

Usability testing of the Norwegian PFDI-20 and PFIQ-7 e-PROMs.

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Abstract

The aim of this study is to provide evidence to support usability and satisfaction, of the Norwegian Pelvic Floor Distress Inventory (PFDI-20) and Pelvic Floor Impact Questionnaire (PFIQ-7) electronic Patient Reported Outcome Measures (ePROMs).

The electronic PFDI-20 and PFIQ-7 Patient Reported Outcome Measurements (ePROMs) were pilot-tested on women with symptomatic Pelvic Organ Prolapse (POP) undergoing surgery at a department of obstetrics and gynaecology at a tertiary centre. Usability was the primary outcome. The level of usability was tested through usability testing followed by cognitive debriefing. The secondary outcomes included level of satisfaction using Patient Reported Experience Measurements (PREMs) and level of ease of use of the electronic compared to the paper version. The patients were invited to fill in the electronic and paper-based versions of the PFDI-20 and PFIQ-7 during the preoperative phase followed by a semi-structured interview 4-21 days after surgery.

Of 74 Norwegian women who were invited to participate in the pilot test, 28 (38%) completed the paper-based version and electronic PFDI-20 and PFIQ-7 versions using a web-based form pre-operatively. The median age of the sample was 55 years (range, 37–80 years). All participants reported that they had a computer at home and/or work and used the internet for email, banking and social activities.

The usability study suggests that women with symptomatic POP and pelvic floor dysfunction found that the PFDI-20 and PFIQ-7 ePROMs were acceptable and easy to use. Furthermore, all patients reported that they were satisfied filling in the electronic versions of the PFDI-20 and PFIQ-7. The majority of patients reported that the electronic version was easier to fill in compared to the paper version.

The Research Ethics Committee, Akershus University Hospital has approved of this study (number 2019-101).

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Original Manuscript

Title:

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Abstract

Title:

Usability testing of the Norwegian PFDI-20 and PFIQ-7 e-PROMs.

Aim: The aim of this study is to provide evidence to support usability and satisfaction, of the Norwegian Pelvic Floor Distress Inventory (PFDI-20) and Pelvic Floor Impact Questionnaire (PFIQ-7) electronic Patient Reported Outcome Measures (ePROMs).

Method: The electronic PFDI-20 and PFIQ-7 Patient Reported Outcome Measurements (ePROMs) were pilot-tested on women with symptomatic Pelvic Organ Prolapse (POP) undergoing surgery at a department of obstetrics and gynaecology at a tertiary centre. Usability was the primary outcome. The level of usability was tested through usability testing followed by cognitive debriefing. The secondary outcomes included level of satisfaction using Patient Reported Experience Measurements (PREMs) and level of ease of use of the electronic compared to the paper version. The patients were invited to fill in the electronic and paper-based versions of the PFDI-20 and PFIQ-7 during the preoperative phase followed by a semi-structured interview 4-21 days after surgery.

Results: Of 74 Norwegian women who were invited to participate in the pilot test, 28 (38%) completed the paper-based version and electronic PFDI-20 and PFIQ-7 versions using a web-based form pre-operatively. The median age of the sample was 55 years (range, 37–80 years). All participants reported that they had a computer at home and/or work and used the internet for email, banking and social activities.

A total of 27/28 (96%) of the patients had a median score of 3 or higher on the usability test. Notably, 26/28 participants reported that the electronic version was easier to fill in compared to the paper version and 28/28 reported a high level of satisfaction while filling out the electronic versions.

Conclusion:

The usability study suggests that women with symptomatic POP and pelvic floor dysfunction found that the PFDI-20 and PFIQ-7 ePROMs were acceptable and easy to use. Furthermore, all patients reported that they were satisfied filling in the electronic versions of the PFDI-20 and PFIQ-7. The majority of patients reported that the electronic version was easier to fill in compared to the paper version.

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Highlight

- Evidence to support that women with symptomatic POP and pelvic floor dysfunction can easily report their symptoms and quality of life through the PFDI-20 and PFIQ-7 ePROMs
- The PFDI-20 and PFIQ-7 ePROMs enable hospitals in Norway to establish local (or national) electronic medical quality registers for patients operated on for pelvic organ prolapse. Such registers would allow surgeons and healthcare professionals to track the patients' progress, symptom burden, and complications and measure the effectiveness of clinical treatment.

Precis:

- The usability study suggests that women with symptomatic POP and pelvic floor dysfunction found that the PFDI-20 and PFIQ-7 ePROMs were acceptable and easy to use.

Keywords:

usability testing; measurement equivalence, user testing; cognitive debriefing, eHealth; electronic patient reported outcome measures; electronic system; PROMs, ePROM; PFDI-20 and PFIQ-7; pelvic organ prolapse.

Compliance with ethical standards:

The Research Ethics Committee, Akershus University Hospital has approved of this study (number 2019-101).

Consent to participate:

Written and oral consent was given for this study in connection with The Medical Quality Register for patients with pelvic organ prolapse at Akershus University Hospital. This study (pilot testing 28 patients) was a part of the quality register's endeavour to improve the implementation of the electronic aspect of the register.

Consent of publication:

No sponsors were provided during this study, therefore no need for a sponsor's approval or censorship of the manuscript. All co-authors have given their permission for publication.

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Competing interests:

The authors have no competing interests

Authors contribution:

C.T. contributed to the study conception and design, data collection, interpretation of the results and manuscript writing; M.E.E. contributed to study conception and design; S.S. interpretation of results and manuscript writing; M.S. contributed to analysis of the data and interpretation of the results; M.H. contributed to data collection; H.T.M. contributed to interpretation of the results; P.H. contributed to data collection; S.P. contributed to data collection; G.E. contributed to study conception and design and interpretation of the results; M.S. contributed to interpretation of the results; and A.M. contributed to study conception and design and interpretation of the results. All authors reviewed the manuscript.

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Background

Patient-Reported Outcomes Measurements (PROMS) are commonly used in healthcare in Norway. Today, the Norwegian self-administered condition-specific health-related quality of life PROMs PFDI-20 and PFIQ-7 [1] have been validated for paper-based administration assessing pelvic organ prolapse symptoms and impact on quality of life [2, 3, 4] and are used in several hospitals in Norway. However, as information technology in Norway is becoming an established part of the

delivery of patient care and research [5, 6], clinicians need to consider how to obtain data electronically while ensuring the usability of ePROM systems is assessed during development to ensure they are fit for purpose [7, 8, 9,10,11,12]. More importantly, versions of ePROMs are increasingly feasible because of smartphone and tablet usage [13].

The United States has recently validated the PFDI-20 and PFIQ-7 ePROMs, which are alternatives to the paper-based PFDI-20 and PFIQ-7 [14]. The availability of the PFDI-20 and PFIQ-7 ePROMs in the healthcare setting in Norway could give doctors or other health personnel direct access to data entered by the patients, thus decreasing costs [6], enabling rapid analysis of collected data and improving data quality and the accuracy of collected data [15]. Notably, the ePROMs can also encourage higher survey response rates [5, 15] and, hence, reduce nonresponse bias [15]. Moreover, the web-based PFDI-20 and PFIQ-7 enable hospitals in Norway to establish local (or national) electronic medical quality registers for patients operated on for pelvic organ prolapse. Such registers would allow surgeons and health professionals to track the patients' progress, symptom burden, complications, higher data quality and response rates, facilitate symptom management and more easily measure the effectiveness of clinical treatment of pelvic organ prolapse and pelvic floor dysfunction [6].

Based on the ISPOR ePROM Good Research Practices Task Force Criteria, it could be established that only minor to moderate modifications were made to the PFDI-20 and PFIQ-7 ePROMs when migrating from paper version. The ISPOR Task Force defines a minor to moderate modification as "not expected to change the content or meaning of the items and response scales" [9,16].

In cases where minor or moderate modifications have been made, ISPOR recommends performing usability testing and cognitive debriefing on the paper-based and ePROM versions of the PFDI-20 and PFIQ-7 before clinical application [7, 9, 16]. Usability testing and cognitive debriefing examines whether patients can use the device and software and complete the ePROMs correctly. If required, changes can be made to the software to resolve issues [8]. Finally, usability testing ensures that the ePROMs system is efficient (in terms of time) [7,12,17], effective (in terms of no or few non-critical errors) and satisfactory to the patient [7,12]

The aim of this study is to provide information on usability and user satisfaction for the PFDI-20 and PFIQ-7 ePROMs) and gather feedback on user experience.

Method:

This is a prospective usability study of the Norwegian PFDI-20 and PFIQ-7 ePROMs involving four phases: (1) observational findings (2) testing of usability; (3) followed by cognitive briefing (i.e. follow-up probing questions concerning usability [9,16] and (4) patient satisfaction survey [7,12]

A user representative with pelvic floor dysfunction was involved in planning and conducting this study. The aim of user involvement was to improve the accuracy of the design and implementation of this study.

Sample

The electronic and paper versions of the PFDI-20 and PFIQ-7 PROMs were pilot-tested on 28 women with symptomatic POP undergoing surgery at a department of obstetrics and gynaecology in a tertiary centre. Statistical power was not calculated in this study. However, based on the literature

from similar studies, 25-30 is recommended as the minimum number [9].

The inclusion criteria in this study were women referred to the Women's Outpatient Department of Obstetrics, Akershus University Hospital, undergoing pelvic organ surgery with or without bowel or urine dysfunctions. Patients had to be at least 18 years of age and Norwegian native speaking (bilingual/monolingual) women. The electronic questionnaires were given out regardless of the severity of the complaint. Patients with a visual impairment or who were cognitively impaired, were excluded from the study.

Data collection and measurements

Clinical data and sociodemographic data:

Clinical data and sociodemographic data, including age [7,11,12] and education [12] were collected in the post-operative phase of the study.

First, the patients were invited to participate in the study and asked to fill in both the electronic and paper versions of the PFDI-20 and PFIQ-7 PROMs during the preoperative period. While filling in the electronic versions of the PFDI-20 and PFIQ-7 on a PC, the study participants were not permitted to skip a question although the subjects could return to view and change prior responses if needed. Notably, both the electronic and paper-based forms are identical in content, but the format had some small differences, e.g., the electronic version of the PFDI-20 and PFIQ-7 presented one item at a time.

After surgery, i.e. 4-21 days post-operative, a semi-structured interview was conducted by telephone by the principal researcher (Table 1). The semi-structured interview comprised of usability testing followed by cognitive debriefing and a patient satisfaction survey concerning the comparability of the paper and electronic versions of the PFDI-20 and PFIQ-7 forms. A total of 4-21 days after surgery was seen as adequate time for the patient to recall their experiences about filling in these electronic and paper-based versions.

The study was based on a multi research method (phases 1-4) employing both observational field notes, usability testing followed by cognitive debriefing interviews and a patient satisfaction survey.

Observational field notes (Phase 1):

Before the operation, the patient filled in both the electronic and paper-based versions of the PFDI-20 and PFIQ-7 PROMs. During this process, observational field notes were taken by the nurses and examined whether the patients from the target population could navigate the electronic platform, follow instructions and complete the computerized questionnaire independently or if they needed help. The nurses also noted the time used to complete the PFDI-20 and PFIQ-7 ePROMs and if there were any hesitations while filling out the ePROMs.

Usability testing and cognitive debriefing (Phases 2 and 3):

After surgery, i.e., 4-21 days post-operative, usability testing and cognitive debriefing of the PFDI-20 and PFIQ-7 ePROMs were conducted. The *usability testing* process (Phase 2) included an interview guide to test the respondents' ability to use the software and computer device appropriately, navigate the ePROM platform, follow instructions, and answer questions (Questions 1a-5a, Table 1) [11,12]. This process helped to determine whether the layout of the electronic instructions was clear or if anything was confusing to the patients [12]. For each question in the interview guide, patients were asked to rate adequacy of the instructions, ease of use and ability to read the screen [12] on a 4-point Likert scale from 4 "very easy" to 1 "very difficult". The median score for questions concerning

usability of 3 or higher (on a 4-point Likert scale) [10,12] by at least 80% of the patients was considered acceptable and indicated a high level of usability. If more than 20% of patients were unable to complete the electronic questionnaire, the questionnaire would be revised and tested on a new POP target group. In addition, acceptability of the time was taken to complete the questionnaires (Question 6a, Table 1).

The Cognitive debriefing process (Phase 3) (1b-6b, Table 1) consisted of verbal probing, where the interviewer asked a follow-up question based on the questions from usability testing (1a-6a, Table 1). The interviewer asked the participant “Could you say slightly more about your answer concerning how and why you experienced following the instructions, filling in the ePROMs, etc., easy or difficult...” (Table 1). These questions focused on how and why the patient experienced the tasks clear, easy or difficult in terms of the instructions and filling in the ePROMs. This process would support the findings of the usability testing.

Patient satisfaction survey (Phase 4):

Following usability testing and cognitive debriefing, the patients were asked to rate their *degree of satisfaction* in completing the ePROMs on a 4-point Likert scale from 4 “extremely satisfied” to 1 “dissatisfied” (Table 1). A median score for questions concerning satisfaction of 3 or higher by at least 80% of the patients was considered acceptable and indicate a high level of satisfaction [12].

The patients were also asked to rate how easy it was to complete the electronic version compared with the paper version on a 4-point Likert scale from 4 “very easy” to 1 “difficult”. A median score for questions concerning ease of use of 3 or higher by at least 80% of the patients was considered acceptable. The satisfaction and ease of use survey collected feedback on user experience [12].

Notably, during data collection, the findings and any resulting changes documented the process [9]. Missing items in the electronic format were also documented.

An expert panel comprising the principal researcher, gynaecologists, a user representative, and a representative from the Information and Communication Technology (ICT) Department examined the data and made necessary amendments to the ePROMs [9]. These amendments were based on the results from the interview guide and observational field notes.

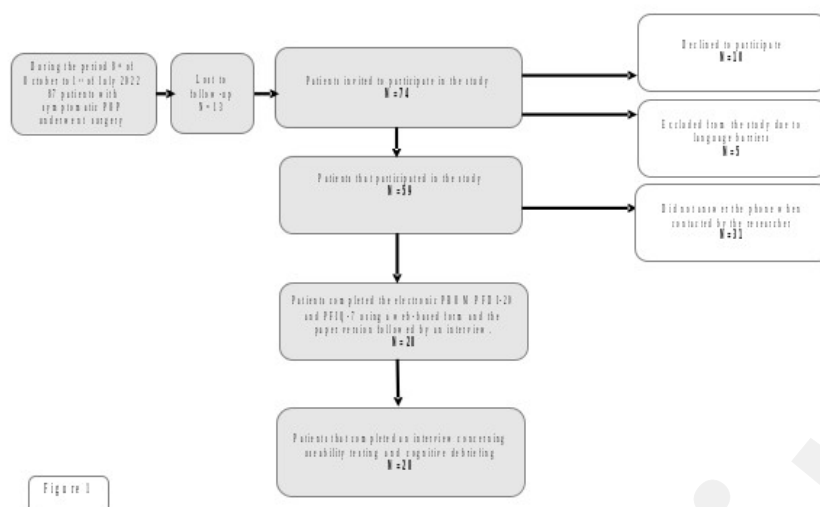
Analysis:

All analyses were performed using Excel.

Results:

During the period 8th of October 2021 to 1st of July 2022 87 patients with symptomatic POP underwent surgery. Thirteen patients were lost to follow-up. Seventy-four patients were invited to participate in the study. Ten of the 74 (14%) patients declined to participate. Of the ten patients, five declined to participate due to dislike of PCs and electronic devices and two due to dislike of PROMs. Five of 74 (7%) were excluded from the study due to language barriers. Fifty-nine of 74 (78%) patients said yes to participate in the study. However, thirty-one of 59 (53%) did not answer the phone when contacted by the researcher (Figure 1).

Twenty-eight of the 59 (36%) completed paper versions of the PFDI-20 and PFIQ-7 and electronic versions using a web-based form preoperatively (Figure 1). After surgery, all patients (28/28) completed questions 1-6 (in the interview guide) except one patient who did not answer Question 3 (Table 1).



Clinical data and sociodemographic data:

The median age of the sample group was 55 years with a range from 37 to 80 years. The majority of women had POP with POP-Q stage 2-3. Anterior compartment prolapse was the most common type of POP, and some had POP in more than one compartment.

A total of 26/28 (93%) patients had completed a high school diploma, and of the 28 patients, 16 (57%) had completed a college/university degree. Six of 28 patients were pensioners. All participants reported that they had a computer at home and/or work and used the internet for email, banking and social activities.

Observational findings:

The observational notes were taken by the nurses at the surgical department during the preoperative period. The nurses reported that all patients were able to use the software, navigate the electronic platform, answer questions, use the device appropriately and able to complete the PFDI-20 and PFIQ-7 ePROMs within the range of 10-15 minutes.

The nurses also noted that twenty-five of 28 (89%) patients experienced no hesitations while filling out the PFDI-20 and PFIQ-7 ePROMs. However, one patient hesitated due to the formulation of a question. Another patient hesitated due to problems clicking to the next question. Finally, one patient hesitated because there was no response alternative that suited her particular situation.

Measurements findings- Usability and Cognitive Debriefing after surgery:

A total of 27/28 (96%) of the patients reported a median score of 3 or higher (for questions 1a-6a) in the usability questionnaire (Table 1). These results provided evidence to support a high level of usability concerning the PFDI-20 PFIQ-7 ePROMs. Furthermore, the cognitive debriefing supported the findings from the usability testing in terms of filling out the electronic questionnaires and reading the screen layout (Table 1). However, 2/28 patients reported one non-critical error stating that it was

difficult to click further because they could not read the screen. Conversely, these non-critical errors did not prevent the patients from completing the ePROMs.

Table 1: Interview guide: usability testing (Phase 2) followed by cognitive debriefing (Phase 3), n=28

Questions concerning usability ^{a,b}	Median ^c (1-4)	Usability testing N	Cognitive debriefing ^d When N=28 patients asked a probing question after usability testing, some patients reported the following:
1a. How easy did you find filling out the questionnaires electronically ^a ?	4	28	1b. 2/28 patients reported “one question at a time using the electronic questionnaire enables the reader to focus better” and 1b. 3/28 patients reported that the electronic system enables the patients to return to view and change prior responses
2a. How easy did you find following the instructions to fill in the questionnaires ^a ?	3	28	2b. No comments
3a. How did you experience reading the screen lay-out ^a ?	3	27	3b. 3/28 patients reported that they experienced that the screen was readable and clear
4a. How did you experience reading and understanding the questions and response alternatives in the questionnaire ^a ?	3	28	4b. 2/28 patients experienced that the font size was good
5a. How easy did find navigating the electronic questionnaire (i.e. clicking to next question) ^a ?	4	28	5b. 2/28 patients experienced that it was difficult to click further because could not read the screen
6a. Would you say it took reasonable time to fill in the questionnaires?	3	28	6b. No comments

Response alternatives to the questions rated on a 4-point Likert scale (questions 1a-6a)^{a,b,c}:

^a Difficult = 1 Somewhat difficult = 2 Easy = 3 Very easy = 4

^b Unreasonably long time = 1 long time = 2 reasonable time = 3 not that long = 4 ; ^c The median score for questions concerning usability of ≥ 3 (on a 4-point scale) by at least 80% of the patients were considered acceptable and indicate adequate measurement equivalence.

Cognitive debriefing question^d: “Could you say more about your answer concerning how and why you experienced.... 1a. filling out the questionnaires electronically; 2a. following the instructions; 3a. reading the screen lay-out; 4a. understanding the questions and response alternatives; 5a. navigating the electronic questionnaire; 6a. using reasonable time on the questionnaire”.

Not all participants commented on the verbal probing question concerning questions 1a-6a.

There were no missing items in the electronic format. A total of 28/28 patients filling in the PFDI-20 and PFIQ-7 ePROMs reported a median of 3 or higher (satisfied to extremely satisfied) in the satisfaction survey (PREMs). These results are considered acceptable and indicate a high level of

satisfaction.

Furthermore, 26/28 participants reported during the PREM survey that the electronic version was easier to fill in compared to the paper version with a median of 3 or higher (easy to extremely easy). These results are also considered acceptable. Of note, three women commented that they would prefer to fill in the PFDI-20 and PFIQ-7 at home using ePROMs. Two reported that ePROMs are environmentally friendly.

The nurse reported their findings back to the expert team. The expert panel comprised of a principal researcher, a gynaecologist, a user representative, and an ICT expert examined the quantitative and qualitative data and concluded that no amendments were necessary to the ePROM.

Discussion

This article presents the results of the usability testing of the PFDI-20 and PFIQ-7 ePROMs in women with symptomatic POP and pelvic floor dysfunction. The PFDI-20 and PFIQ-7 ePROMs were found to have a high level of usability. Several other usability studies have reported similar findings were ePROMs are acceptable and easy to use [7,10,11,12]. Furthermore, Sun et al. have also reported similar findings were ePROM PFIQ-7 are acceptable to use [17]. Of note, the patients completed the PFDI-20 and PFIQ-7 ePROMs within the range of 10-15 minutes like the PFDI-20 and PFIQ-7 paper-versions [18].

Further, all patients reported that they were satisfied to extremely satisfied in filling in the electronic versions of the PFDI-20 and PFIQ-7. Notably, several studies have also reported a high level of satisfaction with and attitude towards ePROMs. Most patients who were exposed to an ePROM found it easy to learn, easy to use, and would like to continue using it [6].

Based on this study, we found that PFDI-20 and PFIQ-7 ePROMs can improve data quality, reduce errors during the data entry process (e.g. missing data), inconsistent answers or the need for separate data entry [14]. Furthermore, the on-screen format was designed to present one item at a time, hence reducing the length of the questionnaire and confusion [14]. The conditional branching or skip logic incorporated in the PFDI-20 and PFIQ-7 ePROMs also reduced the patient burden by minimizing the impact of the questionnaire length [14]. Furthermore, the ePROMs were considered user friendly in terms of returning to view and change prior responses if desired. Finally, the ePROMs were also considered environmentally friendly by some of the participants due to the lack of paper waste [6].

Even though the median score for usability was acceptable one elderly participant (aged 80 years) commented that she had problems navigating the digital platform because she could not click further to the next question. Aging populations can pose a large challenge in the health sector and cause a “digital divide” [6, 19]. Potential solutions can include providing sufficient support and providing a back-up paper-based version to avoid excluding this segment of the population. However, Handa et al. indicated that age does not seem to affect the completion or accuracy of ePROM results [14]. Notably, filling out ePROMs using “Bring Your Own Devices (BYOD)” or mobile devices and completing ePROMs at home (at your own pace and convenience) can be helpful in aging populations [6].

In summary, the strength of this study included the use of a multi research method in testing usability providing a data rich evidence base (i.e. using both observational notes, usability testing and cognitive debriefing), reinforced with a satisfaction survey.

However, there were some limitations in the study. Several potential participants were excluded (due to not being fluent in Norwegian) or declined due to computer illiteracy or lack of interest in a digital platform. Computer illiteracy, or lack of interest in a digital platform is a challenge in the health sector today; however, with the increasing number of both internet and mobile app users in Norway, it will be easier for populations to utilize ePROMs in the future [19]. Notably, the level of e-health literacy is high in Scandinavian countries among the general population combined with a high access to computers and internet. Furthermore, for patients not fluent in Norwegian, ePROMs should be available in several other languages in Norway. Today, the PFDI-20 and PFIQ-7 PROMs have been translated into several different languages [1, 20, 21].

We did not compare possible differences in the outcome when testing the electronic- and paper version. However, we assessed how the patient experienced filling in the electronic version compared to the paper version. Almost all the patients considered the electric version “easy to very easy” to fill in compared to the paper version.

The sociodemographic and clinical characteristics of the patients interviewed were typical (i.e. terms of age and POP condition) and in accordance with those expected from the hospital population. The wide age distribution among the pilot test patients was representative of all ages and indicated that all age groups could complete the ePROMs without difficulty. However, as seen in other studies, the participants in our study sample were highly educated, middle aged, employed and well acquainted with both computers and the internet and may have not been representative of the general population in terms of educational level and computer literacy [14].

Of note, all recruitment of patients of this study was undertaken in a tertiary hospital and included patients undergoing POP surgery with POP-Q stage 2-3. This factor may have resulted in bias, affecting generalizability to the target population. Further validation studies in other target POP populations and contexts are recommended.

Finally, the response rate in the study was low due to contact issues with the participants. Several patients were contacted several times and did not take the telephone. This is an increasing trend: if patients do not recognize a mobile or telephone number, they opt not to answer the phone. We have no further data on this sample group. Notably, the low response rate may have led to a non-responder error resulting in sample bias. Nevertheless, of those, 28 who completed the questionnaires, the response rate of 96.4% was considered good.

This pilot test indicates that a larger-scale usability study is feasible and could be employed testing app/smartphone-based e-PROMs versions of the PFDI-20 and PFIQ-7. Furthermore, future validation studies may be needed in measurement equivalence testing of electronic devices and the app/smartphone-based ePROM versions of the PFDI-20 and PFIQ-7. If this is the case, two study designs are recommended by the ISPOR committee, including (1) the randomized parallel groups design and (2) the randomized crossover design [9].

Conclusion

The usability study suggests that women with symptomatic POP and pelvic floor dysfunction found that the PFDI-20 and PFIQ-7 ePROMs were acceptable and easy to use. Furthermore, all patients reported that they were satisfied filling in the electronic versions of the PFDI-20 and PFIQ-7. The majority of patients reported that the electronic version was easier to fill in compared to the paper

version. The use of these ePROMs in the clinical setting, research and medical quality registers will provide a more user-friendly experience for patients and lessen the burden on patients.

Abbreviations:

PFDI-20 Pelvic Floor Distress Inventory-20

PFIQ-7 Pelvic Floor Impact Questionnaire-7

ISPOR The Professional Society for Health Economics and Outcomes Research

POP – Pelvic Organ Prolapse

POP-Q - Pelvic Organ Prolapse Quantification System

IT - Information Technology

ICT - Information and Communication Technology

Patient-Reported Outcome Measurements (PROMs)

Electronic Patient-Reported Outcome Measurements (ePROM)

Electronic Patient-Reported Outcome (ePRO)

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