

Title

'A two phased study healthcare professionals' perceptions of single or multi-use of intermittent catheters

Running title: catheters for clean intermittent self-catheterisation.

There are no conflicts of Interests.

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Abstract:

Aims: This two phase study aimed to explore health care professionals' teaching and prescribing practice related to intermittent catheterisation and to identify their perceptions about the possible implementation of a mixed (single and multi-use) package for intermittent catheterization.

Introduction: Single-use intermittent catheters are the norm in the UK although multi-use is common in some other countries. A recent Cochrane review found no difference in complications, including urinary tract infection rates, between those using single or multi-use catheters. A flexible option of both multi-use and single use intermittent catheters could provide users with more flexible choices in self-care. However, understanding health care professionals' perspectives is one of the keys to developing a multi-use intervention.

Design: A qualitative research framework using in-depth interviews to inform an on line survey.

Method: In-depth interviews were conducted with health care professionals based in the UK who prescribe catheters, teach intermittent catheterisation or manage an intermittent catheterisation service. The interviewees were selected to represent a range of clinical areas, experience and professions -- continence advisors, urology, multiple sclerosis (MS) and spinal cord injury specialist nurses, and General Practitioners. Following framework analysis the themes and factors identified were used to develop an on-line survey which was disseminated through health care professional networks whose members saw patients who use intermittent catheters.

Results: Nineteen health care professionals participated in the telephone interviews; 206 completed the survey. A wide range of professionals in terms of experience and specialty afforded rich information regarding the contextual issues around the teaching and prescribing of intermittent catheters. The primary finding was that health care professionals were concerned about 'minimising health risk' and maximising 'normalcy' for those using intermittent self-catheterisation. Health care professionals who worked in the acute setting or had no experience of re-use were most resistant to the re-use of catheters. Professionals requested evidence that a multi-use package would not increase the risk of developing a urinary tract infection or increase the burden of use to a patient before a mixed package would be considered.

Conclusions:

For multi-use to be acceptable, evidence based guidelines must be available for healthcare professionals and cleaning methods must be acceptable and safe for intermittent catheter users. Further evidence may be required to establish that a mixed catheter package is equivalent to single use only, particularly for outcomes such as urinary tract infection, urethral injury and quality of life.

Relevance to Clinical Practice:

This paper highlights that if multi-use catheters are to be successfully introduced into clinical practice, the ease of use, safety and effectiveness of the cleaning technique will need to be convincingly demonstrated by a range of well-defined users.

What does this paper contribute to the wider global clinical community?

- Policy with regard to multi-use of single use products is varied around the world and informed debate is hampered by a lack of evidence.
- The work suggests that if a simple and effective cleaning technique was developed then this would remove an important barrier to multi-use and allow for greater choice and wider adoption world-wide.

- For a cleaning technique to be successful it is critical that it is simple and highly effective with minimal user burden.
- Further research is required to establish that multi-use is equivalent to single use in terms of health risk.

Keywords: Attitudes, compliance, health services research, lifestyle, nurse-patient interaction, urology.

Introduction and Background

In the UK, approximately 50,000 community dwelling individuals use clean intermittent self catheterisation (IC) to manage chronic incomplete bladder emptying when other strategies are ineffective (NHSBSA 2015). Overall, the procedure is free of problems and easily adopted by users. However, urinary tract infections remain a key concern and, for some, may have serious health consequences. The introduction of hydrophilic, single-use catheters in the 1980s had an attending message that urinary tract infection would be reduced with these products. This led to a gradual shift from one-person re-use of catheters (typically washed with soap and water and air-dried) to single-use, despite a lack of evidence to support improved outcomes. Indeed, over 20 years later, the evidence remains insufficient to favour either single-use or re-use when comparing any clinical outcome including incidence of urinary tract infection (Drake et al 2016; Prieto et al 2014). None the less, legislation on re-use of all products labelled “single use” (MHRA 2013) means that single-use catheters are now the norm in the United Kingdom.

Internationally single-use and multi-use of catheters varies. In 2015, the Nursing Committee of the International Continence Society (ics.org/nursing-committee) elected to explore intermittent catheterisation practices amongst its membership (N=92 members) and conducted a web based survey with 56 responses from a range of countries and cultures including Canada, United States, Australia, New Zealand, Hong Kong, Singapore and several countries within the European Union. Results revealed a complex and dynamic environment with variability in intermittent catheter practice between countries, within countries and between individual practitioners within a country, province or state. Reuse was common practice in Canada, Australia and Japan; in other countries it varied depending on historical factors, specific market factors (supplier and purchaser) and regulatory factors.

Recent qualitative research with 39 experienced IC users (Sartain et al 2015) indicates that some would select re-use at least some of the time. Reasons cited include fewer catheters when travelling, economically and environmentally sensible, easy storage and never running out of products. Concerns about reuse were the need for a reliable cleaning method, worry about urinary tract infection and carrying a used catheter if away from home. Single use catheters were thought to be protective against urinary tract infection, easy to use, but were costly, required large numbers in luggage if travelling and storage at home, and environmental concerns. The results showed that the individuals interviewed were not adverse to a mixed package of single and reuse depending on circumstances and a reliable cleaning method.

A key concern about reuse is the risk of urinary tract infection and for any change in IC practice to be acceptable, cleaning methods must be trustworthy. Efficacy of catheter cleaning using Milton Method (soap & water wash then Milton soak for 15 minutes) has recently been demonstrated to result in less than .0001% likelihood of detectable bacteria on reused catheters (Wilks et al, 2016). The laboratory method was then assessed in the homes by male and female (n=18) IC users (Macaulay et al, 2016) with one experienced individual describing the Milton Method thus: *The cleaning process was demonstrated at the first meeting and once I got home and read it through again it seemed very easy and straight forward and no I didn't have any problems with that -- I thought it was excellent.*

Another reported that As far as the cleaning was concerned with reusable catheters I found the process straight forward right from the very beginning. As long as you had the equipment set out and had your routine quickly established I found no problem at all, it became an automatic process really just like brushing your teeth.

However, any practice change also requires a thorough understanding of the views of those affected. In this paper, we focus on healthcare professionals' views of reuse and single use and their practice related to teaching and support of intermittent self catheter users. The study was in two Phases: Phase 1 consisted of qualitative interviews with a number of healthcare professionals involved in teaching intermittent self-catheterisation users, prescribing catheters or managing intermittent catheterisation services. Phase 2 was a United Kingdom-wide survey of healthcare professionals to further explore the findings obtained in Phase 1.

Study Aims:

Phase 1: To explore healthcare professional' perceptions about a of single-use and multi-use catheters for intermittent catheterisation which would inform questions for a survey (Phase 2).

Phase 2: To identify via survey the practices and opinions of United Kingdom healthcare professionals involved with teaching and prescribing intermittent catheters and identify potential issues around the possible implementation and integration of a mixed package of intermittent self-catheterisation use.

Method

Ethical Approval

Ethical approval was gained from *School of Life and Health Sciences, Glasgow Caledonian University*, and written informed consent was obtained from all interview participants. For the online survey, participant consent was ensured via a statement on the website: "CONSENT: The researchers assume that if you complete this survey and click the 'submit' button, this means you agree to your responses being combined with the other responses. That way your individual response is part of the total response to these questions. You cannot be identified through completing the survey." Survey data was not coded or identified in any way. No contact was made with any respondents.

Phase 1

In-depth interviews of ranging between 30 to 60 minutes each were conducted to identify indicators for catheter recommendation and to explore healthcare professionals' attitudes and beliefs that could affect the implementation of a mixed package in practice.

Participants: The study was advertised to appropriate clinical networks. The inclusion criteria were that interviewees were familiar with current intermittent self-catheterisation service management or were currently prescribing and/or teaching intermittent self-catheterisation on a regular basis. They were purposively selected to ensure a comprehensive mix of experience.

Data collection: Telephone interviews with health care practitioners explored their reasons for selecting and recommending particular catheters, as well as the potential obstacles and facilitators to the utilisation of a mixed package. The interview guide included the following topic areas: i) experience in continence care, ii) knowledge and experience of different types of catheters, iii) attitudes and beliefs about multi-use catheters, iv) knowledge and beliefs concerning urinary tract infection and catheter use. The interviews were audio recorded and fully transcribed. Figure 1 illustrates the flow of the study from Phase 1 to Phase 2.

Data Analysis: The transcripts were analysed using thematic analysis, which involved several stages [Patton, 2001; Braun and Clarke, 2006]. First, the researcher (JC) familiarised herself with the data by reading the first 5 transcripts and identifying initial categories and codes. Any new issues which arose from these interviews were explored in subsequent ones. Codes and categories were then developed from the whole data set and grouped under broader thematic headings. To check that the data was not being selectively analysed, a two day team meeting (authors JC, DM, DL, AC, and CM) was held to review data coding and categories. Out of the debate and discussion new categories were developed and some extracts re-categorised. A consensus was then reached around collating the categories under broader thematic headings (themes). The meeting thus produced a set of informed themes. This was later developed into a framework by the researcher (JC), which was applied to the whole data set. The framework and writing up were further reviewed, refined and agreed upon at follow- up teleconference team meetings.

Results

In-depth interviews were conducted with 19 HCP over a 6 month period by two researchers (JC and DM). They included nurse continence advisors or consultants, continence service managers, nurses specialising in urology, multiple sclerosis and spinal cord injury and General Practitioners (see Table 1 for characteristics of the interviewees).

Table 1: Characteristics of Interviewees N=19	
Age/Years	Number of interviewees
<30	6(30%)
31-55 years	9(50%)
>56	4(20%)
Sex	Male 1 Female 18
Years in Continence practice	Number of interviewees
<1	1(4%)
1-5	5(27%)
>5	13(69%)

Professional role	Continence advisor	5(28%)
	Continence service manager	3(16%)
	Specialist nurse MS	3(16%)
	Continence nurse consultant	2(10%)
	Urology nurse specialist	2(10%)
	Specialist nurse SCI	2(10%)
	General Practitioner	2(10%)
	Total	19

Through the thematic analysis we characterised the following two themes:

1. 'Minimise health risk'
2. 'Maximise normalcy' (note: 'normalcy is a concept from the sociology of chronic illness which refers to the individual's perception of living as 'normal' a life as possible in the face of management challenges associated with illness and/or disability (Ferguson & Walker, 2012)).

'Minimise Health risk' and 'Maximise normalcy' were each in turn, influenced by four factors:

1. Socio-cultural contexts ;
2. Organisational contexts ;
3. Product attributes (design);
4. Intermittent self catheter user attributes, lifestyle, preference (Figure 1).

Socio-cultural contexts – sterility, convenience

Several interviewees suggested that wider cultural barriers could affect implementation of a mixed package, namely a medical culture of 'sterility' and a societal culture of 'convenience'. Single-use/disposable appliances were noted as optimal for this task. *"I suppose, if you are working in hospitals and you are of the culture of everything gets used once because of infection control, obviously, being the most imperative thing".* Interview 16 Multiple Sclerosis Nurse

It was also suggested that a more general societal culture of 'convenience' would make patients reluctant to try anything that required more preparation or thought about its use:

"Yes, the analogy I have is with ready prepared meals everyone says...when it comes down to it an awful lot of people quite like the convenience of taking it out of the pack, sticking it in the microwave for five minutes and eating it, as opposed to all of the palaver of cooking... I think that it may be just training patients and telling them how easy it is to clean and reuse. I don't think you will ever be able to match the instantaneous ease of use that you get with some of the others". General Practitioner Interview 2

Organisational Contexts

Organizational constraints limit the range of catheters that can be recommended in the UK. Only particular types/brands are available on the National Health Service (NHS)

formulary and some general practitioners only pay for certain types of catheters to stay within their budgets. Nonetheless, most health care professionals said they could prescribe outside the formulary if the patient expressed a particular preference or there were strong clinical grounds. However, several said when they had actually done this, they were challenged by pharmacists within local management and commissioning bodies (NHS England):

“we have a formulary which we developed with Medicines Management... we have only put two very basic ones [catheters] in there with the understanding that...we retain the right to choose what is the most clinically appropriate....[But]...We are challenged more and more these days”.it is our pharmacist....all our locals General Practitioners have a combined prescribing budget which is held centrally...they have usually got pharmacists working within the General Practitioner practices who will go in and look at all their prescribing habits”. Continence Manager Interview 4

Product attributes

Health care professionals considered portability, discreetness, comfort, ease of use and ease of disposal as key product attributes.

“Yes packaging is very important. Discreetness and size is very important I found. Easy to use definitely is up there on the list of important things. But most of all is it concealable, does it look like a catheter, those kinds of questions are important”. Continence Nurse Interview 11

A multi-use catheter would need some of the advantages of single use catheters such as discreetness, lubrication and sterility:

“I think they would have to be almost like a disposable, in the sense that they would have to be compact and...come in a purpose fit case. They took out, used and then put back into a sterile seal that was going to not only clean them, but lubricate them. So, basically, almost like an eyeliner type thing or like a lip-gloss thing, where they can go in and out”. Multiple Sclerosis Nurse Interview 16

Intermittent self-catheterisation user Attributes

When selecting which catheters to show patients, health care professionals typically considered whether the individual's manual dexterity would allow them to use the catheter, and if so, how suitable it would be to their lifestyle:

“...the catheter we chose was very much dependent on what packaging she could open. Sometimes it is looking at their dexterity”. Continence Nurse Interview 4

Interviewees indicated that lifestyle and preferences could affect the type of catheter/s offered:

“.... if you've got a patient who is home all the time, or patient that is going out working, or to college or university. That might influence what catheter we're going to use”. Continence Nurse Interview 15

User preferences which could increase adherence and self-management were also part of the decision-making process. In some clinics, individuals were offered different catheters

to handle and encouraged to reflect on what they liked and disliked about the devices and how they would suit their lifestyle.

Choice for users was deemed important and a mixed package (single use and multi-use catheters) was viewed as a positive option. *"I think it is a good idea. I think what it does is it gives you the element of control. If there is a social environment or a place where you feel using a disposable catheter is the best way to do it, that is fine...the multi-use you would use that at home. The single use, take one if you were going out to a social occasion...I think the key thing around that is it introduces patient choice. What you have then got is they are not tied down to one system alone. You can mix and match it".* General Practitioner Interview 1

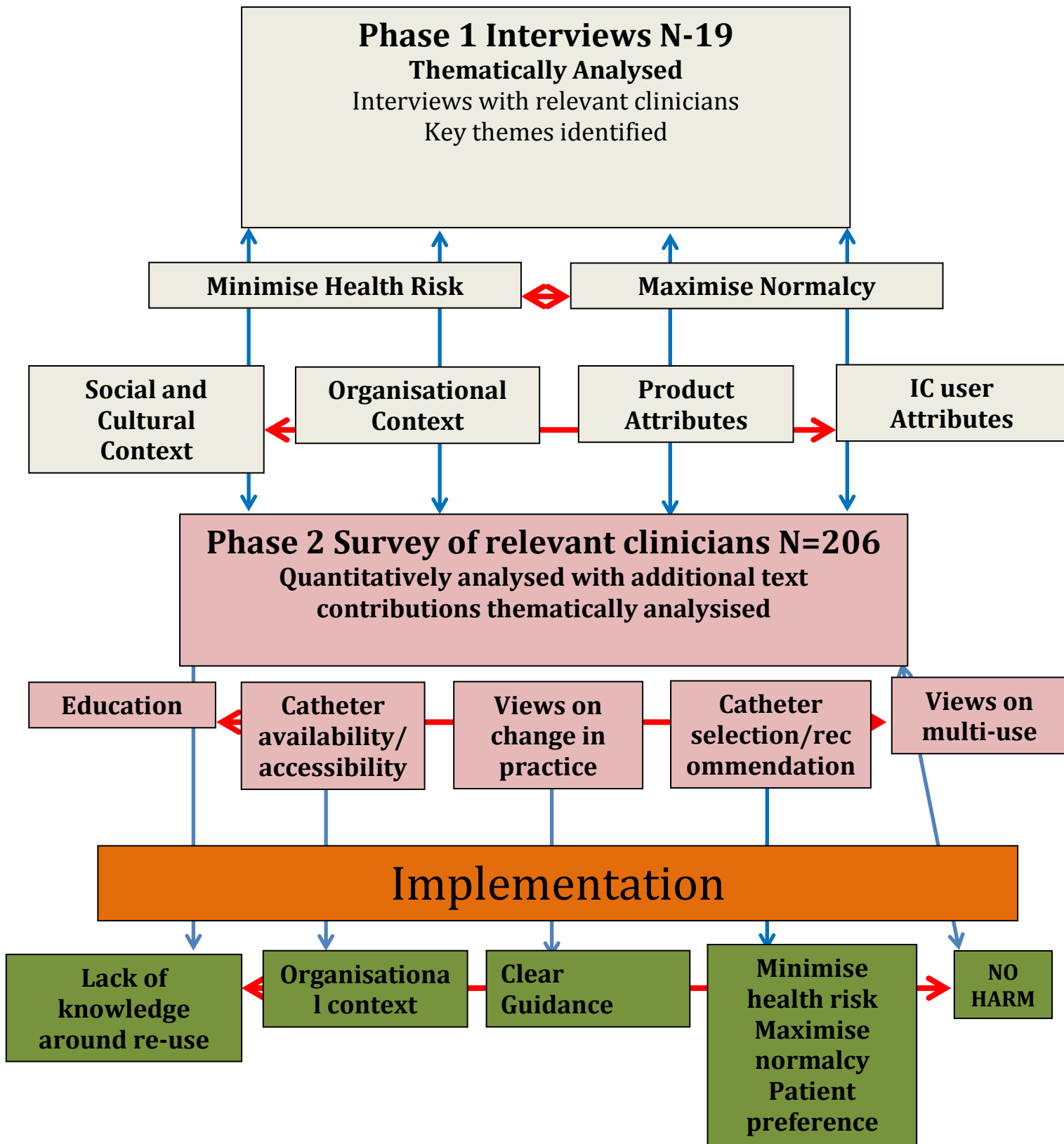
However some healthcare professionals were concerned about the additional 'work' for users (e.g. cleaning procedures) which they believed might increase the risk of infection and/or damage to the urethra.

"For me....it was very much down to patient choice. I have to say most of my patients say, "I would much rather have something that was all nice single, self-contained thing that I can use and throw away. Rather than having to wash things and dry them and so on". General Practitioner Interview 2

Phase 2 Questionnaire Development and Administration

Phase 1 data informed the design of an open web-based survey. The analysis had identified 4 major factors affecting the choice of catheter -- cultural contexts; organizational structure; product design/attributes and user attributes. The survey questions were aimed at contextualizing these factors using a broader sample. We also sought views on the role of education and barriers to implementation of a re-use package.

Figure 1 Flow chart of Phase 1 and Phase 2 data collection and results



Participants – United Kingdom healthcare professionals involved in teaching/prescribing/managing intermittent self-catheterisation were recruited electronically and by print

advertisements via the Association for Continence Advice (ACA), British Association of Urological Nurses (BAUN), Royal College of Nursing (RCN), Welsh Continence Forum, South West Continence Forum, Spinal Cord Injuries Nurses' Association and Multiple Sclerosis Trust. Methods of advertising included web-sites, emails to members, conference fliers and presentations, and information via affiliated social media outlets such as Facebook and Twitter.

Questionnaire development (see Figure 1)

The questions which evolved from Phase 1 (above) were reviewed for face and content validity plus ease of completion with 4 experts involved with teaching intermittent catheterization. The questions were refined, loaded and then retested by the same group. Topics included demographics and clinical experience of the healthcare professionals (including specific training in teaching intermittent self-catheterisation), user demographics, contributing factors to catheter selection and views on single-use and multi-use catheters.

Mock data was extracted to ensure the process was accurate and feasible. Multiple iterations were written and piloted, using colleagues and healthcare professionals. To facilitate completion the overall size of the survey was reduced (from 40 to 33 items), and then disseminated on relevant healthcare practitioner web-sites using SurveyMonkey® (Eysenbach 2014). Responses to open questions were voluntary and mandatory items were highlighted, however consistency checks were not possible. Each multiple choice question was ranked on a 1-7 point scale from 1 = most important response to 7 = least important response; an option of 'other' was included for relevant questions. A final summary question was included to encourage input on changes respondents felt would be required to facilitate a shift in practice if a mixed package of single-use and re-usable catheters was found to be feasible. The final version of the survey is found in **Appendix 1**.

Data collection - SurveyMonkey® (www.surveymonkey.com) was used as the survey platform; this automatically captures responses. Only respondents who had been directed to this web link would have visited the survey site. Once a visitor had viewed this website, commencement or completion of the survey was voluntary. No incentives were offered to respondents.

Data analysis - All responses were imported into Microsoft Excel and reviewed by two authors (DM & JC). Data were extracted to enable mixed-methods analysis. No weighting of responses was performed. Demographic data were analysed using percentages, and responses to open-ended questions were analysed qualitatively using content analysis (Elo & Kyngäs 2008). Textual responses to open questions were initially organised into separate files on Excel spread sheets by copying and pasting from the original survey forms. Files were printed, read and re-read to attain immersion and to gain an overall impression of the data. Codes and categories were then entered into the corresponding

cells of the spread sheets and colour coded for easier reference. Finally, themes were formulated from the major categories. To ensure the trustworthiness and accuracy of the analysis, the co-researchers, who were not involved in this part of the analysis, familiarised themselves with the transcripts and then reviewed and refined the thematic analysis (AC, AL, CM).

Results

The survey links were open from September 2014 to January 2015 netting a total of 206 responses. Unique site visitor or participation identification was not possible hence the completion rate of target participants could not be established. It was not possible to control for multiple entries from the same individual, however it was requested that only one survey was completed per person.

Demographics – Survey responders were similar in type to the participants in the Phase 1 interviews. Table 3 shows details concerning professional practice area, age, time since qualification and professional affiliations.

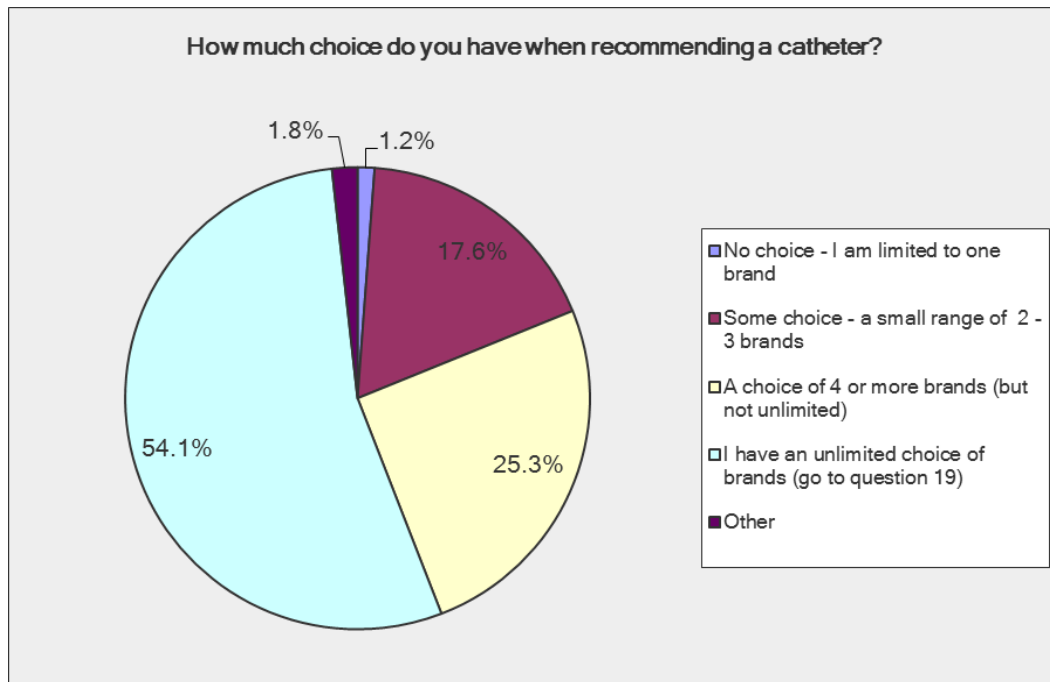
Table 2: Characteristics of survey Respondents N-206		
Age in years	Number of responders	
20-30	7 (2%)	
31-40	26 (12%)	
41-50	87(42%)	
51-60	77(40%)	
>60	9 (4%)	
Sex	Female 94%; Male 6%	
Experience with reuse	75% had no experience, 25% had experience	
Years in Continence practice	Number of respondents	
< 1 year	6(3%)	
1-10 years	74(36%)	
11-20 years	87(43%)	
21-30 years	33(15%)	
>30	6(3%)	
Professional role	Urology nurse specialist	35%
	Continence advisor	32%
	Continence service manager	10%
	Physiotherapist	2%
	Others (General Practitioners, Nursing assistants, managers, industry employees)	21%
Professional Affiliations	Association for Continence Advice	52%
	British Association for Urologic nurses	37%
	Royal College of Nursing	6.5%
	Not stated	4.5%

Fifty per cent of respondents worked within the hospital setting, 37% in the community, 5% nursing homes and the rest varied from industry, sales and marketing and private practice. Forty seven per cent worked with urology patients, 26% with neuro-urology and 16.5% with uro-gynaecology patients; 32% saw 3-7 new patients per month, 29% one or two and 28% saw fewer than one per month. An equal number of male and female patients were seen with most being between 18 and 64 years of age.

Education about intermittent catheterisation - Industry sponsored over 52% of all IC education whilst informal 'on the job' and in-service training accounted for 39%; only 8% of responders had received intermittent catheterisation information via formal accredited courses delivered by higher education establishments such as colleges or universities. The main sources of new innovations or product information was through company representatives (95%), attending conferences (83%), advertising in professional newsletters (68%) and peer to peer contact (52%). Most recent education updates ranged from one year or less to over 10 years.

Catheter Availability - Catheter prescriptions were written by GPs in 74% of cases, with most accepting the recommendation of the nurse teaching IC. The remainder were written by the nurse responsible for the teaching. Overall 54% of responders reported that they had an unlimited choice of catheters available, 25% reported they had a choice of four or more brands (but not unlimited choice) and 18% were limited to two or three brands (Figure 2).

Figure 2



Catheter selection - When choosing a catheter the most important factor reported with respect to catheter design was low risk of causing a urinary tract infection, followed by pre-lubrication and polished eyelets. Over 90% of responders indicated that the main catheter recommended/prescribed was a pre-lubricated single-use product. The main factors that influenced catheter choice for new patients were patient preference, comfort on insertion/removal and ease of use. Ease of opening packaging was seen as moderately important, as was good quality information and instructions. Less important factors included ease of disposal, availability and efficiency of home delivery of supplies

Access to products - In both community and acute care, most catheter samples are provided by industry representatives. Sixty percent of community-based and 72% of acute care healthcare professionals reported relying on representatives to supply products for teaching IC. In addition, 10% of General Practitioners - who are responsible for the catheter budget - would only pay for certain brands of catheter. Other restrictions included space to store catheters and availability of information. In the community, 60% of healthcare professionals tended to rely on company representatives to obtain samples of different catheters. Of those that worked within the acute trust, 72% relied on company representatives supplying free samples of catheters to teach patients intermittent self-catheterisation.

Views on multi-use catheters - 25% of respondents (mainly those who had worked in the field over 20 years) had experience teaching patients multi-use and the majority thought multi-use was good practice. Free text comments of all responders revealed divided views on multi-use of catheters. One respondent wrote: *'Have known lots of patients use re-usable and do not want to change and no increase in urinary tract infection rate'*. Of those with no experience of multi-use, 62% thought it was not good practice with the main concerns focusing on the effectiveness of cleaning the catheter. A respondent with no experience of multi-use wrote: *'Please do not carry on with this study - it completely undermines the healthcare system and is a huge backward step'*.

Opinions on single versus multi use were diverse -- one responder thought that single-use, pre-lubricated catheters were easier to use (especially for disabled people) whereas another felt the opposite - that the uncoated, multi-use catheters were better as the coated catheters were too slippery. A further responder thought multi-use catheters would be really suitable for children, writing:

'The idea of re-usable catheters with children would be ideal as it would be the consistent catheter design they could use for the rest of their lives (only needing to change size of course) making it easier for it to become part of the 'going to toilet routine' - and if using a single-use when out and about say, could make use of the huge selection of designs currently available! I would certainly find it easier in schools teaching classroom assistants who have to 'get used' to a multitude of catheter designs to support young children CIC - a re-usable would be the same familiar design etc.'

The major concerns for those with and without experience of teaching patients to re-use catheters were the increased risk of urinary tract infections, effectiveness of any cleaning method, damage to the urethra and increased patient burden.

Perceived advantages for re-use of catheters included more patient choice, a cost saving to the National Health Service, reducing the fear of running out and environmental advantages. Having fewer catheters to take away on holiday and being easier to remove from the package were thought to be less important. Disadvantages were primarily user burden and worry about urinary tract infections.

Change in practice – Comments on re-use, such as 'it leads to infection', were also made. Sixty-five per cent of responders felt it would be necessary for recommendations to be included in national guidelines before recommending multi-use and over 50% prioritised the availability of easily understood summaries of the recommendations and cleaning methods. Others felt that support of General Practitioners and consultants would be important to bring about change:

'I would certainly be happy to offer this to my patients and recommend it to colleagues. Local Commissioning and Medical Consultant

Discussion

We believe this is the first study in which healthcare practitioners' opinions of catheter re-use is explored. Our respondents represented a range of professional roles but over 50% worked solely in the acute care setting where sterility is mandatory and 75% had never had experience with intermittent self-catheterisation re-use in the community. Thus some of the views expressed reflect an understandable support towards single-use products.

It is evident from our findings that healthcare professionals want to be able to offer the 'best options' for intermittent self catheterisation. This means that the catheter selected should minimise any health risk and facilitate 'normalcy'. If a multi-use catheter package is to be introduced within the UK these two goals need to be evident and achievable. Healthcare professionals therefore need clear evidence based guidelines outlining the

facts on the appropriateness of single and re-useable catheters and IC users need to be given the opportunity to select the catheter that is most applicable to their needs and circumstances. Choice was important and lifestyle and physical attributes such as poor dexterity need to be considered.

Although the introduction of a multi-use system could give IC users a greater choice, the findings of our interviews and survey suggest the majority of HCP who teach and prescribe intermittent self catheterisation would be resistant to such innovation. Many of those who reported resistance had no experience with catheter re-use and practiced in an environment of single use only, with an overriding message that re-use would increase the risk of urinary tract infection. Those healthcare practitioners with experience of re-use were much more amenable to a multi-use package. Conceptually many healthcare practitioners believe single-use to be less likely to cause increased risk to patients yet evidence remains insufficient to support this which is why a randomized controlled non-inferiority trial is required to determine if the risk of developing a urinary tract infection is the same in a multi-use program compared to single-use program.

In order for a mixed package to be successful it was also clear from our findings that those who were teaching patients to use intermittent catheters felt that any increased burden around re-use would impede 'normalcy' for patients. The desire for normalcy has been found to be a key goal for patients with chronic illness, and since urinary incontinence is already a stigmatising and distressing condition, it may be even more important in the context of IC (Lapides et al, 1972, Bhatti et al, 2011, Ferguson and Walker, 2012). Therefore cleaning methods must be simple, effective and involve as few steps as possible.

The lubricity of single use hydrogel catheters was felt by some to be important in the prevention of trauma, although for some intermittent self-catheter users it can make handling difficult and may be a reason for discontinuing use of prelubricated catheters (Chick et al, 2013). Therefore there would need to be a simple option for adding lubrication to a re-usable catheter.

Healthcare practitioners did not rate cost as highly as intermittent-self-catheter user factors when recommending a catheter. However, for the National Health Service, cost is significant and there is potential for substantial cost-savings should multi use methods be shown to be equal to single use in terms of complications – particularly Urinary tract infections. Intermittent catheter costs have risen since 1999 from around £13.5 million to around £50 million per annum in 2007 (National Health Service Information Centre 2007) and are continuing to rise (National Health Service Information Centre 2009), the bulk of this cost being for coated, single-use catheters. For a person catheterising four times per day the cost for coated disposable catheters is around £2000 per annum (based on a single-use catheter cost of £1.40 each). If one multi-use catheter per day is included this will cost around £500 per annum. Using a mixed method (1 multi-use catheter per day plus 1 disposable catheter per day) there would be a saving of around £1000 per annum for such a patient. A mixed approach could be substantially less expensive than a single-use only approach and savings would accrue on a yearly basis. If around half of patients switched to a mixed approach savings could be more than £10 million pa. Further work on the safety outcomes, in particular urinary tract infection, is required and a randomised controlled trial comparing multi and single use is planned (Fader, 2015).

We noted that at present industry is by far the dominant provider of intermittent catheter education. To implement a package of mixed use, education for the HCP needs to be balanced and include views of perceived benefits of re-use from the intermittent self-catheter users' perspective, the research evidence supporting either re-use or single use and the evidence based user-friendly cleaning methods. To bring about change in practice healthcare practitioners need to be supported at a managerial level – in terms of time and funding - to access such education.

Limitations

There are several limitations to our study. Although we recruited our interviewees to cover a wide spectrum of those involved with the teaching and prescribing of intermittent catheterisation and we have over 200 respondents to our survey, the majority had no experience of multi-use of catheters so that their opinions were based on lack of familiarity with the concept of re-use. Rather these beliefs appear to be based on perceptions of working within a prevailing professional culture which emphasises 'sterility' over other concerns. A possible limitation to our survey is that the number of responses were based on our qualitative interviews but would not necessarily have included all possible options. However, these questions did have space for free written comments if anyone found that the listed responses did not adequately cover what they wished to report.

Conclusions

This study is the first that specifically asks Healthcare Practitioners a) about the factors that guide decisions around the intermittent catheter prescribed and b) their views around re-use. We were successful in obtaining a sample of experienced and less experienced healthcare practitioners treating a variety of individuals in various National Health Service settings. The results provide important information on 1) the practicalities of catheter selection and 2) the opinions on requirements to influence a change in practice from single-use only to mixed use (single and multi-use), should further research provide non inferiority evidence.

Our research suggests that healthcare practitioners would be willing to recommend a mixed intermittent catheter package of single and multi-use catheters to intermittent catheter users if they could be assured that there would be no increased health risk or increased burden to the patient. Importantly, 'health risk' was not so much inherent in the multi-use device itself, but rather in an intermittent catheter user's behaviour (poor adherence to recommended cleaning and lubrication methods). It was apparent that the beliefs of many of our responders were based on perceptions from working within a prevailing professional culture which emphasises 'sterility'. To implement a multi-use package, evidence based cleaning methods, innovations in catheter design and appropriate education and training for healthcare practitioners is required. Healthcare professionals believed that individuals benefit from choice when selecting a catheter and multi-use is potentially widening that choice.

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References

- Bhatti, Z.U., Salek, M.S., Finlay, A.Y. (2011) 'Chronic diseases influence major life-changing decisions: a new domain in quality of life research.' *Journal of the Royal Society of Medicine*, 104 (6): 241-250.
- Braun, V. & Clarke, V. (2006) Using thematic analysis in psychology. *Qualitative Research in Psychology*, 3 (2): 77-10.
- Chick HE; Hunter KF; Moore KN. (2013) Parent and child experiences using a hydrophilic or reused PVC catheter for intermittent. *Journal of Clinical Nursing*. 22(3-4):513-20
- Drake MJ, Apostolidis A, Cocci A, Emmanuel A, Gajewski JB, Harrison SC, et al. (2016). *Neurourology & Urodynamics*. 35(6):657-65.
<http://dx.doi.org/login.ezproxy.library.ualberta.ca/10.1002/nau.23>.
- Elo, S., and Kyngas, H. (2008) The qualitative content analysis process: *Journal of Advanced Nursing* 62 (1) 1, 107-115 DOI: 10.1111/j.1365-2648.2007.04569
- Eysenbach, G. (2004) *Improving the quality of web surveys*. The checklist for reporting results of internet E-surveys (CHERRIES). *Med Internet Res*; 6.e34
- Fader, M. (2013) *Development and clinical trial of a mixed (multi/single-use) catheter management package for users of intermittent catheterisation*. National Institute for Health Research (NIHR) under its Programme Grants for Applied Research (PGfAR) Programme (Grant Reference Number RP-PG-0610-10078).
- Ferguson, P. & Walker, H. (2012) 'Getting on with Life': resilience and normalcy in adolescents living with chronic illness. *International Journal of Inclusive Education*, 18 (3): 1-14.
- International Continence Society Nursing Committee 2015 (unpublished data).
ICS.org/nursing
- Lapides J, Diokno A, Silber S, Lowe B. (1972) Clean intermittent self-catheterization in the treatment of urinary tract disease. *Journal of Urology* 107,458-461
- Macaulay M, Morris N, Wilks S, Delgado D, Prieto J, Fader M. (2016). A Novel evidence-based method for reprocessing catheters used for intermittent catheterisation. Abstract 575 *Neurourology and Urodynamics*, 35 (S4): 463-464.
- Medicines and Healthcare Products Regulatory Agency (MHRA) (2013) *Single-use medical devices: implications and consequences of reuse*, Dec 2013. Crown Copyright.[online] Available from:

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/403442/[Accessed:Oct 2015].

NHS Business Service Authority (NHSBSA) (2015) NHS Prescription data (November 2015). [online] London: NHSBSA. Accessed from:
<http://www.nhsbsa.nhs.uk/PrescriptionServices/3494.aspx> [November 2015].

NHS Information Centre. Prescription Cost Analysis England 2007. The Information Centre,2008.

NHS Information Centre. Prescription Cost Analysis England 2009. The Information Centre 2010
http://www.ic.nhs.uk/webfiles/publications/prescostanalysis2009/PCA_2009.pdf
Patton, M. (ed.) (2001) *Qualitative Research & Evaluation Methods*. Thousand Oaks, CA.: Sage.

Prieto J., Murphy C.L., Moore, K.N., & Fader, M. (2014) Intermittent catheterisation for long-term bladder management *Cochrane Database of Systematic Reviews* 9. Art. No.: CD006008. DOI: 10.1002/14651858.CD006008.pub3.

Sartain S, Avery M, Prieto J, Macaulay M, McClurg D, Fader M. Determining the advantages and disadvantages unique to single-catheter and multi-catheter use. Abstract 407 International Continence Society Annual Meeting 2015; ics.org/abstracts.

Wilks S, Morris N, Delgado D, Prieto J, Moore KN, Macaulay M, Fader M (2016). Development of an effective and acceptable cleaning method to allow safe re-use of plain, uncoated catheters for intermittent catheterization. *Neurourology and Urodynamics* Abstract 566. *Neurourology and Urodynamics* 35(S4): 449-450.