## CLINICAL ARTICLE





# Development of a questionnaire set to evaluate adaptations to COVID era: The ICS TURNOVER project (Transition of fUnctional uRology to New COVID ERa)

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#### **Funding information**

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#### **Abstract**

**Objectives:** Coronavirus disease 2019 (COVID-19) pandemic has caused a massive cutdown in outpatient urological investigations, procedures, and interventions. Female and functional urology (FFU) has been probably the most affected subspecialty in urology. Several scientific societies have published guidelines to manage this new situation, providing general recommendations. The aim of this study was to devise a robust questionnaire covering every different aspect of FFU to obtain recommendations on COVID-19 adaptations. **Methods:** Delphi methodology was adapted to devise the survey questionnaires for male/female lower urinary tract symptoms (LUTS), pelvic organ prolapse (POP), chronic pelvic pain (CPP), and neuro-urological disease. Content validity, face validity, and internal consistence were assessed to establish the final questionnaire. This study was ethically approved by the Local Research Ethics Committee.

**Results:** A total 97, 59, 79, 85, and 84 items for female and male LUTS, POPs, CPP, and neuro-urology respectively were approved by the participants. Content validity over 0.70 was obtained which seemed reasonable content validity scores. Internal consistency obtains values of Cronbach's alpha was between 0.70 and 0.90 which was acceptable.

**Conclusions:** The collective wisdom obtained through a global survey using validated questionnaires covering every different aspect of FFU patient management is necessary. We have developed a robust and validated tool consisting of five questionnaires covering the most prevalent pathologies in FFU.

# KEYWORDS

clinical practice, COVID-19, Delphi, female and functional urology, management

## 1 | INTRODUCTION

The acute respiratory syndrome coronavirus type 2 (SARS-CoV-2) pandemic has severely hit healthcare systems all over the world. During the acute phase of this

crisis, normal hospital activity has changed dramatically, with some hospitals treating mostly coronavirus disease 2019 (COVID-19) infected patients.<sup>1</sup>

Some of the actions taken in urology departments include cancellation of face-to-face outpatient and

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nonurgent activity to maintain social distancing, screening of planned clinic appointments, consultations for patients with nonurgent conditions via telephone, and rescheduling appointments for a few months later. Clinicians individually evaluated patients with known or suspected malignancies or other urgent conditions. Likewise, outpatient procedures were screened and stratified by urgency. For benign conditions, the majority of procedures were deferred.2 The surgical activity of scheduled patients was canceled, and only urgent or nondeferrable oncological surgeries were done. This was due to a lack of personnel who may have been diverted to other departments and/or lack of technical resources that have been diverted to the management of COVID-19 patients. Functional Urology activity has been reduced as deemed of low priority and even completely stopped in most hospitals. Patients with benign and disabling conditions (such as urinary fistula, pelvic pain, urinary incontinence, pelvic organ prolapse, etc.) also suffered delays of medical attention with consequent negative influence on physical and psychological health, and with quality of life impairment.

Female and functional urology (FFU) has probably been the hardest hit subspecialty in urology with massive cutdown in outpatient urological investigations, procedures, and urological operations.<sup>3</sup> The likelihood is that the global effect of the COVID-19 pandemic will last for some time during which national health systems will have to treat COVID-19 and non-COVID-19 patients simultaneously. Therefore, functional urology units will have to reorganize their activity according to patient priority and the scope of the pandemic in each region.

At the time of writing this article, the World is being hit by successive waves of the pandemic. We are living a great uncertainty about the future: the threat of future waves, uncertainty about vaccine efficacy and availability, virus mutation, the threat of future viruses and pandemics, and so forth. Dynamic scales according to resource availability and healthcare pressure may be useful to draw strategies in prioritization in this new scenario.

Several scientific societies have published guidelines to manage this new situation, providing general recommendations. Asymmetries among countries, regions, and even hospitals, not only in the number of cases confirmed but in resources available make it impossible to be extremely specific with predictions and recommendations. The aim of this study was to devise a robust questionnaire covering every different aspect of Female and Functional Urology patient management during the COVID era: first visit, diagnosis, imaging and tests, invasive procedures, telemedicine, follow-up, medical therapy, emergencies, and surgical treatment.

Once the questionnaire has proven its validity and internal consistency, a worldwide survey among different specialists in FFU will be developed to obtain optimized recommendations.

## 2 | METHODS

Due to the lack of high evidence studies to obtain guidelines at this time, the expert opinion provides level 5 evidence. Key opinion leaders in the field of FFU and urogynecology from several countries around the world, including ones that have been hardest hit by the coronavirus, were asked to devise a strategy to reorganize functional urological activity (diagnosis and treatment) that would be applicable to most of the world. Countries included Belgium, Brazil, Colombia, France, Iran, Italy, Portugal, Russia, Spain, The Netherlands, Turkey, UK, and USA. A modified nominal group technique was used due to the extraordinary meeting and mobility restrictions during the COVID pandemic. Four authors (HH, LLF, DC, and SA) began with the discussion and development of the first proposal of recommendations during the COVID19 pandemic. This proposal was sent to the rest of the co-authors, encouraging contributions from everyone and facilitating quick agreement on the relative importance of issues, problems, and solutions. A revised version was produced and approved by all authors on April 18, 2020. This manuscript has been published in Eur Urol Focus (https://www.eu-focus.europeanurology. com/article/S2405-4569(20)30158-9/fulltext).5

A better way to obtain recommendations on COVID-19 adaptations would be to use a survey among specialists around the world.<sup>6,7</sup> We decided to take the Delphi methodology to devise the survey questionnaires for male/female lower urinary tract symptoms (LUTS), pelvic organ prolapse (POP), chronic pelvic pain (CPP), and neuro-urological diseases in the crisis of COVID-19.

# 2.1 | Delphi technique

During COVID-19 global pandemic in 2020, a panel was set up to work on how to manage urological conditions during this pandemic under the umbrella of the International Continence Society. The Delphi method has been used for the development of questionnaires for male/female LUTS, POP, CPP, and neuro-urological diseases in the crisis of COVID-19. The goal was to categorize the diseases in the setting of outpatients, diagnosis, follow-up, telemedicine, emergencies, and finally, a surgery that can be delayed during the COVID-19 pandemic as suggested by a panel of expert urologists in

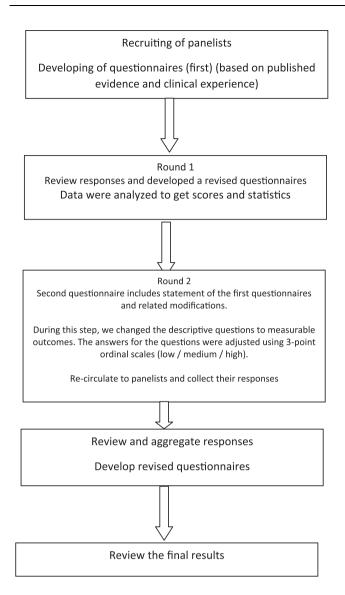


FIGURE 1 The Delphi process of study

the field of female and functional urology and urogynaecologists. This project was done in four stages as are illustrated in Figure 1. In the first stage, the available evidence on how to manage the above conditions in the crisis of COVID-19 was included. In the next step, a survey was created based on the available evidence and sent to the panel members (the ideal number of experts in each panel was 3–4 person). The Delphi steps were then completed using the findings of the panel's consensus for agreement and guidance, and finally, a standard reporting template was designed and approved by the panel.

## 2.2 | Literature review

First, an extensive literature search based on scientific search strategies was performed and related data were extracted. Detailed information is provided in a previously published narrative review that described the limited available data in the urological literature on COVID-19 and the experience of female and functional urological and urogynaecological experts from several countries around the world.<sup>5</sup>

# 2.3 | Questionnaire development

The results of the extensive review were used in designing a guide to strategies and subsequent research steps. The data was gathered using the results of an extensive review of literature, review of international experiences, analyses of the current situation, and expert opinions. The Delphi technique was used to develop and validate the initial framework.

Five panels of experts were assembled, covering the main topics in functional urology: Female LUTS, male LUTS, POP, CPP, and neuro-urology.

The first step was qualitative research with a wide question formulation by the panel experts, covering every different aspect of patient management during the COVID era: first visit, diagnosis, imaging and tests, invasive procedures, telemedicine, follow-up, medical therapy, emergencies, and surgical treatment. For this purpose, after defining the problem and assembling the panel of experts, precise, clear, and independent extensive questions were formulated with 3-point Likert scale answers.

This step was very important to achieve the results in which each panel devised questions or sentences about different aspects that have changed or been affected in each of female LUTS, male LUTS, neuro-urology, POPs, CPP, and neuro-urological diseases in terms of different clinical practices or prioritization due to COVID-19. To avoid overlaps, the general 3–4 coordinators reviewed all questions before preparing the final questionnaire and shared all questions with all panels.

In the compilation step, surveys were administered, and their links were distributed via email.

In this step, participants were asked to independently rank a total of 97, 59, 79, 85, and 84 items for female and male LUTS, POPs, CPP, and neuro-urology, respectively across the domains of outpatients, diagnosis, follow-up, telemedicine, emergencies, and surgery, using a 3-point Likert scale ("agree," "undecided," and "disagree").

After the first round of questions for the panel of experts, and updating the real-time answers, data were analyzed to get scores and statistics. The questions for the second round were finalized.

During this step, we changed the descriptive questions to measurable outcomes. The answers for the questions were adjusted using 3-point ordinal scales (low/medium/high).

# 2.4 | Expert panel recruitment

In the Delphi method, a consensus can be reached with 12–30 respondents. For this purpose, a sample of 40 functional urologists, urogynecologists, and neurourologists were invited via email to participate in this Delphi survey.

# 2.5 | Content validity

In the first step, content and face validity was assessed considering expert opinions. To determine the content validity, the experts were required to evaluate the items in terms of proper wording, grammar, and scoring. The opinions of experts (10 experts) with knowledge and experience in the field of urology, neurourology, or urogynecology were used. Both quantitative and qualitative methods were used to determine the content validity of the content. In the qualitative review of the content, the researcher asked the experts (panel of experts) to provide the necessary feedback after reviewing the quality of the tool based on the criteria of grammar, using the right words, placing the items in the right place, and scoring appropriately. The questionnaire was re-evaluated after receiving the comments and recommendations (primary re-evaluation).

In the quantitative assessment, the Content Validity Ratio (CVR) and Content Validity Index (CVI) of the items and the questionnaire were determined. To determine CVR, experts were asked to rate the items into three categories including "necessary," "useful but not necessary," and "unnecessary." The answers were finally calculated using statistical formulas of CVR = (Ne - N/2)/(N/2) in which the Ne is the number of panelists indicating "essential" and N is the total number of panelists. The calculated CVR numbers ranged from 0 to 1; this number was compared and confirmed considering its equivalent amount based on the number of experts using the "Lawshe" table. Items with inappropriate CVR were omitted and did not make it to the next step.

To determine the item-CVI (I-CVI), the second group of experts who were not attended at the first step of 3-points Likert scale questionnaires generation, evaluated the relevance of the items in a 4-segment Likert scale (1-irrelevant, 2-slightly relevant, 3- relevant, and 4-highly relevant).

The CVI was calculated as the number of experts giving a rating of "very relevant" for each item divided by

the total number of experts. The amount of CVI is in a range of 0–1; a score closer to 1 has a higher validity. Items with scores > 0.79 were accepted, between 0.70 and 0.79, the item needs revisions, and items with CVI < 0.7 needed corrections.

# 2.6 | Face validity

The face validity of the items was evaluated by providing the questionnaires to experts and the target group. <sup>10</sup> The main question in this context was whether the appearance of the questionnaire to subjects is appropriate or not. Qualitative and quantitative measures were used to evaluate the face validity. For qualitative face validity, difficulty, irrelevancy, and ambiguity were evaluated and corrected by 10 experts.

# 2.7 | Internal consistency

Internal consistency was assessed with Cronbach's coefficient alpha. Statistical analysis was performed using the SPSS-24 software. The questionnaires were completed by 30 experts who had no impact on their content validity of them. The values between 0.70 and 0.90 were considered to be acceptable.<sup>9</sup>

## 2.8 | Ethics

This study was ethically approved by the Local Research Ethics Committee.

## 3 | RESULTS

First, after defining the problem, 3–4 experts in each panel assembled, and the general 3–4 coordinators reviewed all questions before preparing the final questionnaire and shared all questions with all panels, and after the consensus, the links of questionnaires were distributed via email (see Appendix 1). Of a total of 35 invited international experts, 34 persons agreed to participate. Response rates were 97.14% (34/35) for neurourology, 88.57% (31/35) for CPP, and 85.71% for female and male LUTS, and POP (30/35), respectively. Among them, 65.71% (23/35) were urologists, 17.14% (6/35) neuro-urologists, and 17.14% (6/35) urogynecologists. 71.42 percent (25/35) works in an academic hospital, and 25.71% (9/35) in private practice.

In female LUTS, of a total of 106 generated questions in the first step, nine questions didn't achieve the consensus of expert panels, and finally, we had 97 questions for the next phase.

In male LUTS, a total of 67 generated questions, eight questions didn't achieve the consensus of expert panels, and finally, 59 questions were included in the final version of the questionnaire. In POP, 98 generated questions at the first phase were rationalized to 79 questions for use in Phase 2. In CPP, at Phase 1 we had 93 questions, which were rationalized to 85 questions for use in Phase 2.

In the neuro-urology questionnaire, nine questions had medium importance according to the results of panel consensus, and finally, we had 84 questions out of 93.

# 3.1 | Content validity results

Results showed that in female LUTS, the CVI for Female LUTS Panel is 0.73, and 0.75 for Control Panel. In male LUTS these amounts were 0.87, and 0.76, respectively. Table 1 shows the results of all questionnaires.

After this process, CVI for every questionnaire was calculated as follows: CVI-Female LUTS = 0.78; CVI-Male LUTS = 0.85; CVI-Neurourology = 0.70; CVI-Pain = 0.71; CVI-POPs = 0.76; which all seemed reasonable CVI scores.

## 3.2 | Internal consistency results

Internal consistency was assessed with the Cronbach's coefficient alpha. Cronbach's alpha based on standardized items for female LUTS was 0.810 (number of items = 85); male LUTS = 0.802 (number of items = 59); POPs = 0.862 (number of items = 81), pain = 0.826 (number of items = 77), and neurourology = 0.775 (number of items = 78). In all questionnaires, the values of Cronbach's alpha was between 0.70 and 0.90 which be acceptable (Table 2).

## 4 | DISCUSSION

The aim of the study was to obtain a validated questionnaire covering every different aspect of female and functional urology and urogynaecology patient management during the COVID era: first visit, diagnosis, imaging and tests, invasive procedures, telemedicine, follow-up, medical therapy, emergencies, and surgical treatment. We used a Delphi methodology to develop questionnaires for each main topic in FFU: female LUTS, male LUTS, POP, CPP, and neuro-urological diseases. The Delphi technique has been described as "a method for structuring a group

TABLE 1 Content validity index (CVI) for all questionnaires

	=	
Female LUTS		0.78
Female LUTS panel	0.73	
Control panel	0.75	
Male LUTS		0.85
Male LUTS panel	0.87	
Control panel	0.76	
POP global		0.76
Pop panel	0.82	
Control panel	0.76	
CPP global		0.71
CPP panel	0.58	
Control panel	0.68	
NEURO-urology global		0.70
NEURO panel	0.67	
Control panel	0.68	

Abbreviations: CPP, chronic pelvic pain; LUTS, lower urinary tract symptoms; POP, pelvic organ prolapse.

TABLE 2 Cronbach's coefficient alpha for questionnaires

Questionnaire	Cronbach's alpha based on standardized items	N of items
Female LUTS	0.81	85
Male LUTS	0.80	59
POP	0.86	81
CPP	0.83	77
Neurourology	0.78	78

Abbreviations: CPP, chronic pelvic pain; LUTS, lower urinary tract symptoms; POP, pelvic organ prolapse.

communication process so that the process is effective in allowing a group of individuals, as a whole, to deal with a complex problem."<sup>11,12</sup> With no doubts, the challenges raised by the COVID-19 pandemic are a complex problem very difficult to deal without a global and comprehensive approach. The collective wisdom obtained using a global survey would be a very preferable strategy to get the best results. An indispensable first step was to devise a validated questionnaire for the global survey. In this study, we aimed to develop validated questionnaires using a Delphi technique, a very well-recognized method for qualitative decision-making research.

Thirty-four experts agreed to participate in the development of the questionnaires, with a response rate over 85%. Most of them were urologists (65.71%) working in academic hospitals (72.42%). Most questions achieved

consensus to be included in the final versions. After the several steps of questionnaire development, 97 questions were included in the FLUTS questionnaire, 59 in MLUTS, 79 in POP, 85 in CPP, and 84 in neuro-urology questionnaire. Content validity was reasonable for every questionnaire (CVI scores from 0.70 to 0.85) and internal consistency acceptable (Cronbach's alpha from 0.77 to 0.86).

Some other initiatives have been developed to obtain a consensus in uro-oncology diseases using variations of the Delphi consensus methodology. The eUROGEN group achieves 80 consensus statements about the management of penile cancer patients during the COVID-19 pandemic after four Delphi rounds. A group of international uro-oncology experts reached a 75 statement consensus after three Delphi rounds in the management of patients who opt for radical prostatectomy during the pandemic. A

We have found some limitations. Although the experts included were from 18 countries covering five continents, most of them were European and from academic public hospitals, which may have introduced a selection bias" by "Experts included were from 18 countries covering 5 continents, most of the European and from academic public hospitals." Getting global pandemic recommendations needs a global view of specialists from a wide representation of countries, healthcare systems, and social-cultural idiosyncrasies. That means that the limited range of experts may have introduced a selection bias. Some other health systems (private hospitals and clinics) may have been underrepresented. Tackling all the aspects that COVID-19 challenges in FFU are a huge task. The number of questions finally included and validated in each topic is high (from 59 to 97). Ideal property of a questionnaire is to be as short as possible to minimize the burden. The higher the number of individual questions included in a questionnaire, the longer the time needed to complete it, increasing the burden. That means a limitation to achieve a good completion of the questionnaires. Moreover, that means a risk of low rate response of the global survey as well.

We obtained five questionnaires covering the most prevalent pathologies covered by FFU: FLUTS, MLUTS, POP, CPP, and Neuro-urology. The questionnaires provided a robust and validated tool to be used to get a more global and wise view of FFU practice during the COVID-19 pandemic. The next steps include an ongoing worldwide survey under the auspicious of the International Continence Society (TURNOVER ICS project, https://www.ics.org/news/1191).

The responses may be low because of the long questionnaires but if we have short questionnaires we will

have a better pick up rate. Also, this is meant to be pragmatic as well as scientific, and responses in surveys are usually about 30% anyway. Therefore we will follow the methodology of Delphi but with the experts we have. On the other hand, the possibility of moving to a Delphi method if insufficient numbers are achieved. There is no high-level evidence regarding the management of LUTS in a pandemic. All the guidelines published in LUTS have not undergone a rigorous methodology process. Expert opinion is the best available evidence and this is what we aimed to do using a Delphi methodology. It is suggested that starting a Delphi with the same survey focused only on the group of experts we selected.

## 5 | CONCLUSIONS

The COVID-19 pandemic is a challenging healthcare activity worldwide, and FFU activities need to be adapted to a changing situation. The collective wisdom obtained through a global survey using validated questionnaires covering every different aspect of FFU patient management is necessary. We have developed a robust and validated tool consisting of five questionnaires covering the most prevalent pathologies in FFU. The Delphi method, like other consensus development methods, should not be viewed as a scientific method for creating new knowledge, but rather as a process for making the best use of available information in a special situation. Getting global pandemic recommendations in the COVID era is important for Urology and especially for Female and functional urology. The development of comprehensive questionnaires will help to urologists, urogynecologists, and neurourologists for a global view and standardized management of patients in female and functional urology.

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#### CONFLICT OF INTERESTS

The authors declare that there are no conflict of interests.

## **ETHICS STATEMENT**

Regional ethics committee of Tabriz University of Medical Sciences (IR.TBZMED. REC.1399.485) approved the current study.

## **AUTHOR CONTRIBUTIONS**

Sakineh Hajebrahimi, Luis López-Fando, Salvador Arlandis, and Hashim Hashim: Project development. Morteza Ghojazadeh: Data analysis. Sakineh Hajebrahimi,

Luis López-Fando, Salvador Arlandis, Hashim Hashim, and Hanieh Salehi-Pourmehr: Manuscript writing. All authors read and approved the final version of the manuscript.

## THE TURNOVER GROUP

Experts panel composition who developed the questionnaire set: Female LUTS: Francisco Cruz, Mauricio Plata, Bárbara Padilla; Male LUTS: John Heesakers, David Castro, George Kasyan; POP: Tufan Tarcan, Frank Van del Aa, David Carracedo; Chronic Pelvic Pain: Roger Domochowsky, Benoit Peyronnet; Sakineh Hajebrahimi; Neurourology: Emmanuel Chartier-Kastler, Marcio Averbeck, Enrico Finazzi.

## CLINICAL TRIAL REGISTRATION

Since the current Delphi study doesn't have an intervention on human participants, clinical trial registration is not applicable for this type of study.

#### DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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## SUPPORTING INFORMATION

Additional supporting information may be found in the online version of the article at the publisher's website.

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