability and appropriateness of PIADS for assessing quality of life outcomes resulting from CD intervention. They were also asked how well the questionnaire captured the impact of continence management products and devices. Finally, they were encouraged to suggest supplemental items, (i.e. issues not represented in the PIADS) perceived to impact upon quality of life outcomes following CD intervention. These additional comments were recorded by the researchers.

### **2.3 Analysis**

Recordings of the interview sessions were subjected to qualitative content analysis (16). Content analysis has three steps: open coding, creating categories, and abstraction. The goal of open coding is to identify narratives that address the fundamental research questions. Transcripts are read line by line. Upon identification of relevant text, a 'heading' is assigned in the margin of the transcript.

Investigators are encouraged to assign as many headings as are required to fully describe the content of the text (17). Next, the headings listed in the margins are reviewed and categories of headings created (18). The final step of content analysis is abstraction. During this phase of content analysis, meaningful patterns within and across interview transcripts are identified, and investigators select descriptors of the data (19). Quotations are identified that help illuminate the central questions.

## **3. Findings**

### **3.1 Semi-structured interviews**

A full analysis of interview findings is not detailed in this paper; instead we focus on the applicability (or otherwise) of the PIADS as a measure of continence ATDs.

Analysis of interview transcripts revealed three main topics: the individual-technology, the public or social settings and the emotional content. In the following paragraphs, we describe each theme, and elaborate on how each may impact psychosocial outcomes of CD technology use.

### 3.1.1 Technology outcomes

When prompted to describe their level of satisfaction with the technology, many participants indicated that they had no choice about their CD, and that the products were simply something that they “had to use”. One participant said, *“I don’t like anything about them other than the fact that they keep me dry”*. A different participant provided a similar sentiment, *“They do the job. I don’t like them”*. These narratives were interpreted by the research team as resignation to a reality of product use, rather than an expression of satisfaction.

Some participants expressed dissatisfaction with their products. For example, some described how the products (specifically pads) that they use are not comfortable in hot weather. Others expressed dissatisfaction because of their perception that the products do not mask odour. One participant interviewed in Ottawa indicated that she had issues with product design,

*“The thing is too long for my purpose. I am not a huge person. I know that people are getting larger, but I am getting smaller with age, and they are just too big and too voluminous. And therefore I have taken it upon myself to modify the pads available to me...I don’t know who they fit. Must be a giant or something.... It is very difficult to hide. The way they are designed now, it is practically impossible.”*

In the UK, the cost of products was frequently mentioned, in particular participants indicated that they were not eligible to receive ‘free’ (i.e. NHS funded) products and were thus self-funding.

Several participants indicated that they were not aware of alternative assistive technology devices and medical interventions to help people with CD and were interested to learn about devices other than containment products. There were intimations that health care practitioners may not be aware of the variety of technology options:

*“My doctor told me that it’s a natural part of aging, and there is nothing more that he can do for me. I had to find my own solutions. I didn’t know about other products and strategies.”*

### 3.1.2. Participation outcomes

Restrictions to social and recreational activities were frequently cited as the initial reason for seeking help for CD from health care professionals. Bladder symptoms caused disruptions when away from home, and its effect on spouse and children caused family tension. Participants used words like

"assurance", "freedom" and "empowerment" in describing what they would like their products to give them and do for them (e.g., *"There's nothing I can't do because of it"*).

However, social participation involved more than simply ATD use. Participants described at length strategies to manage CD in public settings. The need to strategize arose from an ever-present concern that one might have an accident and be embarrassed in public. In the UK, one participant indicated that she *"plans everything around her bladder"*, while another in Canada said,

*"It is VERY chronic now. I am always aware of it. So I would never want to go without a pad or to not have a replacement pad...it is just routine now. It would be nice if I didn't have the worry that caused me to wear them (the pads) in the first place."*

Many participants described worries about the conspicuousness of products in public settings. One participant said, *"it is very difficult to wear a pad and not have it perceptible to others, which bothers me a great deal"*. Participants described how anxieties about others finding out about their CD sometimes led to restrictions in lifestyle and social isolation. Participants opted to hide their condition from others by wearing black in order to disguise any leakage, *"I daren't take a chance"*. Other participants restricted choice of clothing to only those items that could accommodate an absorbent pad, because bulky products made it apparent to others that they had CD,

*"not comfortable, make noise when I'm walking [...] I can tell when people are wearing it and that's one thing I would change, you shouldn't be able to tell"*

Although many participants had issues with the disposal of pads, for some the public-disposal of pads was a challenge and embarrassing, the worst aspect was *"carrying one around all the time and getting rid of it"*.

### 3.1.3. Psychosocial Outcomes

Negative feelings and emotions associated with CD, and ATDs to manage CD were described by many of the participants. They voiced anxieties and fears of future events, whereby their CD and/or products may be exposed to others due to leakage, odour and visibility of device. For example, one participant claimed that *"[I] often have to come home because of stains on my trousers [due to leaks]"*. Another participant described her fear of odour, *"...it's horrible, and then the smell and I know it's me. I know I get used to my smell and then you don't know if you are smelling"*. Some participants described a self-stigma, whereby the CD condition and its treatment had led to negative changes in



how participants viewed themselves. For some participants, the manifestations of CD resulted in shame and a reduction in self-esteem. One participant and his family members indicated that there is a stigma of CD “...they look at you as if you should have a big cross on your head and be like ‘catheter user’...” (participant’s daughter). A different participant expressed this idea by saying “...I feel dirty, it’s horrible, that’s the bad thing”.

### **3.2. PIADS**

In general, participant narratives, as well as the subsequent themes and sub-themes arising from analyses corresponded well to the 26 items in the PIADS, and the three main PIADS dimensions of Competence, Adaptability and Self-esteem appeared to adequately cover the issues experienced by participants (Figure 1).

Most participants appeared to be able to complete the PIADS without difficulty, although the design of the form caused problems for some. Even with the assistance of the PIADS glossary, the items *adequacy*, *productivity*, *expertise*, *performance*, *skillfulness* and *sense of power* were queried by more than 20% of the UK cohort. In the Canadian cohort, some participants said that they either did not understand the meaning of the items *competence*, *confusion*, *efficiency*, *embarrassment*, and *frustration*, or felt that more than one interpretation may apply depending on the circumstances. A few participants in both countries were confused by the reverse rating of the items *confusion*, *embarrassment* and *frustration* (i.e. positive ratings denote negative psychosocial impact).

Several items, *expertise*, *confusion*, *eagerness to try new things* and *sense of power* were not easily identifiable by some as issues relevant to continence from the interview data, and were predominantly attributed a zero score in the PIADS. While most participants did not proffer suggestions for new PIADS items, there were some exceptions. One participant suggested that ‘feeling down’ or ‘depression’ should be included, while another thought that ‘optimism’ was a better reflection of his state than *well-being*. Other participants suggested *convenience* – around storage, portability and disposal of devices, and *knowledge* – understanding of CD and performance of the device (Figure 1).

Few of the participants had difficulty in understanding or relating to the items evaluating *usefulness*, *quality of life*, *well-being*, *ability to participate*, *ability to adapt to activities of daily living*, *ability to take advantage of opportunities*, *eagerness to try new things*, *self-esteem*, *sense of control* and *security to their ATD*.

Some potential new items, derived from interviews with the Canadian cohort, were tested with the 20 participants in the UK cohort who had been asked to complete the PIADS. These included *self-consciousness, fear of being 'outed', social acceptance, secrecy, isolation, revealing to others, social participation* and *intimate relations*. The item *fear of being 'outed'* was not understood by UK participants in the context of their ATD. Items *social acceptance, secrecy* and *revealing to others* were queried by a few participants and several declined to answer *intimate relations* rather than ascribe a zero value.

#### **4. Discussion**

The results indicate that the PIADS instrument, with some modification, is potentially a useful and accurate instrument to assess the psychosocial impact of continence devices. The form design and selection of words or phrases need to be changed for a UK population and for continence device users generally.

In the interviews, the participants repeatedly discussed issues around or about the measurement domains represented in the three subscales of the PIADS (Competence, Adaptability, and Self-esteem). There were no items that were judged to be inappropriate or irrelevant by more than small proportion of the participants. The narratives indicated that the PIADS may be appropriate to assess quality of life effects attributable to CD intervention.

On the other hand one topic of discussion that took a prominent part of the interview component was concealing CD from others and a reluctance to acknowledge the condition to others in the participant's surrounding. This has links with literature in the area of stigma research, in particular the concepts of *self-stigma* (i.e., directing prejudicial attitudes inwards, resulting in shame and reduction in self-esteem and dignity); *felt-stigma* (i.e., emotions associated with the possibility of encountering a stigmatizing event); *enacted stigma* (i.e., episodes of discrimination based solely on stigmatizing attribute (10). Based on our understanding of self- and social-stigmatization associated with age related health conditions, it appears that neither the PIADS nor any of the other CD health-related quality of life outcome measures adequately represent issues related to stigma, which may be an important concept for development of the C-PIADS.

Recognising the potential association of self and social-stigmatization, it is suggested that several key *self-stigma* constructs are already present in PIADS. The self-esteem subscale includes eight items

that assess self-perceptions. If an intervention for CD results in a reduction in self-stigmatizing behaviour (e.g. less frequently directing prejudicial attitudes inwards) the items in this subscale may be sensitive to that change. The participants in this study repeatedly spoke of issues that may be associated with the concept of *felt-stigma*. An important area of discussion was concern about what others might think if an accident occurred and fear of accidents. The original PIADS does not address the fear of accidents. Two specific issues related to felt-stigma coming out of the interviews are: *Fear of being 'outed'*, which refers to fears and anxieties associated with other people discovering your condition or symptoms; and *Social Acceptance*, representing fears that others make negative judgments about you. These items are now being considered as potential new C-PIADS items. Events of stigmatization (i.e. *enacted stigma*) may take place in social settings when people with stigmatizing traits interact with others who do not have this trait. At present, the PIADS does not include items that address this topic.

The issue of stigma warrants further investigation. Continence ATDs differ from many other ATDs in that they assist with an activity (toileting) that is usually carried out by adults in private. Furthermore, the negative connotations with waste, hygiene and contamination are unique. These factors, combined with the associations with sexual activity, separate CD from most other disabilities. While it is important to acknowledge gender in assistive technology assessment, the PIADS is conceived to be equally applicable to both sexes. The putative new items derived from the Canadian study and those from the UK study require further testing to establish validity. The PIADS offers comprehensive coverage for expression of the majority of issues raised. For example, a number of references were made in the interviews to disturbed sleep and this could affect scores for items such as *frustration, performance, productivity or quality of life*. Issues relating to stigma (*secrecy, social acceptance, etc.*) and *relationships* may not be readily ascribed to existing items and thus may need to be included as new items in the C-PIADS. Whether *convenience* and *knowledge* are adequately represented within the PIADS requires further testing. For some participants the use of their continence ATD was a temporary measure prior to a surgical solution. For others, it was considered permanent. This contextual use of the ATD appeared to be an important factor in the dimensions of Adaptability and Self-esteem, but it is not clear if this can be identified through the PIADS.

The C-PIADS could be an useful tool for clinicians to understand and assess the impact of a particular continence device on an individual patient. Ideally, the tool will have sufficient sensitivity to be able to

differentiate between devices and products within the same category, for example between a single use and long term indwelling catheter, and thus become a useful evidence tool for industry.

## **5. Limitations**

One limitation of the study is that the sample included primarily female pad users. As this project moves forward towards the creation of a reliable and validated PIADS for continence, a more diverse sample will be recruited.

## **6. Conclusions**

The PIADS appears to address many of the important psychosocial concerns of adults who have CD, but participants had difficulty understanding some items, and the application of the response scale to other items. A version for continence, the C-PIADS, will require some modifications and is likely to contain the addition of some new items. The next steps in our research will be to pre-test a C-PIADS that incorporates modifications as evidenced by the exploratory interviews with further samples of continence device users to help assure that the questions and response formats are understandable and acceptable to the population of intended respondents. We aim to examine the content validity and reliability of the new instrument as part of a European ERA-net grant.

The development of an instrument to measure the psychosocial impact of continence devices will provide a useful tool for clinical assessment, researchers and for technology developers. Continence has been described as a hidden condition, because (in many instances) the manifestations of CD are not immediately identifiable by others in social settings. The C-PIADS potentially offers users a way to speak out, and make their attitudes about devices known.

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**Table 1. Characteristics of the Study Participants**

<b>Sex M/F</b>	<b>Age</b>	<b>Technologies Used</b>
<b>Ottawa site</b>		
F	74	Incontinence pads
F	85	
F	85	
F	76	
F	85	
F	86	
F	81	
F	63	Incontinence pads + menstrual pads
F	86	Diapers
<b>Bristol site</b>		
F	17	Incontinence pads
F	31	
F	43	
F	46	
F	48	
F	57	
F	57	
F	59	
F	61	
F	62	
F	63	
F	64	
F	64	
F	69	
F	81	
M	64	Incontinence pads
M	62	
M	68	
M	69	
M	69	
M	65	Artificial sphincter (Pads previously)
F	65	Home-made pad
F	75	Incontinence pads + Ring pessary
M	87	Indwelling urethral catheter
F	44	Intermittent catheter
F	43	
M	56	
F	33	
F	48	Intermittent catheter + Pads
F	49	Intermittent Catheter + Pads (at night)
F	26	Suprapubic catheter + Pads



**Figure 1. Mapping of interview responses to PIADS**

