TRANSLATION AND APPLICATION OF CONDITION-SPECIFIC HEALTH-RELATED QUALITY OF LIFE QUESTIONNAIRES FOR WOMEN WITH PELVIC ORGAN PROLAPSE AND PELVIC FLOOR DYSFUNCTION IN THE NORWEGIAN CONTEXT

by

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SUMMARY

Introduction: The goal was to translate to Norwegian, and validate, short versions of the Pelvic Floor Distress Inventory (PFDI-20) and Pelvic Floor Impact Questionnaire (PFIQ-7) using a sample of women with symptomatic POP and pelvic floor dysfunction. For translation and cross-cultural adaptation of the PFDI-20 and PFIQ-7, a new methodology was developed using the Delphi method approach with a bilingual expert panel.

Method: The PFDI-20 and PFIQ-7 were first translated from English into Norwegian using a multistep translation and cultural adaptation method. This new method combined the European Organisation for Research and Treatment of Cancer (EORTC) Quality of Life Group guidelines, the Delphi method, and an expert panel review. It involved two independent forward and back-translations, with the addition of the Delphi method (anonymous voting, controlled feedback, statistical group response) to establish consensus on translated items among a bilingual pelvic floor expert panel. The translated instruments were then pilot tested through face-to-face semi-structured interviews with 20 women with symptomatic POP.

A total of 205 Norwegian women with symptomatic POP (with or without urinary or bowel dysfunction) completed the questionnaires; 50 completed them again after 1 to 3 weeks, and 76 completed them again 6 months after surgery. The median age of the sample was 61 years (range, 27–82 years). Reliability, validity, and responsiveness were evaluated. Additionally, interpretability, smallest detectable change, standard error of measurement, floor and ceiling effects, and percentage of missing items were reported.

Results: This new translation and cultural adaptation method produced a Norwegian PFDI-20 and PFIQ-7 Intermediate Version 2.0 that demonstrated semantic, conceptual, idiomatic, and experiential equivalence with the original versions. This Intermediate Version 2.0 was then ready for pilot testing. During the pilot test minor discrepancies were identified and amended to produce a Norwegian PFDI-20 and PFIQ-7 Intermediate Version 3.0 that was ready for validation.

Cronbach's alpha ranged from 0.66 to 0.93, and intraclass correlation coefficients ranged from 0.85 to 0.94. Both construct validity and responsiveness were noted to be adequate. Responsiveness was further supported for PFDI-20 with areas under the curve above 0.70.

Estimates were lower for PFIQ-7. Smallest detectable change at the individual level constituted 15% to 21% and 17% to 27% for the PFDI-20 and PFIQ-7, respectively. The absolute value for Minimal Important Change for total scores was 48 and 47 for the PFDI-20 and PFIQ-7, respectively. No floor or ceiling effects were evident in the PFDI-20 and PFIQ-7 total score distributions.

Conclusions: Efforts to ensure a good translation and cross-cultural adaptation of the PFDI-20 and PFIQ-7 resulted in the development of a new study methodology, which used the Delphi method with a bilingual expert pelvic floor panel. The controlled feedback approach, the iterative nature and internal logic of the Delphi consensus method appeared to contribute to improving translation results and ensuring good cross-cultural adaptation of the questionnaires.

The translated questionnaires provided adequate reliability, validity and good responsiveness to change. These short versions of the Pelvic Floor Distress Inventory (PFDI-20) and Pelvic Floor Impact Questionnaire (PFIQ-7) are robust measuring instruments that will enable symptom severity and health-related quality of life to be evaluated in the Norwegian context.

DECLARATION

I certify that this thesis does not incorporate without acknowledgement any material previously submitted for a degree or diploma in any university; and that to the best of my knowledge and belief it does not contain any material previously published or written by another person except where due reference is made in the text.

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Catherine Joyce Teig

October 2018

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"Knowledge is invariably a matter of degree: you cannot put your finger upon even the simplest datum and say this we know". T.S. Eliot.

ABBREVIATIONS

AAOS	American Academy of Orthopaedic Surgeons
COSMIN	COnsensus-based Standards for the selection of health Measurement INstruments
CRADI	Colorectal-Anal Distress Inventory
CRAIQ	Colorectal-Anal Impact Questionnaire
EORTC	European Organisation for Research and Treatment of Cancer
EORTC QoL	European Organisation for Research and Treatment of Cancer, Quality of Life Group
e-PAQ-PF	The Electronic Personal Assessment Questionnaire – Pelvic Floor
ERIQA	European Regulatory Issues and Quality of Life Assessment
FSFI	Female Sexual Function Index
HR	Health-related
HRQOL	Health-related quality of life
ICIQ	International Consultation on Incontinence Questionnaire
ICIQ- VS	International Consultation on Incontinence Questionnaire - Vaginal Symptoms
ICIQ-BS	International Consultation on Incontinence Questionnaire - Bowel Symptoms
ICIQ-UI	International Consultation on Incontinence Questionnaire - Urinary Incontinence Short Form
IQOLA	International Quality of Life Assessment
ISPOR	International Society for Pharmacoeconomics and Outcomes Research
ISPOR TCA	ISPOR Translation and Cultural Adaptation Task Force
KHQ	King's Health Questionnaire
MFSQ	McCoy Female Sexuality Questionnaire
P-QoL	Prolapse Quality of Life Questionnaire
PeIFIs	Pelvic Floor Inventories Leiden
PGI-S	Patient Global Impression of Severity
POP-Q	Pelvic Organ Prolapse Quantification System
GRISS	Golombok-Rust Inventory of Sexual Satisfaction
NGT	Nominal group technique
NIH	National Institutes of Health
PAIS	Psychosocial Adjustment Illness Scale
PFDI	Pelvic Floor Distress Inventory
PFDI-20	Pelvic Floor Distress Inventory (PFDI-20)
PFIQ	Pelvic Floor Impact Questionnaire
PFIQ-7	Pelvic Floor Impact Questionnaire (PFIQ-7)
PRO	Patient-reported outcome

PROMs	Patient-reported outcome measurements
PROMIS	Patient-Reported Outcome Measurement Information System
PISQ	Pelvic organ prolapse/Urinary Incontinence Sexual Function Questionnaire
PISQ-12	Pelvic organ prolapse/Urinary Incontinence Sexual Function Questionnaire-12
PISQ-IR	Pelvic organ prolapse/Urinary Incontinence Sexual Function Questionnaire, International Urogynecological Association (IUGA)- Revised
POP	Pelvic organ prolapse
POPDI	Pelvic Organ Prolapse Distress Inventory
POPIQ	Pelvic Organ Prolapse Impact Questionnaire
PR	Principal Researcher
SF-36v2	SF-36v2® Health Survey
SMIS	St. Mark's incontinence score
TAG	Translation advisory group
TCA	Translation and Cultural Adaptation Group
UDI	Urinary Distress Inventory
UIQ	Urinary Impact Questionnaire
Wexner Scale	Wexner Cleveland Clinic Incontinence Score
WHO	World Health Organization
QoL	Quality of Life

OUTPUTS ARISING FROM THIS THESIS

PEER-REVIEWED JOURNAL PUBLICATION

Teig CJ, Grotle M, Bond MJ, Prinsen CAC, Ellström MAE, Cvancarova MS, Kjøllesdal M, Martini A. Norwegian translations, and validation, of the Pelvic Floor Distress Inventory (PFDI-20) and Pelvic Floor Impact Questionnaire (PFIQ-7). Int Urogynecol J. 2017 Jul;28(7):1005-17.

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Teig CJ, Prinsen CAC, Cvancarova MS, Grotle M, Bond MJ, Kjøllesdal M, Martini A. Ellström MAE. Translation and validation of condition-specific quality of life questionnaires for women with pelvic organ prolapse in the Norwegian context. 8-minute presentation at the Norwegian Gynaecological Association (Norsk Gynekologisk Forening) (NGF) Annual Conference, Bergen, Norway, 22–23 October 2015.

Teig CJ, Bond MJ, Cvancarova MS, Grotle, M, Prinsen CAC, Kjøllesdal M, Øresland T, Saga S, Martini A. Translation and validation of condition-specific quality of life PFDI-20 and PFIQ-7 questionnaires for women with pelvic organ prolapse in the Norwegian context. Poster presentation at the 19th International Society for Pharmacoeconomics and Outcomes Research Annual European Congress (ISPOR), Vienna, Austria, 29 Oct–2 Nov 2016.

AWARDS RELATED TO THIS THESIS

Teig CJ, Martini A, Bond MJ, Grotle M, Cvancarova SM, Øresland T, Prinsen S, Kjøllesdal M, Ellström ME. Translation and validation of condition-specific quality of life questionnaires for women with pelvic organ prolapse in the Norwegian context. First prize for best research lecture at the NGF annual meeting in Bergen, Norway, 2015.

NAME CHANGE

Since the commencement of the PhD study, the principal researcher has re-married, and her name has changed from Catherine J. Planke to Catherine J. Teig.

CHAPTER 1

INTRODUCTION AND RESEARCH PROPOSAL

1.1 INTRODUCTION

Pelvic organ prolapse (POP) and pelvic floor dysfunction affect a substantial proportion of women[1,2,3,4] and often cause bothersome symptoms which have a negative impact on lifestyle, psychological and social well-being.[5,6] To better understand a patient's condition and the impact of treatment on their health-related quality of life (HRQOL), it is necessary to use patient-reported outcome measures (PROMs) such as condition-specific HRQOL questionnaires[3,5]

There are no condition-specific HRQOL questionnaires available in the Norwegian language that assess women's pelvic floor dysfunction (POP, bowel, and lower urinary tract symptoms) or its severity and impact on HRQOL, which are validated or highly recommended by the International Consultation on Incontinence (ICI).[7] The Pelvic Floor Distress Inventory (PFDI-20) and Pelvic Floor Impact Questionnaire (PFIQ-7) are condition-specific HRQOL instruments considered appropriate options for the Norwegian population. They are highly reliable and valid multidisciplinary tools for measuring symptom severity across three domains: POP, bowel, and lower urinary tract.[7]

The current program of research, therefore, undertakes the translation and validation of the PFDI-20 and PFIQ-7. The process to be described comprises the translation and cross-cultural adaptation of the PFDI-20 and PFIQ-7 source versions, i.e. English, to target versions, i.e. Norwegian. To determine the need for such instruments in Norwegian, the extent of the problem and a review of available condition-specific HRQOL pelvic floor questionnaires will be examined in detail. The results of a dual quantitative and qualitative translation methodology and the results of a validation study will be presented.

Several methods exist for translating and validating HR PRO instruments, but there is no gold standard. Translation task forces, e.g. the International Society for Pharmacoeconomics and Outcome Research Translation and Cultural Adaptation Group (also referred to as the ISPOR TCA Task Force)[8] and the European Regulatory Issues and Quality of Life Assessment (ERIQA) Group,[9] recommend certain criteria and principles of good practice. The ERIQA Group

recommends a multistep approach during any translation process. In most translation procedures, a bilingual expert panel plays a vital role in facilitating and improving equivalence and cross-cultural adaptation.[9]

For translation and cross-cultural adaptation of the PFDI-20 and PFIQ-7, a new methodology is described that uses the Delphi method approach with a bilingual expert panel. This new procedure represents a modified version of the European Organisation for Research and Treatment of Cancer (EORTC) Quality of Life (QoL) Group guidelines.[10] The measurement properties, i.e. reliability, validity, responsiveness and interpretability of the translated instruments, are then tested in a prospective longitudinal study.

It is anticipated that the translated PFDI-20 and PFIQ-7 will satisfy an unmet need in Norway for robust instruments that are both clinician and patient-centred. The following section summarises the research objectives and methods in this program of research.

1.2 STATEMENT OF RESEARCH OBJECTIVES AND METHODS

This program of research aims to translate, using a new translation methodology, and validate the PFDI-20 and PFIQ-7 for women with POP and pelvic floor dysfunction in Norway. In addition, a critical assessment of these questionnaires will be reported. The overall aim of the thesis is to provide robust evaluation instruments to quantify the HRQOL of patients with POP and pelvic floor dysfunction in Norway.

The research objectives of this thesis are to:

1. Translate and cross-culturally adapt the PFDI-20 and PFIQ-7 into Norwegian.
2. Investigate the viability of a novel translation and cross-cultural adaptation method using the Delphi method consensus approach with a bilingual expert panel.
3. Test the measurement properties, i.e. reliability, validity, responsiveness and interpretability of the Norwegian PFDI-20 and PFIQ-7, with women with symptomatic POP and pelvic floor dysfunction.
4. Critically evaluate the Norwegian PFDI-20 and PFIQ-7 as tools for measuring pelvic floor dysfunction and condition-specific HRQOL.

The research is reported in four stages:

Stage 1: The translation and cross-cultural adaptation of the PFDI-20 and PFIQ-7 from the source version, i.e. American English to the target version, i.e. Norwegian.

A new translation and cross-cultural adaptation method will be employed, based on modified EORTC QoL Group guidelines involving two independent forward and back-translations, with the addition of the Delphi method to establish consensus on translated items among a bilingual pelvic floor expert panel.

Stage 2: Pilot testing with women with symptomatic POP.

Stage 3: Testing the measurement properties validity and reliability of the Norwegian PFDI-20 and PFIQ-7 with women with symptomatic POP.

Stage 4: Testing the measurement properties responsiveness and interpretability of the Norwegian PFDI-20 and PFIQ-7 for women undergoing vaginal repair for symptomatic POP.

1.3 SIGNIFICANCE OF THE STUDY

Application of the Norwegian version of the PFDI-20 and PFIQ-7 in a clinical setting can provide a tool for identifying patient-experienced symptom severity, HRQOL, and a suitable form of treatment. Furthermore, the PFDI-20 and PFIQ-7 instruments allow various types of outcomes to be measured including symptom severity, psychological well-being, social functioning, HRQOL,[11] and treatment adherence.

As patient-reported outcome measures, the PFDI-20 and PFIQ-7 can also improve patient–doctor communication and facilitate shared decision-making between patients and doctors.[12] Validated Norwegian PFDI-20 and PFIQ-7 instruments can also be used to measure the health of populations,[1,13] and provide patient-reported outcome data for promoting patient management and policy decisions in Norway.[12,14]

1.4 OPERATIONAL DEFINITIONS

Since this study undertakes the translation and validation of condition-specific HRQOL PFDI-20 and PFIQ-7 for women with symptomatic POP and pelvic floor dysfunction in Norway, the following key concepts and terms, central to the study, are first defined.

Pelvic organ prolapse (POP) is the symptomatic descent of one or more of the following: anterior vaginal wall, posterior vaginal wall, and apex of the vagina (uterus or vault). Women with POP often experience other symptoms arising from pelvic floor dysfunction.[15]

Pelvic floor dysfunction describes an often-coexisting group of conditions of which the most common are POP and bowel, lower urinary tract, and sexual dysfunction.[3]

Health-related quality of life (HRQOL) refers to an individual's overall sense of well-being and how a disease or condition and treatment thereof impact various health aspects, e.g. emotional, social, and physical health. Efforts to improve the healthcare management of women with POP, such as reducing disease severity and improving patient HRQOL, require continuous monitoring of HRQOL.[16]

Patient-reported outcomes (PROs) refer to a patient's assessment concerning the impact of a health condition or disease and its treatment on their quality of life. PROs are generally measured from the patient perspective by patient-reported outcome measurements (PROMs), usually administered as questionnaires.[12]

Condition-specific HRQOL instruments are devised to assess how a specific disease or condition affects an individual's HRQOL. Condition-specific HRQOLs, unlike generic HRQOL instruments, facilitate a more comprehensive assessment of specific issues pertaining to the disease process and are more responsive to change after treatment.[5,7]

Translation, in this program of research, is defined as the process of adapting the meaning of source-language wording or text using an equivalent target-language text. The translation process for the PFDI-20 and PFIQ-7 will involve several steps focusing on linguistically translating the source version (i.e. English) to the target version (i.e. Norwegian) and cross-cultural adaptation.[17]

Validation, in this program of research, will comprise testing the measurement properties (i.e. validity, reliability, responsiveness) of the PFDI-20 and PFIQ-7 with women with symptomatic POP.[16,17] Following translation, the psychometric properties of the two instruments will be extensively tested.

1.5 STRUCTURE OF THE THESIS

Chapter 1 details the focus, context, and significance of the current program of research that will be presented in four stages. Subsequent sections summarise the key features of these stages and the chapter(s) in which they are presented.

1.5.1 CHAPTER 2: PELVIC FLOOR DYSFUNCTION AND PELVIC FLOOR QUESTIONNAIRES

Chapter 2 reviews the literature on pelvic floor dysfunction and pelvic floor questionnaires. It addresses the anatomy and function of the pelvic floor, causes, presence, symptoms, etiologies, prevalence and risk factors of POP and pelvic floor dysfunction. Chapter 2 also outlines various types of self-administered pelvic floor HRQOL questionnaires (i.e. global, generic, or condition-specific) designed to measure symptoms, severity, degree of bother, and quality of life. Compared to generic instruments, condition-specific HRQOL questionnaires demonstrate higher face validity, more in-depth assessments of condition-specific issues pertaining to the disease process, and a greater sensitivity to change after treatment. Chapter 2 concludes by outlining existing condition-specific HRQOL pelvic floor questionnaires and the ICI standard recommendations for questionnaire selection.

1.5.2 CHAPTER 3: TRANSLATING PELVIC FLOOR QUESTIONNAIRES

Chapter 3 comprises a literature review on pelvic floor questionnaires and outlines different methodologies for translating health-related instruments, the rationale for validation, and method for Stage 1 of the research. Stage 1 involves a cross-cultural adaptation of the PFDI-20 and PFIQ-7 from the source version (i.e. English) to the target version (i.e. Norwegian) using a new multistep translation and cross-cultural adaptation method.

1.5.3 CHAPTER 4: RESULTS OF TRANSLATING PELVIC FLOOR QUESTIONNAIRES

Chapter 4 details Stage 1 of the program of research, involving translation and cross-cultural adaptation of the PFDI-20 and PFIQ-7 into Norwegian using a novel multistep method combining the EORTC QoL Group guidelines,[10] the Delphi method[18] and an expert panel review.[19] The chapter concludes by discussing how modified EORTC QoL Group guidelines and the application of the Delphi method and expert panel offer an enhanced strategy for producing comprehensible linguistically valid questionnaires, with few discrepant items, ready for pilot testing. Relevant findings of Stage 1 are provided in detail.

1.5.4 CHAPTER 5: INITIAL EVALUATIONS

Chapter 5 describes Stage 2 of the program of research, involving pilot testing the translated HRQOL instruments using a qualitative methodology. This entails describing sample selection (i.e. women with symptomatic POP) and administration of an interview to evaluate the initial

Norwegian translations of the PFDI-20 and PFIQ-7. Relevant findings of Stage 2 are provided in detail.

1.5.5 CHAPTER 6: TESTING MEASUREMENT PROPERTIES

Chapter 6 details Stages 3 and 4 of the program of research, involving a prospective longitudinal study using a quantitative methodology. Stage 3 involves testing the reliability (i.e. internal consistency, test–retest, and measurement error) and validity (i.e. construct validity) of the Norwegian PFDI-20 and PFIQ-7 with women with symptomatic POP. Also, the smallest detectable change (SDC), floor and ceiling effects, and percentage of missing items are reported. Stage 4 comprises testing the responsiveness and interpretability of PFDI-20 and PFIQ-7 for women undergoing vaginal repair for POP. Relevant findings of Stages 3 and 4 are provided in detail.

1.5.6 CHAPTER 7: SUMMARY, RECOMMENDATIONS AND CONCLUSIONS

Chapter 7 provides a summary of the main results, strengths, and limitations of the methodologies used; and recommendations for clinical practice and future research. Importantly, research recommendations are inherently interconnected with the clinical application of the PFDI-20 and PFIQ-7. The dissemination and implementation of the PFDI-20 and PFIQ-7 are important tools for addressing an unmet need in developing more evidence-based, effective healthcare services in Norway.

1.6 SUMMARY

POP is a common condition among women of all ages, and several risk factors are associated with this condition.[2,20] Women with POP often experience other pelvic floor dysfunction. Pelvic floor dysfunction describes an often-coexisting group of conditions, the most common being POP, and lower urinary tract and bowel dysfunction. The taboo nature of pelvic floor dysfunction, such as loss of urine and bowel control, can have a devastating impact on the HRQOL of women.[6,21] Furthermore, embarrassment can often prevent individuals from volunteering information concerning their condition.[22]

In recent years, PROMs such as condition-specific HRQOL questionnaires have become useful instruments for identifying and assessing patients' symptoms and their impact on quality of life.[12] No validated Norwegian condition-specific HRQOL questionnaire exists that assesses women's pelvic floor dysfunction (i.e. POP, bowel, and lower urinary tract) and its

impact on quality of life, at least none that is validated and highly recommended by the ICI. The ICI highly recommends two condition-specific, self-administrated HRQOL PROMs, the 20–item Pelvic Floor Distress Inventory-20 (PFDI-20) and the 7-item Pelvic Floor Impact Questionnaire-7 (PFIQ-7).[7] The multidisciplinary questionnaires assess three domains: prolapse, bowel, and urinary.[11] Together, these questionnaires are a suitable choice as an HRQOL PROM in the Norwegian context.

This program of research aims to translate, using new translation methodology, and validate the condition-specific HRQOL PFDI-20 and PFIQ-7 questionnaires for women with POP and pelvic floor dysfunction in Norway. The study comprises two main phases: (1) translation, cross-cultural adaptation, and pilot testing; and (2) testing the measurement properties (i.e. reliability, validity, responsiveness) and their interpretability in a prospective longitudinal study. Efforts to ensure a good translation and cross-cultural adaptation of the PFDI-20 and PFIQ-7 led to the development of a new study methodology, namely to investigate the viability of a new translation and cross-cultural adaptation method using the Delphi method approach with a bilingual expert pelvic floor panel. This is the first known study to use this new methodology.

CHAPTER 2

PELVIC FLOOR DYSFUNCTION AND PELVIC FLOOR QUESTIONNAIRES

2.1 INTRODUCTION

This chapter introduces the anatomy and function of the female pelvic floor and pelvic floor dysfunction. The prevalence and risk factors for pelvic organ prolapse (POP) and pelvic floor dysfunction are also presented. Finally, the need for HRQOL condition-specific questionnaires, measurement issues and the significance of these questionnaires are discussed.

2.2 LITERATURE SEARCH PARAMETERS

The following electronic databases were used in a search for articles involving pelvic floor disorders, pelvic organ prolapse, pelvic floor questionnaires, and the methodology of translating questionnaires: PubMed, MEDLINE, CINAHL, Ovid Nursing, Up-to-date, EMBASE, Google Scholar, Clinical Evidence, Best Practice, the Cochrane library (Systematic Reviews and DARE), the Norwegian Electronic Medical Handbook (NEL), and the Norwegian Electronic Health Library database (Helsebibloteket.no).

The search was restricted to studies conducted between 1946 and 2013 concerning adult women. It was not restricted to English publications. The following combinations of keywords were selected for the search:

1) Pelvic organ prolapse, genital prolapse, uterine prolapse, pelvic floor dysfunction, pelvic floor disorders, incontinence, faecal incontinence, urinary incontinence, lower urinary tract symptoms, bowel symptoms, bowel function, defecation, woman, female, and Norway were matched with prevalence and/or risk factors
2) Pelvic organ prolapse, genital prolapse, uterine prolapse, pelvic floor dysfunction, pelvic floor disorders, incontinence, faecal incontinence, urinary incontinence, lower urinary tract symptoms, bowel symptoms, woman, and female were matched with health-related quality of life and/or questionnaire and/or instrument
3) Pelvic organ prolapse, pelvic floor dysfunction, pelvic floor disorders, faecal incontinence, urinary incontinence, lower urinary tract symptoms, bowel symptoms,

sexual function, woman, and female were matched with health-related quality of life or quality of life

4) Pelvic organ prolapse, pelvic floor dysfunction, woman, incontinence, bowel function, sexual function, woman, and female were matched with bothersome, and/or functioning, and/or social impact and/or treatment and/or surgery
5) Pelvic organ prolapse, pelvic floor dysfunction, incontinence, bowel function, sexual function, woman, and female were matched with condition-specific questionnaire, and/or generic questionnaire, and/or PFDI-20 and PFIQ-7, and/or patient-reported outcomes and/or patient-reported outcome measurements.

A search for guidelines was conducted in the Norwegian Electronic Health Library database (Helsebiblioteket.no) using the following categories: gynaecology, urology, women's health, and genital prolapse. The search identified guidelines for pelvic organ prolapse, incontinence, pelvic floor, and defecation problems, published by national and international organisations such as the National Institute for Health and Care Excellence (NICE), ICI, the Cochrane library (Systematic Reviews and DARE), and Guidelines International Network (GIN). Additional studies were located by reviewing the bibliographies of identified articles.

2.3 PELVIC FLOOR DYSFUNCTION

2.3.1 ANATOMY AND FUNCTION OF THE FEMALE PELVIC FLOOR

The female pelvic floor is supported by the bony pelvis and comprises of **muscles, connective tissues, nerves and suspensory ligaments.** The main function of the pelvic floor is to support the pelvic organs (uterus, cervix, bowel, and bladder)[23] and it plays an important role in maintaining continence (Figure 2.1). Further, the pelvic floor facilitates urination and defecation and enables vaginal childbirth.[24]

The **muscles** of the pelvic floor include the levator ani muscle group (pubococcygeus, puborectalis, iliococcygeus, and coccygeus)[24] and the perineal muscle group[25] (Figure 2.1).[24] The Levator ani is the largest of all the pelvic floor muscles and forms a horizontal shelf for the support of the pelvic floor organs preventing constant strain on the ligaments.[23] The urethra and vagina pass through an opening within the levator ani muscle group referred to as the urogenital hiatus of the levator ani. Genital prolapse occurs through this urogenital hiatus (see Figure 2.1).[24]

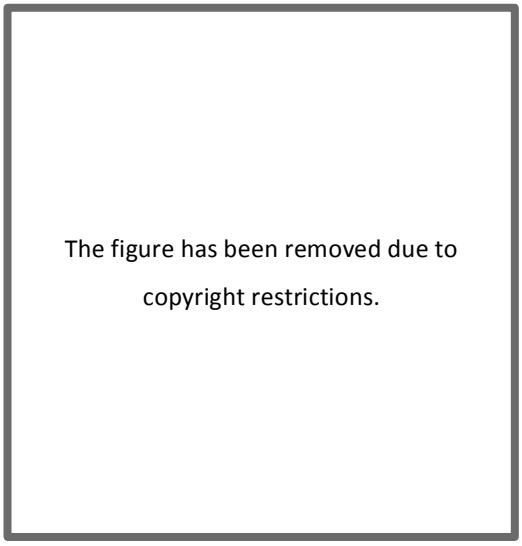

FIGURE 2.1. PELVIC FLOOR ANATOMY.[24]

The organ systems of the pelvic floor are surrounded completely by relatively thick sheets of **neuromuscular connective tissue**. Labelled as endopelvic fascia (see Figure 2.2), this neuromuscular tissue (collagen, elastin, smooth muscle, blood vessels, and **nerve bundles**) provides blood and nerve supply to the organs of the pelvic floor and gives circumferential support to the three cavities that extend across the pelvic floor muscles.[24] Further, they form two separating layers between the organ systems: the vesicovaginal septum and rectovaginal septum.[26]

The **suspensory ligaments** of the uterus (round ligament, uterosacral ligament and cardinal ligament), also part of the connective tissue system, support and stabilise the position of the vaginal apex (uterus). The function of the uterosacral and cardinal ligaments is to prevent the uterus from being displaced anteriorly or interiorly.[27]

2.3.2 PELVIC FLOOR DYSFUNCTION AND PELVIC ORGAN PROLAPSE

Pelvic floor dysfunction (also referred to as pelvic floor disorder) is defined as any weakness resulting in impaired function of any or all of the structures supported by the pelvic floor muscles.[24] It is often classified as a group of coexisting conditions: POP along with urinary incontinence, faecal incontinence, sensory and emptying abnormalities of the lower urinary

tract, and defecatory dysfunction.[1,3,26] These dysfunctions often have the same common risk factors[1] and are often interrelated.[26]

FIGURE 2.2. LATERAL VIEW OF THE PELVIC FLOOR.[24]

Pelvic organ prolapse (POP) is defined as the herniation or loss of support of one or more of the pelvic organs (uterus/vaginal vault, bladder, bowel) into the vagina.[15]

As outlined in Table 2.1, POP is generally classified as a defect (or symptomatic descent) of one or more of the anterior (anterior vaginal wall, cystocele, and urethrocele), apical (uterine and vaginal vault prolapse), or posterior (rectocele, enterocele) compartments.[20]

Vasavada et al reported that POP was most common in the anterior compartment followed by the posterior and apical compartments.[28]

Pelvic Organ Prolapse Quantification (POP-Q) examination quantifies genital prolapse by determining the descent of certain parts of the reproductive tract during Valsalva strain. All measurements are relative to a fixed point, the hymen.[29]

Stage 0: No prolapse.

Stage 1: Most distal part of prolapse is more than 1 cm above the level of the hymen.

Stage 2: Most distal part of prolapse is ≤ 1 cm proximal or distal to the plane of the hymen.

Stage 3: Most distal part of prolapse is ≥ 1 cm below the plane of the hymen.

Stage 4: Complete eversion of the total length of the lower genital tract.

POP usually coexists with other pelvic floor dysfunction symptoms (e.g. lower urinary tract, bowel, and sexual function symptoms). Several studies have found a weak to moderate correlation between the presence of certain pelvic floor dysfunction symptoms and the stage of POP.[5]

The symptoms attributed to POP are commonly divided into four categories: symptoms associated with POP, lower urinary tract symptoms, bowel-related symptoms, and sexual symptoms.[29] A patient-reported outcome measure (PROM) for the assessment of pelvic floor dysfunction, therefore, needs to apply to the following clinical symptoms and findings.[5]

The main **symptoms associated with POP** are a sensation of bulging or fullness in the vagina, pelvic pressure, or seeing or feeling a bulge or lump in the vagina.[1,5,20] The sensation of bulging or seeing or feeling a vaginal bulge, at or below the hymeneal ring, is strongly associated with POP.[1] With the exception of the sensation of bulging, self-reported symptoms are difficult to assess because of the lack of specificity, and prolapse above the hymeneal ring is often asymptomatic.[1]

Lower urinary tract symptoms such as sensory and emptying abnormalities of the lower urinary tract are common among women with POP.[31] Loss of vaginal support directly influences bladder or urethral function resulting in urinary incontinence (stress and/or urge),[31] storage symptoms (frequency and nocturia), and voiding symptoms such as slow stream, urinary hesitancy, and a feeling of incomplete emptying.[5,29] Women with genital prolapse that extends beyond the hymen rarely report stress incontinence. However, they often report urinary hesitancy, a feeling of incomplete emptying, intermittent flow or prolonged stream, and the need to splint the prolapse manually to start or end urination.[5,20,29]

Bowel-related symptoms of POP include hard straining to defecate, evacuation difficulties and the need to apply digital pressure to the vagina or perineum (splint) to start or complete defecation, a feeling of incomplete rectal emptying, and faecal urgency, faecal incontinence (liquid, solid) and anal incontinence (liquid, solid, flatus).[5,29] The symptom of needing to splint the vagina or perineum to defecate is strongly associated with POP. However, studies have shown that bowel-related symptoms are not associated with the severity of posterior compartment POP (rectocele), as many women without POP (rectocele) also present these

symptoms.[5] It is assumed that abnormal perineal descent is associated with bowel symptoms.[20]

TABLE 2.1. OVERVIEW OF POP COMPARTMENT DEFECTS AND CAUSES

ANTERIOR COMPARTMENT DEFECT	**DEFINITION**	**CAUSE**
Cystocele/anterior vaginal wall[30]	Herniation of the anterior vaginal wall and bladder into the vagina[30]	Laceration and/or tearing of the anterior wall endopelvic fascia[30]
Urethrocele[30]	Herniation of urethra into the vagina[30]	Weakening of the ligaments that hold the urethra in place can cause it to move downwards[30]
APICAL COMPARTMENT	**DEFINITION**	**CAUSE**
Uterine prolapse[30]	Herniation of uterus[30]	Loss of support of the uterosacral and/or cardinal ligaments[30]
Vaginal vault prolapse when the uterus has been removed[30]	Herniation of the vaginal vault[30]	Loss of support or weakening of the uterosacral ligaments, cardinal ligaments and loss of attachment of the endopelvic fascia to the white line at the level of the sacrospinous ligament[30 p.19] It can also be a combination of these causes[30]
_5POSTERIOR COMPARTMENT	**DEFINITION**	**CAUSE**
Rectocele[30]	Herniation of the inferior portion of the posterior vaginal wall and rectum into the vagina[30]	Laceration and/or tearing of the posterior vaginal wall and endopelvic fascia[30]
Enterocele[30]	Herniation of the superior portion of the posterior vaginal wall and the small intestine into the vagina[30]	Laceration and/or tearing of the posterior vaginal wall and endopelvic fascia[30]

Women with POP often report a reduced frequency of sexual activity owing to **sexual symptoms** such as incontinence during intercourse, vaginal dryness, low libido, and psychological barriers. However, in studies comparing women with and without POP, no difference in sexual activity has been found.[5,32]

In summary, women with POP can present with various mechanical, urinary, bowel, and sexual symptoms, and symptoms from several domains often coexist. Of note, apart from a vaginal bulge, no other symptoms are specific to POP.[5]

2.3.3 EPIDEMIOLOGY OF PELVIC FLOOR DYSFUNCTION SYMPTOMS

It is important to examine the prevalence and risk factors of pelvic floor dysfunction within the population to evaluate the extent of the problem. Statistical information can help determine the need and requirements for measurement instruments such as the PFDI-20, PFIQ-7, and others as discussed in Section 2.4.

Due to the wide variability in prevalence estimates among various studies, it is difficult to establish an overall picture of the extent of the problem of pelvic floor dysfunction amongst females. However, the prevalence of POP in the female population, based on the sensation of a mass bulging into the vagina, ranges from 5–15%.[4,31] Women with POP often experience symptoms related to bowel and urinary dysfunction.[21,33] Studies in the USA and the UK estimate that 7–31% of women with POP also have symptoms of faecal incontinence.[5,33]

Badlani et al[3] found that women with POP also have symptoms of constipation and other symptoms of bowel dysfunction. The defecatory symptom that appears to correlate strongly with prolapse of the posterior compartment is the need to splint the vagina or perineum in order to defecate.[3]

A study in Sweden reported a substantial overlap between the incidence of urinary incontinence and POP. This study reported 37% of women with POP had one or both types of incontinence, i.e. urge incontinence and stress incontinence.[31]

Davila et al[26] found that dysfunction of the pelvic floor could include rectal prolapse. Patients with rectal prolapse often experience a more advanced degree of pelvic floor dysfunction, with 34% reporting genital prolapse, and 66% reporting urinary incontinence.[26]

The overall ageing of the population has dramatically increased the prevalence of chronic disorders such as POP and pelvic floor dysfunction.[1,26,34] Studies show that pelvic floor

dysfunction is strongly linked to parity, vaginal delivery, BMI, and ageing.[2,3,34] Epidemiological studies have determined age as the main risk factor for POP.[1,3,31] However, age, menopause, and hormonal status seem inseparable.[3] One study in the USA reported that the proportion of women reporting at least one disorder (POP, urinary, or faecal incontinence) increased incrementally with age, ranging from 9.7% in women between 20 and 39 years to 49.7% in those aged 80 years or older.[1] A community study of 17,032 women in family planning clinics across England and Scotland analysed risk factors in POP. Parity had the strongest association with prolapse development.[30] Almost 50% of all parous women in the study had some degree of prolapse, of which 10–20% were symptomatic.[30] In contrast, Tegerstedt et al[31] found that symptomatic POP was present in 2.4% of nulliparous women.

Epidemiological studies have shown a strong relationship between parity and urinary incontinence. Women who had four or more vaginal deliveries were more likely to report urinary incontinence.[35] Studies investigating the prevalence of symptoms post-delivery estimated 4% for faecal incontinence and 8.5% for anal incontinence (incontinence of flatus).[36] Rømmen et al[37] reported a significantly higher prevalence of anal incontinence (20.7%) in women experiencing three or more deliveries. Further, studies have shown long-term faecal incontinence in women with obstetric anal sphincter injuries.[38]

A family history of POP seems to be a risk factor.[2] Family and twin studies have provided evidence of a genetic predisposition to incontinence and prolapse, with genetic variation contributing to half of the population phenotypic variability in elderly women. However, current evidence on the candidate gene approach has not yet produced consistent results.[39]

Individual predisposition and lifestyle (obesity, heavy lifting, and constipation causing non-obstetric strain on the pelvic floor) may play a part in symptomatic POP.[2,31]

In summary, the development of POP, urinary incontinence, and colorectal dysfunction share common risk factors: the effects of ageing, parity, vaginal delivery, BMI, genetic/ individual predisposition, and lifestyle (obesity, heavy lifting, and constipation). The prevalence outlined in this section clearly shows the frequent *coexistence* of risk factors and the presence and symptoms of urinary, prolapse, and colorectal dysfunction. These coexisting conditions require multidisciplinary evaluation and management for women with any of these conditions and symptoms.[5]

2.4 MEASUREMENT ISSUES IN PELVIC FLOOR QUESTIONNAIRES

2.4.1 PATIENT-REPORTED OUTCOMES AND PATIENT-REPORTED OUTCOME MEASURES

The importance and application of patient-reported outcomes (PROs) by way of patient-reported outcome measures (PROMs) are becoming more widely acknowledged as providing an opportunity to deliver care in a patient-centred manner.[40] PROMs are important in gaining a better understanding of a patient's condition and HRQOL. They are also useful in the interpretation of clinical outcomes and treatment decision-making.[40] PROMs play an integral role in the evaluation of women with POP. While they are often divided into three main categories (symptoms, sexuality function, and quality of life), these categories also clearly interact.[12]

2.4.2 SYMPTOMS, QUALITY OF LIFE AND SEXUAL RELATIONSHIPS

The impact of pelvic floor dysfunction is typically expressed as a degree of severity and is characterised by health-scale instruments that measure the effects of prolapse and/or incontinence on quality of life as well as functional status. Pelvic floor dysfunction can have negative effects on health status, lifestyle, social and emotional functioning, psychological well-being, functional performance,[5,6] social support, life satisfaction, and standard of living.[41] Women report such conditions as being painful, disruptive,[42] emotionally stressful, and socially embarrassing.[43,44]

For younger women, the impact of pelvic floor dysfunction is often magnified because they spend more of their productive years coping with this condition.[45] This is of relevance to all clinicians caring for younger women.[30,45] Pelvic floor dysfunction represents a general public health concern,[46] and studies have shown that conditions caused by these disorders significantly reduce quality of life.[47]

These findings underline the need to identify and treat these problems. It is recommended that at least five domains should be reported and recorded: quantification of symptoms, patients' subjective perspective, HRQOL, clinician's perspectives, and socioeconomic measures.[12] Self-administered condition-specific HRQOL questionnaires are useful measurement tools for identifying and assessing the patient's symptoms and their impact on quality of life.[48]

2.4.3 SYMPTOM QUESTIONNAIRES

Symptom questionnaires measure the presence, severity and/or bother of symptoms or groups of symptoms on patients' physiological, mental and social functioning.[49] However, several studies have indicated that symptoms alone are poor health status indicators of the effect of pelvic floor dysfunction on an individual's lifestyle and psychological well-being.[49]

2.4.4 HEALTH-RELATED QUALITY OF LIFE QUESTIONNAIRES

As outlined in Chapter 1, health-related quality of life (HRQOL) refers to an individual's overall sense of well-being and how a disease or condition and treatment thereof impact various health aspects.[16] Research groups such as the United Kingdom Medical Research Council and EORTC QoL Group have identified the need for assessing and measuring HRQOL in health outcome research and subsequently developed policies stipulating that HRQOL should be incorporated as an endpoint in all new trials.[50] Since HRQOL is considered an important PRO in clinical practice and research, understanding the concept and measurement of HRQOL is essential.

Pelvic floor dysfunction can have a negative impact on the lifestyle and psychological well-being and social functioning of women.[51,52] Hence, it is important to measure both the presence of symptoms and their impact on quality of life. Further, the treatment of pelvic floor dysfunction may be either conservative or surgical, and might provide only temporary relief or remission of symptoms. For example, surgical treatment of one pelvic floor dysfunction (e.g. prolapse, urinary, bowel) can improve, worsen, or predispose for another.[11] Efforts to improve the healthcare management of women with POP aim at reducing disease severity and improving patients' HRQOL. This requires continuous monitoring of HRQOL using reliable, valid, and interpretable instruments.[53]

HRQOL instruments generally have multidimensional properties and comprise of physical, mental, and social functioning domains.[12] HRQOL can be measured by global,[49] generic or condition-specific instruments,[12] each instrument category having its own merits and limitations.[17]

Global HRQOL instruments measure more basic and general parameters, which are useful for identifying and describing populations. On the other hand, they are inadequate for more complicated hypothesis testing.[49,54]

Generic HRQOL instruments are designed to measure quality of life across a range of diseases, conditions, and populations.[49] The EuroQol EQ-5D and the Medical Outcomes Study SF-36v2® Health Survey (SF-36v2®) questionnaires are examples of generic instruments that are frequently used to assess HRQOL and impact issues for patients with pelvic floor dysfunction. Generic instruments enable researchers to draw comparisons across disease groups.[17]

Condition-specific HRQOL instruments, outlined in Section 2.4.6, are designed to measure the impact of a specific disease on HRQOL. The merits of generic versus condition-specific measures are continually debated.[17] Compared with a generic HRQOL instrument, a condition-specific HRQOL instrument demonstrates higher face validity and is more responsive to change after treatment. Moreover, condition-specific HRQOL instruments facilitate a more comprehensive assessment of condition-specific issues pertaining to the condition or disease process.[17]

Barber et al[11] state that generic HRQOL questionnaires are less responsive to change when evaluating treatments and impact issues with pelvic floor dysfunction than condition-specific HRQOL questionnaires. Validation studies from Barber et al[11,55] employed the condition-specific PFDI-20, PFIQ-7 and the generic SF-36 questionnaires to demonstrate that a reliable and validated condition-specific HRQOL questionnaire is an appropriate method for measuring the impact of pelvic floor dysfunction. These studies also demonstrated that the condition-specific PFIQ-7 was significantly more responsive to the effects of genital surgery than the SF-36.[11,55] It seems clear, however, that additional research is needed to assess the sensitivities of both condition-specific and generic instruments. This applies to both investigating the impact of coexisting conditions as well as responsiveness after an intervention.[56]

2.4.5 SEXUAL FUNCTION QUESTIONNAIRES

Several instruments have been developed to assess sexual function in women with POP. Examples include the Golombok-Rust Inventory of Sexual Satisfaction (GRISS),[44] Psychosocial Adjustment Illness Scale (PAIS),[44] McCoy Female Sexuality Questionnaire (MFSQ),[5] the Female Sexual Function Index (FSFI),[5] the Pelvic organ prolapse/Urinary Incontinence Sexual Function Questionnaire (PISQ and PISQ-IR), and the short version thereof (PISQ-12).[32] The PISQ is the only current validated condition-specific female sexual function measure

developed to evaluate sexual function in women with POP and urinary incontinence.[57] Patients can find sexual issues embarrassing to discuss, and a sexual function questionnaire can be useful in a clinical setting.[22,44]

While some POP/urinary incontinence questionnaires that measure psychological impact also contain sexual function questions (e.g. King´s Health Questionnaire (KHQ)[5]), the PFDI-20 and PFIQ-7 do not. However, to address sexual issues in clinical studies, the PISQ-12 is sometimes used in conjunction with other instruments such as the PFDI-20 and PFIQ-7.[51,58]

2.4.6 SELF-ADMINISTERED CONDITION-SPECIFIC HRQOL QUESTIONNAIRES

Over the past several years, studies from the USA, Sweden, France, Spain, the Netherlands, Turkey and Denmark have demonstrated that a reliable and validated self-administered condition-specific HRQOL questionnaire is a valid method for measuring the presence, severity, degree of bother, and impact on women with pelvic floor dysfunction.[11,52,59-66] Equally important, this type of questionnaire can show the frequent *coexistence* of symptoms of urinary, prolapse and colorectal dysfunction.[11,21,61] These multidisciplinary questionnaires encompass various components associated with pelvic floor dysfunction (bowel, urine, and prolapse) and are subjective indicators of physical, social, and emotional functioning.[11] They can also help determine and address the impact on a patient's social activities, physical and emotional health issues, and well-being.[51,58,61]

Norwegian-validated questionnaires now exist to assess women's urinary symptoms (e.g. Norwegian Female Incontinence Register Questionnaire (NRIK), International Consultation on Incontinence Questionnaire – Urinary Incontinence Short Form (ICIQ-UI short form))[7] or bowel symptoms (e.g. St. Mark's incontinence score, Wexner Cleveland Clinic Incontinence Score (Wexner Scale), ICIQ Bowel Symptoms (ICIQ-BS) [7]). However, at the commencement of this program of research, there were no known Norwegian-validated *multidisciplinary* questionnaires for assessing women's pelvic floor dysfunction (prolapse, bowel, urine) and impact on quality of life.

2.4.7 CRITERIA AND GRADE OF RECOMMENDATION FOR PELVIC FLOOR QUESTIONNAIRES

Selecting a valid and reliable assessment tool/questionnaire for clinical and research purposes depends on the recommendation level, the specific type of intervention or

treatment, the research topic being addressed, and the patient group/population being assessed.[44]

The Second International Consultation on Incontinence established a standard in 2002 for incontinence and pelvic floor questionnaires.[67] The criteria and grades of recommendation are shown in Table 2.2. The Fifth International Consultation on Incontinence (2013) recommends using Grade A+ or Grade A questionnaires for research or clinical purposes.[7] Table 2.3 lists various questionnaires that are available and their current corresponding grade of recommendation.[7]

TABLE 2.2. CRITERIA AND GRADES OF RECOMMENDATION FOR PELVIC FLOOR QUESTIONNAIRES

GRADE	EVALUATION	CRITERIA
A	Highly recommended[7]	Validity, reliability, and responsiveness established with rigour
B	Recommended[7]	Validity, reliability established with rigour
C	Has potential[7]	Validity or reliability or responsiveness established with rigour

Note. Grades A+, B+, and C+ indicate additional evidence of published content validity.

The Fifth International Consultation on Incontinence recommends using pelvic floor questionnaires from the International Consultation on Incontinence Modular Questionnaire (ICIQ) series. The ICIQ project has developed a questionnaire (ICIQ-VS), one of many pelvic floor PROMs for women with prolapse.[7] The ICIQ-VS meets the needs for a self-administered PROM to evaluate vaginal, urinary, bowel, and sexual issues.[64]

However, the urinary and bowel domains are limited to only one item each,[64] and the ICIQ-VS questionnaire has no detailed assessment of HRQOL issues associated with vaginal symptoms.[7] Furthermore, the ICIQ-VS questionnaire was rated Grade B and was thus not a strong candidate for use in the Norwegian context.

At the commencement of this program of research in 2010, the Pelvic Floor Distress Inventory (PFDI, 46 items) and Pelvic Floor Impact Questionnaire (PFIQ, 93 items) were the only validated multidisciplinary pelvic floor questionnaires with the highest level of evidence

(Grade A).[68] These are among the most commonly used instruments internationally (Section 2.4.9) and the preferred choice for the Norwegian context.

TABLE 2.3. THE FIFTH CONSULTATION CRITERIA AND GRADES OF RECOMMENDATION OF PELVIC FLOOR QUESTIONNAIRES FOR SYMPTOMS AND HRQOL

PELVIC FLOOR QUESTIONNAIRES FOR PELVIC FLOOR DYSFUNCTION	GRADE OF RECOMMENDATION
Pelvic Floor Distress Inventory (PFDI and PFDI-20)[7]	Grade A
Pelvic Floor Impact Questionnaire (PFIQ and PFIQ-7)[7]	Grade A
Prolapse Quality of Life Questionnaire (P-QoL)[7]	Grade A
ICIQ-UI Short Form[7]	Grade A+
ICIQ-BS[7]	Grade A+
ICIQ-VS Vaginal Symptoms (ICIQ-VS)[7,64]	Grade B
The Electronic Personal Assessment Questionnaire – Pelvic Floor (e-PAQ-PF)[7,65]	Grade B
The Australian Pelvic Floor Questionnaire (APFQ)[7,66]	Grade B
Pelvic Floor Symptom Bother Questionnaire (PFBQ)[7]	Grade B
Urinary Incontinence Sexual Questionnaire (PISQ/PISQ-12)[7]	Grade B
Danish Prolapse Questionnaire[7]	Grade C
Pelvic Organ Prolapse Symptom Score (POP-SS)	Not graded
Pelvic Floor Inventories Leiben (PeIFIs)[33]	Not graded

2.4.8 THE PELVIC FLOOR DISTRESS INVENTORY AND PELVIC FLOOR IMPACT QUESTIONNAIRE

The short versions of the Pelvic Floor Distress Inventory (20 items, PFDI-20) and Pelvic Floor Impact Questionnaire (7 items, PFIQ-7)[11] have been derived from their respective parent scales to reduce the burden on participants. Both have demonstrated moderate to excellent reliability, validity, and responsiveness to change against their longer versions.[11] The PFDI-20 assesses the presence of symptoms and bother in three domains (POP, bowel, and urinary), while the PFIQ-7 assesses the impact on HRQOL in these domains. Both the PFDI-20 and

PFIQ-7 are designed to evaluate the efficacy of therapy and are proven to discriminate between women with and without improvement following treatment.[11,65] The questionnaires can also be used in both clinical and research settings. Furthermore, they can improve patient–doctor communication, including facilitating shared decision-making between patients and doctors.[7,12,14]

The PFDI-20 measures symptom distress during the previous three months. Responses are provided on a five-point scale ranging from 'no' (0) to 'yes, quite a bit' (4).[11] Three subscales are available: Urinary Distress Inventory (UDI-6), Pelvic Organ Prolapse Distress Inventory (POPDI-6), and Colorectal-Anal Distress Inventory (CRADI-8). The total score is converted to a range from 0 to 300, while the subscales are scored 0 to 100. In all cases, higher scores equate to greater distress.[11]

The PFIQ-7 measures HRQOL issues of women with PFD (e.g. daily physical/social activity, travel, and emotional health) during the previous three months. A four-point scale ranging from 'not at all' (0) to 'quite a bit' (3) is provided to quantify responses. The PFIQ-7 also has three subscales: Urinary Impact Questionnaire (UIQ-7), Pelvic Organ Prolapse Impact Questionnaire (POPIQ-7), and Colorectal-Anal Impact Questionnaire (CRAIQ-7).[11] Again, the total score is converted to yield a range from 0 to 300 (subscales 0–100). Higher scores indicate greater symptom distress and impact on patients' HRQOL.[11]

2.4.9 PFDI-20 AND PFIQ-7 QUESTIONNAIRES IN PELVIC ORGAN PROLAPSE STUDIES

Over the last several years, the PFDI-20 and PFIQ-7 self-administered condition-specific HRQOL questionnaires (ICI recommendation Grade A) have been employed in randomised controlled trials to assess responsiveness to POP surgery,[51,58,62,69,70] and as tools to identify candidates for POP surgery.[47,71] The PFDI/ PFIQ and PFDI-20/ PFIQ-7 questionnaires are also applied as tools to evaluate conservative treatments such as the use of pessaries[72] and improving pelvic muscle strength.[72] One study in China examined how the PFDI Pelvic Organ Prolapse Distress Inventory (POPDI) scoring could be used among other factors (e.g. stage of prolapse, urodynamic stress incontinence) for choosing surgical treatment.[21] PFDI and PFIQ are also used to study the prevalence of pelvic floor dysfunction[1] and anal incontinence among post-partum women following obstetrical anal sphincter injury.[73]

2.4.10 SIGNIFICANCE OF ASSESSING PELVIC FLOOR DYSFUNCTION USING HRQOL QUESTIONNAIRES

The clinical and research applications of the PFDI-20 and PFIQ-7 questionnaires provide tools for identifying patients who have experienced symptom severity, bothersomeness, and HRQOL issues. Measuring pelvic organ prolapse and pelvic floor dysfunction symptom severity is important, both for identifying whether the patient should begin invasive or expensive therapy and for choosing the suitable form of treatment.[12] Furthermore, the PFDI-20 and PFIQ-7 can allow various types of outcomes to be measured. These include symptom distress, psychological well-being, social functioning, HRQOL, treatment adherence, and clinical trials.[48,51]

These self-administered questionnaires are also beneficial for identifying life impact issues and barriers (e.g. faecal incontinence) that female patients might not otherwise discuss during an outpatient consultation.[43] Furthermore, these questionnaires can quantify how two female patients with the same symptom severity may have dramatically different responses about their subjective well-being.[11]

With the complex nature of pelvic floor dysfunction, the PFDI-20 and PFIQ-7 questionnaires can help clinicians to understand how these conditions can be interrelated with one another rather than being seen as separate isolated conditions.[11,60] Questionnaires or instruments such as the PFDI-20 and PFIQ-7 are essential in assessing pelvic floor dysfunction. They allow quantification of subjective data to objective information[11] and provide a robust measurement in the clinical setting. Of note, a study in the United Kingdom showed that it is the patients' subjective well-being, rather than the objective medical condition, that determines their treatment-seeking behaviour,[13] their compliance,[14] and their evaluation of treatment.[13]

The overall ageing of the population has and will continue to dramatically increase the prevalence of chronic conditions such as pelvic floor dysfunction.[1,4,46] Studies show that pelvic floor dysfunction is a common problem among women and it is strongly linked to childbirth and ageing.[46] Valid and reliable HRQOL instruments like the PFDI-20 and PFIQ-7 can be used to measure the health of populations, particularly the health of ageing females,[1] providing data for improving patient care management[14] and supporting policy decisions.[12]

2.4.11 CHAPTER SUMMARY

Pelvic floor dysfunction represents a public health concern. Numerous studies have shown that symptoms caused by pelvic floor dysfunction significantly reduce QoL and negatively affect women's physical, mental, and social function. Etiological and prevalence studies clearly demonstrate the frequent presence and symptoms of urinary and colorectal dysfunction. Outcome measurements are essential for better understanding a patient's condition, treatment, and improvement in or deterioration of quality of life. To date, no validated Norwegian multidisciplinary PROMs exist for assessing pelvic floor dysfunction and its impact on patient quality of life. PFDI-20 and PFIQ-7 are among the most commonly used HRQOL PRO instruments and the preferred choice for the Norwegian context. They are not only highly reliable and valid PROMs but also are useful in both clinical and research settings.

CHAPTER 3

TRANSLATING PELVIC FLOOR QUESTIONNAIRES

3.1 INTRODUCTION

The availability and routine use of validated multidisciplinary health-related quality of life (HRQOL) and patient-reported outcomes measures (PROMs) for pelvic floor dysfunction are absent in Norway. Many reviews have indicated that the multidisciplinary 20-item Pelvic Floor Distress Inventory (PFDI-20) and 7-item Pelvic Floor Impact Questionnaire (PFIQ-7) (Appendix 3.1) are Grade A instruments of choice,[7] and therefore the preferred option for the Norwegian context. The PFDI-20 and PFIQ-7 questionnaires are robust tools that have the potential to assess symptoms and condition-specific HRQOL for Norwegian women with pelvic organ prolapse (POP) and pelvic floor dysfunction.[11]

In a situation where the desired instrument does not exist in a language, the clinician has two options: (1) develop a new instrument, or (2) translate and cross-culturally adapt an existing instrument from another language.[19] A simple translation or non-validated HRQOL instrument may yield misleading information or fail to identify important clinical changes.[7,19,49]

Many PRO questionnaires are developed in English. Using translated and validated PRO questionnaires in a local language (e.g. Norwegian) allows institutions, hospitals, and national healthcare services outside the English-speaking world to assess their performance against international standards.[14]

Following the literature review, outlined in Section 3.2, the methodology of translating PROMS, the development of a new multistep translation methodology, and Stage 1 of the study are introduced. Stage 1 includes the translation and cross-cultural adaptation of the PFDI-20 and PFIQ-7 from the source version (i.e. English) to the target version (i.e. Norwegian) using the new multistep translation and cross-cultural adaptation method. This novel multistep method combines the European Organization for Research and Treatment of Cancer (EORTC) Quality of Life (QoL) Group guidelines,[10] the Delphi method[18] and an expert panel review.[19] The results and findings of Stage 1 are discussed in Chapter 4.

3.1.1 ETHICS APPROVAL

Ethics approval was granted for Stage 1 by the Regional Committees for Medical and Health Research Ethics (Norway) (Appendix 3.4b and 3.4d), the Akershus University Hospital Ethics Committee (Norway) (Appendix 3.4g), and the Flinders University Social and Behavioural Research Ethics Committee (Australia) (Appendix 3.4h). The approval grant for Stage 1 by the Regional Committees for Medical and Health Research Ethics (Norway) was translated into English and is given in Appendix 3.4a and 3.4c.

3.2 LITERATURE SEARCH PARAMETERS

The following electronic databases were used in a search for articles involving pelvic floor dysfunction questionnaires, the methodology of translating questionnaires, pilot testing and measurement theory: PubMed, MEDLINE, CINAHL, Ovid Nursing, Up-to-date, EMBASE, Google Scholar, Clinical Evidence, Best Practice, the Cochrane library (Systematic Reviews and DARE), the Norwegian Electronic Medical Handbook (NEL), and the Norwegian Electronic Health Library database (Helsebibloteket.no).

The search was restricted to studies conducted between 1946 and 2013. It was not restricted to English publications. Additional studies were located by reviewing the bibliographies of identified articles.

The following combinations of keywords were selected for the search:

1) Health-related quality of life questionnaires, instruments, patient-reported outcome measurements, health status indicators were matched with translation, and/or forward and back-ward translation and/or psychometric validation, and/or cross-cultural adaptation, and/or linguistic validation, and/or translation methodology.
2) PFDI-20 and PFIQ-7 questionnaires were matched with translation and/or validation.
3) The Delphi method and Delphi technique were matched with expert panel, and/or expert committee, and/or consensus, and/or Likert scale.
4) The Delphi method and Delphi technique were matched with health-related quality of life questionnaires and/or instruments and/or patient-reported outcomes measurements and/or development, and/or translation.
5) Pilot testing, cognitive debriefing were matched with interview techniques, health-related quality of life questionnaires and/or audio recording, and/or transcribing.

6) Pilot testing, interviews were matched with qualitative research and/or triangulation and/or interpretivism, and/or thematic analysis.
7) Health-related quality of life questionnaires and patient-reported outcomes measurements were matched with measurement theory and/or measurement properties, constructs and/ or testing, and/or validity and/or reliability, and/or responsiveness.

3.3 AIM AND METHODOLOGY OF TRANSLATING PATIENT-REPORTED OUTCOMES MEASURES

The aim of translation in the context of an HRQOL PRO measure is to achieve equivalence (linguistic validation) between the source version and the translated version of the scale.[17] The translation process of an HRQOL instrument involves several steps focusing on linguistically translating and adapting the source version to the target version.[19] The process can vary from the Swaine-Verdier et al[74] dual panel technique to the American Academy of Orthopaedic Surgeons (AAOS)[8] and EORTC QoL Group[10] multistep translation processes involving independent forward and back-translations.

3.4 DEFINITIONS AND GUIDELINES FOR TRANSLATION AND CROSS-CULTURAL ADAPTATION

Beaton et al[75] and Guillemin et al[19] recommend that during a translation process of PROMs, items should be both correctly linguistically translated and cross-culturally adapted to reach equivalence of the instrument across different cultures. While preparing and applying an HR-PRO instrument outside its original intended context, cross-cultural adaptation is a process that addresses the challenges associated with language (translation) and cross-cultural adaptation.[75]

Mokkink et al[103(p.743)] define cross-cultural validity as "the degree to which the performance of the items on a translated or culturally adapted HR-PRO instrument are an adequate reflection of the performance of the items of the original version of the HR-PRO instrument."

Translation is defined as the process of adapting the meaning of the source-language wording or text using an equivalent target-language text.[17] A well-translated questionnaire cannot be expected to be equivalent across languages. Therefore, the cross-cultural adaptation process can be viewed as more appropriate than the translation. Cross-cultural

adaptation should be assessed when examining the different settings and scenarios. Guillemin et al[19] suggested five settings where adaptation should be investigated when comparing two cultures[19]:

1. The instrument is used in the same population. No change in language or culture or country from source.
2. The instrument is used with immigrants well established in the source country.
3. The instrument is used in another country, but the same language
4. The instrument is used with recently settled foreign-language speaking immigrants in the source country.
5. The instrument is used in another country and another language.

Translation and cross-cultural adaptation are essential in Settings 4 and 5 while only cross-cultural adaptation is required in Settings 2 and 3. The degree of adaptation can vary depending on the similarities and differences between the languages. Settings 4 and 5 require translation methodology. Of note, these translation methodologies vary (Section 3.5), so it is important to develop criteria for principles and guidelines of good practice for both the translation and cross-cultural adaptation processes.

In 1999, ISPOR[8] established the Translation and Cultural Adaptation group (TCA Task Force) to develop guidelines and standards for translation and cross-cultural adaptation.[8] The ISPOR TCA Task Force[8] has developed criteria for principles of good practice for the translation and cross-cultural adaptation processes of patient-reported outcome measures. The ISPOR TCA Task Force recommends ten steps in the translation process: preparation, forward translation, reconciliation, back-translation, back-translation review, harmonisation, cognitive debriefing, review of cognitive debriefing results, proofreading, and final report. The harmonisation step is only implemented when several new translations need to be compared with the source version.[8]

McKenna and Doward[76] assert that the ISPOR TCA Task Force "good practice" is based mainly on the opinions of some organisations on how to translate PROMs, and little on empirical evidence, particularly regarding back-translation. The ERIQA Group[9] has also developed a checklist providing an overview of the steps used for translation to evaluate the rigour of applied methodologies. The ERIQA Group findings were comparable to the ISPOR TCA Task Force for translation and cross-cultural adaptation, although the methods reviewed

did not match.[8,9] More importantly, as Wild et al[8] state, it is necessary to choose similar methods when comparing findings using different language versions of the same HRQOL PRO measures.

Neither the ISPOR TCA Task Force[8] nor the ERIQA Group[9] could recommend a best practice method. Nevertheless, the groups developed certain criteria and checklists on the principles of good practice, e.g. a multistep approach and documentation of each step. Furthermore, the ERIQA Group asserts that re-checking is essential and, in terms of equivalence, notes that results improve with the application of rigorous procedures.[9]

3.5 COMPARISON OF EXISTING TRANSLATING METHODS

Translation and cross-cultural adaptation methods vary, and Table 3.1 gives an overview of those that are currently used and recommended.[8,9] This overview compares the different multistep phases of translation and cross-cultural adaptation: forward translation, back-translation, an expert panel review and pre-testing/cognitive debriefing. Translation terminology also varies widely.[8] For example, the term 'provisional forward translation' is also referred to as 'intermediate version' and 'single forward version'. 'Pilot testing' is referred to as 'cognitive debriefing' or 'pre-testing'.

3.6 DEVELOPING NEW TRANSLATION METHODOLOGIES

As outlined in Section 3.5, several translation methods exist for cross-cultural adaptation of health measurement scales, e.g. PROMs. To date, there is no evidence supporting a 'gold standard', and new methodologies continue to be developed.[8,9] Notably, it is challenging to develop new translation methods and to assess existing ones due to this lack of empirical evidence.[78]

One important component of cross-cultural adaptation processes is the expert panel. Methods vary within the expert panel phase as outlined in Section 3.9. Face-to-face meetings are the common component in this phase. However, face-to-face communication can be a disadvantage due to the influence of dominant personalities, and a situation can arise where there is a certain form of group pressure for conformity.[18] Thus, formal methods for achieving group consensus within the expert panel phase should be explored, e.g. the Delphi method. Incorporating the Delphi method into the expert panel phase could be advantageous for avoiding the influence of dominant personalities and group pressure for

conformity. Furthermore, the iterative nature of the Delphi method (Section 3.10) can provide panellists with the opportunity to reassess their previous responses, improve ideas or add alternatives.[18]

Finally, during cross-cultural adaptation, the expert panel is a significant part of the multistep process of identifying items of discrepancy and verifying comprehensibility and equivalence between the source and target versions.[19,67,75,77]

3.7 EQUIVALENCE

As outlined in Section 3.3, the aim of translation and cross-cultural adaptation is to ensure equivalence between the source version and the target version of the health measurement scale.[17] Several taxonomies of equivalence have been developed over the years, and key types of equivalence include operational, conceptual, experiential, idiomatic, semantic, and measurement.[17] The process of establishing the first five equivalences listed is referred to as linguistic validation and is completed before measurement equivalence commences.

3.7.1 OPERATIONAL EQUIVALENCE

Operational equivalence assesses whether the format of the instructions, questionnaire, and mode of administration can be employed in the target population.[17]

3.7.2 CONCEPTUAL EQUIVALENCE

Conceptual equivalence (also referred to as cultural equivalence) examines how individuals in two different cultures see a concept in the same way.[17,19,79] This also determines if a concept or item is relevant to the target population. When examining conceptual equivalence between the source and target cultures, the scale can range from the two concepts being identical in two cultures to the extreme where the concept does not exist at all in the target culture. Another scenario is when the concept exists in both source and target cultures but is interpreted differently.[17]

Conceptual equivalence can be checked and verified using different approaches: a cultural anthropological literature review about target groups, interviews with focus groups, or seeking the advice of several experts.[17]

In the forward translation process, it is important that the project manager/principal researcher and translators focus on the conceptual and idiomatic meanings rather than the

literal translation.[8,17] Furthermore, once the back-translations are completed, both the source and back-translation versions should be compared for conceptual equivalence.[8,79]

3.7.3 EXPERIENTIAL EQUIVALENCE

Experiential equivalence is important in the forward translation process as it examines how the situations described in the source version are, or need to be, compatible with the target cultural context. This may result in amendments to a questionnaire item. For example, in a Brazilian translation of a questionnaire into Portuguese, one item from English needed modification; the item "using a car" [19(p.1423)] was replaced with "using public transport" [19(p.1423)] since few Brazilian citizens have a car.[19]

3.7.4 IDIOMATIC EQUIVALENCE

Idiomatic equivalence (also referred to as functional equivalence) is defined as a common saying or phrase that is typical of a person or people in their use of language.[19] If idiomatic expressions are directly translated, they often lose their meaning. Therefore, it is important to translate the meaning.[19,77] For example, an idiom in the Nottingham Health Profile questionnaire was translated from "I am feeling on edge" [19(p.1423)] in English to "I have my nerves outside my skin" in Italian.[19 (p.1423)] Idiomatic equivalence can be checked and verified using different approaches: forward and back-translation review,[17] interviews with focus groups,[74] or seeking the advice of several experts.[19]

3.7.5 SEMANTIC EQUIVALENCE

Semantic equivalence examines the meaning attached to a questionnaire item.[77] Obtaining equivalence may require changing the vocabulary, syntax or grammar. It is a common occurrence that grammar and syntax can change dramatically from language to language.[19]

Back-translation and pilot testing (i.e. asking patients to rephrase the question in their own words) are useful for checking semantic equivalence.[19]

3.7.6 MEASUREMENT EQUIVALENCE

Measurement or psychometric equivalence is the degree to which an HRQOL PRO measure and its corresponding data can show reliable and valid results about the same construct(s) across different populations.[77] This is conducted after linguistic validation, i.e. operational, conceptual, experiential, idiomatic, and semantic equivalence, has been completed.[17]

TABLE 3.1. OVERVIEW OF EXISTING TRANSLATION METHODS USED AND RECOMMENDED TODAY

This overview compares the different phases of translation and cross-cultural adaptation: forward translation, back-translation, review and pre-testing/cognitive debriefing.

GUIDELINE	FORWARD TRANSLATION	RECONCILIATION	BACK-TRANSLATION	REVIEW	PRE-TESTING
AAOS guidelines[8] Detailed documentation of each step is recommended	Minimum of two bilingual translators. Both translate independently	Performed by the translators	Two independent translators. No background knowledge of concepts	Expert panel — translators, healthcare specialists, language professionals	n=30–40 from target population followed by interviews
EORTC QoL Group[10] Detailed documentation of each step is recommended	Minimum two translators (native speakers) working independently	Performed by the coordinators with translators	Two independent translators (native speakers). No knowledge of translation	Performed by the coordinators with translators	n=10–15 individual interviews
EuroQoL group[8] Detailed documentation is recommended	Two native speakers — at least one with healthcare background. Both trained by the project leader. Work independently	Two translators and project leader	Two independent native speaker translators. One literal and one polished translation	Yes	n=8 low education level including healthy individuals interviewed
FACIT group[8]	Two translators. One based on source and one on target country	Performed by a third translator	Single back-translation. Completed by a fourth translator	Performed by 3–4 health professionals from target country	n=10–15
IQOLA[9] Rigorous and time-consuming method	Minimum two translators work independently and simultaneously rate difficulty	First by original translators, then followed by two new translators working independently	Two translators	By USA IQOLA team	n=up to 50
Eurogroup for health measurement, translation of the NHP[9]	8–12 from the target population. Consensus version produced	Bilinguals respond to both source and consensus target version	Conducted only for items of discrepancy. Performed by teachers of target version	Yes	Participants in target culture respond to and discuss the questionnaire

GUIDELINE	FORWARD TRANSLATION	RECONCILIATION	BACK-TRANSLATION	REVIEW	PRE-TESTING
MAPI Institute[77] The method recommends clear justification and documentation of each step	Two translators. Translators work independently and live in the target country	Project manager works with the instrument developer	One translator. No previous knowledge of source version	Project manager reviews target version with instrument developer	Two reviews simultaneously: n=5–10 Cognitive debriefing with target population and clinicians review who are stakeholders
Medical Outcomes Trust[8]	Minimum two translators	Yes	Minimum one translator	Reviewed by expert panel	
Swaine-Verdier et al[74] Detailed documentation is recommended	Number not specified. Translators should be lay people. Specifies one native speaker of the source language	Yes	Not recommended. Dual panel technique	Reviewed by the project coordinator	n=5–7 Lay panel
World Health Organization (WHO)[9]	Minimum one translator	A bilingual panel reviews the target version and monolingual panel tests the instrument. Afterwards, the bilingual panel modifies the target version	One translator	A bilingual panel group reviews forward and back target versions. Alternatively, a bilingual panel assesses equivalence	

3.8 TRANSLATION PROCEDURE

As outlined in Section 3.4, the main steps in a translation process include preparation, forward translation, reconciliation, back-translation, and back-translation review followed by cross-cultural adaptation using an expert panel review and cognitive debriefing.

3.8.1 PREPARATION

The preparation process involves obtaining permission from the instrument developer and defining the concepts and items in the questionnaire or instrument. Some guidelines recommend inviting the questionnaire developer to be involved in the preparation phase to clarify any ambiguities and explain the concepts behind each item.[10]

3.8.2 FORWARD TRANSLATION

Forward translation is the translation of the source (original) language into the target language. Several translation groups recommend two independent bilingual translators.[8,10,17,19,75] Guillemin et al[19] suggest two or more bilingual translators or even a team should perform the forward translation. Further, some of the translators should be aware of the purpose of the concepts of the intended PROM.[19] The ISPOR TCA Task Force recommends that the two prescribed translators be professional translators and live in the target country. One of the translators may reside outside the target country; however, it is preferred that both live in the target country.[8]

Other groups such as the EuroQoL Group outline a procedure where there are two bilingual translators: one with health-related experience, trained by the project manager, and one referred to as the native professional translator. The native professional translator should have no medical background and be unaware of the concepts being quantified. The two translators should work independently.[9]

In the translation process, there should be more focus on the conceptual rather than literal translation and on the intent of each item and scale as a whole.[8]

In some situations it may be required to have the wording and phrasing kept compatible with certain reading levels or ages.[8] Guillemin et al[19] recommend that the wording in a translation be kept compatible with 10- to 12-year-old children.

3.8.3 RECONCILIATION

Reconciliation is the process of comparing and merging more than one forward translation into a single forward translation.[9,77] The people involved in this phase should have a high level of fluency in both the source and target languages. The aim of the forward translation and reconciliation process is to produce a consensus target-language version.[9]

There is an ongoing debate on the reconciliation process and, as a result, a lack of consistency between guidelines.[9] The EORTC[10] and EuroQol group[9] methods entail merging the first and second translators' versions into a single forward translation. The project manager often supervises this reconciliation process. The project manager and translators discuss any problem items identified in the forward translations and create a reconciled version of the translations.[9.10]

The MAPI Institute[77] recommends that the project coordinator merges the two forward translations into a single forward translation, preferably with the assistance of the instrument developer. The AAOS guidelines described by Beaton et al[75] recommend that both forward translators and a recording observer sit down to produce a single forward translation. An observer is present at the meeting to record the session. Notably, some groups do not merge the forward translations.[9]

The ISPOR TCA task force[8] recommends reconciliation and outlines three general recommended approaches: using a translation panel, a native speaker of the target language who has not been involved in any of the forward translations, or an appointed in-country investigator who has worked with one of the translations. Of note, the ISPOR TCA Task Force[8] acknowledges that there are other ways to achieve reconciliation.

3.8.4 BACK-TRANSLATION

Back-translation is the process of translating the items in the (reconciled) forward translation back into the source language.[17] The main aim of the back-translation is to provide quality control and resolve item discrepancies by examining how the back-translation reflects the source-language scale.[8,17,77]

There are disagreements, and thus a lack of consensus, as to how the back-translation should be performed.[8] While many guidelines include a single back-translation, some

recommend two or more back-translations conducted in parallel. Others recommend that a panel perform the back-translation.[9]

Several translation groups and authors acknowledge that the back-translation should be done by two independent translators, who are native speakers and have a high level of fluency in the target language.[10,16,17,79] The translators should have no knowledge of the original source-language instrument or be aware of the purpose of the scale.[10,17] Some guidelines recommend that each of the forward translations is back-translated separately, while others recommend merging the forward translations into a single document.[9]

The different approaches are determined by several factors including methodological differences between the groups, definitions of equivalence, and resources available at the time the translation is undertaken.[9]

Back-translation is one way of checking equivalence, but there is no clear scientific proof supporting the use of back-translation.[76,78] In addition, even if the forward translation is good, the back-translation may not accurately resemble every aspect of the source questionnaire. Swaine-Verdier et al[74] argue that the method of forward and back-translations is debatable for needs-based HRQOL instruments, and suggest a method using dual translation panels. The dual translation panel method is based on the assumption that a quality translation in the first instance is better than checking quality by way of back-translation.[74] Nevertheless, Wild et al[8] contend that if back-translation is not employed, there is a risk of the initial translation being in error, particularly in terms of speech patterns and colloquialisms of the target culture. Back-translation can also help preserve the psychometric properties of the source scale.[19]

The ISPOR TCA Task Force[8] and other authors[17] also acknowledge the importance of a back-translation review for cross-cultural adaptation. This process can identify any discrepancies and omissions that may otherwise be overlooked. Some guidelines recommend a project manager and/or key in-country person to perform the review, while others recommend employing an expert panel.[9] Of note, several translation guidelines emphasise the importance of documenting the back-translation review at each step of the translation process.[9,77]

3.9 EXPERT PANEL

Selecting members for an expert committee/panel depends on the objectives of the task at hand.[80] During the cross-cultural adaptation of an HRQOL PRO questionnaire, the expert panel is seen as a significant part of the process of assessing and verifying equivalence between the source and target versions.[19,75,77]

The MAPI Institute,[77] World Health Organization,[9] AAOS guidelines[9] and the Medical Outcomes Trust[9] employ an expert committee step in their respective cross-cultural adaptation processes. However, the ISPOR TCA Task Force does not list an expert committee as a criterion for good practice.[8]

Beaton et al[75] assert that an expert committee should comprise health specialists, language professionals, translators, and a methodologist. Notably, it is important to have a multidisciplinary team evaluating the target-language version. Preferably, the multidisciplinary team should have bilingual members.[19]

Several studies have also used an expert panel or expert clinicians in the translation phase to assess equivalence and cross-cultural adaptation.[57,67,81] A French study employed expert clinicians in the cross-cultural adaptation of the French PFDI-20 and PFIQ-7 to assess equivalence and specific domain terminology.[57]

There are different practices as to when an expert committee should be employed in the translation process.[9] WHO involves the expert committee after the forward translation and before the back-translation. The MAPI Institute involves expert clinicians in parallel with the pilot testing or, in some instances, before pilot testing with patients.[77] Beaton et al[75] involve the expert panel after the back-translation and before pilot testing.

3.10 THE DELPHI METHOD

The Delphi method is a consensus method often used in health-related quality of life research that focuses on generating ideas and determining priorities. Consensus methods are essentially about attaining quantitative estimates through qualitative approaches.[82]

The Delphi method is seen as a reliable and effective system to facilitate and achieve general agreement or consensus on an opinion by a group of experts, facilitated by an investigator. It was developed by Dalkey and Helmer[18] in the 1950s and 1960s and has been applied to

research fields such as medical, government, business and environment.[83] Over 1,000 publications exist where the Delphi method has been used in a healthcare setting.[82] The Delphi method is based on the notion that multiple contributions are better than one.[18] It is defined as: "A series of sequential questionnaires or rounds interspersed by controlled feedback, that seek to gain the most reliable consensus of opinion of a group of experts".[84(p.376)] These questionnaires are sent, either by mail or electronically, to a pre-selected group or expert panel. Expert panel members use specially designed questionnaires to create their individual responses to the problem posed. This enables experts to iterate on their points-of-view as the panel's work moves forward.[84]

The Delphi method has three distinctive attributes: anonymity, controlled feedback, and statistical group response.[18] **Anonymity** entails the panellists not knowing who made what response. Using written or email communication between the expert panellists achieves this.[83] Anonymity is useful to avoid dominant personalities or a profession that could dominate the communication process.[18,83] A face-to-face meeting approach might cause members who have diverging viewpoints to feel pressured to join an emerging consensus.[18] Furthermore, anonymity can result in a lack of accountability for viewpoints expressed and might encourage rushed choices and decisions.[84] **Controlled feedback** is a process involving a sequence of rounds where a statistical summary of results from the previous rounds is communicated to the expert panel members. This reduces noise.[18] **Statistical group response** indicates a level of consensus that represents the sum of the opinions from within the expert panel.[18]

Another consensus method that is widely used in health-related research is the nominal group technique (NGT).[85] The NGT, which is always based on face-to-face communication, and the Delphi method are both techniques that involve an expert panel to generate ideas, clarify issues, and determine priorities.[86] These methods also employ both qualitative and quantitative approaches. Even though there are similarities between the two methods, and both are used in the healthcare setting, an advantage of the Delphi method is that individuals across different locations and fields of expertise can be involved anonymously.[85,87] Dalkey[18] reported the possibility of face-to-face communication as resulting in: a) influence of dominant personalities, b) noise, and c) group pressure for conformity. Dalkey defines noise as the communication in a discussion group that has to do

with individual or group interest, not with solving the problem at hand. This kind of communication, although it appears problem-oriented, is often irrelevant or biasing.[18]

In the healthcare sector, several criteria (e.g. validity, feasibility, or agreement) are used to select indicators via the Delphi method. Boulkedid et al[82] found that the most frequently used criterion was validity. Often when new indicators are developed in a given field, validity criteria are the most common. Indicators chosen using consensus methods such as the Delphi method have high face validity. This is a prerequisite for any quality indicator such as an HRQOL questionnaire.[82]

Boulkedid et al[82] reported several methodological aspects in a systematic review (including 80 studies) of the Delphi method used for selecting healthcare quality indicators. Boulkedid et al[82] concluded that the methodology varied greatly, For example, response rates for all rounds were reported by only 39% (31/80) of studies, feedback between rounds was given by 60% (48/80), 77% (62/80) stated which specific method was used to achieve consensus, and merely 57% (48/80) of studies specified details of the selected quality indicators.[82]

Planning and conducting a Delphi survey requires several design aspects to be carefully considered, including: expert selection and recruitment, the purpose of the survey, the number of rounds, defining the criteria for reaching consensus, type and duration of Delphi procedure, and rating scale.[82] Furthermore, Boulkedid et al[82] reported a common practice entailing a face to face meeting, if necessary, after completion of the regular Delphi rounds. This practice is referred to as “the modified Delphi method”.

Today, several studies have employed the Delphi method to *develop* PRO questionnaires.[82] However, no studies are known to have used the Delphi method to *translate and validate* PRO questionnaires.

3.10.1 EXPERT PANEL SELECTION

Determining the selection criteria for the expert panel is a crucial step in the cross-cultural adaptation process. Studies have reported that the panel composition influences ratings.[18,82] The panellists should have relevant knowledge, expertise, and background within the target issue[80,82] and be willing to contribute.[84] Boulkedid et al[82] and Day et al[83] assert that the selection criteria in the study design should be clearly defined by knowledge, position, age, occupation, qualification, and a high skill in writing and communication.

Several authors point out the danger of bias in the selection of the panel.[80,84] Selecting on the basis of acquaintance to a researcher can pose a bias. However, this may be a difficult factor to address in intensely specialised areas.[84]

Notably, the panel should comprise experts who are potential users of, or stakeholders in, the findings.[82] The panel should also comprise experts with a varied background to gain different viewpoints and a wide range of alternatives. Importantly, a heterogeneous panel group will yield better results than a homogeneous group.[82,83]

3.10.2 PANEL SIZE

The size of the panel is debatable, and there are no set rules.[86] Delphi panels have been found to vary in size from 4 to 3,000 panellists.[80] Some authors assert that useful results can be obtained from a small size: 10–15,[86] while others recommend a panel size of 11–30.[18]

Of note, several authors have acknowledged that for *some panels*, the issue of representation is based on the qualities and attributes *of each candidate*, rather than on panel size.[80,82] As Powell notes, representativeness of an expert panel does not equate to representativeness as required for statistical purposes.[84]

3.10.3 QUESTION DESIGN AND SCORING OPTIONS

The question design and scoring system are important. When formulating questions for a Delphi study, the investigator composes clear, concise, and unambiguous questions together with clear instructions. The investigator should avoid formulating questions in a way that does not allow different views to come forth.[17]

Response options can include dichotomous yes/no options or scales with multiple options (e.g. five-point category Likert scale), adjectival scales, continuous visual analogue scales, rating scales, event logs, checklists, and pictorial scales.[88] Likert scales are similar to adjectival scales with one major difference: adjectival scales are unipolar. In contrast, Likert scales are bipolar, e.g. they might range from ‘strongly agree’ to ‘strongly disagree’.[16,17]

Likert scales are often employed in Delphi studies. Devised by psychologist Rensis Likert in 1952, the scales are in a useful question/answer format that can measure an attribute, opinion, or particular topic such as frequency (always – never), agreement (strongly agree – strongly disagree), or quality (very good – very poor).[17] A Likert scale is “an ordered set of

discrete terms or statements from which patients are asked to choose the response that best describes their state or experience."[88(p.244)]

A Likert item is a statement/question that the research participant is asked to assess. Ideally, for Likert scale questions, all the categories would be categorically similar so that the summed score becomes a reliable measurement of the particular attribute or attitude. If the item on the scale does not correspond with the intended topic, the total score for the respondent can become contaminated/polluted and the results difficult to decipher.[17]

There are several different aspects to consider when constructing a Likert scale: the number or range of boxes or scale divisions, whether all the divisions should be labelled, and whether there should be a neutral category.[17] The range of possible responses for a scale can vary. Norman and Streiner[17] assert that five or seven-point formats should be the minimum. Studies have shown that loss in reliability is slight when comparing seven to ten categories. However, when using five categories, the reliability is reduced by 12% compared to seven categories. Reducing the number of categories from five to two results in a loss of reliability by 35%.[17]

A Likert response scale could be *strongly disagree, disagree, neither disagree nor agree, agree, strongly agree*. Numerical descriptors can be used with Likert scales, where the respondents select a number corresponding to their level of agreement. For example, a question might prompt respondents to indicate their level of agreement by choosing a number ranging from 1 to 5, where 1 is *strongly disagree* and 5 is *strongly agree*.[17]

If numbers are used, the investigator should consider whether the numbers will range from 1 to 5 or -2 to +2. Norman and Streiner[17] point out that placing numbers under the words can result in the respondents using the numbers to assist them in interpreting the meanings of adjectives.

Regarding the neutral category, there is no definite rule as to whether the response should have an even or odd number of categories.[17] This depends on the needs of the investigator.[17] Usually on a Likert scale, the scale is balanced on both sides of a neutral category (strongly agree – strongly disagree), which creates a less biased measurement. The neutral category should also reflect a neutral option and not the inability to answer the question. Under this circumstance, *neither agree nor disagree* or *neutral* would be more

appropriate terms.[17] If the investigator wishes for the respondent to choose positive or negative answers and commit to one or the other side, four or six categories can be used.[16]

Several studies that have developed PROMs have employed an expert panel, the Delphi consensus method and a Likert scale system to generate and select items.[82,89] Benhamou et al[90] used the Delphi consensus method and an 11-point Likert scale in developing and validating a self-report questionnaire for multiple sclerosis, Parkinson's disease and stroke. For each generated item, experts were asked to rate on an 11-point Likert scale (0, disagree, to 10, agree) as to whether they believed the item should be selected in the final tool. They were also asked to state the degree of agreement with the formulation of the item. Items with a median relevance score of less than 8 were excluded. The responses for each Delphi round were reported by stating the percentage of experts choosing each value of the 11-point Likert scale.[90]

3.10.4 NUMBER OF ROUNDS AND CONSENSUS

The number of rounds should be determined as well as the consensus criteria and time frame.[82] The Delphi method specifies a minimum of two rounds. However, there is ongoing debate as to the recommended number of rounds.[82] Most studies recommend two or three rounds.[83]

Adler et al[86] describe the Delphi method in two phases: the exploration phase (Round 1 and/or 2) and the evaluation phase (Round 2 and/or 3). In Round 1, experts can argue in favour or against. The **exploration phase** questionnaire (Round 1) poses the problem in broad terms and invites answers and comments. This process results in a questionnaire ready for the **evaluation phase**. In Round 2, the experts are asked to rank the items in the *evaluation phase questionnaire* and prioritise them according to the instructions given.[86]

In Round 2 or 3, the panellists gather and assess the experts' views. There may be consensus or disagreement. If there is significant disagreement, this can be explored further in Round 3 or 4 to uncover the underlying reason. Deciding when to end a Delphi procedure and defining consensus are two important factors that should be addressed when planning a study design.[82]

Consensus is rarely equal to a unanimous vote, however it is usually achieved when the majority of panellists are in some degree of agreement. Consensus in the Delphi method

varies from study to study,[82] and can range from 55–100% agreement.[84] Boulkedid et al[82] state that determining consensus involves deciding beforehand how agreement is to be measured and the cut-off level of agreement that will define consensus.

Boulkedid et al[82] conducted a systematic review of the Delphi method for selecting healthcare quality indicators and described several ways to achieve consensus on them. For example, one study was based only on selecting a median score greater than a threshold, e.g. indicators having a median score of 7 or more were selected. The Rand UCLA agreement criteria were also found to be in frequent use, involving a nine-member panel using a nine-point Likert scale. Consensus was reached when no more than two members rated the indication outside the three-point region (1–3, 4–6, 7–9) containing the median.[82] Another consensus method commonly used entailed median scores above a predefined threshold and a high level of agreement among expert panel members. For example, consensus could be reached when the indicators defined for an item had a median score of 8 or more with 75% or more of the ratings being in the lowest or highest tertile.[82]

Boulkedid et al[82] also reported in their review that 49/80 studies used a modified Delphi procedure (combination of Delphi rounds and a final meeting). Notably, in most studies, the meeting was convened at the end of the rounds.[82] A meeting is seen as useful when there is difficulty reaching consensus. Both disagreements and discrepancies in items can be resolved with a consensus meeting.[82]

The results of a Delphi study can undoubtedly be used to enrich traditional face-to-face meetings.[82] Further, the efficiency of face-to-face meetings can be increased by a supplementary group communication process obtained through the Delphi method.[82,89] During a face-to-face meeting, anonymity can still be partial. Even though the panellists will know each other, their contributions can remain anonymous.[89]

The face-to-face meeting should be well structured with a facilitator in order to contain any dominant personalities. In addition, the facilitator could, if needed, call for a test for consensus. To do this, the facilitator enquires if there are any unsolved issues that have not been discussed.[82]

The Delphi method is seen as a valid and effective system for consensus on an opinion by a group of experts. Numerous face-to-face meetings can be difficult to organise due to time

and cost constraints. The task of iteration can also encourage the expert panel to become more focused on problem-solving and give them time to revise and improve ideas.[84]

However, the Delphi method can be seen to "produce a watered-down version of the best opinion".[84(p378)] Furthermore, it is seen as time-consuming, and it can take up to several weeks or months to complete each round.[82,84] Powell[84] argues that even though the Delphi method can facilitate an in-depth discussion among experts, it is still a challenge to produce high-quality results among experts.

3.10.5 STATISTICAL AND DATA ANALYSIS

The Delphi process and analysis can involve both quantitative and qualitative data. The qualitative data is usually from the first round, using open-ended questions to gather participants' opinions and new alternatives. Subsequent rounds (Rounds 2 and 3) seek out additional information, as well as any influence and change of opinion among panel members until the desired level of consensus is achieved.[91]

It is recommended that both collective and individual feedback be frequently given to the panellists between rounds. Boulkedid et al[82] recommend that, after each round, the panellists are given the collective group's results, the panellists' response, and an overview of all comments. The feedback includes qualitative comments and quantitative measures.[82] A five, seven or eleven-point Likert scale is often used to evaluate individual and group responses.[17] The quantitative data presented to the panellists are statistical measures of central tendency (e.g. mean, median, mode) and level of dispersion (e.g. standard deviation, inter-quartile range, inter-percentile range).[82] The statistical measures inform the panellists about the collective opinions and judgements of the panel members.

Dalkey et al[18] highlight that statistical reporting of a group response can lower the chance of group pressure for conformity. In addition, providing statistical feedback to the group is a way of assuring that every member of the group is considered in the final response. The Delphi method can also result in the panellists feeling a sense of shared responsibility.[18]

Validation of a Delphi study can be done in several ways, such as by comparing the findings with a gold standard or with data from other sources, evaluating internal logic (i.e. checking the consistency of the group's output), or evaluating face validity. Evaluating face validity

entails assessing the usefulness of the Delphi rounds in terms of the extent of correctness, commitment and implementation.[82,84]

The Delphi method has been criticised for its lack of reliability since the opinions of panel members may be person-dependent.[82,84] Powell[84] stated that the use and reporting of studies employing the Delphi method need to be improved in quality indicator research.

3.10.6 BURDENS AND RISKS

The Delphi method can be time-consuming and a burden for expert panel members. With the time commitments involved in completing the rounds, the investigator risks having panellists withdraw from the study. Anonymity can also lead to a lack of accountability by the expert panel members and decisions being made too hastily.[84]

3.11 METHOD

3.11.1 METHOD – TRANSLATION AND CROSS-CULTURAL ADAPTATION (STAGE 1)

The overall aim of the translation procedure and cross-cultural adaptation was to ensure a translation that has semantic, conceptual, operational and experiential equivalence (i.e. linguistic validation) between the PFDI-20 and PFIQ-7 source version and the Norwegian PFDI-20 and PFIQ-7 version.[19] There are two official written forms of Norwegian, *Bokmål* (Book Language) and *Nynorsk* (New Norwegian).[112] As outlined in Chapter 5, Norwegian *Bokmål* (Book Language) was chosen as the target language for the PFDI-20 and PFIQ-7 questionnaires.

The PFDI-20 and PFIQ-7 were translated from English into Norwegian *Bokmål* (Book Language) using a new multistep translation and cross-cultural adaptation method which combined the EORTC QoL Group guidelines[10], the Delphi method[18] and an expert panel review.[19] It involved two independent forward and back-translations,[10] and used the Delphi method (anonymous voting, controlled feedback, statistical group response) to establish a consensus on translated items[18] in a panel of bilingual pelvic floor experts[19] that included gynaecologists, colorectal surgeons, a urologist, a physiotherapist, and a urotherapist.

The method section includes design methodologies for:

- Translation procedure
- Expert panel using the Delphi consensus method

One of the main objectives of this study was to examine the Delphi method (Section 3.10) incorporated into the expert panel phase as a means of facilitating and improving the linguistic validation of the PFDI-20 and PFIQ-7. The suggestion to study this concept arose from discussions with the principal supervisor at Flinders University.

During the literature search, it became evident that the concept of using the Delphi method while conducting the expert panel phase of a translation and validation process had not been undertaken before for PRO questionnaires. As outlined in Section 3.4, good practice recommendations by the ISPOR TCA Task Force[8] and the ERIQA Group[9] involve a multistep approach. Additionally, several translation procedures recognise the expert panel as an important component of a multistep procedure. The expert panel is seen as playing an important role in facilitating and improving equivalence and cross-cultural adaptation.[19]

Methodologies vary within the expert panel phase; however, face-to-face meetings are the common component in this phase. These face-to-face meetings are beneficial for assessing equivalence and resolving items of discrepancy. Face-to-face communication can be a disadvantage if there are dominant personalities present, because a situation can arise where there is a certain form of group pressure for conformity.[18] Therefore, additional methods for achieving group consensus within the expert panel phase should be explored. One such method is the Delphi method, which embodies the three concepts of anonymity, controlled feedback and statistical group response.[18] Incorporating the concept of anonymity into the expert panel phase could be advantageous for avoiding both the influence of dominant personalities and group pressure for conformity. Furthermore, the Delphi method described in Section 3.10 can give panellists the opportunity to reassess their previous responses through controlled feedback and statistical group response, leading to improved ideas or alternatives.[18] These iterative attributes of the Delphi method can improve the quality of the translation and cross-cultural adaptation of health measurement scales, e.g. PROMs.[18]

These factors led to the selection of an existing set of guidelines, the EORTC translation guidelines,[10] and its synthesis with the expert panel phase using the Delphi method to develop a new multistep method of translation. The EORTC QoL Group was chosen as the translation procedure as it met the ISPOR TCA Task Force criteria for principles of good practice for translation.[8]

The study design included both qualitative and quantitative methodologies applied to the cross-cultural validation of the PFDI-20 and PFIQ-7 questionnaires. Qualitative methodology was applied to both the expert panel phase and the cognitive debriefing (pilot testing) phase. Quantitative feedback was also employed during the expert panel phase, which consisted of statistical reviews showing the collective opinion and degree of consensus of the expert panel.[18]

In summary, the EORTC QoL Group translation procedure[10] combined with an expert panel phase[19] was employed to facilitate and improve comprehensibility, the use of specific domain terminology, and equivalence between the PFDI-20 and PFIQ-7 source version and the target version, i.e. Norwegian.

Translation procedure

As outlined in Section 3.5, many disease-symptom-specific and HRQOL questionnaires are translated by international translation groups (e.g. Health Outcomes Group, EORTC QoL Group, Quality Metric Medical Outcomes Trust).[8,9] The PFDI-20 and PFIQ-7 condition-specific and HRQOL questionnaires currently do not have an international translation group or project responsible for translating these documents into other languages. It is therefore important to find a translation procedure that ensures a cross-cultural adaptation yielding equivalency between the source questionnaire and the target version.[8,9]

The translation procedure for this study is mainly based on modified guidelines from the EORTC QoL Group, published in 2009.[10] Specifically, the EORTC QoL Group guidelines[10] are augmented through an additional phase involving multidisciplinary expert panel review using the Delphi method.[19] The expert panel review was integrated into the EORTC translation guidelines to ensure rigorous cross-checking and good cross-cultural adaptation.[9,19] The multidisciplinary expert panel review was also deemed as a necessary step in this translation process because of the nature and complexity of the questionnaires (e.g. multidisciplinary symptoms and HRQOL issues pertaining to urine, prolapse, and bowel).

The EORTC QoL Group began in 1998 and is responsible for translating the EORTC GLQ-C30 cancer quality of life core questionnaires and its modules. These questionnaires and disease and symptom-specific modules are available in more than 85 countries.[10]

Principles and guidelines of good practice for translation and cross-cultural adaptation

The EORTC QoL Group is one of ten translation groups that were examined in the ISPOR TCA Task Force[8] article discussing the criteria for principles and guidelines of good practice for translation and cross-cultural adaptation for patient-reported outcome measures.[8] The EORTC QoL Group guidelines meet the ISPOR TCA Task Force criteria for principles of good practice.[8,9]

There are several other known international translation procedures that meet the criteria for principles of good practice, e.g. Euro QoL Group, Health Outcomes Group HOG, and World Health Organization.[8] However, the EORTC QoL Group guidelines were selected for this study, not only for meeting the ISPOR TCA Task Force criteria for principles of good practice for translation, but also for methodology, extensive research supporting its translation practices, and broad experience with translating disease-symptom and quality of life questionnaires and modules into several languages.[8,9] In addition, the EORTC QoL Group guidelines focuses on a clear rationale and documentation of each step.

Modification of the EORTC QoL Group guidelines

The translation procedure for this study was mainly based on modified guidelines from the EORTC QoL Group Third Edition, 2009.[10] The four main modifications were:

1. Roles and responsibilities were modified. The principal researcher/project manager in this project was a combination of both the EORTC translations coordinator and project manager (Table 3.2).
2. The principal researcher/project manager, if required, had a Translation Advisory Group (health specialists and language specialists) involved in all stages of the translation, replacing the role of the EORTC Translation Committee.
3. An additional phase was added to the EORTC QoL Group procedure, namely an expert panel review using a modified Delphi survey. The principal researcher implemented the Delphi method through email circulation (experts responded by email and/or by telephone). Two to three rounds were to be completed, and if there were still items with discrepancies, a final meeting among the experts would be organised for discussion and amendment. This final meeting is the part that goes beyond the original Delphi method, thus the phrase “modified Delphi method”. To

ensure the quality of this translation phase, the principal researcher asked the EORTC QoL Group to have an advisory role in the modifications of the procedures.

4. The preparation phase involved obtaining permission from the instrument developer to carry out the translation and validation of the HR PRO instrument. The instrument developer also contributed to the clarification of some concepts/items in the questionnaires. This phase did *not* involve cross-referencing in the EORTC QoL Group computerised item bank because the EORTC QoL Group does not act as a translation group for the PFDI-20 and PFIQ-7 questionnaires.

Roles and responsibilities

Table 3.2 lists the individuals and institutions involved in the translation process and their background and responsibilities.[10]

Preparation

The developer of the questionnaires authorised the translation and was asked for information on any notable translation difficulties.[10] Definitions of all concepts in the questionnaires were examined by the principal researcher before the translation process commenced to avoid misinterpretations or ambiguities.

Forward translations

Forward translation of the English PFDI-20 and PFIQ-7 into Norwegian *Bokmål* (Book Language) required two individuals, both Norwegian native speakers with a high level of fluency in English.[10] The two translators independently translated the instructions, the questionnaire items, and the response categories into Norwegian.[10] The wording in a translation was kept compatible with a 12-year-old.[19]

The principal researcher compared the translations. The principal researcher had a high fluency level in Norwegian so that she could arbitrate any disagreements. The principal researcher could consult an advisory group if additional guidance were needed.[10]

Reconciliation of the two forward translations

The first and second translators' versions were merged into one single forward translation. The principal researcher coordinated this reconciliation process. Thereafter, the principal

researcher and translators would review any problem items in the single forward translation and create a reconciled version of the translations. The principal researcher supervised this process, and if additional guidance was needed, the translation advisory group (TAG) was contacted.[10]

According to the EORTC Guidelines, four reconciliation scenarios needed to be taken into account[10]:

a) In cases where the two forward translations yielded results with a high level of agreement, the wording was considered ready for further processing.[10]

b) If the two forward translations differed, the principal researcher would work with the two forward translators, using recommendations from the TAG if necessary, to resolve the differences. The resulting single forward version would then be considered ready for further processing.[10]

c) If the two forward translations differed significantly on a few items, alternative wordings would be suggested as a basis for discussion and resolution during the back-translation.[10]

d) In the event of unresolvable disagreements, a third forward translator might be invited to resolve the situation. The subsequent discussion would take place after the third translator had independently translated the problem items.[10]

This resulted in a single forward translation ready for back-translations.

Back-translations

The back-translations acted as a quality-control step, and the review of the two back-translations against the source version verified and ensured equivalence[8,16,19] and resolved any discrepancies.[17] During this process, it was crucial that the translation produced questionnaires that were both comparable in terms of idiomatic, experiential, conceptual, and semantic equivalence.[17,19]

Two native English speakers with a high level of fluency in Norwegian were required.[10] Each translator independently translated the instructions, examples, questionnaire items, and response categories from the reconciled single forward translation back into English. The translators had no knowledge of the English source questionnaires.[10]

TABLE 3.2. ROLES AND RESPONSIBILITIES OF INDIVIDUALS AND INSTITUTIONS INVOLVED IN THE TRANSLATION PROCESS

ROLES	TITLE AND BACKGROUND	RESPONSIBILITIES	RATIONALE
Principal researcher (PR)/project manager (PM)[10]	PhD student Stoma care nurse Administrative manager at a Pelvic Floor Centre	PR/PM managed and coordinated the entire translation project	PR had a coordinating role for the entire project[10]
PFDI-20 and PFIQ-7 questionnaire developer[10]	American Gynaecologist, Dr Matthew Barber	The questionnaire developer authorised the translation of the PFDI-20 and PFIQ-7 questionnaires into Norwegian	In the preparation phase, it was important to have authorisation to copyright material[8,77] The developer also helped avoid any ambiguities or misinterpretations of items[8,77]
Translation Advisory Group (TAG) [10]	Language specialist Healthcare specialists with experience in translating condition-specific HRQOL questionnaires and language specialist	Advisory role for translation issues until Intermediate Version 1.0 was completed	The PR had a Translation Advisory Group to consult on translation issues[10]
Forward translators[10]	Amesto authorised translators[92] Forward translation of PFDI-20 and PFIQ-7 questionnaires involved two professional translators, both Norwegian native speakers with a high level of fluency in English. The translators resided in Norway. Each of the two certified translators had several years' experience in translating medical, healthcare and research documentation[92]	Translated the PFDI-20 and PFIQ-7 from source version (English) to target version (Norwegian)	The two forward translations were compared to detect any errors or digressing interpretation of ambiguous items in the source version and to diminish the potential bias of each forward translator. After the two forward translations had been completed, reconciliation commenced to resolve items of discrepancy and to obtain equivalence. This produced a single forward translation ready for back-translation.[8]

ROLES	TITLE AND BACKGROUND	RESPONSIBILITIES	RATIONALE
Back-translators[10]	Amesto authorised translators[92] Two native English translators with a high level of fluency in Norwegian were used in the back-translation. The translators had several years' experience in translating medical health and research documentation. One of the translators had previously worked for the University of Oslo, the University of Bergen and The Norwegian Research Council. The other translator has worked for Oslo University Hospital in the Department of Obstetrics and Gynaecology	Translated the PFDI-20 and PFIQ-7 from target version to source version	The back-translations acted as a quality-control step, and the review of the two back-translations against the source version verified and ensured equivalence of the translations[19]
Third translator[10]	Amesto authorised translators[92]	In the case of disagreements, translate the ambiguous items of the PFDI-20 and PFIQ-7 from target version to source version	A third translator can introduce additional concepts in cases of unresolvable differences
Translation agency[10]	Amesto translation firm collaborating with University Oslo[92]	The translation agency was responsible for selecting forward and back-translators and for reporting to the PR/PM. The agency was also responsible for proofreading the PFDI-20 and PFIQ-7 questionnaires.	A Norwegian translation agency that had access to certified translators working within the medical research and health fields[8]
EORTC translation advisor	EORTC Quality of Life Group	Advisory role for the modifications made in the EORTC Translations procedure, third edition	To ensure the quality of the translation process and principles of good practice for translation

ROLES	TITLE AND BACKGROUND	RESPONSIBILITIES	RATIONALE
Pelvic floor expert panel[19]	Professor, Colorectal surgery Consultant, Colorectal surgery Consultant, Urology Consultant, Gynaecology Consultant, Gynaecology Consultant, Gynaecology Pelvic Floor Physiotherapist Specialised Nurse in Urology	The expert panel was involved in reviewing Intermediate Version 1.0, Intermediate Version 2.0 and approval of the written report and final translated version (Intermediate Version 3.0). The pelvic floor expert panel examined specific domain terminology, clear wording, the common use of language and equivalence	The expert panel review was a necessary step in this translation process because of the nature and complexity of the questionnaires (e.g. multidisciplinary symptoms and quality of life questions about urine, prolapse and bowel)

Back-translation review

The English back-translation was compared with the source (original) questionnaires. The principal researcher supervised this process, and if additional guidance was needed, the advisory group was contacted.[10] The principal researcher's high fluency level in Norwegian and English enabled her to arbitrate any disagreements.[19]

a) Where there was agreement between the English back-translation and the source (original) version, a single forward version (referred to as the Intermediate version 1.0) was considered adequate and ready for expert panel review.

b) In the case of *differences*, the principal researcher would discuss with the forward translators to reach agreement. Where agreement was reached, the corresponding sections of the single forward translation were regarded as semi-final and ready for expert panel review.[10]

c) Should the situation arise that agreement could not be reached through discussion, additional forward translations would be undertaken. This might call for a third translator. The process would be applied to produce a single forward translation, if necessary repeated until the back-translation closely resembled the source version.[10]

d) If difficult, unresolvable items remained, alternative wordings would be chosen for each problem item. This would result in a provisional translation used in the pilot testing. The principal researcher and the expert panel would select persistent difficult items for pilot testing. Correspondingly, questions would be designed and applied during pilot testing to identify wordings that met the objectives of the translation process, i.e. clear and common use of language and equivalence.[10]

Conclusion

The first part of Stage 1 of the study involved translating the English PFDI-20 and PFIQ-7, i.e. forward translation, reconciliation, back-translation, and back-translation review. This process of translation aimed to produce PFDI-20 and PFIQ-7 translated version (Intermediate Version 1.0) that showed equivalence with the original versions, ready for expert panel review.

3.11.2 METHOD – EXPERT PANEL USING THE MODIFIED DELPHI METHOD (STAGE 1)

The second part of Stage 1 of the study involved the pelvic floor expert panel[19] using a modified Delphi survey reviewing the Intermediate Version 1.0 to verify equivalence.[19] During the Delphi rounds with the expert panel, three distinctive attributes of the method were employed: anonymity, controlled feedback and statistical group response.[18]

Expert panel

The expert panel was a significant and integral part of the process to verify semantic, idiomatic, experiential, and conceptual equivalence between the source and target versions.[19] The expert panel's role was also to assess comprehensibility, readability and specific domain terminology, identify discrepancies of any items, modify, or reject items, and hence produce a cross-culturally adapted Intermediate Version 2.0 ready for pilot testing.[19]

Comprehensibility and readability entailed formatting sentences so that they could be understood by a 12-year-old,[8] and using simple, short sentences with keywords in each item. Selection of grammar was important as was using the active rather than passive voice, and repeating nouns instead of using pronouns.[93] Furthermore, metaphors, passive forms, sentences containing different verbs and adverbs, and prepositions telling where and when were avoided.[93]

Expert panel selection

In selecting the expert panel, the nature of the multidisciplinary questionnaires required a heterogeneous group that had relevant knowledge within pelvic floor dysfunction and expertise within urology, gynaecology, colorectal surgery, and physiotherapy.[80] The diversity of the panel and varied background ensured different viewpoints and a wide range of alternatives.[80,82,84]

The expert panel selection criteria included gynaecologists, colorectal surgeons, a urologist, a physiotherapist, and a nurse with diverse expertise and varied background[84] within pelvic floor dysfunction and/or senior academic rank.[84] The panel members had to be bilingual, highly skilled in written communication,[19] and preferably working in a multidisciplinary pelvic floor centre in a hospital setting.[84] Some of the panellists were potential users of the questionnaires who were interested in the field[86] but were impartial to the findings.[84] The composition of the expert panel employed in this study is shown in Table 3.2

Panel size

The sample size of the expert panel was based on recommendations by several authors stating a minimum of seven as an appropriate size.[80,83] Eight panellists were thus invited to comment on Intermediate Version 1.0. Representation in the panel was assessed by the qualities of the panel members and the scope of the problem rather than its numbers.[80,82,84]

The modified Delphi method

Using the modified Delphi method outlined in Section 3.10, a selected sample of multidisciplinary experts was invited to join an expert panel and comment on the Norwegian PFDI-20 and PFIQ-7 Intermediate Version 1.0 to verify equivalence.[19] Two to three Delphi rounds were to be completed, and if there were still items with discrepancies, a face-to-face meeting among the expert panellists would be organised for discussion and amendment.[19]

The Intermediate Version 1.0 (with an assessment form) was sent either by mail or electronically to each expert group member. The experts responded by email and/or by telephone. The question format in the assessment form was designed to acquire individual responses to the problem items and enable experts to improve their opinions during the rounds. This iterative approach to the process gave the panel time to assess the group judgement and revise and improve ideas.[86]

The three main attributes of the Delphi procedure were implemented, namely anonymity, controlled feedback, and statistical group response.[18] Anonymity entailed the panellist not knowing who made what response. Using written or email communication between the panellists achieved anonymity.[18] The controlled feedback involved a sequence of rounds (2 to 4), where a summary of the results from the previous rounds was communicated to the other expert panel members. The statistical group response was the measure of consensus for each item that quantified the expert panel's opinion for each round.[18]

The expert panel review ensured that as many issues as possible were resolved before the pilot testing, detailed in Chapter 4. During the pilot test phase, the patients could then focus on commenting on a minimum of unresolved items where alternatives were specified by the expert panel.[19]

Question design assessing the Intermediate Version 1.0

The question design and scoring system were important for the evaluation of Intermediate Version 1.0 (Appendix 3.2), with emphasis placed on clear and unambiguous questions. The question format and interview guide differed from Round 1 (Appendix 3.3) to subsequent rounds (also Appendix 4.3).

The question format in the first round was a semi-structured format to find the *areas* of agreement and disagreement between the panellists, reasons for their choices, and more importantly, alternatives.[91] This structured format comprised a set of questions: Have all the four areas of equivalence been met? If not, why? Can you suggest a change or alternative wording?

The question format in the subsequent Delphi rounds (rounds 2-4) was a structured question with a five-point Likert scale (*strongly disagree, disagree, undecided, agree, strongly agree*): Have all the equivalences been met and do you believe the item should be selected in the final PFDI-20 and PFIQ-7 Norwegian questionnaires? - State the degree of agreement with specific domain terminology and four areas of equivalence.

Statistical analysis of responses was employed to find the level of agreement or establish whether consensus had been reached.[91] The five-point Likert scale was balanced on both sides of a neutral option (*undecided*), creating a less biased measurement.[17] Further, all the items were categorically similar, so the summed score became a reliable measurement to accurately represent the opinion of each panellist.

Number of rounds and consensus

The number of rounds was determined as were the consensus criteria. The Delphi method in this study was divided into two phases and up to four rounds: the exploration phase (Round 1) and the evaluation phase (Rounds 2 and/or 3 and/or 4).[86] In Round 1, the experts could argue in favour or against.

In Round 2 and subsequent rounds, the experts were asked to rank the items (using a five-point Likert scale) and provide comments according to the instructions given.[91] In Round 2 or 3, the panellists assessed and gathered the other experts' views. There might be a consensus (agreement) or disagreement. If there was significant disagreement, this could be explored further in Round 3 or 4 to uncover the underlying reason.[82]

This study design defined consensus as items with no further comments rated as median ≥4 and general agreement of the substantial majority.[94] The substantial majority of the expert panel was defined as 75% of members agreeing on instructions, examples, items, and responses in the questionnaires. Based on previous Delphi studies, items that were rated as median ≥4 and by at least 75% of the panellists were included in the Norwegian language versions of the PFDI-20 and PFIQ-7 questionnaires.[82]

In Rounds 2, 3 and 4, the aim was to reach consensus and establish the degree of agreement.[18,82] If there was significant disagreement on any items after Round 3, a face-to-face meeting (Round 4) was called.[82]

If a meeting was required, decisions were reached when all present members consented to a proposal. The meeting was well-structured, and the facilitator would call for a test for consensus. To do this, the facilitator would identify whether any unsolved issues needed to be discussed.[82]

In this study design, the panellists in a meeting would know each other, but their contributions could remain anonymous. They would vote using short message service (SMS) or paper. The votes would not be disclosed to the other participants.[89]

In summary, the data collection in this modified Delphi study entailed:

1. Creation and emailing of the **Round 1** Intermediate Version 1.0 to the expert panel for comments.
2. Expert panel modified items and provided comments.
3. Principal researcher consolidated comments and responses from Round 1.
4. Creation and emailing of the **Round 2** Intermediate Version 1.0 for voting and comments to the panel.
5. Principal researcher consolidated comments and responses from Round 2.
6. Creation and emailing to panel the **Round 3** Intermediate Version 1.0 for voting and comments to reach consensus. If there were any discrepancies in items from Round 3, a meeting would be organised.
7. If a **final meeting (Round 4)** was required, the expert panel reviewed Round 3 Intermediate Version 1.0 in an attempt to reach consensus on any discrepancies. Any remaining discrepant items would be carried into the pilot test phase of the validation process.

The Delphi rounds and, if necessary, the expert panel meeting would result in consensus and produce the Intermediate Version 2.0 of the translated questionnaires for pilot testing. The timeframe would be 6–8 months to complete all rounds.

Statistical and data analysis

The Delphi process and analysis of data involved both **quantitative** and **qualitative data**. The **qualitative data** included the first round, using open-ended semi-structured questions to gather participants' opinions, and subsequent rounds to give feedback to the panellists. The aim of the subsequent rounds (Rounds 2 and 3) was to seek information and achieve the desired level of consensus.[18] The objective was to reach consensus at Round 3, or if necessary, Round 4.

The **quantitative data** used in the subsequent rounds presented panellists with statistical measures of central tendency.[91] This study design employed the median as the measure of central tendency and lowest and highest as the measure of dispersion since the literature study uncovered these as the most prevalent measures in previous Delphi method surveys (Section 3.10.5).[82]

Quantitative feedback consisted of statistical reviews showing the collective opinion such as median and percentage of consensus.[82] Consensus in this study was defined as items rated as no further comments with a median ≥4, as long as the majority of the group were in general agreement.[82,94] The question format in the subsequent rounds was a structured question with a five-point Likert scale (*strongly disagree-1, disagree-2, undecided-3, agree-4, strongly agree-5*)[91,94] and an analysis of responses was employed to reach consensus and find the degree of agreement. During each round, collective and individual statistical feedback was given so each panellist could review his or her response and compare it to the group's results (median, lowest and highest). Providing statistical feedback to the group was a way of assuring that every member of the group was considered in the final response.[18]

Qualitative feedback consisted of a summary of individual and collective comments from the panellists between rounds. During each round, the investigator recorded qualitative comments on each item. After each round, a document containing all the comments, individual or collective, was circulated to the panel members. This measure was used to

inform the panellists of their comments and the collective opinions and judgements of the panel members.[82]

Burdens and risks

The modified Delphi method was known to be time consuming[84] and thus a burden for the panellists. With the substantial time commitment anticipated to complete the rounds, the investigator was aware of the risk of fatigue and respondent withdrawal.[80] To reduce this risk, the study was planned within a six- to eight-month timeframe, and the panellists could choose among several methods for responding: email, SMS, or telephone.[82]

Ethical matters

Ethical issues were another important consideration. When approaching candidates for the expert panel, ethical issues of informed consent and individual autonomy were addressed.[17,90,95,96] As outlined in section 3.1.1 ethics approval was granted for Stage 1.

Information to participants and informed consent

A cover letter (Appendix 3.5) and the interview guide (Appendix 3.3) were sent by email together with the Intermediate Version 1.0 (Appendix 3.2) and source questionnaires (Appendix 3.1), inviting the expert panel members to participate in the research project. The cover letter informed the panellists of the following[95,96] :

- Title and purpose of the research project
- Expert panel selection criteria
- That the panellists were participating in a study
- What the study entailed
- What role the panellist would have in the study.

Consent by the participants was given by email or by telephone.

The interview guides explained that an inventory of questions and analysis of responses would be conducted to find areas of agreement and disagreement among the clinicians. The inventory of questions and analysis of responses was modified and re-circulated for clarification where consensus was not achieved.

Conclusion

The final part of Stage 1 of the study involved an expert panel review of the translated PFDI-20 and PFIQ-7 questionnaires (Norwegian Intermediate Version 1.0) using the Delphi method (i.e. anonymous voting, controlled feedback, statistical group response) to establish consensus on translated items among the bilingual pelvic floor expert panel comprising gynaecologists, colorectal surgeons, a urologist, a physiotherapist, and a nurse (urotherapist). This process aimed to produce PFDI-20 and PFIQ-7 translated version (Intermediate Version 2.0) that showed equivalence with the original versions, ready for pilot testing.

CHAPTER 4

RESULTS OF PELVIC FLOOR QUESTIONNAIRE TRANSLATIONS

4.1 INTRODUCTION

Chapter 4 details the qualitative and quantitative study findings of Stage 1. Stage 1 includes the translation and cross-cultural adaptation of the PFDI-20 and PFIQ-7 questionnaires from the source version (i.e. English) to the target version (i.e. Norwegian *Bokmål* (Book Language)) using a new multistep translation and cross-cultural adaptation method. The linguistic validation undertaken during Stage 1 is evidence that the Norwegian Intermediate Version 2.0 (Appendix 5.1) demonstrated equivalence with the original versions with few discrepant items. Ethics approval was granted (for Stage 1) and detailed in Section 3.11.2.

4.2 RESULTS

4.2.1 TRANSLATION PROCEDURE (STAGE 1)

This section presents the results and findings of the preparation, forward translation, reconciliation, and back-translation phases of the translation process.

Summary of the translation procedure implementation

Since the adaptation setting was classified as translating from the source language (English) into the target language (Norwegian), both translation and cross-cultural adaptation were necessary (Section 3.4). The translation and cross-cultural adaptation procedure included several stages over an 11-month period (Figure 4.1).

The 20-item Pelvic Floor Distress Inventory PFDI-20 and 7-item Pelvic Floor Impact Questionnaire PFIQ-7 were translated into Norwegian and then validated by interviewing multidisciplinary pelvic floor experts for cross-cultural comparison of the translation and equivalence. This novel multistep method combined the EORTC QoL Group guidelines,[10] the Delphi method,[18] and an expert panel review.[19]

Before translating the instrument or sending it out to be translated, the principal researcher examined certain concept definitions in the questionnaires to avoid any misinterpretation.[10]

Two forward translators independently translated the questionnaires from American English into Norwegian *Bokmål* (Book Language). Both translators were native Norwegians and fluent in English.

Any disagreements were resolved via a reconciliation process (between the principal researcher and the translators) resulting in a single forward translation. Some recommendations were given from the pelvic floor translation advisory team. To verify that the single forward translation was an adequate reflection of the original English version, two back-translations were performed by back-translators working independently. The back-translators in this phase were different from the forward translators and fluent in both English and Norwegian.

The principal researcher, the translators and the Translation Advisory Group (TAG), (bilingual health specialists and language specialists), were involved in most stages of the translation of the PFDI-20 and PFIQ-7 target-language versions, yielding the Intermediate Version 1.0. The entire translation process was traceable through the appropriate reports (see also Figure 4.1 and Appendix 4.1).[10]

The Intermediate Version 1.0 (Appendix 3.2) was then ready for review by an expert panel. Using a modified Delphi method, a selected sample of multidisciplinary clinical experts were invited to comment on the Intermediate Version 1.0.

Figure 4.1 illustrates the sequence of events of the 12-step translation process and shows the starting point of the Source Questionnaires and the end product of the Final translation versions (Intermediate Version 3.0). The 12 translation and cross-cultural adaptation process steps were as follows:

1. Preparation
2. Two forward translations
3. Reconciliation (single forward version)
4. Two back-translations
5. First interim report (Section 4.2.1; Appendices 4.1e-h)
6. Intermediate Version 1.0 (sent to the expert panel)
7. Second interim report (Section 4.2.2; Appendices 4.2a-b and 4.4a-f)
8. Intermediate Version 2.0 (sent to pilot test)
9. Third interim report based on the pilot test (Section 5.2.3)

10. Final review with expert panel (Section 5.3)
11. Fourth interim report based on the final expert panel review (Section 5.3.2)
12. Final translation version (Intermediate Version 3.0) (ready for further validation)

At each step, the principal researcher/project manager recorded feedback, decisions, persistent difficult items, and amendments in a report. This process resulted in an Intermediate Version 2.0 ready for pilot testing with patients, as detailed in Chapter 5.

Roles, responsibilities and rationale for roles

There were several individuals and institutions involved in the translation, cross-cultural adaptation, and proofreading process. Table 3.2 lists the individuals and institutions involved in the translation process and their roles, the rationale behind their roles, and their responsibilities.

Preparation

The developer of the PFDI-20 and PFIQ-7 questionnaires authorised the translation from the English version into Norwegian. Although the questionnaires had previously been translated into several other languages, no major translation difficulties had been reported to the developer (Table 4.1).

Before the translation process commenced, all items in the PFDI-20 and PFIQ-7 questionnaires were examined in order to identify any challenging concepts. The principal researcher worked with the Translation Advisory Group to provide definitions and clarifications of the concepts that were considered difficult (Table 4.1). The concepts that needed to be closely examined in English and Norwegian *Bokmål* (Book Language) were genital area, pelvic area, bowel movement, lower abdomen, experience, and feel.

Forward translations

The two forward translators, using the EORTC translation procedure, translated the source questionnaires into the Norwegian *Bokmål* Forward Translations 1 and 2 (Figure 4.1 and Appendix 4.1). The two translators independently translated the title, instructions, example, question items, and response categories. The translators were asked to target the comprehension level to a 12-year-old's level.[19] Furthermore, the translators were requested to go beyond semantic translation, and use conceptual and idiomatic language.[19]

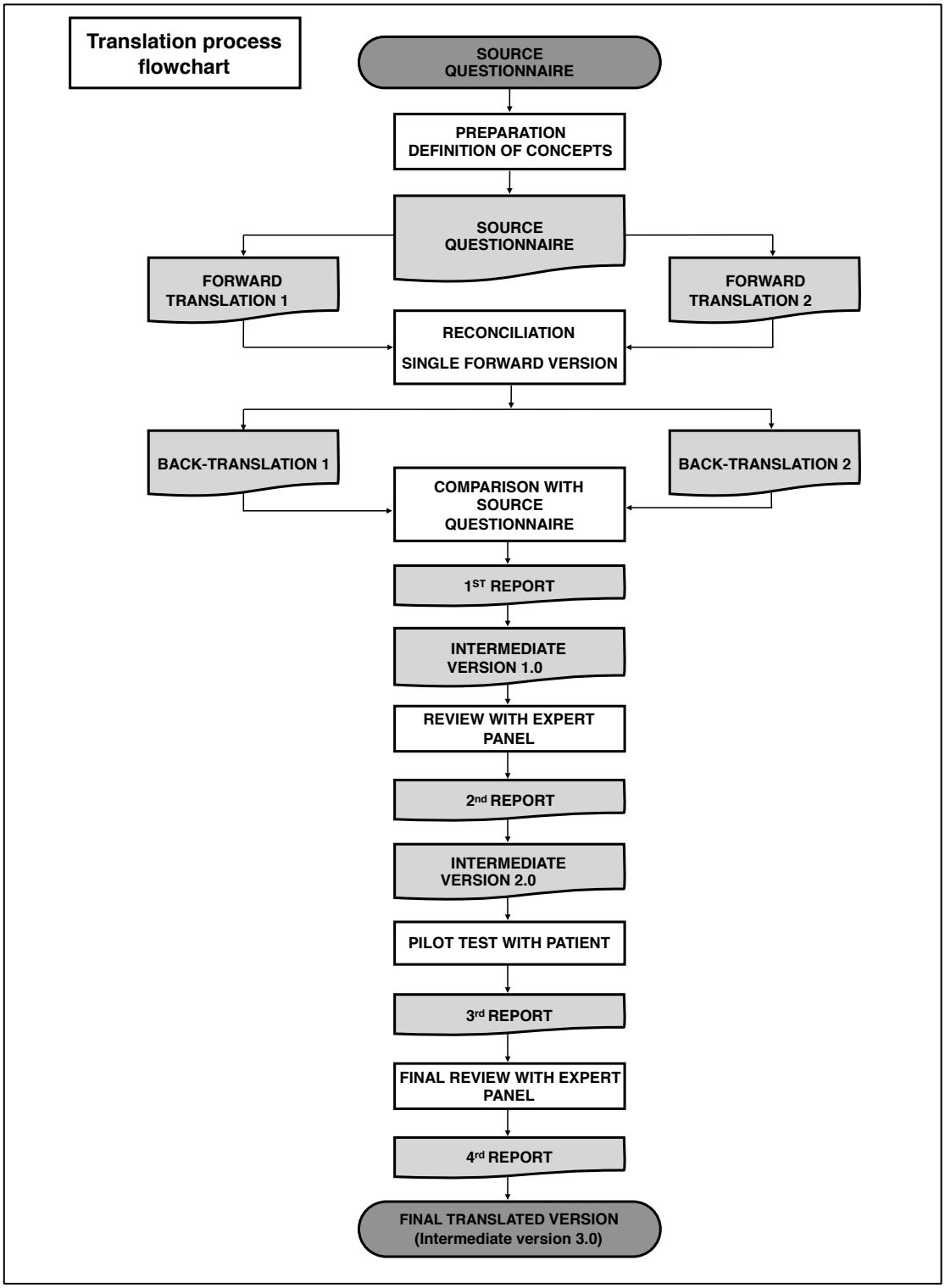

FIGURE 4.1. TRANSLATION PROCEDURE FLOW CHART. SUMMARY OF IMPLEMENTATION

Findings for PFDI-20 and PFIQ-7 forward translations:

The principal researcher compared the translations.[8,19] Most items (i.e. title, instructions, example, questions, and responses) in the two forward translations differed significantly, requiring reconciliation of the two forward translations (Appendix 4.1).

Reconciliation of the two forward translations

The principal researcher coordinated the reconciliation process of merging the two forward translations into one single forward translation (Appendix 4.1). The principal researcher made an initial comparison of the translations. During the reconciliation process, the two forward translations were analysed for discrepant items[8] and semantic, conceptual, idiomatic and experiential equivalence.[19] Where differences arose between the two forward translations, the principal researcher (using some recommendations from the Translation Advisory Group (TAG)) resolved these through discussions via email with the two forward translators to produce a provisional forward translation. There were no unresolvable disagreements concerning the items in PFDI-20 and PFIQ-7; thus, a third independent translator was not needed in this process.[10]

The TAG was useful during the reconciliation process in addressing PFDI-20 Questions 2, 3 and 6 and in modifying PFIQ-7 Question 3 — entertainment activities. The discussions between the principal researcher, the TAG and the forward translators throughout the reconciliation process are described in Appendix 4.1.

Findings for PFDI-20: title, instructions, example, and question items

During the reconciliation process, the title, instructions, example and 20/20 (100%) question items were flagged as areas of discrepancy between the two forward translations and required resolution. Following discussion, amendments were made to the title, instructions, and all question items. In comparing the source questionnaires with the target version, semantic and idiomatic equivalence were the main problem areas. Several adjustments to the grammar and syntax changed the Norwegian items dramatically and, by doing so, achieved semantic equivalence.[93] For example, in PFDI-20 Question 1, the Norwegian syntax of the preposition *et* (a) was discussed. The discussion was whether it should be *et trykk* (a pressure) or simply *trykk* (pressure). The syntax *et trykk* (a pressure) in the Norwegian PFDI-20 Question 1 *Kjenner du et trykk i nedre delen av magen* (Do you feel pressure in your lower

abdomen) was chosen because *et trykk* (a pressure) signifies a physical sensation of something pressing against an organ. On the other hand, *trykk* (pressure) is more associated with gas pressure, meaning the patient could misunderstand the question, thinking it was about feeling bloated. Of note, the principal researcher used the health specialists in the TAG to discuss equivalence and domain-specific terminology issues in several items as described in Appendix 4.1.

TABLE 4.1. DEFINITIONS AND CLARIFICATIONS OF SOME CONCEPTS IN THE QUESTIONNAIRES

SOURCE QUESTIONNAIRE CONCEPTS	OXFORD DICTIONARY OF ENGLISH[97]	MERRIAM-WEBSTER MEDICAL DICTIONARY[98]	NORWEGIAN TRANSLATION
Genital area	Adjective: relating to the human or animal reproductive organs	Genital – adjective: of, relating to or being a sexual organ	*Underlivet*
Pelvic area	Adjective: relating to or situated in the bony part of the pelvis	Pelvic – adjective: of, relating to, or located in or near the pelvis (pelvic organs) Pelvic noun: a pelvic part	*Bekkenet*
Bowel movement	Adjective: the act of defecation	–	*Ha avføring/å tømme tarmen*
Lower abdomen	Noun: the part of the body of a vertebrate counting the digestive and reproductive organs	Abdomen– adjective: the part of the body between the thorax and the pelvis	*Nedre delen av magen*
Feel	Verb: Experience (an emotion or sensation). Be aware of (something happened) through physical sensation	–	*Kjenne/Føle*
Experience	Verb: An event or occurrence. Feel (an emotion or sensation)	–	*Oppleve*

During this forward translations and reconciliation process, there were some cases of persistent difficulty in alternative wording concerning:

- PFDI-20 Questions 3, 13,and 16
- The PFDI-20 colloquial expression “do you usually” in Questions 1–2, 9–12, 17–19, 20.

The colloquial expressions and the idioms “do you usually” and “do you usually experience” in the forward translations were discussed between the principal researcher and the translators, and some amendments were made. It was difficult to choose idioms that were both suitable for the clinical setting and understandable to the patient (Appendix 4.1). The principal researcher flagged these items for further discussion during pilot testing (Table 5.3).

Findings for PFIQ-7: title, instruction, example, and question items

The title, instructions, example and 7/7 (100%) question items were flagged as areas of discrepancy between the two forward translations and required discussion. Following discussion, most items from the first translator’s version were used with minor amendments. This translation was chosen because it appeared to demonstrate a higher level of equivalence. The second translator agreed to use the first translator’s version.

During this forward translations and reconciliation process, there were some cases of persistent difficulty in alternative wording concerning:

- PFIQ-7 wording “activity” and “relationship” in instructions.

The principal researcher flagged these items for further discussion during pilot testing.

Findings for PFDI-20 and PFIQ-7: response categories

The PFDI-20 and PFIQ-7 response questions and (3/4) 75% response categories were flagged as areas of discrepancy and required resolution. Following discussion, amendments were made to one response question and the three discrepant response categories. With an even number of response categories (i.e. four response categories) in the PFDI-20 and PFIQ-7 questionnaires, it was important that the response options were distinctive enough so that the patient could differentiate between the choices.[17]

The reconciliation process resulted in a single forward translation ready for back-translation.

Back-translations

Two translators, different from those employed for the initial forward translation, undertook the back-translation process. Each translator independently translated the instructions, questionnaire items and response categories from the single forward translation into English. They had no knowledge of the questionnaires prior to translation. The translators were asked to translate into American English since the original versions of the PFDI-20 and the PFIQ-7 originated in the United States (Appendix 3.1).

The back-translations were compared to the American English source versions by the principal researcher. The first interim report (Appendix 4.1) documents the findings from this comparison in detail.

Back-translation findings for PFDI-20: question items

2/20 (10%) question items in the PFDI-20 questionnaire were flagged in the first interim report as areas of discrepancy and required discussion. Following the discussion, no amendments were made to the Single Forward Version question items, thus no new alternative were given in the first interim report as input for the expert panel review of the Intermediate Version 1.0.

Of note, during the back-translation process, the following items were flagged as problematic:

- PFDI-20 Question 16
- PFDI-20 Question 20

Back-translation findings for PFIQ-7: question items

1/7 (15%) question items in the PFIQ-7 questionnaire were flagged in the first interim report as areas of discrepancy and required discussion. Of note, no amendments were made to the Single Forward Version question items, thus no new alternative were given in the first interim report as input for the expert panel review of the Intermediate Version 1.0.

Of note, during the back-translation process, the following item were flagged as problematic:

- PFIQ-7 Question 6

The principal researcher flagged these PFDI-20 and PFIQ-7 items for further discussion during pilot testing (Table 5.3).

Back-translation findings for PFDI-20 and PFIQ-7: response categories

No response categories in the PFDI-20 and PFIQ-7 questionnaires were flagged as areas of discrepancy. No amendments were made to the Single Forward Version, and no new alternatives were given in the first interim report for expert panel review of the Intermediate Version 1.0. It was agreed among the principal researcher, translators, and the TAG that the conceptual equivalence was retained in the back-translation.

However, The opening question in the PFIQ-7 questionnaire was flagged as an area of discrepancy and required discussion. However, no amendments were made and no new alternatives were given in the first interim report for expert panel review of the Intermediate Version 1.0.

Of note, during the back-translation process, the following items were flagged as problematic:

- PFIQ-7 phrasing “your” in Questions 1–7

The principal researcher flagged these PFIQ-7 items for further discussion during pilot testing (Table 5.3).

Back-translation review report

The source versions, Single Forward Version, the two back-translations, and the first interim report were sent to the back-translators for feedback. The back-translators agreed to all the comments in the first interim report. There were no disagreements concerning the items, so a third independent translator was not required.

In summary, this process of analysis of back-translations resulted in the Intermediate Version 1.0 ready for the expert panel (Appendix 3.2). Furthermore, the first interim report (Appendix 4.1) listed all findings of discrepant items and suggestions for alternate wording as a comprehensive basis for discussion in the pilot test (Table 5.3).

4.2.2 EXPERT PANEL REVIEW (STAGE 1)

This section presents the results and findings from the expert panel review (second interim report) (Appendices 4.2 and 4.4). The purpose of the expert panel review was to improve the

quality of the translation and cross-cultural adaptation of the PFDI-20 and PFIQ-7 questionnaires. The modified Delphi method was implemented as a tool supporting the expert panel, encompassing the following methodological aspects[82]:

- Type of Delphi procedure
- Expert selection criteria
- Number of rounds
- Duration of the Delphi procedure
- Rating scale, feedback
- Consensus criteria during and between rounds
- Quality indicators: selection criteria are based on agreement and validity

Applying the Delphi procedure to the expert panel in the process design

As outlined in Section 3.11.2, this study employed the Delphi procedure[18] for interviewing the expert panel.[19] The Panel's role was to consolidate all versions of the questionnaires and develop what would be considered an Intermediate Version 2.0. The modified Delphi procedure allowed three rounds and a physical meeting with the expert panel to reach consensus.[19]

There were ten phases in the data collection for this part of the study (Figure 4.2):

1. Intermediate Version 1.0 was emailed to eight experts for comments.
2. Expert panel modified items and provided comments.
3. Principal researcher consolidated comments and responses from Round 1.
4. Creation of the Round 2 Intermediate Version 1.0, which was emailed to the panel for voting and comments.
5. Principal researcher consolidated comments and responses from Round 2.
6. Creation of the Round 3 Intermediate Version 1.0, which was emailed to the panel for voting and comments.
7. Principal researcher consolidated comments and responses from Round 3.
8. Creation of Round 4 Intermediate Version 1.0 and convening of the expert panel for voting.
9. Principal researcher consolidated comments and responses from Round 4.
10. Creation of Intermediate Version 2.0 ready for pilot testing.

Figure 4.2 illustrates the sequence of events for the four rounds of the proposed translation process.

Selecting and recruiting the expert panel

Eight candidates (i.e. three gynaecologists, two colorectal surgeons, a urologist, a physiotherapist, and a nurse (urotherapist)) were invited to participate in the expert panel. All candidates accepted the invitation, and all members participated in all four rounds. The panel comprised experts of varied backgrounds, ranging from experience in multidisciplinary pelvic floor clinical practice to senior academic rank. This varied background and experience accommodated different viewpoints, a wide range of alternatives, and hence the capability to improve the quality of the review outcome. Three of the candidates had PhD degrees, and one held a professor position. Several were nationally and internationally recognised within the pelvic floor field. The average years of experience in the pelvic floor field were 21 (range 5–32 years). Finally, the panellists were selected for their high skill in bilingual written communication and credibility with the target audience. Importantly, three gynaecologists and the physiotherapist on the panel were potential users of the questionnaires.

Interviews with the expert panel using the modified Delphi method

The modified Delphi method included four rounds: three Delphi rounds and a physical meeting with the panellists. Each round is described in more detail later in this chapter. The Delphi procedure took 11 months and involved several different Norwegian hospitals and clinics. The diagram in Figure 4.2 illustrates the overall progression and consensus for the Intermediate Version 1.0 between rounds.

Statistical and data analysis for Rounds 1, 2, 3, and 4

As outlined in Section 3.11.2, the Delphi process and analysis of data in this study involved both quantitative and qualitative data.

The qualitative data was based on responses to open-ended questions posed during each round. This feedback was presented to the panellists in Round 2 and subsequent rounds.

Quantitative feedback in this study consisted of statistical reviews of Rounds 2 to 4 showing the collective opinion as median and dispersion (lowest, and highest) and percentage of

consensus. Between each round, individual feedback was also given so that the panellists could review his or her response and compare it to the collective response .

As shown in Figure 4.3a and Figure 4.3b, consensus was reached during Round 4 with most expert panellists agreeing or strongly agreeing to all four equivalence criteria.

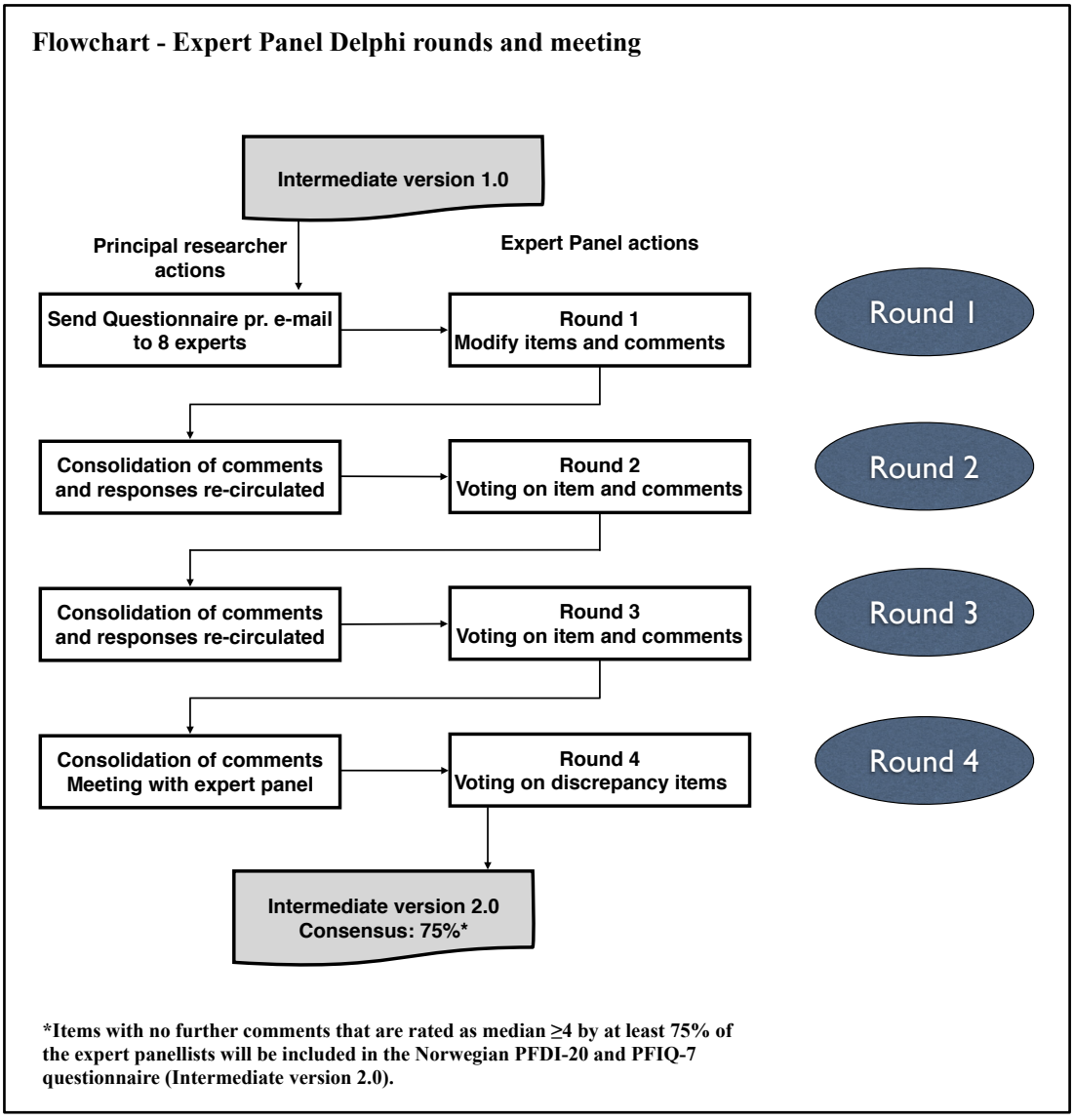

FIGURE 4.2. THE SEQUENCE OF EVENTS DURING THE FOUR DELPHI ROUNDS

Round 1

The Norwegian Intermediate Version 1.0 (Appendix 3.2), the source questionnaires (Appendix 3.1), and the interview guide (Appendix 3.3) were circulated by email among the

experts for comments. An interview consisting of structured questions and open-ended questions was conducted to find areas of agreement and disagreement between the clinicians (Appendix 4.2).

The experts responded by email, telephone, and/or face-to-face meetings. The principal investigator consolidated all responses and comments into a new set of documents. This documentation was subsequently distributed to each member of the expert panel, thus initiating Round 2.

Figure 4.4 illustrates the number of panellists who stated that the four equivalences had not been met and suggesting new alternatives, compared to the number of panellists who agreed that all four equivalences had been met.

Findings for PFDI-20 and PFIQ-7

The expert panellists questioned and challenged 30/36 (83%) items (i.e. instructions, example, and question items) in the PFDI-20 and PFIQ-7. None of the response categories were challenged (Figure 4.4).

The expert panellists proposed 53 alternatives to the Intermediate Version 1.0. PFDI-20 Questions 3, 5, 6, 11, 13, and 16 and PFIQ-7 Questions 5, 6, and 7 were discussed in detail. Reasons for the proposed alternatives were that the areas of equivalences had not been met. Idiomatic equivalence, semantic equivalence, and specific domain terminology were the primary reasons for disagreement, and the analysis of responses was re-circulated for clarification. (Appendix 4.2)

The idioms in the PFDI-20 questionnaire were challenging. Several specialists did not agree with the Norwegian colloquial expression and idiom *kjenner du vanligvis* (do you normally) in Questions 1–2, 9–12, 17–19, and 20. During Round 1, several panel experts proposed the expression *har du ofte* (do you normally) and contended that this idiom was commonly used in the clinical setting. Notably, during the back-translation, the colloquial expressions *har du ofte* and *kjenner du vanligvis* were both back-translated to *"do you normally"* (Appendix 4.1). The principal researcher compared the adverbs *"normally"* and *"usually"* in the Oxford dictionary[97], and both were defined as "*under normal conditions*".

Brief overview of Rounds 2, 3, and 4

For each round, a review guide with questions was circulated to the panellists for voting and comments.[94] The question format in the second through fourth rounds is outlined in Appendix 4.3.

The content of questions, consolidation of changes and analysis of responses were re-circulated by email for clarification where consensus was not achieved. The experts responded by email, telephone, and/or face-to-face meetings. Round 2 also included consolidation of the responses and comments for re-circulation ahead of Round 3.

The panellists were given information about the anonymous answers of the other panellists and a collective statistical opinion (using median). Statistics outlined in Appendix 4.4 were gathered on how many specialists agreed to the four areas of equivalence and how many did not agree and proposed a change.

Items that satisfied the study's inclusion criteria (Section 3.11.2) were added to the Norwegian PFDI-20 questionnaire (Intermediate Version 2.0) and required no further rounds (Figure 4.2). As shown in Figures 4.3a, 4.3b and 4.5, thirty-six items (twenty-four items in PFDI-20 and twelve items in PFIQ-7) were examined during this round. Further, it was evident that for many of the items (12/36) in Rounds 2 to 4, the panel agreed more over time.

Findings overview for PFDI-20

Figure 4.5 illustrates the PFDI-20 items (i.e. title, instructions, examples, question items, and responses) discussed during the subsequent rounds and the new suggestions or comments given.

Round 2: Twenty-four items were discussed. Twenty-two items gained consensus; however, twelve items had comments. In summary, fourteen items (i.e. two items with no consensus and twelve items that reached consensus with comments) were brought into Round 3 for further discussion and voting.

Round 3: The two items not reaching consensus in Round 2 were discussed; however, neither gained consensus. These items were brought into Round 4 for further discussion and voting. In addition, it was agreed that the twelve items that reached consensus with comments in Round 2 should not be voted on, but instead be discussed further in Round 4.

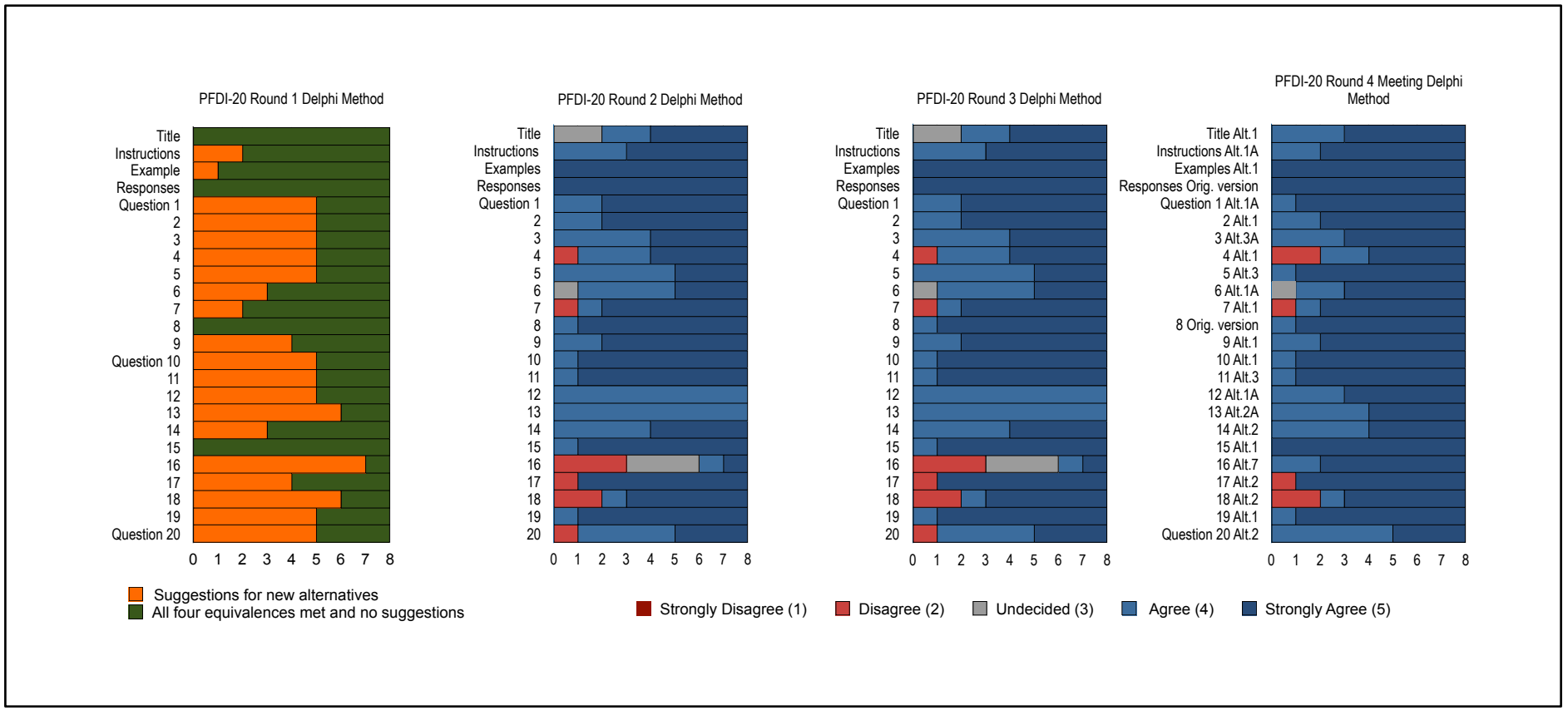

FIGURE 4.3A. DIAGRAM OF REVIEW STATISTICS FOR ROUNDS 1 THROUGH 4 OF THE DELPHI METHOD AS APPLIED TO THE TRANSLATION OF PFDI-20

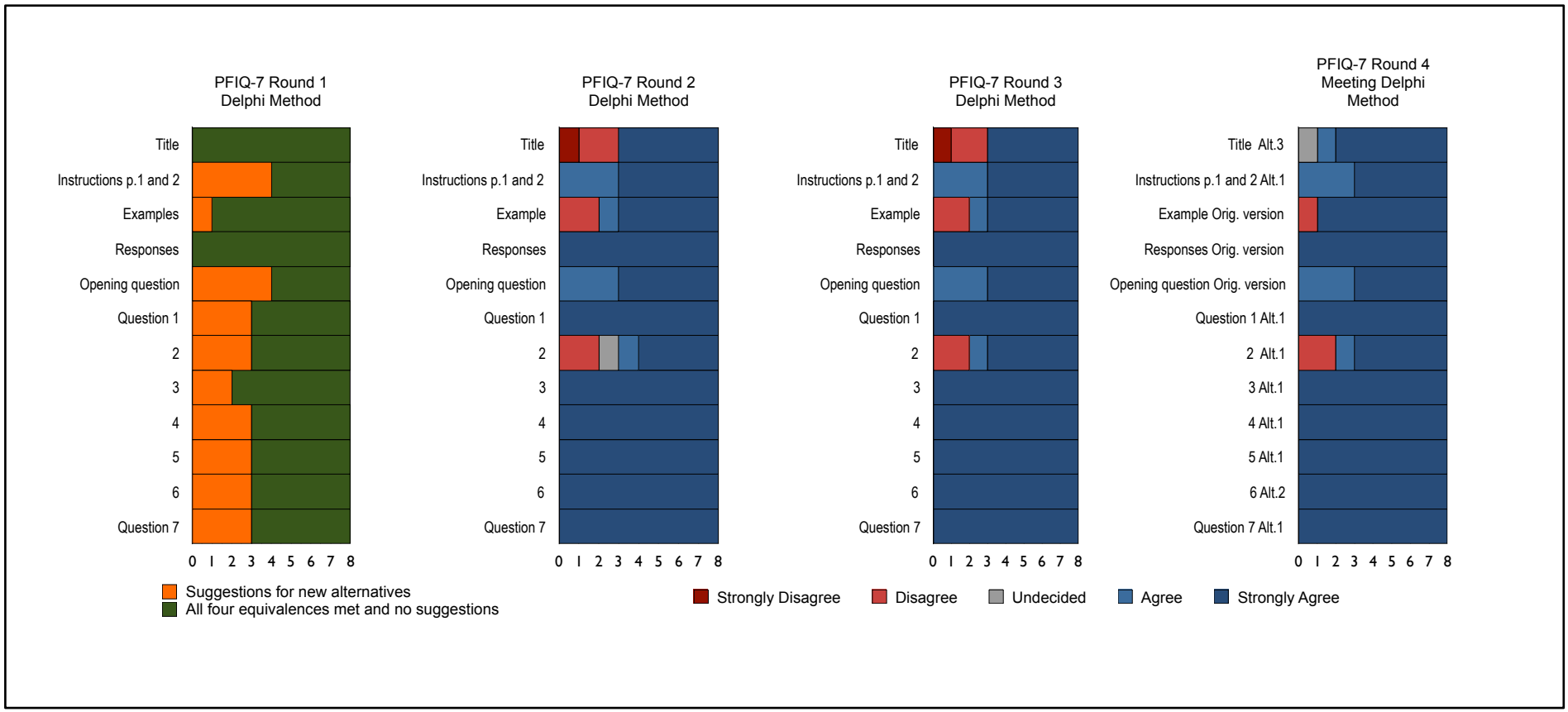

FIGURE 4.3B. DIAGRAM OF REVIEW STATISTICS FOR ROUNDS 1 THROUGH 4 OF THE DELPHI METHOD AS APPLIED TO THE TRANSLATION OF PFIQ-7

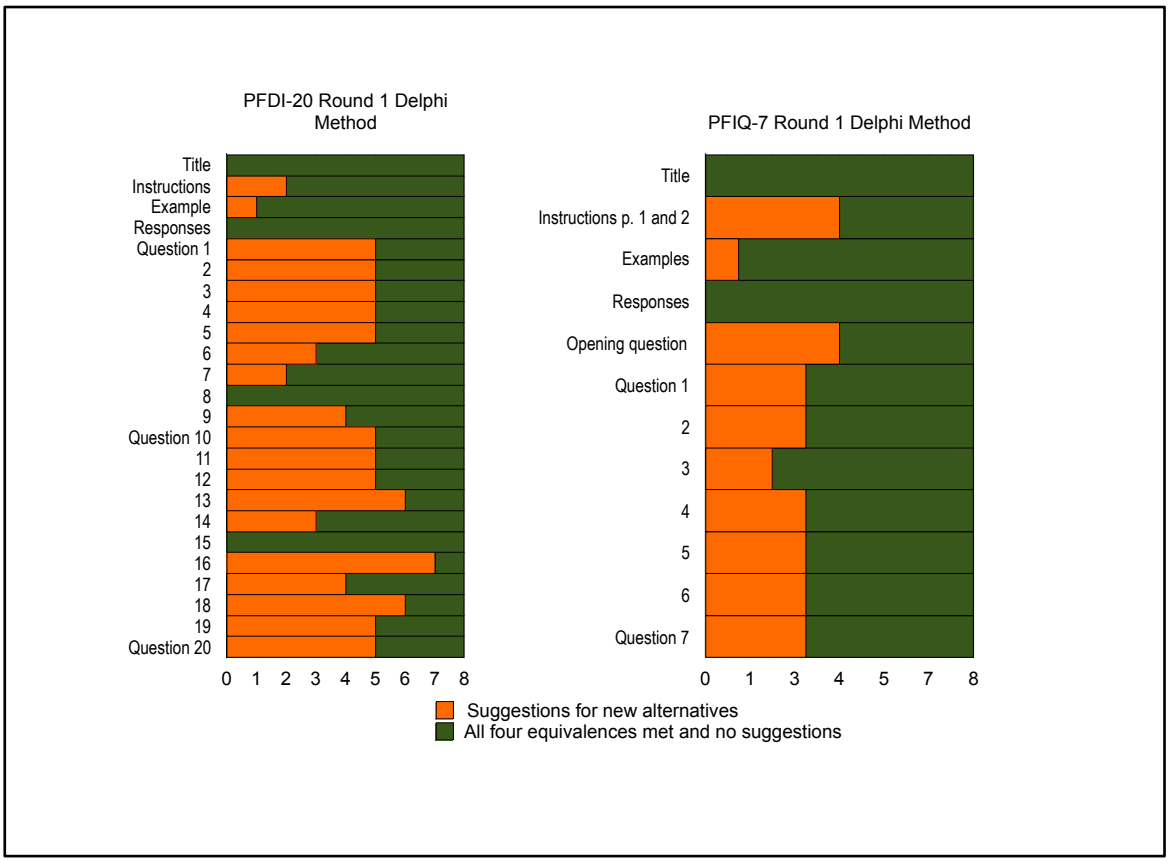

FIGURE 4.4. ROUND 1. PFDI-20 (LEFT) AND PFIQ-7 (RIGHT)

Round 4: Fourteen items were discussed: two items that had not reached consensus in Round 3 and twelve items that had been discussed but not voted on in Round 3. Full consensus was reached on all items in Round 4 with no further comments.

Findings overview for PFIQ-7

Figure 4.6 illustrates the PFIQ-7 items (i.e. title, instructions, examples, question items, and responses) discussed during the subsequent rounds and new suggestions or comments given.

Round 2: Twelve items were discussed. Ten items reached consensus, but one of the items had comments. In summary, three items (i.e. two items with no consensus and one item that reached consensus with comments) were brought into Round 3 for further discussion and voting.

Round 3: Three items were discussed. One item reached consensus. In summary, two items (i.e. one item with no consensus and one item that reached consensus with comments) were brought into Round 4 for further discussion and voting.

Round 4: Two items were discussed: one item that had not reached consensus in Round 3 and one item, with comments, that had been discussed but not voted on in Round 3. Full consensus was reached on all items in Round 4 with no further comments.

Round 2

Findings for PFDI-20 and PFIQ-7:

19/36 items reached consensus with no further comments with a median score of 4 to 5 (agree to strongly agree). 17/36 items required further discussion and voting in Round 3 (Appendix 4.4). Idiomatic equivalence, semantic equivalence, and specific domain terminology were the primary reasons for disagreement.

Given that only 19/36 items in the PFDI-20 and PFIQ-7 passed the criteria after Round 2, there is reason to doubt the overall quality of the forward translations. This underlines the importance of a multidisciplinary process in cross-cultural adaptation.

Findings for PFDI-20:

10/24 items reached consensus with no further comments with a median score of 4 to 5 (agree to strongly agree):

- 7/24 items reached 100% consensus
- 2/24 items reached 87.5% consensus
- 1/24 items reached 75% consensus.

Findings for PFIQ-7

9/12 items reached consensus with no further comments with a median score of 4 to 5 (agree to strongly agree):

- 9/12 items reached 100% consensus

Round 3

Findings for PFDI-20 and PFIQ-7

17/36 items were discussed during Round 3. One item (1/36) reached 75% consensus with a median score of 4 whereas three PFDI-20 and PFIQ-7 items (3/36) did not reach consensus. In addition, the 13 items (13/36) that reached consensus with comments in Round 2 were voted on, however the voting outcome was unchanged from Round 2. All 13 items would be discussed in Round 4 (Appendix 4,4). Hence, 17/36 items (i.e. 14 PFDI-20 items and 3 PFIQ-7 items) required further discussion and voting. Idiomatic equivalence, semantic equivalence and specific domain terminology were the primary reasons for disagreement.

Even though only one item reached consensus, Round 3 was considered important due to the iterative process allowing the panellists to reflect and make further suggestions, particularly in the case of Question 16. Notably, Question 16 was already identified as a difficult item during the reconciliation phase of the translation process. The vote remained unchanged for Question 16, and three new alternatives were proposed in Round 3. (Figure 4.7)

Findings for PFDI-20 Question 16

Figure 4.7 illustrates the overall progression and consensus for PFDI-20 Question 16 between rounds. To reach consensus, four rounds were necessary. The diagram illustrates the importance of the panellists being given the opportunity to re-evaluate their previous response to see if they wanted to reassess, improve ideas, or add alternatives.

Of note, Question 16 was already identified as a difficult item during the reconciliation phase of the translation process. In addition, Questions 3 and 13 were flagged as difficult both in the reconciliation phase and in the subsequent Delphi rounds. This indicates that difficult items were identified both by the translators (without domain level expertise) and by the domain experts (without formal translation skills). This supports the notion of a multistep approach being beneficial for the translation process, and that re-checking will yield the best results.

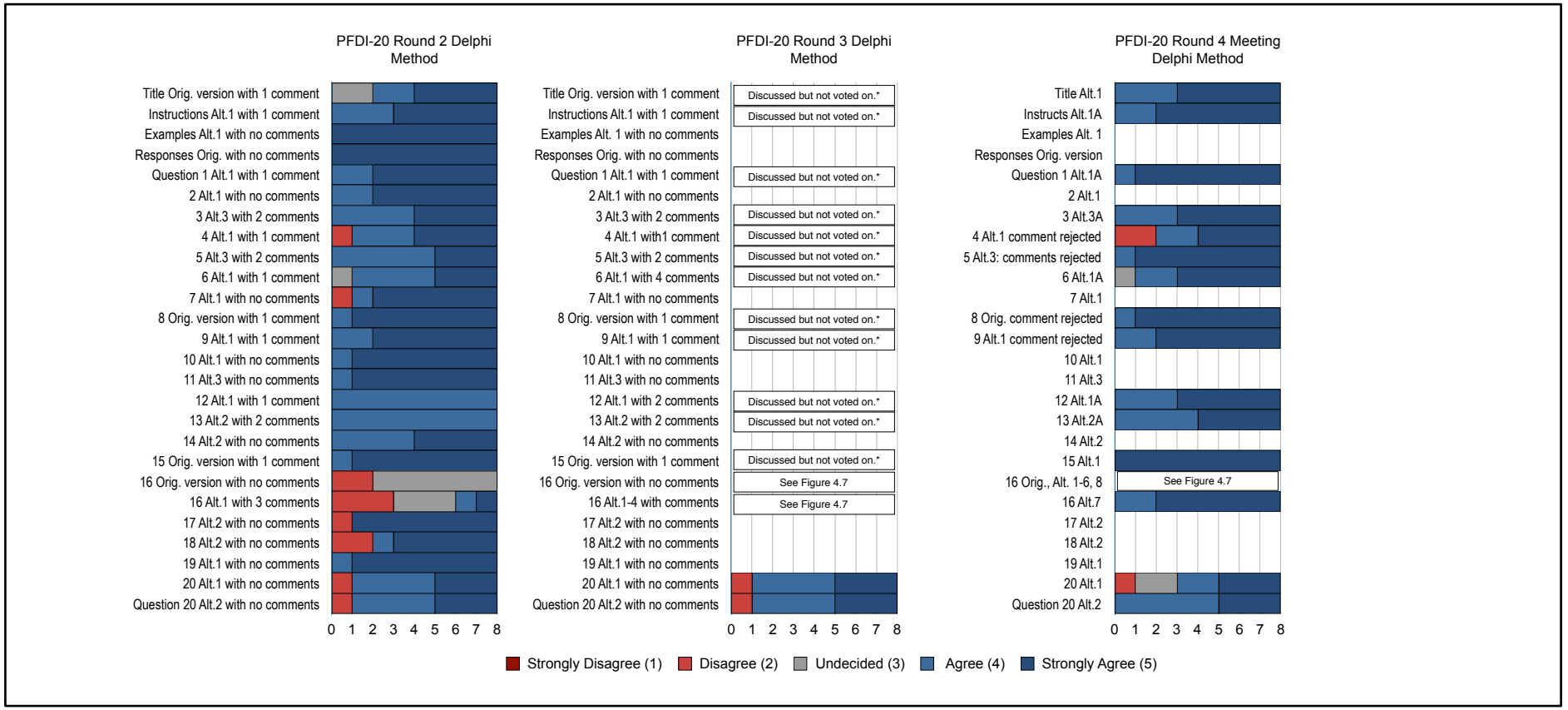

FIGURE 4.5. DIAGRAM OF REVIEW STATISTICS FOR ROUNDS 2 THROUGH 4 OF THE DELPHI METHOD AS APPLIED TO THE TRANSLATION OF PFDI-20

*Item not voted on, continue directly to Round 4

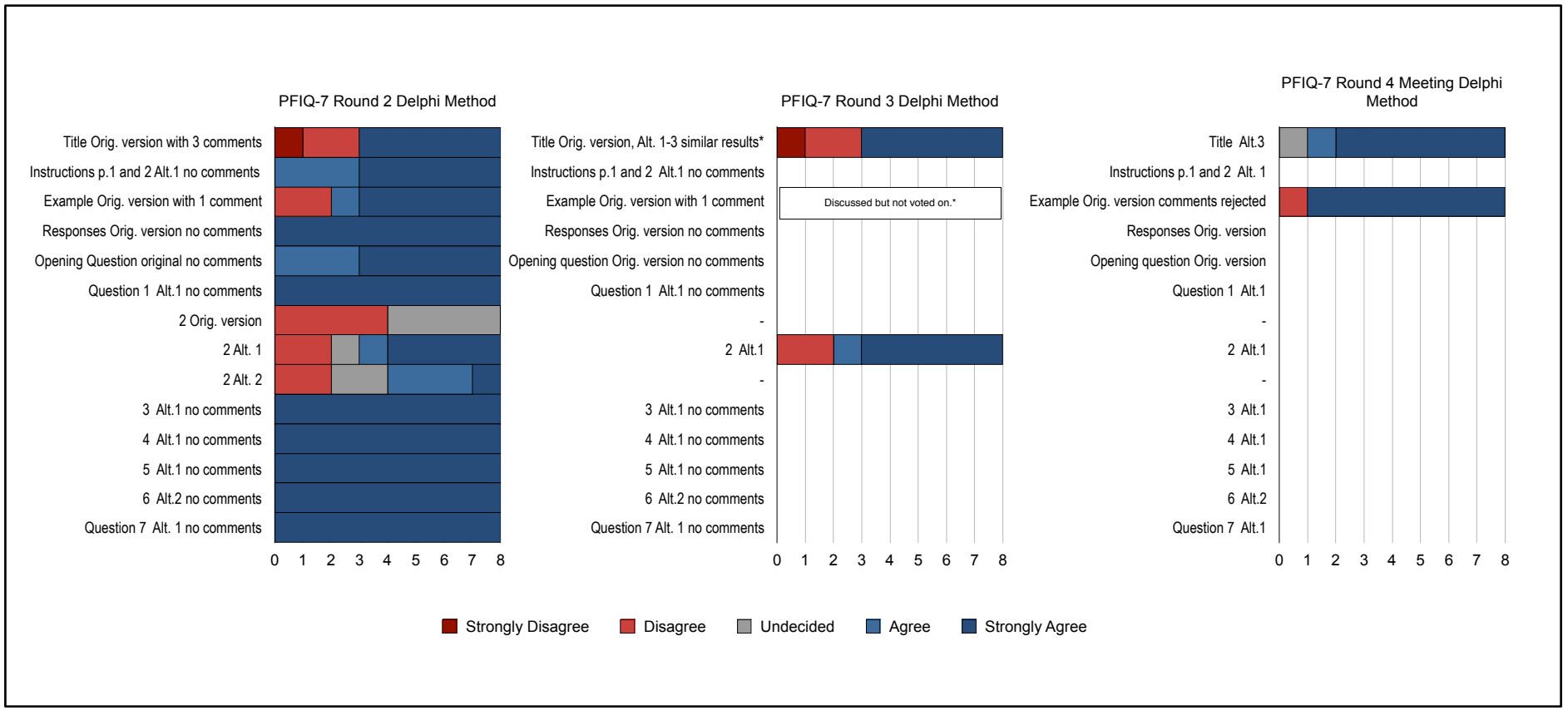

FIGURE 4.6. DIAGRAM OF REVIEW STATISTICS FOR ROUNDS 2 THROUGH 4 OF THE DELPHI METHOD AS APPLIED TO THE TRANSLATION OF PFIQ-7

*Item not voted on, continue directly to Round 4

Round 4 — Expert panel meeting

Following Round 3, the expert panel was invited to attend a face-to-face meeting as outlined in Section 3.11.2 to discuss problem items and reach consensus on which items would be included in the Intermediate Version 2.0 ready for pilot testing.

An agenda and the following documents were distributed to the panellists before the meeting:

- The source version (English PFDI-20 and PFIQ-7) (Appendix 3.1)
- Intermediate Version 1.0 (Appendix 3.2)
- Statistical information from Rounds 1, 2 and 3 (Appendices 4.2 and 4.4).

The two independent forward translations, single forward translation and two independent back-translations were used during the meeting to clarify any unresolved discrepancies. PFDI-20 Question 13 was the only item requiring all documents (Figure 4.5).

All eight expert panellists attended the 90-minute meeting. Five of the eight panellists attended the meeting in person, and three attended through telephone conferencing.

Discussion technique during Round 4 (meeting)

The facilitator/principal researcher chaired the meeting and began by asking each panellist if there were any unresolved concerns or issues regarding the questions/items that had reached consensus in the previous rounds. The principal researcher then proceeded to present the items of discrepancy one by one.

The principal researcher allowed for new information and brainstorming during the discussion of each discrepant item. Brainstorming was conducted for each discrepant item by reading from a list of new options and concerns. Of note, there seemed to be one dominant member on the expert panel. To ensure input from all panel members, the principal researcher asked each panellist to comment in turn.

Findings for PFDI-20 and PFIQ-7

As shown in Figures 4.5 and 4.6, 17/36 items for PFDI-20 and PFIQ-7 reached consensus with no further comments (Appendix 4.4). The items that were rated as median ≥4 and by at least 75% of the panellists were included in the Norwegian language versions of the PFDI-20 and PFIQ-7 questionnaires.[82]

Findings for PFDI-20

- 12/24 PFDI-20 items reached 100% with a median of 4 to 5 (agree to strongly agree)
- 1/24 PFDI-20 item reached 87.5% or more with a median of 4.5 (agree).
- 1/24 PFDI-20 item reached 75% or more with a median of 4 to 5

Findings for PFIQ-7

- 2/12 PFIQ-7 items reached 87.5 % consensus with a median of 4.6 (agree).

Findings for PFDI-20 and PFIQ-7

During Round 4, three items were flagged as difficult. First, PFDI-20 Question 9 did not gain consensus in the first voting round (62.5%), so the process of listing all concerns and allowing the group to reflect was needed. After a brief discussion, the panel voted again with 100% consensus.

Second, after reviewing all documents for the PFDI-20 Question 13, the panellists voted 100% consensus on Alternative 2A (Figure 4.5).

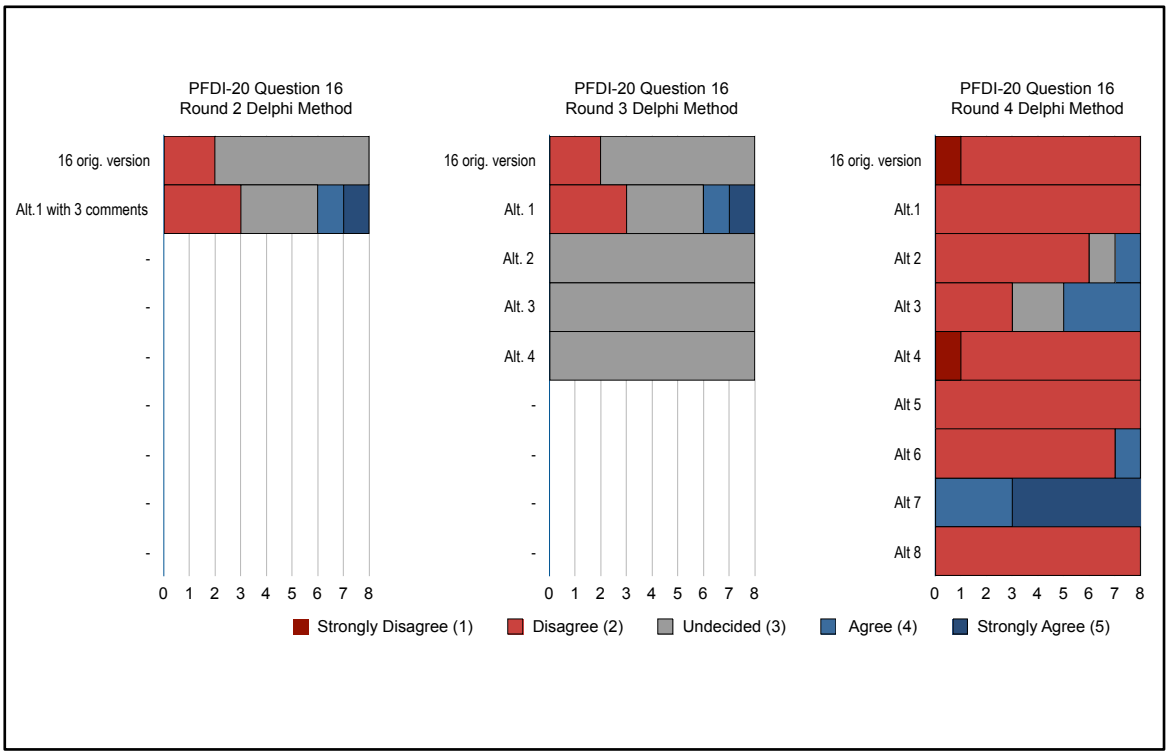

FIGURE 4.7. OVERALL PROGRESSION AND CONSENSUS FOR PFDI-20 QUESTION 16

Last, PFDI-20 Question 16 was considered a difficult item. It was identified as an item of discrepancy during the reconciliation phase. A total of eight alternatives were voted on in Round 4. (Figure 4.7) The iterative process of Rounds 2 and 3, followed by an in-depth discussion in the Round 4 meeting, seemed to be beneficial and resulted in the group unanimously voting 100% for PFDI-20 Question 16 Alternative 7. This strongly indicated that PFDI-20 Question 16 had good equivalence in its final form. The anonymous system of voting during the meeting ensured that when the panellists finally voted, the other panellists' viewpoints or any pressure for conformity did not influence them.

During Round 4, consensus was reached with no comments for all items, and the Delphi survey was concluded. However, as outlined in Section 3.11.1, the EORTC translation guidelines[10] strongly recommend bringing forth persistent discrepancy items from previous iterations into the pilot study phase.

Importantly, both the principal researcher (during the reconciliation process and back-translation review) (Section 4.2.1) and expert panellists (Section 4.2.2) flagged the same persistent items of discrepancy illustrated in Table 4.2. These problem items and alternative wordings of the item(s) were incorporated in the Intermediate Version 2.0 used in the pilot testing.

Notably, the expert panel members did not have access to the translation reports, so they did not have *a priori* knowledge of any problem items. Hence, several of the problem items identified during the forward/back-translation phase were re-confirmed during the expert panel review.

Qualitative data

This section provides a summary of comments between rounds and after the meeting.

Benefits of the modified Delphi method

Two panellists stated, "The Delphi procedure was time consuming, however it seemed to improve the quality of the Intermediate Version 1.0".

One panellist stated, "the time span of 11 months was long, however it gave us time to reflect and reconsider our initial suggestions and it did seem to improve the quality of the translation".

TABLE 4.2. ITEMS OF DISCREPANCY AND ALTERNATIVE WORDING OF THE ITEM(S) INCORPORATED IN THE INTERMEDIATE VERSION 2.0 USED IN PILOT TESTING.[14]

QUESTIONS	ORIGINAL PHRASINGS IN QUESTION ITEMS	SOURCE VERSION (ENGLISH)	ALTERNATIVE PHRASINGS
PFDI-20			
Questions 1–2	Phrase: *Kjenner du ofte*	Do you usually	*Kjenner du vanligvis*
Question 3	Phrase: *Buler ut eller faller ut av skjeden*	A bulge or something falling out	*En kul eller noe som faller ut av skjeden*
Questions 9–12	Phrase: *Har du ofte*	Do you usually	*Har du vanligvis*
Question 13	Phrase: *så sterk avføringstrang at du må løpe til toilettet*	A strong sense of urgency and have to rush to the bathroom to have a bowel movement	*ved avføringstrang at det haster veldig*
Question 16	*Opplever du så sterk vannlatingstrang at du ikke rekker til toalettet før du får lekkasje?*	Do you normally experience urine leakage associated with a feeling of urgency, i.e. a strong sensation of needing to go to the bathroom?"	*Har du ofte urinlekkasje ved kraftig trang til vannlatning:, dvs. så sterk følelse av hast at du må på toalettet?*
Questions 17–19	Phrase: *Har du ofte*	Do you usually	*Opplever du ofte Opplever du vanligvis*
Question 20	Phrase: *Har du ofte*	Do you usually	*Kjenner du ofte Kjenner du vanligvis*
PFIQ-7			
Instructions	Term: *Gjøremål*	*Activities*	*Aktiviteter*
Instructions	Term: *Samliv*	Relationship	*Forhold*
Questions 1–7	Term: *Din*	Your	Remove term *din*
Question 6	Term: *Psykiske helsetilstand*	Emotional health	*Emosjonelle helsetilstand*

Another panellist stated, "The rounds gave us an opportunity to reflect and allow ideas to mature over time. It was also beneficial not be influenced by the other panellists and you could come with independent comments".

Two panellists stated, "The meeting to discuss the difficult questions and wording was seen necessary because you could hear the arguments and rationale from the other panellists".

Five panellists stated, "With the three rounds and a meeting it resulted in a very good translation".

Finally, one panellist stated, “I was so pleased my suggestion about Question 16 was accepted by the doctors on the panel”.

Observations between and during the rounds

It was evident that the iterative nature of the rounds gave the expert panellists an opportunity to reflect and allow ideas to mature over time. It was also apparent that the panellists were not influenced by the other panellists. Interestingly, the panellists all agreed, even if they did so without knowledge of the other panellist’s views.

Finally, the multidisciplinary expert panel review was a necessary step in this translation process due to the nature and complexity of the questionnaires. The translation and reconciliation phases alone would not have produced an optimal translation.

4.2.3 SUMMARY

The expert panel review rendered a Norwegian PFDI-20 and PFIQ-7 Intermediate Version 2.0 (see Chapter 5) with a clear set of items and demonstrated semantic, conceptual, idiomatic, and experiential equivalence with the original versions. This Intermediate Version 2.0 was ready for pilot testing.

4.3 DISCUSSION

4.3.1 INTRODUCTION

In this study, a new translation and cross-cultural adaptation method was developed that combined the EORTC QoL Group translation procedure[10] (forward- and back-translations) and an expert panel using the Delphi method[19] as a key decision-making tool. This section summarizes the main results, issues, and limitations of this novel multistep translation and cross-cultural adaptation method.

The PFDI-20 and PFIQ-7 were first translated from English into Norwegian using a new multistep translation and cross-cultural adaptation method. This method combined the EORTC QoL Group guidelines,[10] the Delphi method,[18] and an expert panel review.[19] The translation process involved two independent forward translations, a reconciliation phase, and two back-translations. This process of analysing and reconciliation resulted in the Intermediate Version 1.0 ready for the expert panel review.

The expert panel review resulted in an Intermediate Version 2.0 that was cross-culturally adapted to the Norwegian target population. The statistical results from the expert panel rounds and final meeting strongly indicated that the Norwegian Intermediate Version 2.0 was fully comprehensible and showed equivalence with the original versions. Statistics were gathered on how many specialists agreed to the four areas of equivalence. Figure 4.3a and Figure 4.3b demonstrate not only all items reaching consensus but also most items (28/36) reaching 100% consensus with a median score of 4 to 5 (agree to strongly agree).

Furthermore, an internal logic was evident during rounds 2 through 4 in which the expert panel demonstrated increasing agreement (Figure 4.3a and Figure 4.3b). In each round, the panellists were asked to respond to a structured set of questions for each unresolved questionnaire item. The iterative nature of the Delphi process gave the expert panel members time to assess the group judgement and revise and improve ideas. The item of discrepancy related to PFDI-20 Question 16 clearly illustrates the outcome of this opportunity. Following the final meeting, several of the panellists commented that the iterative nature of the Delphi procedure seemed to improve equivalence with the original versions (Section 4.2.2 and 4.3.3).

Of note, incorporating controlled feedback into the expert panel in the form of a quantitative statistical representation, detailed in Appendices 4.2a-b and 4.4a-f, also provided a far more precise and accurate measure of the expert panel's collective opinion and degree of consensus.

In addition, the Delphi method proved to be a highly structured, systematic communication technique with a rigorous documentation process (Appendices 4.2a-b and 4.4a-f). This systematic communication technique and documentation process can help elicit an even more rigorous procedure, which is often recommended by international translations task forces, within translation and cross-cultural adaptation.

4.3.2 TRANSLATION PROCEDURE

Several discussion topics and some limitations and risks emerged during the preparation, forward translations, reconciliation phase, back-translations and the back-translation review process. These features are explored further below.

Roles and responsibilities

Several individuals and institutions were involved in the translation process and viewed as integral to the project (Table 3.2). Two important roles seemed to contribute to improving the linguistic translation of PFDI-20 and PFIQ-7 questionnaires.

First, the role of the instrument developer was important for clarifying and reporting translation problems and ambiguities concerning questionnaire items in any of the other language adaptations.[77] Furthermore, the developer solicited important feedback, clarifying potential item misinterpretation. Ideally, the instrument developer should have been more involved in the translation process in terms of defining the concepts and intentions behind each question.[77]

Second, the EORTC Group[10] took an advisory role in discussing the sequence of events and addressing the issue of where to include the expert panel phase. The EORTC Group recommended that the expert panel phase precede the pilot test because women with POP needed to be able to comment on the comprehensibility and relevance of the expert panel's amendments to the Intermediate Version 1.0.

Preparation phase

Preparation was important in the translation phase. Before translating the instrument, the principal researcher examined certain definitions for concepts and items in the PFDI-20 and PFIQ-7 questionnaires to avoid misinterpretations.[77] Six concepts were explored before the translation project commenced. However, exploring the meaning behind additional concepts in the preparation phase could have avoided ambiguities or misinterpretations during the cross-cultural adaptation process. This situation was particularly the case with PFDI-20 Questions 4 and 16. Question 4 was extensively discussed because the conceptual meaning behind "push on the vagina" (in Norwegian, *presse i skjeden*) was unclear to the panellists. The discussion involved whether the intention was for the patient to press on the vagina with the fingers or using the pelvic floor.

Question 16 was extensively discussed because of the complexity of the sentence. Involvement of the instrument developer in examining the concepts behind Question 16 during the preparation phase would have been beneficial.

Forward translations and reconciliation phase

One core issue arose during the forward translations and reconciliation phase. During the reconciliation phase, the limited similarities between the two forward translations became evident. One reason for the differences between the two forward translations may have been the competency level of the forward translators. The translators fulfilled the EORTC Group's criteria for forward translators; however, only one translator was familiar with translating PRO health measures. Given that only 19/36 items in the PFDI-20 and PFIQ-7 (Figure 4.3a and Figure 4.3b) met the criteria after Round 2, there is reason to doubt the overall quality of the forward translations and reconciliation phase.

Back-translations and back-translation review

Even though the ISPOR task force TCA[8] and other authors acknowledge the importance of a back-translation review for cross-cultural adaptation,[8,10,17] the principal researcher supports Swaine-Verdier's[74] criticisms of the limitations of back-translations. Swaine-Verdier et al.[74] and other authors assert that back-translation is merely another way of checking, and clearly a scientific basis for back-translation is lacking.[76-78]

This program of research also demonstrated the limitations of the back-translation and review phases. A situation arose in which the single forward translation seemed too literal and hewed too closely to formal aspects of the original version in terms of syntax. The back-translations should have revealed this issue but instead indicated that the single forward translation was adequate.

Finally, the shortcomings of back-translation identified the need for a multistep procedure (i.e. expert panel review and pilot testing after cross-cultural adaptation) for re-checking and identifying poor specific domain terminology and semantic, idiomatic, conceptual, and experiential equivalence.

Limitations

Even though the principal researcher was bilingual and a specialist within the field of pelvic floor dysfunction, English was the researcher's native language. This factor could have been seen as a limitation in the reconciliation phase of merging the two forward translations. However, the principal researcher's consultations with the TAG during this phase counteracted this limitation.

Burdens and risks

The translation process depended on the work of several translators over an 11-month period. To minimise the risk of interrupted or incomplete translation work, the process should be performed over a shorter period.

Ethical issues

No major ethical issues were identified in this part of the design study.

Summary of forward translations and back-translations

No major deviations, limitations, or ethical issues arose during translation. The new translation and cross-cultural adaptation method produced a Norwegian PFDI-20 and PFIQ-7 Intermediate Version 2.0 with a clear set of items showing equivalence with the original versions. These versions were then ready for expert panel review.

4.3.3 EXPERT PANEL REVIEW USING THE DELPHI METHOD

To date, several studies have employed the Delphi method through interviews with an expert panel in the development of HRQOL questionnaires.[82,90,99] However, no studies have used the expert panel combined with the Delphi method in translating and linguistically validating HRQOL questionnaires. This part of the study was based on extending the expert panel approach[17] by adding a series of iterative interview and information dissemination cycles or rounds before the physical meeting.[82] The Delphi method was selected in this study for interviewing the expert panel and quantifying the results of each round. Each item discussed in the rounds and the final meeting was scored on a 5-point Likert scale. The aim of applying this new technique was to improve translation of the PFDI-20 and PFIQ-7 questionnaires in terms of equivalence and cross-cultural adaptation.

Several discussion topics and themes identified during the expert panel phase involved inclusion of qualitative data, professional asymmetry on the expert panel, advantages of anonymity and its affect on the translation, importance of a multidisciplinary expert panel, and advantages of a multistep procedure to address disagreements about idioms/phrases. These themes and other issues are explored below.

Inclusion of qualitative data

The inclusion of qualitative data indicated that the new method (i.e. incorporating the Delphi method into the expert panel phase) improved the translation quality of the PFDI-20 and PFIQ-7 questionnaires. Participant comments and research observations during the study supported iteration through the Delphi method in the expert panel phase, as well as the importance of anonymity.[86] Several panellists stated that the Delphi procedure was time-consuming;[84] however, it seemed to improve the quality of the Intermediate Version 1.0. During the expert panel phase, the panellists received information about their answers and the anonymous answers of the other panellists, as well as a statistical collective opinion (using medians). This information gave the panellists the opportunity to re-evaluate their previous responses and decide if they wanted to reassess and change their rating.[86] No panellists suggested that the Delphi method should not have been used. One panellist stated that "the time span of 11 months was long, however, it gave her time to reflect and reconsider her initial suggestions and did seem to improve the quality of the translation".

Another panellist said, "the rounds gave us an opportunity to reflect and allow ideas to mature over time. It was also beneficial not to be influenced by the other panellists. You could come with independent comments". The iterative nature of the Delphi process gave the expert panel members time to assess the group judgement and revise and improve ideas. This opportunity is clearly illustrated in the item of discrepancy related to PFDI-20 Question 16.[86] During Round 2, consensus was not reached for Question 16, and the panellists proposed three alternatives. During Round 3, another four alternatives were proposed and a meeting called. The iteration process of the Delphi rounds with the expert panel proved beneficial in exploring several alternatives. During Round 4 (meeting), the expert panel reached 100% consensus with a median of 5 on PFDI-20 Question 16 Alternative 7 (Figure 4.7).

Furthermore, during Rounds 2 through 4, for many of the items (14/36), panel agreement increased over time. The statistical findings documenting the convergence of each item in this study are supported by other studies evaluating Delphi surveys.[82] Nevertheless, the possibility that the iterative process would wear down participants should be considered when evaluating these results.

Professional asymmetry in the expert panel

Professional asymmetry was evident during the expert panel review phase. This section details aspects of professional asymmetry in the expert panel, the advantages of anonymity and how these factors impact translation.

During Rounds 2 and 3, two panellists commented several times that they felt their opinions were perhaps not as valuable. However, the principal researcher considered these panellists among the most active members of the group, contributing several suggestions that were incorporated into the result. Additionally, these panellists commented, "it was good having the rounds and not knowing who the other health specialists were". These panellists felt the other suggestions would otherwise have influenced their opinion on the subject matter.

After the final meeting, one of the panellists commented, "I'm pleased that my suggestion on one of the items was voted for and included in the questionnaires by the doctors". Furthermore, the panellist commented that "it surprised me that the colorectal surgeons, gynaecologist, and urologist supported my proposal". These comments support the literature stating that health professionals often feel a degree of professional asymmetry and different levels of hierarchy.[100]

The principal researcher also observed during the meeting that two senior expert panel members dominated the group in the decision-making process. When these two specialists suggested an alternative to any items, the other panel members often immediately agreed without further discussion. Steins' studies from 1967[101] and 1990[102] identify significant changes in nurses' behaviour in what he calls the "doctor–nurse game".[100,102] In the 1960s, nurses would mitigate their lower workplace rank by influencing decision-making without directly challenging doctors' points-of-view. Instead, they would depend on quoting observations, information, and experience. In the 1990s, however, nurses were more likely to challenge doctors in a direct manner during joint clinical decision-making.

A Norwegian study showed that although nurses are reforming their inter-professional relationships, a traditionally dominant group—physicians—prevails in the hospital organisational structure.[100] Other authors have reported a trend of moving away from a stereotypical doctor–nurse pattern of interaction.[102] Nevertheless, nurses today are still generally reluctant to challenge doctors' authority.[102]

Of note, the Norwegian study[100] reported that a lack of inter-professional cooperation is not a big problem in Norwegian hospitals—at least not by (particularly male) doctors. Differences in professional culture (i.e. rooted in perceived and/or formalised competence monopolies) may, however, still affect inter-professional cooperation and expectations. Differences in professional cultures were expressed by Norwegian doctors who rated nurses' competence and their knowledge of patients lower than they rated their own. These attitudes can affect doctor–nurse communication patterns on all levels. Doctors tend to self-confidently concentrate on what they consider the dominant aspects of clinical practice, namely medical treatment and diagnosis.[100]

This disparity creates an environment of professional asymmetry and different levels of hierarchy.[100,102]

The dynamics of hospital professions are challenging, and the Delphi method in the expert panel situation can be beneficial in dealing with a dominant panellist. Anonymity was useful in this situation to avoid such dominance from particular panel members in the communication process based on their profession, age, or personality.[18,82,84] Thus, the method facilitated a situation in which all panellists felt that they could express their opinions freely and share their extensive knowledge.

In summary, employing an anonymous voting technique during the expert panel final meeting ensured that the panellists could vote without pressure to conform to other panel member opinions.

Importance of a multidisciplinary expert panel

Of interest, on many questions, the expert panel voted almost unanimously for or against a given suggested item phrase. Analysis of the instrument subscales containing these items also revealed that the panel was extremely efficient in evaluating results of the initial translation stages for items involving clinical domain terminology. Furthermore, different panellists pointed out that a layperson would seldom use Latin words to describe anatomical structures in Norwegian and that using such terms could result in misunderstandings and ambiguities.[52] For example, several panellists noted that the Norwegian layman term *skjeden* was a better term than the Latin-based "vagina".

The importance of a multidisciplinary expert panel was evident throughout the process.[84] Each domain specialist contributed to the various subscales in the questionnaires. Although they all contributed to the PFDI-20 and PFIQ-7 questionnaires, the urology specialist tended to comment mostly on the urological UDI-6 items (Questions 15–20)[11]; the gynaecologists often commented on the pelvic floor prolapse POPDI-6 items (Questions 1–6)[11]; and the colorectal surgeons commented on CRADI 8 items (7–15)[11] questions, all within their particular areas of expertise.[84]

There were two items in the PFDI-7 questionnaire (i.e. Questions 6 and 7) that were contended from the domain outside of the combined expertise of the expert panel. These items were specifically within the psychiatry domain, and a psychiatrist on the panel would have been beneficial.[19]

Advantages of a multistep procedure

A multistep procedure was important in improving equivalence and ensuring good cross-cultural adaptation during the translation of the PFDI-20 and PDIQ-7 questionnaires.[19] Particularly, in the case of disagreements concerning items, idioms and phrases. The examples below illustrate the importance of both the multistep procedure and incorporating expert panel reviews in a translation and cross-cultural adaptation project.

First, during the forward translation process of PFDI-20, one of the translators proposed the Norwegian idiom *har du ofte* (do you normally) in several PFDI-20 questions. This idiom was not included in the reconciliation phase or Intermediate Version 1.0, and *kjenner du vanligvis* (do you normally) was selected. The expert panel, without prior knowledge of the forward translation, recommended using the idiom *har du ofte* (do you normally) and commented that it was more equivalent, comprehensible, and clear for the target population (Section 4.2.2 and 4.3.3). The pilot test detailed in Chapter 5 verified that the idiom *har du ofte* was clearer and more to the point than *kjenner du vanligvis*. Therefore, several steps can ensure a rigorous cross-checking system during the process of translation and cross-cultural adaptation.

Second, discrepant items would have been difficult to resolve without domain-level expertise. During the pilot test, PFDI-20 Question/Item 2 was an item of discrepancy (Section 5.2.3) with 5/20 patients commenting that it was both confusing and difficult to understand.

During the final review, the expert panel voted to replace the specific domain term *tyngdefornemmelse* (sensation of heaviness) with *tyngdefølelse* (feeling of heaviness).

Finally, the overall translation procedure might have been improved by giving the expert panel more information around the problem items identified during the early steps of the process. In the Guillemin approach,[19] the panellists receive all versions of the translation and documentation of each step with the notion that this process enables the panellists to identify areas of concern much faster. However, in the process applied in this study, the consequence of withholding information on problem items produced a verification effect that helped to confirm which persistently difficult items should be included in the pilot testing.

Deviations in the translation procedure and expert panel

No major deviations from the study design and protocol occurred.

Limitations

Several limitations were identified in the design of this study. First, members of the expert panel considered the study time-consuming. Even though none of the panellists dropped out, there was a risk of participants losing interest and not properly evaluating comments from other members and simply agreeing with them.[84]

Second, it was difficult to assess and measure whether the Delphi method employed during the expert panel phase improved the quality of the cross-cultural adaptation.

Third, the Likert scale option “undecided” could be interpreted as being unable to answer the question. A “neutral” option might have improved the chances that participants would not misunderstand.[17]

Last, the criteria changed between rounds, which could have created bias in the analysis of data. Round 1 was designed to collect opinions from the panellists and encourage them to suggest changes or alternative wording. Rounds 2, 3, and 4 were aimed at achieving a consensus by voting using a 5-point Likert scale. The scale could have been used in all four rounds; however, the principal investigator might have risked not receiving several new suggestions for alternatives.[17]

Burdens and risks

The expert panel review depended on input from eight panellists over an 11-month period. To reduce the burden for the panellists and avoid the risk of their withdrawing from the study, the process should have been shorter.

Because Norway has a small clinical and academic community within the specialised area of pelvic floor dysfunction, the principal researcher was acquainted with some of the expert panellists, so there was a risk of selection bias.[84]

Ethical issues

No major ethical issues were identified in this part of the design study.

Summary of expert panel review

No major deviations, limitations, or ethical issues arose during the study. In terms of administrative burden on the expert panel, future review meetings should be conducted over a shorter time span. This new translation and cross-cultural adaptation method produced a Norwegian PFDI-20 and PFIQ-7 Intermediate Version 2.0 with a clear set of items that showed equivalence with the original versions.

The main component of the new approach incorporated the Delphi method into the expert panel phase. The expert panel review comprised four rounds, and the eight panellists completed each round. Throughout the rounds, several alternatives were reviewed, and the task of iteration resulted in the expert panel becoming more focused on problem-solving. This iterative approach enabled the panel time to assess the group judgement and to revise and improve ideas.[86] During this study, internal logic could be seen during Rounds 2, 3, and 4 where the group agreed more (Figure 4.3a and Figure 4.3b) about the items over time. Following the final meeting, several of the panellists also commented that the iterative nature of the Delphi procedure seemed to improve the cross-cultural adaptation.

Finally, anonymity and statistical group response[18] improved the cross-cultural adaptation between rounds and ensured that feedback from every member of the panel was considered during the process and final response.

4.3.4 CONCLUSION

During Stage 1, a new multistep, cross-cultural adaptation method was developed using both the EORTC QoL Group translation procedure and an expert panel. The main novel component was the Delphi method in the expert panel phase. This method produced a Norwegian PFDI-20 and PFIQ-7 Intermediate Version 2.0 that demonstrated semantic, conceptual, idiomatic, and experiential equivalence with the original versions. This Intermediate Version 2.0 was ready for pilot testing, as described in Chapter 5.

To the author's knowledge, this study is among the first to use an expert panel and the Delphi method to translate and culturally adapt PROMs. More studies obviously are needed to examine whether this method is suitable, viable, and reliable.

CHAPTER 5

INITIAL EVALUATIONS

5.1 INTRODUCTION

Chapter 5 details Stage 2 of the study, involving:

- Qualitative and quantitative method and study findings of Stage 2 (pilot testing)
- Expert panel review of the pilot test
- Qualitative evaluation (using pilot test dataset and interpretive research) to understand female patients' experience of pelvic organ prolapse (POP)

First, the pilot test theory, methodology, and the qualitative and quantitative results of Stage 2 of the study (pilot study) are detailed. The pilot test undertaken during Stage 2 is evidence that the Norwegian Intermediate Version 2.0 (Appendix 5.1) showed equivalence with the original versions with few discrepant items. Second, the discrepant items are included in a report for the expert panel final review, which rendered an Intermediate Version 3.0. The qualitative and quantitative study findings based on the expert panel review are described.

These steps rendered the Norwegian Translated Version (Intermediate Version 3.0) (Appendix 5.5) a comprehensible, linguistically valid set of items ready for further extensive validation in Chapter 6.

Third, the theory, methodology, and results of the qualitative interpretive approach are detailed. This qualitative methodology (using the pilot test dataset) was employed to explore and understand the female patient experience of POP and pelvic floor dysfunction and in so doing, to critically evaluate the Norwegian PFDI-20 and PFIQ-7 as a measurement tool.

A literature review on pilot testing was performed, as comprehensively outlined in Section 3.2.

5.1.1 ETHICS APPROVAL

Ethics approval was granted (for Stage 2) by Regional Committees for Medical and Health Research Ethics (Norway) (Appendices 3.4b and 3.4d), the Akershus University Hospital Ethics Committee (Norway) (Appendix 3.4g), and the Flinders University Social and Behavioural Research Ethics Committee (Australia) (Appendix 3.4h). The approval of grants

for Stages 3 and 4 by the Regional Committees for Medical and Health Research Ethics (Norway) were translated into English and are given in Appendices 3.4a and 3.4c.

5.2 PILOT TEST

This section presents the theory, methodology, and results of pilot testing (Stage 2).

5.2.1 THEORY: PILOT TEST

Pilot testing is the final step in the linguistic validation process, to check equivalence from the source version to the target version along with the cultural relevance of the target population.[10,19] The objective is *not* to significantly change the wording of the original questionnaires but to ensure that the wording or items are expressed clearly in the target language of translation.[10] Pilot testing is a qualitative method which involves selecting a target population and conducting an interview procedure to evaluate the target language.[8]

The interview guide and probing techniques are designed to identify and resolve any problem items in the translated instrument, such as deviations, errors or wording that might cause confusion.[10,19,93] Translation groups have consensus on the aim and necessity of pilot testing.[8] If pilot testing is not performed, the result can be missing data and misunderstood items on the part of the respondents.[8]

Several translation groups consider pilot testing to be the assessment of the instrument or questionnaire by relevant representatives of the target population for linguistic validation (i.e. equivalence), deviations in the translations, and cultural relevance.[8,17] Swaine-Verdier et al[74] assert that pilot testing evaluates the instrument for linguistic, **face,** and **content validity**. Guillemin et al[19] states that through pilot testing, face validity is verified by confirming that the questionnaire's items and responses are acceptable without causing hesitation or reluctance.

Face validity shows whether, at first glance, the health-related patient reported outcome (HR-PRO) instrument seems to be assessing the desired qualities and attributes.[103] The COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) panel considers face validity to be demonstrated if a given number of items in an HR-PRO instrument indeed appear to adequately reflect the construct targeted for measurement.[103] **Content validity** is "the degree to which the content of an HR-PRO instrument is an adequate reflection of the construct to be measured"[103(p.743)]

Selection of sample size

Several translation method guidelines (Section 3.5) specify different sample sizes for pilot testing. The AAOS guidelines recommend 30–40 individuals, the EORTC group recommends 10–15 participants, and the International Quality of Life Assessment (IQOLA) project recommends up to 50 individuals from the target population.[8]

Some translation groups and guidelines[10,93] recommend pilot testing with a sample of the intended target group for the instrument, while others[8] (i.e. EuroQoL Group) recommend a combination of both healthy individuals and the target group.

Pilot testing with a sample of the intended target group should include native speakers of the language[10,19,93] and representation in terms of sociodemographic (e.g. sex, age) and clinical characteristics.[10]

Interview procedure and technique

Several guidelines recommend an in-depth face-to-face semi-structured interview in which each participant completes the questionnaire (if self-administered) or responds (if interviewer-administered). An investigator then interviews the participant using a prepared interview guide[10,77,79] to analyse deviations and errors, check for levels of clarity, and whether appropriate concepts have been captured.[19]

The content of the semi-structured interviews can differ. The EORTC Group interview focuses on determining whether the translated items are confusing, upsetting, or difficult to understand.[10] If the participant finds the items difficult/confusing, a probing technique is employed in which the participant (patient) is asked to explain why a particular question is too difficult/confusing and how they would restate the item.[19]

By comparison, Guillemin et al,[19] and the MAPI Institute,[77] employ a different probing technique when filling in a questionnaire. This technique involves investigating what the participant thought each questionnaire item meant and why they gave the response they did.

An audio recording of the interview can be used to determine whether the translation is acceptable to potential participants/patients and whether the included items are applicable and have linguistic/conceptual equivalence. The audio recording ensures that all comments

are captured accurately and that topics can be easily identified by playing back and transcribing.[104]

Burdens, risks and ethical issues

The Australian National Statement on Ethical Conduct in Human Research[95] (the National Statement) declares that investigators administering HRQOL questionnaires should consider respondent risks and burden. These considerations include burdens related to time and effort taken and the risks associated with level of comprehension, personal issues, and confidentiality.[95]

Inconvenience, time, and effort should be considered when planning and administering questionnaires and interviews.[95] Investigators may want to minimise the risk of inconvenience by interviewing participants after outpatient consultations. Compensation should be considered if participant completion of questionnaires and interviews does not correspond with outpatient visits.[95] Also needing consideration is the risk that participants will not comprehend the written information and questionnaires because reading and comprehension level can vary in the target population.[19]

Qualitative research exploring sensitive issues in-depth (e.g. specific health problems or personal issues) may present emotional and other risks for the participant.[95,96] If any issues arise, the research should be conducted in a way that respects both participant and hospital concerns and requirements.[95,96]

Finally, administration burden is another important consideration. Resources needed to implement the research project should be regarded when planning and administering the project.[95]

Ethical matters — confidentiality and anonymity assurances

Research involving interaction with other people has several ethical dimensions. Ethically conducting human research is more than simply doing the right thing; it is about respect and concern for fellow humans.[95,96] Ethical considerations are as important as considerations of burdens and risks. When approaching participants for a study, ethical issues to consider are confidentiality, free and informed consent, and individual autonomy.[95,96]

The Australian National Statement on Ethical Conduct in Human Research (Chapter 2.2)[95] and Norwegian Health Research Law (Chapter 5)[96] state that individual autonomy is about informing participants in a study so that they can decide to participate in the study or not. The first step towards individual autonomy is informing the participants in a way that allows them to understand what they are agreeing to. This step is referred to as informed consent. It includes informing the participants that they are participating in a research study, explaining what the study entails, and explaining the role of the participant in the study.[17] The other dimension to individual autonomy and free and informed consent is the freedom not to participate and to withdraw from the study. This form of consent can be violated in several ways. Coercion is one way and often occurs when an investigator or clinician recruits the participant or patient into a research project. Some patients may agree to participate in a study because they are concerned that they may not receive the same degree of treatment if they decline.[17] Other patients, participate *out of a sense of gratitude.* One way to avoid this form of coercion is to have someone not involved in the project (e.g. a research assistant or independent clinician) recruit participants.[17]

Finally, confidentiality and assurances should be addressed when planning and implementing a research project. Following data collection, research findings and records should be collected personally by the researcher and locked and stored in a collection box. Names should be removed and replaced by identification numbers shortly after data collection. In addition, the patients must be informed that no information that identifies them will be published or written in the research report.[95,96] Care must be taken to ensure that the dignity of all participants is respected and that their opinions and judgements are valued.[95]

5.2.2 METHOD: PILOT TEST (STAGE 2)

The pilot test was modelled after the EORTC QoL Group translation procedure[10] and aimed to identify problem items within the translated questionnaire (e.g. wording that caused confusion or words that were difficult to understand) and to check equivalence.[19] The target population was women with symptomatic POP.

This qualitative study consisted of two phases, namely administering the Intermediate Version 2.0 to a group of patients and then conducting a recorded three-part qualitative interview with each patient.[10,19,105] The research materials for the pilot, such as verbal

scripts, letter of introduction, information sheet, and consent form are shown in Appendix 5.2. The interview protocols in English and Norwegian are given in Appendix 5.3. The interview protocol was conducted in Norwegian.

Based on the patient interview, the Intermediate Version 2.0 may require further adaptation. The summary of the qualitative and quantitative dataset from the pilot test was then given to the pelvic floor expert panel for review, which resulted in an Intermediate Version. 3.0 (Final Translation Version) for further validation.

Interview procedure and technique guide

Based on the EORTC QoL Group translation procedure, an in-depth face-to-face interview was conducted during the pilot test (Stage 2). For this step, each participant completed the PFDI-20 and PFIQ-7 questionnaires and was then interviewed by the principal researcher using a prepared interview guide.[10,19,105] The face-to-face interview was divided into three parts. The first part comprised a semi-structured interview directed to each independent item separately to establish whether the wording made any of the translated items confusing, upsetting, or difficult to understand (Appendix 5.3).[10]

The second part involved a semi-structured interview with general questions to determine whether there were any irrelevant items or items that should be added or covered in greater depth (Appendix 5.3).[105]

The third part involved a semi-structured interview to focus on persistent difficult items. In each case of a persistent difficult item identified during the expert panel review, an alternative wording of the item(s) in question was incorporated into the provisional translation used in pilot testing (Appendix 5.3).[10] Parts 1 and 3 were based on the EORTC QoL Group interview guidelines; however, Part 2 was based on the anal incontinence questionnaire interview guide by Cotterill et al.[105]

A digital audio recording of the semi-structured interview was undertaken to ensure that the translation was acceptable to potential participants and that the included items were applicable and retained equivalence.[104] Without an audio recording, comments from patients could be lost in the interview section. The audio recording ensured that all comments were recorded accurately and that themes could be easily identified through transcribing and analysis.[104]

Pilot-testing interview and questionnaires

Administering the translated questionnaires

The translated questionnaires were administered to 20 patients from the target population. The principal researcher recorded the approximate time taken to complete the PFDI-20 and PFIQ-7 and checked for any hesitation or reluctance in completing the questions[104] which would be discussed in the expert panel review after pilot testing. Hesitations are summarised in Appendix 5.4.

Three-part semi-structured interview

A recorded three-part semi-structured interview was conducted with each patient individually to determine whether the participant experienced difficulties while responding.

Part 1: Discussing each item separately (Appendix 5.3)[10]

The interview was directed to each item separately to determine whether any of the translated items were[10]

a) difficult to answer[10]
b) confusing[10]
c) difficult to understand[10]
d) upsetting/offensive[10]

or if the patient would have asked the question differently.

If the answer was 'yes' to any of a–d, the principal researcher probed and asked: "if so, why?"[10]

Whenever a patient reported a problematic item and/or suggested that the item would be improved by alternative wording, the item was recorded on the patient response sheet along with the patient's description of the perceived difficulty with the item. Items that patients found satisfactory were left uncommented for ease of administration. The interview transcript thus consisted of the commented list of problem items along with the patient's suggestions for improved wording.

A form sheet was used to document this information. There was no need to record adverse comments during pilot testing. The problem items and related comments were summarised for further communication in the report.

Part 2: General questions (Appendix 5.3)[105]

The interviewer asked general questions concerning the questionnaires:

a) Do the questionnaires cover all issues related to bowel, urine, and prolapse?
b) Should any items be added or covered more in-depth?
c) Were any items irrelevant or unimportant?
d) Were any response categories unclear or inappropriate?
e) Are the title, instructions, and examples clear?
f) Comments?

Each participant was interviewed to examine the relevance and clarity of the PFDI-20 and PFIQ-7 questionnaires. Further, any missing items that explored life impact issues, barriers or enablers that patients with pelvic floor dysfunction may have experienced were identified and addressed. Identifying missing items that might explore life impact issues enabled the researcher to assess the PFDI-20 and PFIQ-7 as tools for measuring HRQOL for patients with pelvic floor dysfunction in the Norwegian context.

Part 3: Assessing alternative wording (Appendix 5.3)[10]

This part of the interview focused on persistently difficult questionnaire items. Alternative wordings of such items were identified in the previous translation phase and during expert panel rounds. These alternative wordings of item(s) were proposed during the pilot test. The patients were asked to state whether they preferred the alternative(s) item to the original. In addition, the interviewer probed the patients about what each question meant by asking them *why* they had chosen that particular item.[19]

Recruiting the patients/participants

All patients with symptomatic POP referred to the outpatient clinic at the Department of Obstetrics and Gynaecology, Akershus University Hospital from June 2013 to November 2013 were eligible to participate in the pilot study.

The inclusion criteria included being Norwegian native-speaking (bilingual/monolingual) women coming to the outpatient clinic with a POP regardless of the severity or extent. Female patients under 18 years of age or unable to fill in the questionnaires were excluded.

One week before starting the pilot study, all healthcare personnel at the department were informed about the project through email and departmental meetings. A poster, with details of the study, was placed in the outpatient clinic for the duration of the study.

The health secretaries/nurses introduced patients to the study and principal researcher at the end of a consultation using a Norwegian verbal script. Recruitment continued until 20 women were included in the study. If the appointment did not correspond with the outpatient visit, compensation for transport and parking was offered. The verbal script in English and Norwegian are given in Appendix 5.2. The principal researcher also had weekly telephone meetings with the health secretaries and nurses at the department to identify potential pilot study participants.

The principal researcher explained the purpose of the study in a consultation room within the outpatient clinic. Participants were provided with written information in Norwegian (letter of introduction, information sheet, consent form, and interview guide; Appendices 5.2 and 5.3) describing the nature of the study and informing them that participation was voluntary. Participants indicated their willingness by first giving their verbal consent and then signing a consent form. If the participants declined, they were thanked for considering the request.

Burdens and risks

Respondent and administration burdens were considered during this study. As outlined in Section 5.2.1, qualitative research exploring sensitive topics in-depth may evoke emotional and other risks to both the participant and the researcher.[95,96] During the interviews concerning the PFDI-20 and PFIQ-7 questionnaires, sensitive personal issues, anxiety issues, and specific health problems were investigated. A protocol developed to deal with participant emotional distress during the interview entailed offering a follow-up appointment with their gynaecologist for a more in-depth discussion about the emotional distress.[95,96]

Most interviews were conducted in conjunction with a visit to the outpatient clinic, so compensation was considered unnecessary.[95,96]

To minimise burden and respect department routines, the principal researcher arranged appropriate times with the health secretaries to discuss the patient list and potential pilot study participants.

Ethical issues

Confidentiality, free and informed consent, and individual autonomy issues were considered when planning and administering this research project.[95,96] Participation was voluntary, with all potential participants assured that their decision to participate or not would not affect current or future treatment.[95,96] Informed consent was obtained from all participants.

Further assurances were provided that individual anonymity and confidentiality would be maintained throughout the study (Appendix 5.2). Coercion issues in this study were addressed by involving health secretaries/nurses to recruit research participants.[95,96] Nonetheless, the principal researcher acknowledges that a patient could still have felt a sense of gratitude towards the department and agreed to participate.

Participant control of data use

Data collected during this study was de-identified. Assurances were provided to pilot study participants that safe storage of identifiable and de-identified data and recordings would be maintained throughout the study. All consent forms, recordings, and questionnaires that participants completed were retained and not made available for general view. Only the principal researcher, supervisors, and project coordinators had access to the lists of names and thus the ability to identify the participants.

The questionnaires that were given to the selected patients were indexed (101, 102, etc.). No name or information that would identify the patient was written on the questionnaires. For audio recordings, participants were advised not to identify themselves, and the principal researcher indexed the interview only by number (e.g. 101, 102). All transcripts were identified by a code rather than by name to ensure anonymity and confidentiality.[95,96] The data was stored in a secure collection box at Akershus University Hospital and Flinders University, South Australia, and will remain stored for at least 5 years from the date of publication.[95,96]

According to the European Union directive 95/96EF guidelines, identifiable data including consent forms, recordings, and electronic data containing sensitive data (e.g. patient name,

code, and birth date) and recordings were exclusively stored at the Akershus University Hospital and are not permitted to leave the European Union.[96]

5.2.3 RESULTS: PILOT TEST (STAGE 2)

This section presents the results of the pilot testing (third interim report; Figure 4.1). The pilot test (Stage 2) comprised two phases, namely administering the Intermediate Version 2.0 to 20 patients with POP, as described above, and then conducting a three-part qualitative interview with each patient individually (Appendix 5.3).

Participants

The 20 patients who agreed to participate ranged in age from 35 to 83 years, with a median age of 75 years.

Interview results

As outlined in Section 5.2.2, qualitative interviews were divided into three parts. The transcripts of the digital recordings of the interviews consist of a list of problem items along with the patient's suggestions for improved wording. A summary of the three-part interviews was then communicated to the expert panel.

Results: Interview Part 1 — individual item analysis

Findings for PFDI-20and PFIQ-7 — items of discrepancy

There were three main items of discrepancy in the PFDI-20 (Questions 1, 2, and 15) during the first part of the semi-structured interview. Corresponding results for the PFIQ-7 indicated four discrepant items (Questions 1, 2, 4, and 6). Table 5.1 summarises these.

Findings for PFDI-20 — items of discrepancy

Question 1	Two patients reported that Question 1 was confusing and also difficult to answer because of the word *underlivet* (lower abdomen). Four patients suggested alternative wording. One patient suggested that the word *trykk* (pressure) replace *et trykk* (a pressure). Two patients suggested that the word *nedre del* (lower part) replace *den nedre delen* (the lower part).
Question 2	Four patients reported that Question 2 was difficult to answer and understand, whereas five patients found the question confusing. Five

commented that the word *tyngdefornemmelse* (sensation of heaviness) was the reason that the question was confusing and difficult to understand. Three patients suggested alternative wording.

Question 15 Even though the patients found Question 15 clear and comprehensible, three patients suggested that the alternative wording *vanligvis hyppig vannlatning* (usually experience frequent urination) replace *som oftest hyppig vannlatning* (frequent urination more often than not).

Findings for PFIQ-7 — items of discrepancy

Question 1 Two patients suggested replacing *å utføre* (to do or to perform) with *å gjøre* (to do) because the latter is the more common phrasing.

Question 2 Two patients reported that Question 2 was difficult to answer, and one patient found the question confusing. Another three patients suggested alternative wording.

Question 4 Two patients suggested replacing *lengre enn* (longer than) with *i mer enn* (in more than) because the latter is the more common phrasing.

Question 6 One patient reported that Question 6 was difficult to answer and understand, whereas three patients found the question confusing. Three patients suggested alternative wording. These patients commented that the term *psykisk helse* (emotional health) was confusing.

Findings for PFDI-20 and PFIQ-7 — items experienced as upsetting

As indicated in Table 5.1, most patients (17/20) did not find any of the PFDI-20 questions upsetting. However, some reported Questions 2, 3, and 4 as upsetting.

Findings for PFDI-20 — upsetting items

Question 2 One patient found this question upsetting but gave no further comments.

Question 3 One patient stated that the last part of Question 3 *bulge or something falling* out was upsetting because it made specific reference to the patient's condition and reminded her of a hard reality she constantly faced.

TABLE 5.1. PART 1: FEEDBACK ON EACH SEPARATE QUESTION ITEM GATHERED FROM 20 PATIENT INTERVIEWS DURING THE PILOT STUDY. THE SHADED COLUMNS WERE IDENTIFIED AS ITEMS OF DISCREPANCY AND INCLUDED IN THE SUBSEQUENT FINAL EXPERT PANEL REVIEW

***PFDI-20**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**
1. Do you find the questions difficult to answer?	2	4	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1	0	0
2. Did you find this question confusing?	2	5	0	1	0	1	0	1	0	0	0	0	0	0	0	0	0	0	0	2
3. Did you find any of the words used difficult to understand?	0	4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
4. Did you find the manner in which the question was asked to be upsetting?	0	1	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
5. How would you have asked the question?	4	3	1	1	1	1	1	2	1	1	2	1	2	1	3	2	1	2	2	2

*Answers Yes=1 No=0

PFIQ-7*	**1**	**2**	**3**	**4**	**5**	**6**	**7**
1. Do you find the questions difficult to answer?	0	2	0	0	0	1	1
2. Did you find this question confusing?	0	1	0	0	1	3	1
3. Did you find any of the words used difficult to understand?	0	0	0	0	0	0	0
4. Did you find the manner in which the question was asked to be upsetting?	0	0	0	0	0	0	0
5. How would you have asked the question?	2	3	2	2	2	3	2

*Answers Yes=1 No=0

Question 4 One patient found PFDI-20 Question 4 upsetting because of the nature of the question “Do you usually have to push on the vagina or around the rectum to have or complete a bowel movement?” (Appendix 3.1).

Findings for PFIQ-7 — upsetting items

No patients found any of the PFIQ-7 questions upsetting.

Results: Interview Part 2 — general questions

During the second part of the interview, several patients reported missing items and one unclear topic in the PFDI-20 and PFIQ-7 questionnaires. The missing items, upsetting items and unclear topics were evaluated in the final expert panel review (Section 5.3.2).

Findings for PFDI-20 and PFIQ-7 — missing items

As illustrated in Table 5.2, the statistics indicated four missing items in the PFDI-20 and PFIQ-7. To identify missing items, the patient answered either Question 1 or Question 2 and in some cases both.

The interviewed patients recommended: (1) questions pertaining to life impact issues such as sexuality; (2) a comment field in the Norwegian PFDI-20 version concerning questions asking about pain; (3) a question covering urinary incontinence and the use of panty liners; and (4) more questions pertaining to emotional health issues in PFIQ-7.

Findings for PFDI-20 and PFIQ-7

PFDI-20/PFIQ-7 Eight patients commented that sexuality and sexual function should be covered in the questionnaires. These participants stated they experienced partner-related issues, physical issues, and emotional issues associated with their sexuality.

Findings for PFDI-20 — missing items

PFDI-20 One patient recommended having a comment field in the Norwegian PFDI-20 version concerning those questions asking about pain.

PFDI-20 One patient commented that a question could be added covering the issue of urinary incontinence and the use of panty liners.

TABLE 5.2. PART 2: FEEDBACK ON THE GENERAL QUESTIONS IN THE PILOT STUDY

	Part 2: General questions concerning PFDI-20 — PFIQ-7 Total of 20 patients interviewed	**Yes**
1	Does the questionnaire cover all the questions relating to the intestines, urine and prolapse that you consider to be important?	15
2	Do you feel that the questionnaire should have contained additional points so that more topics are raised, or so that topics that are included are covered in more detail?	6
3	Are there points that cover topics you consider to be irrelevant or unimportant?	2
4	Were any of the answer categories unclear, inappropriate or not relevant enough for you to feel that they expressed what you feel?	3
5	Were the instructions and examples clear?	17
6	Do you have any other comments or questions you would like to ask?	0

Findings for PFIQ-7 — missing items

PFIQ-7 One patient commented that the PFIQ-7 should have more questions about emotional health issues.

Findings for PFDI-20 and PFIQ-7 — unclear topics

During the interview, several patients stated that the examples in the instruction section of the PFDI-20 and PFIQ-7 were unclear (Table 5.2, Question 5).

Example Three patients reported that the examples in the instruction sections of the PFDI-20 and PFIQ-7 were unclear. One of these patients commented that the examples in PFDI-20 and PFIQ-7 were not necessary and added confusion. The patient suggested, “It would be better to have the instructions, followed by the questions”.

Of note, 13 participants completed the example in PFDI-20 and PFIQ-7. Four of the thirteen patients commented that they did not realise it was an example until they had filled it in. Two suggested enlarging the font size for the “Example” title (Appendix 5.4).

Most patients 90% (18/20) found the topics in PFDI-20 and PFIQ-7 relevant for the application of the instrument (Table 5.2, Question 3). Two patients reported that PFIQ-7 Questions 6 and 7 were irrelevant because they did not experience emotional health issues.

Lastly, most patients 85% (17/20) found the response categories in PFDI-20 and PFIQ-7 clear and appropriate (Table 5.2, Question 4). However, three patients reported them as unclear or inappropriate but did not explain why.

Results: Interview Part 3 — alternative wording when persistent difficulties are identified

Findings for PFDI-20 and PFIQ-7

This part of the interview focused on the persistently difficult questionnaire items identified during the translation phase and expert panel rounds. These items are outlined in Table 5.3 and, as shown, the original item was often the preferred choice over the alternative item. Based on the comments from the pilot test interviews, the term *kul* (a bulge) and *samliv* (relationship) were identified as problem items and included in the subsequent final expert panel review.

Findings for PFDI-20

Question 3 — Five patients found the alternative item *kul* (noun: a bulge) the preferred choice over the original item *buler ut eller faller ut* (bulges out or falls out).

Findings for PFIQ-7

Instructions — Even though 19/20 patients voted for *samliv* during the interviews, the probing technique revealed that the word has a mixed meaning. *Samliv*, literally “living together” in Norwegian, is often defined as an intimate relationship. However, in English, the word covers all types of relationships (e.g. interpersonal, intimate, mother–daughter, colleague). During several interviews, the patients commented that *samliv* for them was a relationship with their partner/husband and not other types of relationships. When examining the nature of the questionnaires, particularly PFDI-20 Question 5, it became evident that *forhold* was more appropriate for the PFIQ-7 questionnaire. *Forhold* in Norwegian is often defined as a general relationship or human relationship. Further, another patient voted for *forhold* and gave as a reason that they were neither

married nor had a partner. During the interviews, 3/20 patients commented that both *samliv* and *forhold* were appropriate.

Results: Hesitance

Some minor hesitations were noted during the completion of the PFDI-20 questionnaire. Five participants hesitated slightly when filling in PFDI-20 Question 2 and two patients hesitated to fill in Question 1. Patients comments from the interview also indicated that PFDI-20 Question 2 was confusing and difficult to understand.

Results: Missing data

No missing data was found in the PFDI-20 during pilot testing; however, one participant did not fully complete the PFIQ-7 questionnaire's POPIQ subscale. The participant stated that she *did* comprehend the questions in the PFIQ-7 POPIQ subscale but did not complete the subscale because she experienced neither physical nor emotional difficulties.

5.2.4 SUMMARY

The pilot testing undertaken during Stage 2 in this study provided evidence that the Norwegian Intermediate Version 2.0 showed equivalence with the original versions with no major hesitations and a clear set of items with few discrepancies. No major hesitations indicated adequate linguistic validation or, as Guillemin et al asserted, face validity.[44]

Nevertheless, some items indicated some potential cross-cultural adaptation problems, which were included in the summary of the qualitative and quantitative data for subsequent final review by the expert panel.

TABLE 5.3. PART 3: ALTERNATIVE PHRASINGS IN QUESTION ITEMS SOLICITED DURING THE PILOT TEST

QUESTIONS	ORIGINAL PHRASINGS IN QUESTION ITEMS	SOURCE VERSION (ENGLISH)	ALTERNATIVE PHRASINGS IN QUESTION ITEMS	ANSWERS; NUMBER OF PATIENTS THAT PREFER ALTERNATIVE(S)
PFDI-20				
Questions 1–2	Phrase: *Kjenner du ofte*	Do you usually	*Kjenner du vanligvis*	1
Question 3	Phrase: *Buler ut eller faller ut av skjeden*	A bulge or something falling out	*En kul eller noe som faller ut av skjeden?*	5
Questions 9–12	Phrase: *Har du ofte*	Do you usually	*Har du vanligvis*	1
Question 13	Phrase: *så sterk avføringstrang at du må løpe til toalettet*	A strong sense of urgency and have to rush to the bathroom to have a bowel movement	*Ved avføringstrang at det haster veldig*	8
Question 16	*Opplever du så sterk vannlatingstrang at du ikke rekker til toalettet før du får lekkasje?*	Do you normally experience urine leakage associated with a feeling of urgency, that is, a strong sensation of needing to go to the bathroom?	*Har du ofte urinlekkasje ved kraftig trang til vannlatning:, dvs. så sterk følelse av hast at du må på toalettet?*	2
Questions 17–19	Phrase: *Har du ofte*	Do you usually	*Opplever du ofte* *Opplever du vanligvis?*	4
Question 20	Phrase: *Har du ofte*	Do you usually	*Kjenner du ofte?* *Kjenner du vanligvis*	4
PFIQ-7				
Instructions	Term: *Gjøremål*	Activities	*Aktiviteter*	6
Instructions	Term: *Samliv*	Relationship	*Forhold*	1
Questions 1–7	Term: *Din*	Your	*Remove term din*	2
Question 6	Term: *Psykiske helsetilstand*	Emotional health	*Emosjonelle helsetilstand*	1

5.3 FINAL EXPERT PANEL REVIEW AFTER PILOT TESTING

5.3.1 METHOD: FINAL EXPERT PANEL REVIEW AFTER PILOT TESTING

The final expert panel review entailed two parts, which included a face-to-face meeting with all panellists followed by interviewing each panellist separately.

First, the pilot test report was presented at the final expert panel review face-to-face meeting. The test report consisted of:[10]

a) A summary of the procedure, including the sample population attributes. Any departures from the standard interview were also recorded.

b) An account of qualitative and quantitative data from the pilot test supporting the final translation.

In cases where panellists could not attend the meeting, they gave their feedback before the meeting. The facilitator/principal researcher chaired the meeting and presented the items of discrepancy. When there seemed to be general approval of the proposal, the principal researcher requested a call for consensus. The Delphi method was used in this process, and consensus was reached on all items of discrepancy.[18]

Had consensus not been reached, the expert panel would have had to submit a written response with their reasons for disapproval and recommended procedures to allow for a subsequent translation to be accepted.[10]

The final expert panel review aimed to examine the qualitative and quantitative data from the pilot test (Intermediate Version 2.0), review discrepant, missing and upsetting items, and finally make necessary amendments to produce a final translated version (Intermediate Version 3.0) that demonstrated equivalence with the original versions.

Second, following the final expert panel review meeting, each panellist was interviewed to investigate if the questionnaires were relevant to the study population and comprehensively reflected the construct to be measured —pelvic floor dysfunction. The results from these interviews are detailed in Section 5.3.3.

5.3.2 RESULTS: FINAL EXPERT PANEL REVIEW AFTER PILOT TESTING

The panellists reviewed the summary of qualitative and quantitative pilot test data outlined in Section 5.2.3. The panel dismissed most of the discrepant items as irrelevant or minor and decided that 11 items needed to be discussed in detail. Missing and upsetting items were reviewed but not discussed further by the panel. Eleven discrepant items were discussed in the expert panel meeting based on the pilot test report detailed in Section 5.2.3.

A summary of the 11 discrepant items and associated suggestions were given to the panel. The final review (Fourth interim report: Figure 4.1) entailed a face-to-face 80-minute meeting with six of the eight panellists. The remaining two panellists gave their feedback before the meeting. The facilitator/principal researcher chaired the meeting and presented the discrepant items one by one. When there seemed to be general approval of the proposal, the principal researcher requested a call for consensus. The Delphi method was used in this process, and consensus was reached on all discrepant items (11/11). This process rendered the final translated version (Intermediate Version 3.0) ready for further validation detailed in Chapter 6.

Of note, the expert panel's statistical collective opinion (using median) was unchanged from Round 4 (Figure 4.3). The panellists generally indicated that the amendments were necessary. However, some panellists felt that the changes improved the questionnaire items only marginally. Furthermore, they indicated that the Delphi method was unnecessary in this round because the items of discrepancy required only minor adjustments.

PFDI-20 and PFIQ-7 results

The 11 discrepant items were discussed in the final expert panel meeting resulting in nine amendments. The amendments were mainly based on discrepancies related to specific domain terminology and semantic equivalence in Norwegian *Bokmål*.

The amendments to the PFDI-20 and PFIQ-7 questionnaire items are detailed below.

PFDI-20 results

Questions 1, 20 The expert panel voted to replace *den nedre delen* (the lower part) with *nedre del* (lower part) in Question 1 because two patients suggested it. The expert panel agreed that this change would improve semantic equivalence.

To maintain consistency, *den nedre delen* in Question 20 was also altered to *nedre del*.

Question 2 — The expert panel voted to replace: (1) the idiom *kjenner du ofte* (Do you usually) with *har du ofte* (Do you often) and (2) the specific domain term *tyngdefornemmelse* (sensation of heaviness) with *tyngdefølelse* (a feeling of heaviness) because 5/20 patients commented that the wording was confusing and 4/20 found the wording difficult to understand.

Question 3 — The word *kul* (noun: a bulge) was discussed in detail. However, the panel dismissed the issue because, during Part 3 of the interview, 75% (15/20) of the patients stated that the original item *buler ut eller faller ut* wording was preferable over the suggested alternative wording *kul*. However, to improve semantic equivalence, the expert panel chose to replace *buler ut eller faller ut* (bulges out or falls out) with *buler og faller ut* (bulges and falls out).

Question 15 — To improve specific domain terminology, the panel replaced *som oftest hyppig vannlatning* (frequent urination more often than not) with *vanligvis hyppig vannlatning* (usually experince frequent urination) Although several patients found the original item clear and comprehensible, three patients suggested the same alternative wording *vanligvis hyppig vannlatning*.

PFIQ-7 results

Question 1 — In terms of common use of language, the expert panel chose to replace "*å utføre* (to do or to perform) with *å gjøre* (to do) based on a patient's suggestion.

Question 4 — To improve semantic equivalence, the expert panel chose to replace *lengre enn* (longer than) with *i mer enn* (in more than) based on a patient's suggestion.

Instructions — The expert panel voted to replace the specific domain term *samliv* (relationship, living together or cohabitation) with *forhold* (relationship). The reason was that during the interviews, several patients defined *samliv*

specifically as an intimate relationship and not generally as a relationship or human relationship.

Example — Since several patients reported that the example in the instruction section of the PFDI-20 and PFIQ-7 was not clearly an example, the panel agreed to enlarge the font size for the "Example" title (Section 5.5.4).

The expert panel voted not to amend the following PFIQ-7 items of discrepancy:

Question 2 — No amendment made. The expert panel reviewed the patients' comments but agreed that the suggested changes did not significantly improve semantic equivalence. Moreover, the formulation of the question was chosen to correspond with the one used in Question 1.

Question 6 — No amendment made. The expert panel voted not to replace the specific domain term *psykisk helsetilstand* (emotional health) because most patients found this term clear and comprehensible. In addition, during Part 3 of the interview, 95% (19/20) of the patients stated that the original item wording was preferable over the suggested alternative wording.

5.3.3 RESULTS: EVALUATION OF PFDI-20 AND PFIQ-7 BY THE EXPERT PANEL

Finally, following the expert panel review meeting, each panellist was interviewed individually to investigate whether the relevance and comprehensiveness were appropriate to the target population.

All panellists (8/8) strongly agreed that all items in the PFDI-20 and PFIQ-7 were relevant to the study population and the purpose of the application of the instrument (Table 5.4).

The majority of panellists (6/8) strongly agreed that all items accurately reflected the construct to be measured — pelvic floor dysfunction.[103] The remaining panellists (2/8) were "unsure" if all items together accurately reflected the construct because sexuality was missing in the questionnaires. This finding aligns with similar comments made by the pilot test patients as described in Section 5.2.3.

5.3.4 SUMMARY

The final expert panel review facilitated and verified the linguistic validation of the Norwegian PFDI-20 and PFIQ-7 questionnaires (Intermediate Version 3.0) with no items of

discrepancy. Intermediate Version 3.0 (Appendix 5.5) is ready for further extensive validation. The panellists indicated that most of the amendments suggested by the pilot test patients were necessary; however, the panellists considered them to improve the questionnaire items only marginally. Furthermore, the panellists indicated that the use of the Delphi method (anonymous voting, controlled feedback, statistical group response) was unnecessary in the final expert panel meeting and simply facilitating an open discussion during the face-to–face meeting might have sufficed.

The expert panel considered all items in the PFDI-20 and PFIQ-7 relevant to the study population and the purpose of the application of the instruments. Most of the panel considered the questionnaires to comprehensively reflect the construct to be measured. However, two panellists stated that sexuality issues were missing.

TABLE 5.4. EVALUATION OF THE PFDI-20 AND PFIQ-7 BY THE EXPERT PANEL

QUESTION ADDRESSED TO THE EXPERT PANEL	EVALUATION OF CONTENT VALIDITY BY THE EXPERT PANEL: (1) STRONGLY DISAGREE, (2) DISAGREE, (3) UNDECIDED, (4) AGREE, (5) STRONGLY AGREE
Do all items refer to relevant aspects of the construct?	8/8 panellists agreed that all items referred to the relevant aspects of the construct (Median 5.0)
Whether the items in the PFDI-20 and PFIQ-7 were relevant to the study population	8/8 panellists agreed that the items were relevant to the study population (Median 5.0)
Whether all items were relevant for the application of the instrument	8/8 panellists agreed that all items were suitable and relevant for the application of the instrument (Median 5.0)
Whether all items together accurately and comprehensively reflect the construct to be measured	6/8 panellists agreed that all items together comprehensively reflected the construct to be measured (Median 5.0) 2/8 panellists answered “undecided” and were unsure whether all the items accurately and comprehensively reflected the construct to be measured. They stated that sexuality was missing in the questionnaires (Median 3.0)

5.4 QUALITATIVE INTERPRETIVE RESEARCH

It is important to ensure that the items in a PRO instrument cover the pertinent issues for accurate assessment of presence, symptom severity and HRQOL.[5] One of the objectives of this study was to evaluate critically the Norwegian self-administered PFDI-20 and PFIQ-7 questionnaires as tools for measuring symptoms and condition-specific quality of life (QoL).

To achieve these aims, the questionnaires had to be appraised for comprehensiveness. Such an appraisal can be seen as a step in the cross-cultural validation of the instruments.[19] This section discusses an interpretive research approach towards understanding the experiences and perspectives of women with symptomatic POP.

5.4.1 Theory in qualitative interpretive research approach for data analysis

Common qualitative research paradigms in social science include post-positivism, critical theory, and interpretivism.[106] The interpretive paradigm of qualitative research seeks to understand the experiences and perspectives of different people in the context studied.[106,107] Interpretive research can contribute to the understanding of symptom severity and HRQOL issues by identifying the definitions of a problem. This type of research is also useful in revealing various interpretations of how individuals[106] with chronic conditions such as pelvic floor dysfunction experience them. With an interpretive perspective, the researcher can move from merely formulating to interpreting and constructing joint accounts or themes, revealing participant perspectives and experiences.[106,107]

Conducting a qualitative interpretive design study involves formulating a study question in the context of *how* this is happening rather than *why*. It involves collecting data by interviews and direct observation and analysing the data.[106] The analysis comprises organising, describing, classifying, and interpreting the data.[107] With data interpretation, the researcher can choose from several qualitative methods including narrative, case study research, and phenomenological and thematic analysis.[106-108]

Thematic analysis using a qualitative interpretive process has become common in qualitative research and focuses on identifying, analysing, and reporting patterns (themes) within data.[109] Thematic analysis is the process of encoding and classifying qualitative information. Furthermore, thematic analysis explores themes that emerge as essential to describing a phenomenon.[109]

Thematic analysis is a step-by-step approach starting with the researcher's becoming familiar with the data and generating initial codes. Next is placing the aspects of text interpretation (codes) into patterns (themes), and then continually reviewing and defining the themes.[110] The analysis should be adapted depending on the subject and its context and the purpose of the study. Analyses of qualitative information entail continually moving back

and forth through the entire data set and can occur either inductively (data-driven) or deductively (theory-driven).[109,110]

In thematic analysis, codes are seen as labels that assign symbolic meaning to the descriptive information, which is classified as semantic (i.e. explicit level) or latent (i.e. interpretative level) content.[108-110] A theme is an outcome of coding, categories of *broad* units of information, where data can be interpreted in a meaningful way regarding a phenomenon. A sub-theme is a second-order tag assigned to the primary theme, which provides more detail about the primary theme.[110] In general, this interpretive process within thematic analysis results in an analytical narrative that seeks to understand the experiences and perspectives of different women with pelvic floor dysfunction.

Thematic analysis is a flexible method and can produce unanticipated insights. In contrast to narrative theory and other methods, thematic analysis is not linked to any known theoretical framework, so it can be used with or without such frameworks.[110] Nevertheless, Braun and Clarke[110] contend that thematic analysis has limited power beyond description. This limitation may be improved, however, if an existing theoretical framework anchors claims based on the findings. Of note, a good thematic analysis should specify whether a theoretical framework is applied or not.[110]

Determining the criteria for assessing the quality of the qualitative research design is important. Creswell and Poth[108] contend that the process of verification and validation gives validity and authenticity in a research project. Verification and validation can be accomplished by searching the literature, adhering to chosen qualitative research methods, and using adequate sample size. Validation can be achieved by a detailed description of the target population and triangulation. Triangulation involves cross-checking information to support findings derived from a qualitative survey. This process can be achieved by corroboration from several information sources to converge on an interpretation and enhance the trustworthiness of the analysis.[108]

Denzin (1978) identified four main types of triangulation[108,111]:

- Investigator: employing multiple investigators in interpreting data
- Data: checking the consistency of different data sources
- Method: employing multiple research methods

- Theory: using multiple perspectives to explain the data

Reliability and dependability are underlying issues that need to be addressed when interpreting data in qualitative research. Reliability and dependability can be achieved through clear study design, detailed field notes, recording with high-quality devices, intercoder agreement checks and peer review.[108]

Finally, data analysis is enhanced by referencing existing literature to investigate whether the researcher's findings are consistent with other research findings.[108]

5.4.2 Method for pilot test interviews

It is important to ensure that the items in a PRO instrument cover the pertinent issues for accurate assessment of presence, symptom severity, and HRQOL.[5] One of the objectives of this study was to critically evaluate the Norwegian PFDI-20 and PFIQ-7 questionnaires as tools for measuring pelvic floor dysfunction symptoms and HRQOL.

To achieve this aim, the questionnaires had to be appraised for comprehensiveness. This appraisal can be seen as a step in the cross-cultural validation of the instruments.[19] Hence, this section discusses an interpretive research approach towards understanding the experiences and perspectives of women with symptomatic POP.

Research design

This part of the study was conducted using an interpretive paradigm of qualitative research[106,107] seeking to understand the experiences and perspectives of female patients experiencing pelvic organ prolapse and pelvic floor dysfunction. In this way, the Norwegian PFDI-20 and PFIQ-7 questionnaires were critically appraised as a measurement tool. Interpretive research can contribute to the development of the pelvic floor field by identifying different definitions of the problem being examined. This type of research is also useful in understanding the experiences of individual participants.[110]

Data collection

The data was collected using qualitative in-depth face-to-face interviews (Section 5.2.3). An interview guide was used to ensure that the interviews focused on the purpose of the study, which was designed according to Cotterill et al.[105]

The semi-structured interview guide consisted of two questions: “Do the questionnaires cover all issues related to bowel, urine, and prolapse?” and “Should any items be added or covered more in-depth?” (Appendix 5.3, general questions 1 and 2).

The questions were followed by a probing question: “Can you tell me more about …?” (Appendix 5.3). This open-ended question aimed to encourage the participants to describe the dimensions of the phenomenon giving the researcher a better understanding of the experiences female patients have with pelvic floor dysfunction. Verbatim transcription of interview data was performed.

Data analysis

The analysis was performed rigorously through a process of thematic analysis outlined in Sections 5.4.1 and 5.4.2. It was deductive (theory-driven) at a semantic, or explicit, level.[109,110] Interpretive *coding*, also known as semantic coding, was employed to categorise the units of information and form broader units of information theme(s).[110] Each interview was analysed separately, with coding and identification of themes/subthemes done manually.

The following steps were employed[110]:

- Transcribing data and reading through the text several times
- Generating initial codes using highlighters to indicate potential patterns
- Searching for themes that capture important elements of the data in relation to the research question
- Reviewing “thematizing meanings”
- Defining and naming themes and subthemes
- Producing the report

Finally, strategies for validation or verification (Sections 5.4.1 and 5.4.2) were accomplished by using an adequate sample size, keeping field notes, and conducting comprehensive interviews, thus achieving saturation of data.[110] Validation was performed by applying multiple data collection methods (observations, audio interviews, and literature) and investigator and data (person) triangulation.[110] Investigator triangulation was used to explore interview data from the divergent perspectives of the principal researcher and one other senior researcher. The experienced researcher found similar coding, themes,

subthemes, and related formulated meanings to those produced by the qualitative study. Data (person) triangulation involved collecting data from different patients with different ages and multiple perspectives.

Reliability was achieved primarily through clear study design, keeping detailed field notes, intercoder agreement checks, and peer review.[108]

5.4.3 RESULTS OF THE QUALITATIVE INTERPRETIVE ANALYSIS OF DATA

Data was coded and subsequently analysed. An interpretive process was used in the thematic analysis of the data. Three main themes emerged, all of which related to sexuality:

(1) Partner-related issues related to sexuality
(2) Emotional issues related to sexuality
(3) Physical issues related to sexuality

Specifically, 55% (11/20) commented that quality of life issues such as sexuality related to their POP was not covered in either the PFDI-20 or PFIQ-7 (Table 5.5). Several subthemes were embedded in these themes. Similar to other studies, participants reported the importance of asking questions pertaining to partner-related issues (e.g. difficulty discussing sensitive issues, low sexual desire), emotional issues (e.g. feelings of disgust, anxiety), and practical and physical issues (e.g. pain during sex) related to sexual function.[57,64] Subthemes varied from hygiene issues and pain during sex (dyspareunia) to episodes of incontinence during sex. These women can also experience difficulties being open with their partner and discussing sore, sensitive issues (Table 5.5).

Further, women with symptomatic POP can experience several emotional issues such as anxiety, feelings of disgust for their body after physiological changes, and feeling the loss of control particularly associated with sex (Table 5.5). It was apparent during the interviews that the participants sometimes had difficulty putting their experiences into words concerning sexuality, especially when talking about relationships with their partners.

As outlined in Section 5.4.1 and 5.4.2, different strategies for triangulation (i.e. investigator, data and method triangulation) were employed which contributed to validity and authenticity of the analysis of the data. Investigator triangulation was accomplished by exploring interview data from the different perspectives of the principal researcher and one other senior researcher. Both the principal researcher and the other experienced senior

researcher found similar coding, themes, subthemes and related formulated meanings to those produced by the qualitative study (Table 5.5). Data (person) triangulation was accomplished by the data being collected from different patients with different ages (aged 35–83 years) and multiple perspectives (Table 5.5). Finally, method triangulation was accomplished by using multiple research methods for collecting data (i.e. observations, audio interviews and literature). See Section 5.4.2.

Furthermore, clear study design, intercoder agreement checks and peer review (outlined in Section 5.4.2) were employed and by doing so, the trustworthiness and reliability of the analysis was enhanced.

5.4.4 SUMMARY

During Stage 2 of the study, thematic analysis of data using an interpretive approach revealed that the life impact issue of sexuality was not covered in the PFDI-20 and PFIQ-7 questionnaires. This gap included subthemes such as partner-related issues, emotional issues, and physical issues. Since sexuality function was identified in this study as important for women with pelvic floor dysfunction, it is proposed to add a third health measurement scale assessing sexuality to complement the Norwegian PFDI-20 and PFIQ-7 questionnaires. Finally, some women experienced some items in PFDI-20 as upsetting (i.e. Questions 2, 3, and 4).

5.5 DISCUSSION

5.5.1 INTRODUCTION

In this part of the study, a pilot test and an expert panel review of the pilot test were performed. A qualitative evaluation (using the pilot test dataset and interpretive research) was also undertaken to understand female patients' experiences of genital prolapse. These were undertaken to critically assess the Norwegian PFDI-20 and PFIQ-7 questionnaires.

5.5.2 SUMMARY OF MAIN RESULTS

Pilot testing with 20 female native speaking patients with POP aged 35–83 years rendered an Intermediate Version 2.0 showing no major hesitations in completing the questionnaires, few missing items, and a clear set of items with few discrepancies.

The sociodemographic characteristics of the patients interviewed were typical and in accordance with those expected from the hospital population. The wide age distribution in the pilot test patients indicates that all age groups can complete the questionnaires without difficulty. Nevertheless, some items indicated some potential cross-cultural adaptation problems (Section 5.2.3) and were included in the summary of the qualitative and quantitative data for subsequent review by the expert panel (Section 5.3). This process of final review rendered an Intermediate Version 3.0 ready for further validation. A Norwegian authorized translation agency, detailed in Table 3.2, proofread the Intermediate Version 3.0 for typing, spelling and grammatical errors.

Both the patients and expert panel reported that all items were relevant to the target population and the purpose of the instruments (Sections 5.2.3 and 5.3.3). In particular, they comprehensively reflected the construct to be measured (see Table 5.2).[16] However, the pilot test identified sexuality as a missing life impact issue in the questionnaires. Moreover, thematic analysis of the data with an interpretive approach revealed that participants were experiencing partner-related issues, physical issues and emotional issues associated with their sexuality. Since sexual function was identified in this study as important for women with pelvic floor dysfunction, a third scale might be needed to specifically assess sexuality, complementing the Norwegian PFDI-20 and PFIQ-7 questionnaires.

The main results are discussed more fully in the subsequent sections.

5.5.3 WRITTEN OFFICIAL LANGUAGES IN NORWAY

Norway is divided into regions with different written official languages. There are two official written forms of Norwegian, *Bokmål* (Book Language), and *Nynorsk* (New Norwegian).[112]

Under these circumstances, translating patient result outcome measures (PROMs) can pose a challenge because these two official forms can influence a patient's interpretation of the HRQOL questionnaires. Most Norwegians (92%) use Norwegian Bokmål as their written language,[112] so it was the preferred choice for the PFDI-20 and PFIQ-7 questionnaires. The pilot test verified the linguistic validation of most items of the *Bokmål* Intermediate Version 2.0, with no major hesitations, few missing data, and a clear set of items with few discrepancies (Section 5.2.3).

Since different forms of written Norwegian can influence cross-cultural adaptation, more consideration towards written variations should have been undertaken during pilot testing. In future, the recommendation is to incorporate questions into an interview addressing whether the participant's written Norwegian language is Bokmål or Nynorsk.

5.5.4 OPERATIONAL EQUIVALENCE

Operational equivalence assesses whether the format of the instructions, questionnaire, and mode of administration can be employed in the same target population.[17] As reported in Section 5.2.3, several patients commented that the format of the examples in the instruction sections of the PFDI-20 and PFIQ-7 questionnaires made it unclear that they were examples. Based on this feedback, the heading *Example* was significantly enlarged.

5.5.5 PFDI-20 AND PFIQ-7 QUESTIONNAIRES LACKING SEXUALITY QUESTIONS

Sexual function and sexuality were reported (Sections 5.2.3 and 5.4.3) as important issues for women with pelvic floor dysfunction.[32,64] One of the objectives of this study was to critically evaluate the Norwegian PFDI-20 and PFIQ-7 questionnaires as tools for measuring symptoms and condition-specific quality of life of patients with pelvic floor dysfunction.

Evidence that sexual function and sexuality are issues for women with pelvic floor conditions was identified (Table 5.5) and is also reflected in relevant literature. Barber et al.[113] assert that sexuality is an important issue for women with pelvic floor conditions. These authors also found that one-third of patients reported that their condition/POP affected their ability to engage in sexual relations, a rate significantly higher than in other groups.

As one participant in this study stated, "It is one year or two without having visitation with your husband. It goes beyond the psyche between us." A 2011 study published in Sweden showed that bladder, bowel, and sexual problems are associated with a marked reduction in quality of life.[33] Özel et al.[114] reported that women with POP are more likely to report a negative impact on sexual relations, including absence of libido, decreased sexual excitement, and difficulty achieving orgasm during intercourse. Embarrassment, low sexual self-image, concerns over malodour, and feelings of less attraction to their partner because of POP and incontinence were also reported.[114] Conversely, some studies comparing women with and without POP showed no difference in sexual activity.[5,32]

Despite several studies reporting sexual function symptoms of dyspareunia,[66] vaginal dryness, and orgasm among women with POP,[42,64] the pilot study only uncovered one case of dyspareunia. Pauls et al.[22] assert that patients are often hesitant to volunteer information regarding sexual complaints. It was evident in the current study that some patients were reluctant to discuss these specific topics. When the topic was broached, diffuse phrases such as "Close intimacy is not possible in our relationship" were used. Of note, some participants mentioned sexuality as a missing domain but did not elaborate one their sexual concerns. One patient even asked if they were allowed to discuss these types of issues and barriers with healthcare personnel.

Since this study identified sexuality function as important for women with pelvic floor dysfunction,[32,42,64,65,113] it is proposed to add a third health measure scale (PROM) assessing sexuality to the Norwegian PFDI-20 and PFIQ-7 questionnaires. As one patient stated during the pilot test, "If you do not talk about it (sexuality) and find solutions – the problem becomes bigger than it needs to be. Had there been a few questions about sexuality, it could be the gateway to resolve things."

Several instruments (Section 2.4.5) have been developed for assessing sexual function and sexuality for women with POP and pelvic floor dysfunction. One is the POP/Incontinence Sexual Function Questionnaire (PISQ-12). Some reviews have indicated that the PISQ-12 is the instrument of choice in gynaecology for assessing sexual function.[48] PISQ-12 is often employed in studies as a tool for identifying and assessing sexual issues in women with pelvic floor dysfunction.[47,57,70]

A self-administered questionnaire, as opposed to an interviewer-based questionnaire, can be a helpful tool when assessing a taboo and embarrassing condition such as POP and pelvic floor dysfunction.[44] As reported here and in other studies, patients might otherwise not discuss their condition or quality of life issues during an outpatient consultation.[22,43]

Comparative analysis reveals that some clinicians prefer the flexibility of an unstructured interview, which allows for tailoring questions concerning sexuality and modifying of more in-depth questions.[44]

In conclusion, a future research project could use the novel multistep translation method discussed in Chapters 3 and 4 to translate and cross-culturally adapt the PISQ-12 sexuality questionnaire into Norwegian.

5.5.6 DEVIATIONS DURING THE PILOT TEST

One minor deviation from the standard interview protocol occurred. During the process of verbatim transcription of interview data, one recording was accidentally deleted during data transfer. The principal researcher took notes, however, so the information was preserved nonetheless.

5.5.7 LIMITATIONS DURING THE PILOT TEST

No major limitations were identified in this part of the research. However, the probing techniques in the EORTC QoL Group interview guide are limited to asking patients about items that are difficult/confusing and for alternative ways of reformulating the questions.

Guillemin et al.[19] and the MAPI Institute[77] assert that after each question, the participant should be asked, “What do you mean?” or “How do you understand this question?” This approach encourages the participant to explain their understanding of each item in an open-ended interview.[19] Applying this form of probing technique in the pilot study interviews might have improved the chances of identifying any further deviations or errors and ensuring that the patient truly understood the intention behind each question.

TABLE 5.5. SEXUALITY AND SEX: SIGNIFICANT STATEMENTS, CODES, THEMES (RELATED FORMULATED MEANINGS) AND SUBTHEMES

SIGNIFICANT STATEMENTS	CODE	THEME-RELATED FORMULATED MEANINGS	SUBTHEMES
"In relation to the prolapse. It does not ask anything about your relationship and how difficult it can be in relation to sex." "I'm thinking specifically of intercourse. It is a big issue in relation to urine, faeces and sexuality. It is a sore subject. Openness with my partner is also a problem. The way I see it, you have been married for many years and have an incredible relationship. Then suddenly something happens in your life and it robs you of that part of your marriage. That is what I think it is difficult." "In relation to hygiene. I need the possibility or opportunity to wash myself properly." "It can be painful to have sex."	Sexuality/ Sex	Women with symptomatic POP can experience partner-related issues associated with their sexuality. Women see the importance of reporting these issues in the PFDI-20 and PFIQ-7.	Physical and emotional difficulties in relation to sex with partner: • Difficulty in terms of openness with a partner • Difficult, sore, sensitive issue in relation to partner • Loss and adaptation issues in relation to sex with partner • Pain (dyspareunia) and hygiene issues in relation to sex with a partner
"In reflection, I detest and despise myself. It is disgusting to have a prolapse." "It is disgusting and uncomfortable having part of your vagina fall out." "During intercourse, I sometimes feel air coming from my rectum and vagina. I think this is horrid and disgusting." "It can give a form of anxiety and having a prolapse does not give you a sense of completeness/wholeness as a human being. It makes you want to do something about it."	Sexuality	Women with symptomatic POP can experience emotional issues associated with their sexuality. Women see the importance of reporting these issues in the PFDI-20 and PFIQ-7.	Emotional difficulties (i.e. anxiety, feelings of disgust for one's body after physiological changes, feeling loss of control particularly in relation to sex, low self-esteem in terms of body image and sexuality). Physiological changes are unpleasant/difficult to reconcile with. Not feeling a sense of completeness/wholeness as a human being.
"In relation to hygiene. I need the possibility or opportunity to wash myself properly." "During intercourse, I sometimes feel air from my rectum and vagina." "It is difficult to use a tampon during menstruation." "It can be painful to have sex."	Sexuality	Women with symptomatic POP can experience practical and physical issues associated with their sexuality. Women see the importance of reporting these issues in the PFDI-20 and PFIQ-7.	Hygiene issues related to sex. Difficulty using tampons during menstruation. Anal incontinence related to sex. Pain during sex.

5.5.8 BURDENS AND RISKS

Respondent burdens and risks during the pilot test

As outlined in Section 5.2.2, Australian and Norwegian regulations on respondent and administrative burden and risk during pilot testing and expert panel review were adhered to during the study.[95,96]

As outlined in Section 5.2.3, the qualitative semi-structured interviews exploring the cultural-adaptive nature of the PFDI-20 and PFIQ-7 questionnaires addressed sensitive personal topics and evoked emotional responses in two of the participants. After the interview, using a planned distress protocol, the principal researcher offered the participants a follow-up appointment with their gynaecologist to discuss in greater depth the emotionally distressing situation that occurred during the interview. Both participants declined the offer.

To minimise the risk of participants not comprehending the written information and the PFDI-20 and PFIQ-7 questionnaires, the reading and comprehension level was targeted to a 12-year-old's level. Despite these efforts, five patients commented that *PFDI-20 Question 2* was confusing. Two patients stated that they did not understand the question at all. During the final expert panel reviews, the phrasing and specific domain terminology of PFDI-20 Question 2 were evaluated and amended (Section 5.3.2).

Administration burdens and risks during the expert panel review

The final review meeting was seen as time-consuming and a burden for panellists. Thangaratinam et al.[80] states that too many rounds can risk respondent fatigue, withdrawal, or lost interest. The panellists did not withdraw, but they indicated that the meeting was time-consuming and taxing. Nevertheless, the panel considered all of the comments in the report and made 11 amendments based on patient comments and the summary of qualitative and quantitative results. It was clear that the panel was focused on improving the quality of the questionnaires from the patient's point of view. In the future, simply distributing a report and allowing the panellists to respond in writing is another option to reduce respondent burden.

5.5.9 ETHICAL ISSUES CONCERNING THE PILOT TEST

The study was designed to comply with relevant regulations as set forth by Norwegian and Australian health authorities about anonymity, individual autonomy, informed consent, and coercion issues (Section 5.2.1). No major ethical issues arose during the pilot test.

After reading the information sheet, two patients expressed concerns that the study might have consequences for their future treatment.[95,96] Both patients were assured orally and in writing that there would be none.

5.5.10 PARTICIPANT CONTROL OF DATA USE CONCERNING THE PILOT TEST

As outlined in Section 5.2.1, Australian and Norwegian regulations on privacy, anonymity, confidentiality issues and safe storage of identifiable and de-identified data and recordings were adhered to during the study.[95,96] No significant deviations from the protocol occurred.

5.6 CONCLUSION

No major deviations, limitations, ethical, or data control issues arose during this part of the study. Pilot testing and review by the expert panel were a necessary step in this translation process. Stages 1 and 2 of this translation and cross-adaptation study (detailed in Chapters 3, 4, and 5) facilitated a rigorous cross-checking system during the translation project of the PFDI-20 and PFIQ-7. These steps rendered the Norwegian Translated Version (Intermediate Version 3.0) (Appendix 5.5) a comprehensible, linguistically valid set of items ready for further extensive validation in Chapter 6.

During Stage 2 of the study, thematic analysis of data using an interpretive approach revealed that the life impact issue of sexuality was not covered in the PFDI-20 and PFIQ-7 questionnaires. Since sexuality function was identified in this study as important for women with pelvic floor dysfunction, the addition is proposed of a scale assessing sexuality to complement the Norwegian PFDI-20 and PFIQ-7 questionnaires.

CHAPTER 6

MEASUREMENT PROPERTIES

6.1 INTRODUCTION

Further validation processes are required for the PFDI-20 and PFIQ-7 questionnaires to be considered valid and reliable tools for measuring HRQOL of women with pelvic organ prolapse (POP) and pelvic floor dysfunction in clinical and research settings in Norway. After the cross-cultural adaptation and completion of linguistic validation outlined in Chapters 3, 4, and 5, the following measurement properties should be tested as a minimum requirement: reliability, validity, responsiveness, and interpretability.

Chapter 6 details the quantitative findings of Stages 3 and 4 of the study. This part of the study aimed to test the measurement properties (e.g. reliability, validity, and responsiveness to change) of the PROM PFDI-20 and PFIQ-7 in a prospective longitudinal study of women with POP and pelvic floor dysfunction in a tertiary setting. Stage 3 involved testing the measurement property validity and reliability of the PFDI-20 and PFIQ-7 for women with symptomatic POP. For Stage 4, the focus was testing the responsiveness and interpretability of PFDI-20 and PFIQ-7 for women undergoing reconstructive surgery for POP.

The extensive validation studies undertaken during Stages 3 and 4 are evidence that the validated PFDI-20 and PFIQ-7 indicate adequate reliability, validity, and good responsiveness among a homogeneous target population.

6.1.1 ETHICS APPROVAL

Approval was granted (for Stages 3 and 4) by Regional Committees for Medical and Health Research Ethics (Norway) (Appendix 3.4f), the Akershus University Hospital Ethics Committee (Norway) (Appendix 3.4g), and the Flinders University Social and Behavioural Research Ethics Committee (Australia) (Appendices 3.4h). The approval of grants for Stages 3 and 4 by the Regional Committees for Medical and Health Research Ethics (Norway) were translated into English and are given in Appendix 3.4e.

6.2 LITERATURE SEARCH

A literature review on measurement theory and testing measurement properties of HRQOL PROMs was performed, as detailed in Section 3.2.

6.3 MEASUREMENT THEORY

A measurement theory examines how the scores generated by items represent the construct to be measured.[16] The constructs in this study are defined as pelvic floor dysfunction, the degree of bother, and the impact of pelvic floor dysfunction symptoms.

Two well-known measurement theories are used to assess measurement properties of a translated instrument: classical test theory (CTT) and modern test theory (MTT) (e.g. item response theory).[16] CTT is the most commonly used measurement theory to test an instrument such as the PFDI-20 and PFIQ-7. Within the CTT framework, the following measurement properties are essential for assessing the PFDI-20 and PFIQ-7 instruments: reliability, validity, responsiveness, and interpretability.[16]

6.3.1 RELIABILITY

Reliability aims to examine the amount of error, both random and systematic, in a PROM. Reliability (also known as reproducibility, agreement, or consistency) is defined as measurement accuracy.[17,103]

There are several types of reliability when testing measurement properties in translating PROMs: internal consistency, test–retest reliability, and measurement error.[103]

Internal consistency is defined as "the degree of interrelatedness among the items"[103 p.743] and is determined by calculating Cronbach's alpha coefficients of the instrument's summary and subscale scores. Cronbach's alpha values vary between 0 and 1.0, and values greater than 0.70 demonstrate a high correlation between the multiple items in the measurement subscales. A high correlation suggests an adequate internal consistency.[17,115]

Test–retest reliability is defined as "the extent to which scores for patients who have not changed are the same for repeated measurement under several conditions".[103 p.743] Retest intervals vary, but 1- or 2-week intervals are common.[115]

The assumption is that the interval would be short enough for the participant's condition to remain unchanged but long enough to ensure that they would not recall their first

response.[115] The statistical method often employed for analysing test–retest reliability is by calculating intraclass correlation coefficients (ICCs). ICC values vary between 0 and 1.0. The closer a value is to 1.0, the higher the reliability of the instrument in question. Coefficients greater than 0.70 are considered adequate.[115]

Measurement error is also considered an aspect of reliability and can be regarded as the Standard Error of Measurement (SEM).[17] Measurement error is defined as "the systematic and random error of a patient's score that is not attributed to true changes in the construct to be measured".[103(p743)] It is considered acceptable when the Smallest Detectable Change (SDC; 1.96*√2*SEM) is smaller than the Minimal Important Change (MIC).[115] The SEM is calculated as the square root of the error variance of an ANOVA including systematic differences ($SEM_{agreement}$) or ($SEM_{consistency}$).[115]

Another parameter of agreement is the Limits of Agreement (LoA) by Bland and Altman. When assessing the instrument, the SDC or LoA (upper or lower limit, depending on whether the patient's condition should improve or deteriorate) should be smaller than MIC.[115]

6.3.2 VALIDITY

Validity aims to determine whether valid and accurate conclusions can be drawn from the PROM in question.[17,103] Mokkink et al state that validity is "the degree to which an HR-PRO instrument measures the construct(s) it purports to measure" [103(p743)]

The three well-known types of validity, when testing measurement properties in translated PROMs, are **content** and **face validity**, **criterion validity** and **construct validity**.[16]

Content validity is the degree to which an HR-PRO measure or instrument accurately represents all significant items. **Face validity** examines how the instrument measures what it is intended to measure at first glance. Hence, content validity and face validity are closely related.[17,103] As outlined in Chapter 5, face and content validity are examined during pilot testing and expert panel review.

Mokkink et al.[103] and Terwee et al.[115] defined **criterion validity** as the degree to which the scores on an HR questionnaire are an adequate reflection of a gold standard, i.e. external criterion. Criterion validity is seldom applied in HR-PRO research due to the lack of availability of gold standards. HR-PROs often lack a gold standard because they focus on the patient's subjective perceptions and viewpoints.

Finally, Mokkink et al state that **construct validity** is "the degree to which the scores of an HR-PRO instrument are consistent with hypotheses based on the assumption that the HR-PRO instrument validly measures the construct to be measured"[103(p743)] Construct validity is seen as less significant than criterion validity. However, by applying strong theories and specific hypotheses, adequate and substantial evidence can be acquired to confirm that the instrument accurately measures the construct(s) or concept(s) it is intended to measure. There are three aspects of construct validity: hypothesis testing, structural validity, and cross-cultural validity.[103]

Hypothesis testing, detailed in Section 6.4.5, is the most common method used in testing the validity of a translated instrument. COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) contends that the predefined hypotheses should be made regarding direction and magnitude.[16]

Furthermore, at least 75% of the findings should correspond with these hypotheses.[115] The main subcategories of hypothesis testing are convergent and divergent validity. Convergent validity is defined as the degree to which the instrument is correlated with other instruments of similar construct.[16,17] Divergent validity is defined as the degree to which the instrument does not correlate with other instruments of dissimilar construct, i.e. a divergence in scores between dissimilar constructs. Finally, discriminate validity is another subcategory often used to discriminate between different groups of individuals.[16,17] Correlation coefficients are used to estimate the degree by which any two instruments are related to each other. Correlations between similar measures should be high, whereas correlations between dissimilar instruments should be low.[16]

Cross-cultural validity is an important measurement property of a translated HR-PRO instrument. As outlined in Chapters 3, 4, and 5, cross-cultural validity is examined during expert panel review. Furthermore, the validity of the translated and cross-cultural adapted PROM should be confirmed by assessment of its construct validity.[16]

Structure validity (i.e. "the degree to which the scores of an HR-PRO instrument are an adequate reflection of the dimensionality of the construct to be measured"[103(p743)] is another important measurement property of a translated instrument.[16] Structure validity is tested by using factor analysis (confirmatory or exploratory factor analysis) or Item Response Theory.[16] Structure validity is discussed in Chapter 7.

6.3.3 RESPONSIVENESS TO CHANGE

Mokkink et al state that **responsiveness to change** measures longitudinal validity and describes "the ability of an HR-PRO instrument to detect change over time in the construct to be measured".[103(p743)] Similar to construct validity (Section 6.3.2), responsiveness should be measured by testing predefined hypotheses.[103] Furthermore, the instrument should distinguish clinically important change from measurement error. Responsiveness should, therefore, be tested by relating the SDC to the MIC, as described in Section 6.3.3.[115]

Another adequate measure of responsiveness is the area under the receiver operating characteristic (ROC) curve (AUC), which is a measure of the ability of a questionnaire to distinguish patients who have and have not changed according to an external criterion. Terwee et al[115] consider a value of at least 0.70 to be adequate.

6.3.4 INTERPRETABILITY

Interpretability is defined as the degree to which one can give qualitative meaning to quantitative scores.[103,115] Two main methods are used to determine a clinically meaningful interpretation of the HRQOL scores: a distribution-based method (examining distribution scores within a set of data in statistically distinct subgroups) or an anchor-based distribution method (examining the relationship between scores on an instrument and an external measure or anchor).

Floor and ceiling effects

The presence of **floor and ceiling effects** may influence the reliability (lowest and highest score cannot be distinguished from each other), content validity (extreme items are missing in the lower or upper ends of the scale), responsiveness (changes cannot be measured), and interpretability of an instrument. If more than 15% of participants achieve the highest or lowest possible score, then floor and ceiling effects are present.[16,115]

6.3.5 MISSING DATA

Finally, the amount and percentage of **missing data** of the items should be determined. Based on COSMIN recommendations, <3% missing scores is acceptable and >15% is unacceptable.[16] The COSMIN recommendations view the threshold between "acceptable" and "unacceptable" as arbitrary.[16]

6.3.6 SAMPLE SIZE

COSMIN recommends a minimum of 50 participants for every subgroup analysis (test–retest, construct validity, responsiveness, floor and ceiling effects, missing values, and interpretability), except for internal consistency.[115] The recommendation for internal consistency is based on the subject-to-item ratio (4:1 or more) of the measurement scales.[115]

6.3.7 BURDENS AND RISKS

The National Statement[95] and Norwegian Health Research Act[96] state that investigators administering HRQOL questionnaires should consider respondent risks and burden. These considerations include burdens relating to time and effort taken, and the risks associated with the level of comprehension, personal issues, and confidentiality. These issues are comprehensively outlined in Section 5.2.1.

6.3.8 ETHICAL MATTERS — CONFIDENTIALITY AND ANONYMITY ASSURANCES

As outlined in Section 5.2.1, The Australian National Statement on Ethical Conduct in Human Research[95] (The National Statement) and Australian and Norwegian Health Research Law state that several ethical issues must be considered when approaching participants for a study. These ethical issues include confidentiality, free and informed consent, and individual autonomy.[95]

6.3.9 PARTICIPANT CONTROL OF DATA USE

As outlined in Sections 5.2.1 and 5.2.2, Australian and Norwegian regulations on privacy, anonymity, confidentiality issues, and safe storage of identifiable and de-identified data should be adhered to during a study.[95,96]

6.4 METHOD: TESTING MEASUREMENT PROPERTIES

6.4.1 RESEARCH DESIGN (STAGE 3 AND 4)

This part of the study (Stages 3 and 4) was conducted within quantitative research, testing measurement properties of the PFDI-20 and PFIQ-7 questionnaires (Appendices 5.5 and 6.4) in Norwegian women experiencing pelvic organ prolapse and pelvic floor dysfunction.

Measurement properties were employed to examine psychometric characteristics of PROMs PFDI-20 and PFIQ-7 and to assess how the scores generated by the items represented the

construct to be measured.[16] The construct to be measured was defined as pelvic floor dysfunction and the presence, degree of bother and impact of symptoms. The PFDI-20 and PFIQ-7 summaries and subscales are designed to measure the same construct by using multiple items.

The application of statistical techniques outlined in Section 6.3 was used to test the measurement properties (reliability, validity, responsiveness) and interpretability of the PFDI-20 and PFIQ-7 questionnaires (Intermediate Version 3.0). In addition, measurement error, floor and ceiling effects, and missing data were assessed. Furthermore, the Norwegian SF-36v2®[116] was employed as a reference scale for construct validity.

6.4.2 RECRUITING PATIENTS/PARTICIPANTS

Participants for Stages 3 and 4 were patients recruited through the Department of Obstetrics and Gynaecology of the Akershus University Hospital, Norway, from June 2014 to September 2015. Two cohorts were included: those with POP (non-surgical patients), and those undergoing surgery for POP (surgical patients) (Table 6.1). The inclusion criterion for non-surgical patients was symptomatic POP (with or without urinary or bowel dysfunction) referred to the outpatient department. The inclusion criterion for surgical patients was undergoing vaginal repair for symptomatic POP with an anatomic POP Stage 2–4, according to the POP quantification system (POP-Q system).[29] Exclusion criteria were age less than 18 years, an inability to understand Norwegian and/or complete a PRO questionnaire, and visual impairment.

The health secretaries/nurses introduced the patient to the study using a verbal script in Norwegian after consultation with both non-surgical patients and surgical patients. The verbal scripts in English and Norwegian for non-surgical and surgical patients are given in Appendices 6.2a, 6.2b, 6.3a, and 6.3b. Non-surgical and surgical patients were provided with written information in Norwegian (letter of introduction, information sheet, HRQOL questionnaires (Intermediate Version 3.0 and SF-36), and health information forms describing the nature of the study and informing them that participation was voluntary. Surgical patients were asked to fill in the clinical health information forms and HRQOL questionnaires before undergoing vaginal repair. The patients indicated their willingness by first giving their verbal consent and then signing a consent form. After completion of the consent form, the participant proceeded to complete the clinical health information forms

and HRQOL questionnaires in Norwegian. Recruitment continued until the minimum recommendation of participants for every subgroup analysis was fulfilled.

The letter of introduction and information sheet explained the background and purpose of the study, what the study entailed, patient anonymity in the study, and potential advantages and disadvantages. The letters also stated that participation in the study was voluntary and that participants could withdraw from the study at any time without explanation. A withdrawal would have no further consequences for their treatment.

The completion of the clinical health information forms and HRQOL questionnaires took place on the same day as the consultation for the baseline target population (non-surgery and surgery patients). If the participants declined to participate in the study, they were thanked for considering the request.

The letter of introduction, information sheets, clinical health information forms, HRQOL questionnaires (Intermediate Version 3.0), and consent forms for non-surgical and surgical patients in English and Norwegian are given in Appendices 5.5, 6.1a-f, 6.2c–f, and 6.3c–f.

Sample size

The sample size was based on COSMIN recommendations of a minimum of 50 participants for every subgroup analysis (test–retest, construct validity, responsiveness, floor and ceiling effects, missing values, and interpretability) except for internal consistency.[115] The sample size for internal consistency (minimum 108 participants) was based on the subject-to-item ratio (4:1 or more) of the PFDI-20 and PFIQ-7 scales.[115]

6.4.3 ADMINISTERING THE TRANSLATED QUESTIONNAIRES AND DATA COLLECTION

The participants completed the PFDI-20, PFIQ-7, and SF-36v2® Norwegian Health Survey (SF36)[116] at two time-points: baseline (T0) and 1–3 weeks later (T1). This interval was chosen on the assumption that it would be short enough for the participants' POP condition to remain unchanged, but long enough to ensure that they would not recall T0 responses. Patients scheduled for POP surgery also completed the questionnaires six months post-surgery (T2). At T0, participants provided sociodemographic (age, sex, births), body mass index (BMI), and previous surgery data as sample descriptors. A POP examination (POP-Q) was performed at both T0 and T2. Figure 6.1 displays the study's patient flow.

The clinical and sociodemographic data are also given in Table 6.1. Notably, surgical and non-surgical participants did not differ significantly in sample characteristics and summary statistics for key study variables (Table 6.1).

6.4.4 MEASUREMENT INSTRUMENTS

PFDI-20

As outlined in Chapter 2 (Section 2.4.8), the 20-item PFDI-20 has three subscales: Urinary Distress Inventory (UDI-6), POP Distress Inventory (POPDI-6), and Colorectal-Anal Distress Inventory (CRADI-8). The total score is converted to a range from 0 to 300, while the subscales are scored from 0 to 100. In all cases, higher scores equate to greater distress.[11]

PFIQ-7

As outlined in Chapter 2 (Section 2.4.8), the 7-item PFIQ-7 has three subscales: Urinary Impact Questionnaire (UIQ-7), POP Impact Questionnaire (POPIQ-7), and Colorectal-Anal Impact Questionnaire (CRAIQ-7).[11] Again, the total score is converted to yield a range from 0 to 300 (subscales 0–100). Higher scores indicate greater symptom distress and impact on patient HRQOL.[11] The English version and Norwegian translations (Intermediate Version 3.0) of the measurement instruments PFDI-20 and PFIQ-7 are given in Appendices 3.1 and 5.5.

SF36

The SF36 is a multipurpose generic health outcome measure comprising 36 items. It consists of an eight-scale profile of functional health and well-being, as well as two psychometrically based measures: Physical Component Summary (PCS) and Mental Health Component Summary (MCS). For the current study, only the PCS and MCS scores are reported. In both cases, lower scores are indicative of poorer health.[116] The Norwegian SF-36v2®[116] was employed as a reference scale for construct validity.

Global change scale

At retest (T1), participants were asked in Norwegian if their condition had changed during the interim period[16] with the question, “Compared to the first time you completed the questionnaires, has your vaginal prolapse condition changed?” If they responded ‘yes’, women were excluded from the retest. The English and Norwegian translations of the Global change scale are given in Appendices 6.1e and 6.1f.

Global response scale

At T2, participants were also asked in Norwegian, "In general, how much did the treatment improve your ?" The Global Rating of Change (GRC) was used to establish a patient-based anchor. A six-point response scale ranged from 'improved significantly' to 'no significant improvement'.[16] This anchor was used to distinguish women who had 'importantly improved' after surgery from those that had 'not importantly changed'.[21] The English and Norwegian translations of the GRC are given in Appendices 6.1b and 6.1d.

6.4.5 STATISTICAL METHODS AND DATA ANALYSIS

All analyses were conducted using SPSS (Version 22.0). Statistical significance was assumed at $p<0.05$. COSMIN recommendations and definitions (outlined in Sections 6.3.1–6.3.5) were used as a guide for evaluating the statistical properties of the Norwegian PFDI-20 and PFIQ-7.[91]

The evaluation of statistical properties of the Norwegian PFDI-20 and PFIQ-7 included floor and ceiling effects, missing data, reliability (internal consistency and test–retest), measurement error, validity (construct validity), and responsiveness. In addition, interpretability was assessed.

First, **floor and ceiling effects** were examined and considered problematic if more than 15% of participants achieved the highest or lowest possible score.[16,115]

Item-level **missing data** was also noted. Based on COSMIN recommendations, <3% is acceptable, with >15% considered unacceptable.[16,115]

Cronbach's alpha was calculated for PFDI-20 and PFIQ-7 scores as a measurement of **internal consistency**. Adequate internal consistency is considered to be a value of 0.70 or higher.[115]

Test–retest reliability the degree to which measurement scores for patients who have not changed are the same when repeated over time)[103] was evaluated using intraclass correlation coefficients (ICCs) to quantify agreement between PFDI-20 and PFIQ-7 scores, respectively.[91,115] ICCs were calculated according to McGraw and Wong.[115] Coefficients of at least 0.70 are considered adequate.[91,17,115]

Measurement error (the systematic and/or arbitrary error of a score that cannot be credited to true changes in the construct or concept to be measured)[103] was also assessed. It is

considered acceptable when the smallest detectable change (SDC; 1.96*√2*SEM) is smaller than the minimal important change (MIC).[115] The standard error of measurement (SEM) was calculated as the square root of the error variance of an ANOVA including systematic differences ($SEM_{agreement}$).[115]

Construct validity was assessed by testing eight hypotheses expressed in terms of the expected direction and magnitude of the effect. Correlations were calculated between the PFDI-20 and PFIQ-7 scores and the SF36 at baseline.[16] Both convergent and divergent validity were tested.[16] The expectation was that correlations between related constructs would be high, while those between unrelated constructs would be low or non-existent.[16] Coefficients were arbitrarily considered low (<0.30), moderate (0.30–0.59), or high (≥0.60).

Responsive to change (the ability to notice change over a period of time in the construct being measured[103]) of the PFDI-20 and PFIQ-7 was assessed by addressing the five hypotheses. These were tested by correlating change scores of the PFDI-20 and PFIQ-7 with change scores of the SF36.[16]

Each questionnaire was considered responsive if at least 75% of the relevant hypotheses were supported.[115] It was expected that correlations among related constructs would be higher than among unrelated constructs.[16] Compared to the PFDI-20 and PFIQ-7, the SF36 should be relatively unresponsive to change in women undergoing POP surgery.[11] Furthermore, Receiver Operating Characteristic (ROC) curves were constructed, and Area Under the Curve (AUC) calculated.[16] Change scores were calculated between T0 and T2. After surgery, patients who reported being 'much improved' or 'greatly improved' in response to the GRC[54,69] were classified as 'improved significantly' while those who reported 'little improvement' or 'no change' were classified as 'no significant improvement'.[16] Women who reported deterioration in the GRC were excluded from responsiveness analyses. The PFDI-20 and PFIQ-7 were considered responsive to change if AUC values exceeded 0.70.[16]

The MIC (smallest change perceived as important), a measure of the **interpretability of change scores**, was also calculated.[16] This value was determined using the anchor-based MIC distribution, with the ROC approach.[16] Optimal ROC cut-off points were identified by examining the value for which the sum of the proportions of misclassification (1 – sensitivity) + (1 – specificity) was smallest.[61] MIC has to be bigger than the SDC for change to be distinguishable from measurement error. Interpretation of change scores was tested using

an anchor-based MIC distribution method to assess which changes from PFDI-20 and PFIQ-7 total scores corresponded with MIC defined on the anchor (i.e. GRC). This approach distinguished patients who had 'improved significantly' after surgery from those who had 'no significant improvement'.[16]

6.4.6 BURDENS AND RISKS

As outlined in Section 6.3.7, respondent and administration burdens were taken into consideration during Stages 3 and 4 of this study.

Compensation was not given to baseline and 6-month follow-up subgroups because the participants' completion of the questionnaires corresponded with the outpatient visit.[95,96] However, compensation was given to the test–retest subgroup because the participants' completion of the questionnaires and interviews did not correspond with their outpatient visit.[95,96] Hence, to minimise the burden on patients participating in the test–retest part of the study, those who returned to the clinic for retest were compensated for travel and/or parking expenses.[95,96]

To minimise the burden on and be respectful of the department's routines, the principal researcher employed two research nurses to identify potential study participants (non-surgery and surgery) and coordinate the recruitment process.

6.4.7 ETHICAL ISSUES

As outlined in Section 6.3.8, confidentiality, free and informed consent, and individual autonomy issues were considered when planning and administering this research project (Appendix 3.4).[95] Participation was voluntary, with all potential participants assured that their decision would have no consequences for their treatment.[95,96] Informed consent was obtained from all participants. Coercion issues in this study were addressed by involving health secretaries/nurses to recruit the research participants.[95,96]

6.4.8 PARTICIPANT CONTROL OF DATA USE

Data collection, de-identification, and data storage practices followed relevant directives, as outlined in Section 6.3.9. All consent forms and questionnaires filled in by the participants were retained and not made available for general view. The questionnaires given to the selected patients were indexed. Only the principal researcher, supervisors, and project coordinators had access to the lists of names and thus the ability to identify the participants.

Assurances were provided to the participants that safe storage of identifiable and de-identified data would be maintained throughout the study. According to the European Union directive 95/96EF guidelines, identifiable data was stored exclusively at the Akershus University Hospital and not permitted to leave the European Union.[96]

6.4.9 CONCLUSION

Stages 3 and 4 of the study tested and evaluated the measurement properties of the Norwegian PFDI-20 and PFIQ-7 final cross-cultural adapted versions (Intermediate Version 3.0) by reliability, validity, and responsiveness in a prospective longitudinal study of women with POP and pelvic floor dysfunction in a tertiary hospital setting. In addition, floor and ceiling effects, the percentage of missing items, measurement error, and interpretability were assessed.

6.5 RESULTS: MEASUREMENT PROPERTIES

This section presents the evaluation and findings of missing data, measurement properties, measurement error, and interpretability of the Norwegian PFDI-20 and PFIQ-7.

6.5.1 ADMINISTERING THE TRANSLATED QUESTIONNAIRES AND DATA COLLECTION

One month before the start of Stages 3 and 4, all healthcare personnel at the department were informed through email and departmental meetings. A poster, with details of the study, was placed in the outpatient clinic for the duration of the study.

Two research nurses were employed to identify potential study participants (non-surgery and surgery) and coordinate the recruitment process. The health secretaries/nurses introduced the patient to the study using a verbal script. Participants were provided with written information and indicated their willingness by first giving their verbal consent and then signing a consent form. All interviews took place on the same day as the consultation for non-surgery and surgery patients.

6.5.2 RECRUITING PARTICIPANTS AND SELECTING THE TARGET POPULATION

There were 716 consecutive referrals to the outpatient clinic for POP during the study period. Of these, 424 (58%) did not fulfil the inclusion criteria or declined to participate. A further 80 (13%) were not invited to participate for logistical reasons, leaving 212 (29%) eligible women who consented to participate (Figure 6.1). Logistical reasons included: the

nursing staff not having sufficient time to invite patients to participate or the nursing staff forgetting to extend invitations to patients to participate in the study.

Of the 212 eligible women, 205 completed the questionnaires (PFDI-20 or PFIQ-7 or SF36) at T0. The response rate was excellent at 96.7%. A subsample of 56 (27.3%) completed questionnaires at T1. Of the 96 women undergoing surgery, 76 (79.1%) completed questionnaires at T2. The retest evaluation (T1) was completed a median of 11 days (range 6–21) after T0. Six T1 patients indicated a change in symptoms and severity of their POP and were not considered further for the study (Figure 6.1). The T2 evaluation was completed a median of 184 days (range 153–189) after T0.

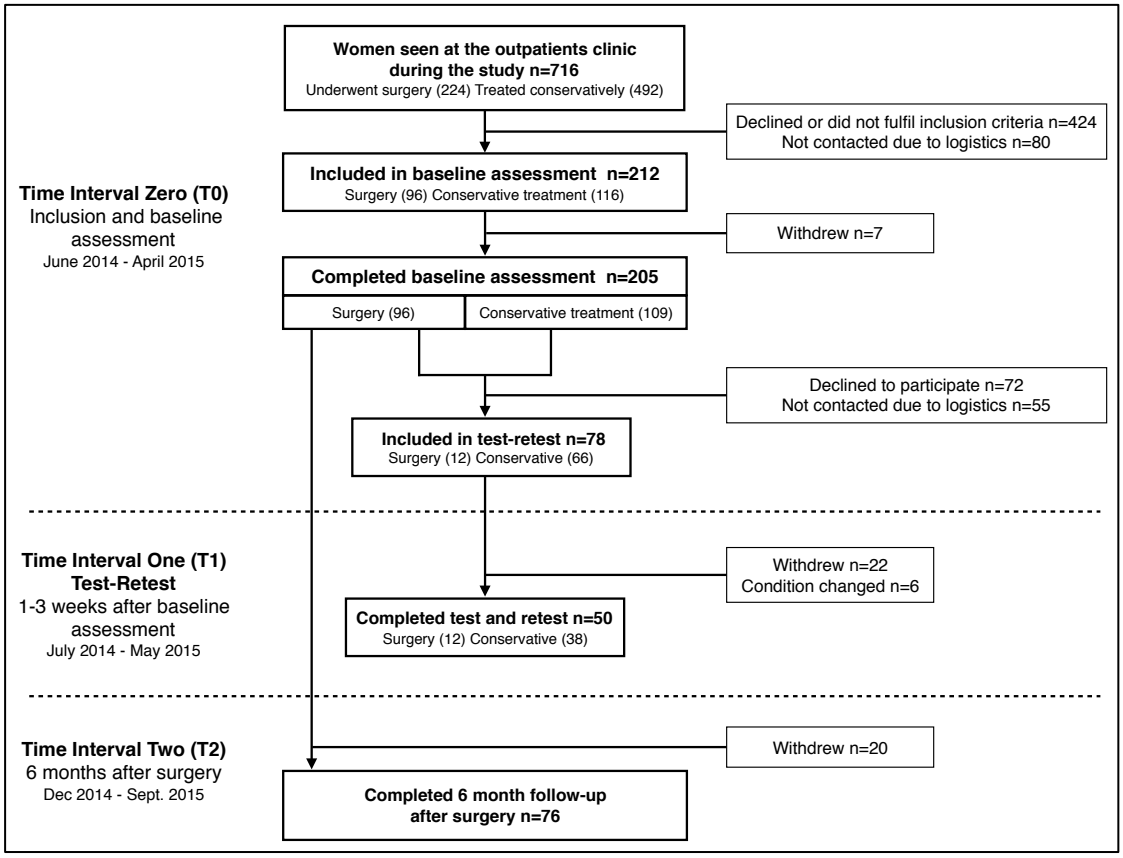

FIGURE 6.1. FLOWCHART OF PATIENT RECRUITMENT AND PARTICIPATION

TABLE 6.1. BASELINE CHARACTERISTICS OF PARTICIPANTS AND SUMMARY STATISTICS FOR KEY STUDY VARIABLES.

	Total sample *(N = 205)*	Non-surgical participants *(N = 109)*	Surgical participants *(N = 96)*
Body mass index (kg/m^2), median (range)	26 (17–45)	25 (17–45)	27 (18–45)
Parity, median (range)	2 (1–8)	2 (1–8)	2 (1–7)
POP-Q stage, *n* (%)			
1	7 (3.4%)	3 (3.1%)	4 (3.7%)
2	83 (40.5%)	40 (41.7%)	43 (39.4%)
3	77 (37.6%)	35 (36.5%)	42 (38.5%)
4	8 (3.9%)	3 (3.1%)	5 (4.6%)
Category of POP Stage 2–4, *n* (%)[a]			
Cystocele (anterior compartment)	154 (75.1%)	76 (79.2%)	78 (71.6%)
Rectocele (posterior compartment)	111 (54.1%)	53 (55.2%)	58 (53.2%)
Apical prolapse (middle compartment)	32 (15.6%)	13 (13.5%)	19 (17.4%)
Previous pelvic reconstructive surgery, *n* (%)	41 (20.0%)	19 (19.8%)	22 (20.2%)
Previous hysterectomy, *n* (%)	43 (21.0%)	21 (21.9%)	22 (20.2%)
Surgical procedure (n = 76), *n* (%)[b]			
Anterior colporrhaphy	42 (55.3%)		42 (55.3%)
Posterior colporrhaphy	22 (28.9%)		22 (28.9%)
Manchester operation	3 (3.9%)		3 (3.9%)
Vaginal hysterectomy	17 (22.4%)		17 (22.4%)
Sacrospinous fixation	2 (2.6%)		2 (2.6%)
Isolated amputation of the cervix	4 (5.3%)		4 (5.3%)
Enterocele operation	1 (1.3%)		1 (1.3%)
Questionnaire scores, mean (SD)			
PFDI-20	107.7 (54.3)	106.3 (55.2)	108.9 (54.2)
POPDI-6	45.5 (22.3)	47.7 (23.5)	43.5 (22.4)
CRADI-8	24.9 (18.9)	25.7 (20.1)	24.2 (19.8)
UDI-6	37.4 (24.6)	36.1 (25.3)	38.6 (24.9)
PFIQ-7	60.9 (53.8)	59.2 (55.2)	62.4 (54.7)
UIQ-7	25.4 (23.2)	26.2 (24.1)	24.7 (23.9)
CRAIQ-7	14.2 (19.8)	12.1 (20.3)	16.1(20.1)
POPIQ-7	21.2 (22.4)	21.6 (23.1)	20.8 (22.9)

[a] Several patients had POP in more than one compartment. The highest stage reported in any compartment is recorded.

[b] Several patients underwent more than one surgical procedure.

The median age of the sample was 61 years (range 27–82 years). The majority with POP were at POP-Q Stage 2 or 3. Anterior compartment prolapse was the most common type of POP. Several had POP in more than one compartment. Women who were treated surgically underwent vaginal repair only. Anterior and posterior compartment repair were the most common procedures (Table 6.1). A total of 172 patients (83.9%) completing the PFDI-20 reported symptoms from all three pelvic floor dysfunction domains, while 27 (13.2%) noted symptoms from two pelvic floor dysfunction domains, and 6 (2.9%) reported symptoms from only one domain. All 205 patients completing the PFDI-20 reported symptoms of POP[a], 192 (94%) patients reported lower urinary tract symptoms[b], and 184 (88%) patients reported bowel symptoms[c].

6.5.3 EVALUATION OF MEASUREMENT PROPERTIES

The statistical techniques outlined in Section 6.3 were applied to test and evaluate floor and ceiling effects, missing data, internal consistency reliability, test–retest reliability, measurement error, construct validity, responsiveness, and interpretability of the PFDI-20 and PFIQ-7 questionnaires.

No **floor or ceiling effects** were found in the PFDI-20 and PFIQ-7 total score distributions (Table 6.2). Similarly, no ceiling effect was observed in any of the PFDI-20 or PFIQ-7 subscales. The UQI-7 subscale (19.5%) showed a small floor effect. Notably, major floor effects were found in the POPIQ-7 (26%) and CRAIQ-7 (47%) subscales (Table 6.2).

TABLE 6.2. FLOOR AND CEILING EFFECTS OF BASELINE SCORES

Measurement instrument	Score range	Floor, *n* (%)	Ceiling *n* (%)
PFDI-20	0–300	0 (0)	0 (0)
POPDI-6	0–100	0 (0)	14 (7)
CRADI-8	0–100	1 (0.5)	6 (3)
UDI-6	0–100	0 (0)	14 (7)
PFIQ-7	0–300	14 (7)	0 (0)
POPIQ-7	0–100	52 (26)	0 (0)
CRAIQ-7	0–100	94 (47)	0 (0)
UQI-7	0–100	39 (19.5)	0 (0)

[a] based on a sensation of a bulge in the pelvic area (i.e. PFDI-20)
[b] based on lower urinary tract symptoms (i.e. PFDI-20)
[c] based on bowel symptoms (i.e. PFDI-20)

Missing data at baseline reflected only 0.82% of PFDI-20 items and 1.92% of PFIQ-7 items. Cronbach's alpha coefficients for the PFDI-20 and PFIQ-7 total scores were 0.83 and 0.93, respectively, demonstrating very satisfactory **internal consistency**. Similarly, subscale coefficients (Table 6.3) were generally satisfactory to excellent, except for POPDI-6 (0.66). In all cases, for both scales, **test–retest** ICC values (Table 6.3) indicated adequate reliability ($p<0.001$ for all coefficients). The **Smallest detectable change** (SDC) at the individual level constituted 16.7 (16.7%) to 26.3 (26.3%) for the PFDI-20 subscales (range 0–100), whereas the SDC was 46.1 for the PFDI-20 total score (range 0–300) or a relative SDC of 15.3% of the total score. For the PFIQ-7, the SDCs were slightly larger. SDC constituted 26.1 (26.1%) to 27.2 (27.2%) for the PFIQ-7 subscales (range 0–100), whereas the SDC was 62.1 for the PFIQ-7 total score (range 0–300) or a relative SDC of 20.7% of the total score (Table 6.3).

TABLE 6.3. INTERNAL CONSISTENCY AND TEST–RETEST STATISTICS

Measurement instrument	α*	Reliability		Change in score		
		Intraclass correlation coefficient	95% confidence interval	Mean (SD)	Standard error of measurement (%)	Smallest detectable change (%)
PFDI-20	0.83	0.944	0.897–0.969	12.3 (23.5)	16.7 (5.6)	46.1 (15.3)
POPDI-6	0.66	0.895	0.807–0.943	4.2 (13.4)	9.5 (9.5)	26.3 (26.3)
CRADI-8	0.72	0.938	0.887–0.966	6.0 (8.5)	6.0 (6.0)	16.7 (16.7)
UDI-6	0.71	0.918	0.849–0.955	2.2 (11.5)	8.1 (8.1)	22.5 (22.5)
PFIQ-7	0.93	0.899	0.821–0.943	13.0 (31.7)	22.4 (7.5)	62.1 (20.7)
POPIQ-7	0.88	0.891	0.807–0.938	4.8 (13.6)	9.6 (9.6)	26.7 (26.7)
CRAIQ-7	0.91	0.852	0.737–0.916	3.8 (13.9)	9.8 (9.8)	27.2 (27.2)
UIQ-7	0.88	0.903	0.827–0.945	4.5 (13.3)	9.4 (9.4)	26.1 (26.1)

*α = Cronbach's alpha coefficients

Construct validity was determined to be adequate, with 88% (7 of 8) of predefined hypotheses confirmed (Table 6.4). The exception was the association between POPDI and POPIQ-7 (0.58), which was only a moderate positive correlation. In all other cases, as hypothesised, measures of the same construct provided high positive correlations. In addition, scales measuring similar, but not equivalent, constructs provided moderate correlations, and scales measuring unrelated constructs demonstrated a low correlation (Table 6.4).

TABLE 6.4. CONFIRMATION OR REJECTION OF BASELINE HYPOTHESES

Hypothesis tested		R^d	Confirmed?
Correlation expected	Between		
High positive[a]	1. PFDI-20 and PFIQ-7 total scores	0.75	Yes
	2. PFDI-20 POPDI and the PFIQ-7 POPIQ-7	0.58	No
	3. PFDI-20 CRADI-8 and the PFIQ-7 CRADIQ-7	0.68	Yes
	4. PFDI-20 UDI-6 and the PFIQ-7 UDIQ-7	0.76	Yes
Moderate negative[b]	5. PFDI-20 total score and SF36 PCS	–0.33	Yes
	6. PFIQ-7 total score and SF36 MCS	–0.33	Yes
	7. PFIQ-7 total score and SF36 PCS	–0.44	Yes
Low[c]:	8. PFDI-20 total score and SF36 MCS	0.22	Yes

MCS, Mental health component summary score; PCS, Physical component summary score.

[a] PFDI-20 and PFIQ-7 measure the same construct

[b] PFDI-20 and PFIQ-7 subscales and the SF36 MCS/PCS components appear to measure similar but not equivalent constructs [7]

[c] PFDI-20 and SF36 MCS do not appear to measure similar constructs [7]

[d] Correlation coefficient (*r*)

Adequate **responsiveness** was achieved with 100% (5 of 5) of the predefined hypotheses confirmed (Table 6.5). Change scores measuring the same construct provided high positive correlations. Those measuring similar but not equivalent constructs demonstrated moderate negative correlations, while those measuring unrelated constructs provided a low correlation. Responsiveness to change for the PFDI-20 was further supported with AUC values ≥0.70, whereas the AUC estimates were lower for PFIQ-7 (Table 6.5).

The MIC for the PFDI-20 total score (0–300) was 48, which was slightly larger than the SDC (Table 6.6: 46.01). This finding suggests that an improvement score of ≥48 points on the PFDI-20 can be regarded as a clinically relevant change. Patients who 'improved significantly' on the GRC 6 months after surgery achieved a mean change of 63, thus demonstrating clinically relevant improvement. The absolute value of MIC for the PFIQ-7 total score (0–300) was 47, which was smaller than the SDC (Table 6.6: 62.1). Hence, a score of ≤47 points cannot be considered a clinically relevant improvement. Although patients may consider such a change important, it cannot be distinguished from measurement error.

TABLE 6.5. CONFIRMATION OR REJECTION OF RESPONSIVENESS HYPOTHESES

Hypothesis tested		r[d]	Confirmed?
Correlation expected	Between		
High positive[a]	1. PFDI-20 and PFIQ-7 total change scores	0.65	Yes
Moderate negative[b]	2. PFDI-20 total and SF36 PCS change scores	–0.42	Yes
	3. PFIQ-7 total and SF36 PCS change scores	–0.34	Yes
Low[c]	4. PFDI-20 total and SF36 MCS change scores	0.15	Yes
	5. PFIQ-7 total and SF36 MCS change scores	0.14	Yes

MCS, Mental health component summary score. PCD, Physical component summary score

[a] PFDI-20 and PFIQ-7 measure the same construct[4,5]

[b] PFDI-20 and PFIQ-7 appear to measure similar but not equal constructs to the SF36 PCS component[4,5]

[c] PFDI-20 and SF36 MCS do not appear to measure similar constructs[4,5]

[d] Correlation coefficient (*r*)

TABLE 6.6. RESPONSIVENESS AND INTERPRETABILITY OF THE PFDI-20 AND PFIQ-7 IN TERMS OF THE CHANGES IN TOTAL SCORES FROM T0 TO T1 IN 76 WOMEN COMPLETING THE 6-MONTH FOLLOW-UP (T2)

Global rating of change	Number of women (%)	Change in score, mean (SD)[a]	
		PFDI-20	PFIQ-7
Improved significantly	66 (89%)	–63 (44.2)	–49 (50.5)
No significant improvement	8 (11%)	–0.4 (66.7)	–36 (53.1)
Missing cases	2 (0.3%)	–	–
AUC (95% CI)		0.74 (0.600; 0.928)	0.586 (0.345; 0.826)
p-value		0.035	0.459
MIC		–48	–47
Sensitivity/specificity for MIC estimate		0.839/0.701	0.763/0.672

MIC, Minimal Important Change

[a] PFDI-20 and PFIQ-7 total score range (0–300). Negative scores indicate a reduction in distress and/or impact of symptoms.

6.5.4 SUMMARY

A total of 205 Norwegian women with POP (with or without urinary or bowel dysfunction) and with Pelvic Organ Prolapse Quantification (POP-Q; stages 1–4) completed the questionnaires; 50 completed them again after 1 to 3 weeks, and 76 completed them again 6 months later. The sociodemographic characteristics of the sample interviewed were typical and in accordance with those expected from the hospital population.

The measurement properties' reliability, validity, and responsiveness were tested and reported. Additionally, floor and ceiling effects, interpretability, and percentage of missing items were reported. The translated PFDI-20 and PFIQ-7 questionnaires provided adequate

reliability, validity, and good responsiveness to change. The PFDI-20 captured change better than the PFIQ-7.

6.5.5 CONCLUSION

Testing of measurement properties and interpretability of the Norwegian PFDI-20 and PFIQ-7 were undertaken during Stages 3 and 4 of this study. This process provided evidence that the translated questionnaires (Appendix 6.4) demonstrated adequate reliability, validity, and good responsiveness to change among women with POP and pelvic floor dysfunction in a tertiary hospital setting.

6.6 DISCUSSION

6.6.1 SUMMARY OF MAIN RESULTS

As outlined in Section 6.5, a total of 205 Norwegian women completed the initial questionnaires (T0), with 50 completing them again after 1 to 3 weeks (T1), and 76 a further six months after surgery (T2). No floor or ceiling effects were revealed. Cronbach's alpha ranged from 0.66 to 0.93, and ICCs ranged from 0.85 to 0.94. Construct validity was adequate with more than 75% of predefined hypotheses confirmed. Responsiveness was adequate with all predefined hypotheses confirmed. Furthermore, adequate responsiveness was supported for PFDI-20 with AUC >0.70, but AUC estimates were lower for PFIQ-7. The smallest detectable change at the individual level constituted 15–21% and 17–27% of the total scores and subscales, respectively.

The absolute values of MIC for the PFDI-20 total score (0–300) and PFIQ-7 total score (0–300) were 48 and 47, respectively. In conclusion, the translated questionnaires provided adequate reliability, validity, and good responsiveness to change.

During Stages 3 and 4 of the study, some significant findings and issues arose while testing measurement properties and interpretability. Deviations, strengths and limitations, respondent and administration burdens, ethical issues, and data control issues were among several aspects considered during this part of the study.

6.6.2 TESTING MEASUREMENT PROPERTIES

In accordance with prediction,[11] all retest assessments for the PFDI-20 and PFIQ-7 provided adequate reliability. In general, internal consistency was at least acceptable. The exception

was the POPDI-6, with an internal consistency that was less than desirable (0.66). Of note is that other cross-cultural adapted versions report a similar issue for the POPDI-6.[52,61]

Responsiveness was high for PFDI-20 and moderate for PFIQ-7. Hence, PFDI-20 captured change better than PFIQ-7. During sensitivity analysis using the ROC method, GRS was dichotomised as 'improved slightly/much improved' and 'improved greatly'.[16] This overall dichotomisation revealed similar responsiveness results for the PFDI-20 and PFIQ-7. In addition, the results for the PFDI-20 were similar to those from a Danish translation study, which also noted appropriate responsiveness to change.[63]

In this study, the Global Rating of Change might be seen as not measuring the same construct as the PFDI-20 and the PFIQ-7 scales. However, Gelhorn et al[69] reported that the Global Rating of Change (referred to as Patent Global Impression of Change) is considered a sound external criterion of change for the PFDI-20 and PFIQ-7 scales.

6.6.3 INTERPRETABILITY

PFDI-20 demonstrated MIC points of 48, which is similar to the minimally clinically important difference (MCID) of 45 points reported by Barber et al.[11] The PFDI-20 can detect clinically relevant improvement, but the measurement error of PFIQ-7 was too large to do so. The Dutch studies found similar results with both the PFDI-20 and PFIQ-7.[61]

As seen in Swedish, Dutch, Brazilian, and Finnish studies,[52,61,117,118] no ceiling effects were observed for total or subscale scores of these measures. However, since floor effects were found in the PFIQ-7, POPIQ, and CRAIQ-7, it is suggested that in the case of the PFIQ-7, interpretation should consider both total scores and subscales. This recommendation supports the findings of similar floor effects in Dutch, Brazilian, and Polish studies.[61,117,119] In these cases, the authors pointed out that patients can experience various types of pelvic floor dysfunction but might not experience all associated symptoms (e.g. POP and defecation problems without UI).[61]

6.6.4 DEVIATIONS

No major deviations from the standard protocol occurred.

6.6.5 STRENGTHS AND LIMITATIONS

The strengths of Stages 3 and 4 of this study included the extensive quantitative evaluation of measurement properties including reliability, validity, responsiveness, and interpretability in a homogeneous sample population in a tertiary setting. The sociodemographic characteristics of the patients interviewed were typical 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 questionnaires without difficulty. The adequate sample size (i.e. consecutive referrals to the tertiary hospital) in Stages 3 and 4 were considered representative, even though the response rate for the baseline questionnaire was low with 212/716 (30%) eligible women consenting to participate. Of those, 205 completed the questionnaires, and the response rate of 96.7% was considered excellent.

Furthermore, the adequate sample size for the surgery subgroup was considered representative, with 96/205 (46.8%) completed questionnaires at T1.

The response rate for the subgroups was considered excellent with 76/96 (79.2%) completing T2. The adequate sample size for the test–retest subgroup was considered representative, even though the subsample group of 56/205 (27.3%) completed questionnaires at T1. The response rate for the subgroup was considered good with 56/78 (71.8%) completing T1.

The comparatively large sample size recruited in this part of the study (Stages 3 and 4) was considered a strength. It produced an adequate set of data for testing and validating measurement properties and interpretability of the questionnaire items.

Of note, all recruitment of patients for Stages 3 and 4 of this study was undertaken in a tertiary hospital. This factor may have resulted in bias, affecting generalizability to the target population. That is, recruited patients potentially represented those with moderate to severe and numerous symptoms (most patients were POP-Q Stage 2–3, with 83.9% who completed the PFDI-20 reporting three pelvic floor dysfunction symptoms). In addition, validation data was collected only within a tertiary setting, also limiting generalizability. Further validation studies in other contexts are recommended.

Some caveats regarding the interpretation of the current results should be acknowledged. First, a limitation was the recruitment of only women with symptomatic POP (with or without urinary or bowel dysfunction). Thus, women with only urinary or bowel dysfunctions were not recruited. However, both urinary and bowel dysfunctions were highly frequent in the total sample, with only 6 (2.9%) participants reporting having POP exclusively. Further recommendations include responsiveness testing for conservative treatment and establishing confirmatory factor analysis and clinically meaningful interpretations of PFDI-20 and PFIQ-7 total scores and subscales.

Although education levels of respondents were reported in other PFDI-20 and PFIQ-7 translation and validation studies,[117-120] education baseline characteristics were not included in this study. Hence, the study could not demonstrate if Norwegian PFDI-20 and PFIQ-7 questionnaires were comprehensible for all levels of education.

Furthermore, during the pilot test, sexuality was an aspect identified as important to patients but not covered in PFDI-20 and PFIQ-7.

Finally, validation of electronic administration versions of the PFDI-20 and PFIQ-7 is also recommended in clinical and research settings.[43] Web-based questionnaires in the United States are used as alternative or complementary modes of administration and data collection. Studies have shown that responses to web-based questionnaires are similar and comparable to responses yielded by conventional (i.e. paper-based) modes of administration [121] in terms of age, level of education, and familiarity with computers.[43] Web-based questionnaires also can reduce the time and costs of collecting HRQOL data, improve data quality, and reduce errors during the data entry process.[43,122]

6.6.6 BURDENS AND RISKS

Respondent burdens and risks during the pilot test

As outlined in Sections 6.3.7 and 6.4.6, Australian and Norwegian regulations on the respondent and administrative burdens and risks during Stages 3 and 4 were adhered to during the study.[95,96]

Of note, a small percentage of patients consented to take part in the test–retest hospital appointments (56/205; 27%). The respondent burden for those participants (i.e. attending a face-to-face meeting) was considered attributable to the lower consent rate of the test–

retest part of the study. This respondent burden could have been foreseen and postal administration would be recommended for future validation studies.

6.6.7 ETHICAL ISSUES

The study was designed to comply with relevant regulations as set forth by Norwegian and Australian health authorities[95,96] pertaining to anonymity, individual autonomy, informed consent, and coercion issues (Sections 6.4.7). No major ethical issues arose during the pilot test.

6.6.8 PARTICIPANT CONTROL OF DATA USE

As outlined in Section 6.4.8, Australian and Norwegian regulations on privacy, anonymity, confidentiality, and the safe storage of identifiable and de-identified data were adhered to during the study.[95,96] No significant deviations from the protocol occurred.

6.6.9 SUMMARY AND CONCLUSION

No major deviations, limitations, ethical, or data control issues arose during Stages 3 and 4 of the study. In terms of administrative burden on the participants involved in the test–retest, it is recommended that future test–retests be administered through the postal administration. Further validation studies in more general contexts are recommended. Additional recommendations are responsiveness testing for both surgical and conservative treatments and establishing confirmatory factor analysis and clinically meaningful interpretations of PFDI-20 and PFIQ-7 total scores and subscales.

The translated and validated versions of the PFDI-20 and PFIQ-7 (Appendix 6.4) are effective measures of symptom distress and HRQOL among Norwegian women with POP and pelvic floor dysfunction. The PFDI-20 captures change better than the PFIQ-7. Application of these instruments in clinical and research settings will provide data for promoting patient management and policy decisions in Norway.

CHAPTER 7

SUMMARY, RECOMMENDATIONS, AND CONCLUSIONS

7.1 INTRODUCTION

This thesis describes the translation, using new translation and cross-cultural adaptation methodology, and validation of the condition-specific HRQOL Pelvic Floor Distress Inventory-20 (PFDI-20) and Pelvic Floor Impact Questionnaire-7 (PFIQ-7) for women with pelvic organ prolapse (POP) and pelvic floor dysfunction in the Norwegian context. The study also critically assessed these questionnaires as tools for measuring symptoms and condition-specific quality of life.

Chapter 7 provides a final summary of the main results, strengths, and limitations of the research, and importantly, recommendations for both clinical practice and future research.

The research objectives of this thesis were to:

1. Translate and cross-culturally adapt the PFDI-20 and PFIQ-7 into Norwegian.
2. Investigate the viability of a novel translation and cross-cultural adaptation method using the Delphi method consensus approach within a bilingual expert panel.
3. Test the measurement properties (reliability, validity, and responsiveness) and interpretability of the Norwegian PFDI-20 and PFIQ-7 with women with symptomatic POP.
4. Critically evaluate the Norwegian PFDI-20 and PFIQ-7 as tools for measuring pelvic floor dysfunction and condition-specific HRQOL.

7.2 SUMMARY OF THE MAIN RESULTS

This study involved four stages. During Stages 1 and 2, qualitative and quantitative studies were undertaken with translators and clinical experts to translate and culturally adapt the PFDI-20 and PFIQ-7 from the source version (English) to the target version (Norwegian). A new method was employed for these tasks, based on modified EORTC QoL Group guidelines involving two independent forward and back-translations. It also involved the addition of the Delphi method to establish consensus on translated items among a bilingual pelvic floor expert panel. The expert panel was employed to verify equivalence between the translated and original versions of the PFDI-20 and PFIQ-7. Furthermore, qualitative studies were

undertaken (i.e. pilot testing) with women with symptomatic POP to check equivalence and assess PFDI-20 and PFIQ-7 as a tool to measure symptom severity and HRQOL in the Norwegian context.

The pilot testing and expert panel final review undertaken during Stages 1 and 2 provided evidence that the Norwegian versions comprised a set of comprehensible, linguistically valid items ready for further validation. Notably, during Stage 2, thematic analysis of data using an interpretive approach revealed that the life impact issue of sexuality was not covered in the PFDI-20 and PFIQ-7 questionnaires

During Stages 3 and 4, quantitative studies were undertaken to evaluate the measurement properties (reliability, validity, and responsiveness) and interpretability of the PFDI-20 and PFIQ-7 for women with symptomatic POP and undergoing vaginal repair for POP.

Stages 3 and 4 provided evidence of validity, reliability, responsiveness, and interpretability for the Norwegian PFDI-20 and PFIQ-7. It was concluded that the translated and validated PFDI-20 and PFIQ-7 questionnaires are suitable for use in clinical practice and research for women with POP and pelvic floor dysfunction in Norway.

7.3 STRENGTHS AND LIMITATIONS

While the strengths and limitations of this study have been discussed in detail in Chapters 3–6, they are nevertheless reviewed here for clarity and completeness.

7.3.1 STRENGTHS AND LIMITATIONS OF STAGES 1 AND 2

In summary, the strengths of Stage 1 include the use of mixed methodology in the translation and cross-cultural adaptation of the PFDI-20 and PFIQ-7 to produce a data-rich evidence base (i.e. forward and back-translations), reinforced with qualitative and quantitative studies (i.e. the Delphi consensus method with an expert panel). Further, the iterative nature and internal logic of the Delphi procedure seemed to improve cross-cultural adaptation. Two main limitations were identified in the design of Stage 1. First, the members of the expert panel considered the study time-consuming. Even though none of the panellists dropped out, there was a risk of participants losing interest and not properly evaluating the others' comments. Second, it was difficult to assess and measure whether the new method (the Delphi method employed during the expert panel phase) improved the

quality of the cross-cultural adaptation. That is, a comparison with the more common method of translation was not possible.

The strengths of Stage 2 (pilot testing) included the use of qualitative methodology that facilitated a rigorous cross-checking system during the translation project of the PFDI-20 and PFIQ-7. This approach rendered the Final Norwegian Translated Version (Intermediate Version 3.0) as a comprehensible, linguistically valid set of items ready for further extensive validation in Stages 3 and 4. The wide age distribution among the pilot test patients indicated that all age groups could complete the questionnaires without difficulty. Both the patients and expert panel reported that all items were relevant to the study population and the purpose of the application of the instrument.

The sample in Stage 2, recruited from consecutive referrals to a tertiary hospital, was of a size considered representative for the purpose. All 20 women who consented to participate completed the questionnaires. No major limitations were identified in this part of the design. However, the probing techniques in the EORTC QoL Group interview guide are limited to asking patients about items that are difficult/confusing and for alternative ways to reformulate the questions. A more open-ended interview technique could have been employed to improve the chances of identifying any further deviations or errors. Furthermore, since different forms of written Norwegian (Bokmål or Nynorsk) can influence cross-cultural adaptation, more consideration towards variations between these written forms should have been given during pilot testing.

Stages 1 and 2 of this study demonstrated that using a multistep approach, re-checking with an expert panel, and conducting a pilot test yielded a good linguistic translation and cross-cultural adaptation. However, the final face-to-face meeting of the expert panel, involving a review and summary was considered time-consuming and taxing. In the future, simply distributing a summary report and allowing the expert panellists to respond in writing would reduce their burden.

7.3.2 STRENGTHS AND LIMITATIONS OF STAGES 3 AND 4

The strengths of Stages 3 and 4 of this study included extensive quantitative evaluation of measurement properties including reliability, validity, responsiveness, and interpretability in a homogeneous sample population in a tertiary setting. However, criterion validity was not

evaluated because of the lack of a gold standard for measuring pelvic floor dysfunction outcomes.[61] The sociodemographic characteristics of the patients interviewed were typical and in accord 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 questionnaires without difficulty. The adequate sample size (consecutive referrals to the tertiary hospital) in Stages 3 and 4 was considered representative, even though the response rate for the baseline questionnaire was low, with only 212/716 (29%) eligible women consenting to participate. Of these, 205 completed the questionnaires, and this response rate of 96.7% was considered excellent.

Of note, there were no significant differences in the sample characteristics and summary statistics for key study variables between surgical and non-surgical participants (Table 6.1).

The sample size recruited for this study was considered a strength and provided an adequate dataset for testing and validating measurement properties and interpretability of the questionnaire items. The comprehensive analysis of this dataset provided adequate evidence of the measurement properties for the PFDI-20 and PFIQ-7.

Some caveats to the interpretation of the current results should be acknowledged in Stages 3 and 4. All recruitment was undertaken in a tertiary hospital, which may have resulted in bias affecting the results. In addition, validation data was collected only within a tertiary setting, limiting generalizability. Another limitation was that only women with symptomatic POP (with or without urinary or bowel dysfunction) were recruited. Thus, women with only urinary or only bowel dysfunctions were not recruited. However, urinary and bowel dysfunctions both were highly frequent in the sample, with only six (2.9%) participants reporting having POP exclusively. The recruited patients potentially represented those with moderate to severe and numerous symptoms (most patients were POP-Q Stages 2–3, and 83.9% completing the PFDI-20 reported three pelvic floor dysfunction symptoms).

Furthermore, a reference population was not included in this study, which may be considered vital in interpreting the score distribution of the general population. Moreover, it can determine whether patients report more symptom distress (PFDI-20) and more impact on daily activity (PFIQ-7) compared to the reference group. A reference group also can be beneficial for evaluating whether these differences remained significant after adjusting for age and educational level.[61]

A small percentage of patients consented to take part in the test–retest hospital appointments (56/205; 27%). The respondent burden to those participants was considered attributable to the lower consent rate of the test–retest part of the study. Postal administration would be recommended for future validation studies.

As detailed in Chapter 6, Cronbach's alpha coefficients for the Norwegian PFDI-20 and PFIQ-7 total scores demonstrated very satisfactory internal consistency. Similarly, Norwegian subscale coefficients (Table 6.3) were generally satisfactory to excellent, except for POPDI-6 (0.66). Results from previous translations (Swedish,[52] Dutch,[61] and Sesotho[123]) also show low to moderate internal consistency for the POPDI-6 subscale. The author of the original source English PFDI-20 and PFIQ-7 has not assessed internal consistency, so it is not possible to compare results between the source and target languages.

The moderate internal consistency (Cronbach's alpha 0.66) could indicate that some of the items in the POPDI-6 subscale might measure something other than the intended construct (i.e. pelvic floor dysfunction). According to Bump et al.,[29] POPDI-6 appears to have combined two functional symptom groups: (1) prolapse symptoms for anterior, posterior, and apical prolapse and (2) other local symptoms like vaginal heaviness or pressure. One plausible explanation is that the combination of these two functional symptom groups can reflect two different constructs in the POPDI-6, resulting in low to moderate Cronbach's alpha values.

Finally, education baseline characteristics were not included. Therefore, the study could not demonstrate whether the educational level of the questionnaires was appropriate for the target population.

7.4 RECOMMENDATIONS FOR CLINICAL PRACTICE

The application of the Norwegian version PROMs PFDI-20 and PFIQ-7 in clinical practice provides an accurate and reliable tool for identifying pelvic floor dysfunction, patients experienced symptom severity and a suitable form of treatment. Moreover, the PFDI-20 and PFIQ-7 can assist clinicians in gaining a better understanding of how these conditions are interrelated rather than being isolated conditions.

This self-administered format also provides an opportunity for patients to non-verbally communicate their socially stigmatised experiences and create a basis from which the healthcare professional can discuss sensitive topics during a consultation. Further, the

condition-specific, self-administered PFDI-20 and PFIQ-7 instruments allow various outcomes to be measured including symptom severity, psychological well-being, social functioning, HRQOL, treatment adherence, and clinical trials in Norway. For example, the Norwegian PFDI-20 and PFIQ-7 questionnaires can be employed in randomised controlled clinical trials to assess responsiveness to both POP surgery and conservative treatment.

Implementation of the PFDI-20 and PFIQ-7 in clinical practice is encouraged to standardise assessment and ongoing monitoring in this clinical field. Efficient monitoring of these patients would entail completion of the PFDI-20 and PFIQ-7 before the first and follow-up consultations, enabling the gynaecologist to assess symptom severity, HRQOL, psychological well-being and social functioning. It also would support creation of an in-depth plan of action before the consultation. In addition, patients can document their own experiences and progress in their own words.

Furthermore, POP surgery can improve symptoms and quality of life for women with POP. Identifying women who are likely to benefit from POP surgery is an important step towards successful surgical intervention. Nevertheless, set criteria are lacking for identifying patients with POP for surgery. Moreover, there is often no accurate or strict correlation between the abnormal descent or herniation of the pelvic organ and changes in symptoms and impact on daily life after surgical treatment. For example, two female patients with the same anatomical abnormality, POP-Q score, and symptoms can often have dramatically different responses and levels of bothersomeness. PFDI-20 and PFIQ-7 summary scores can be used to determine a preoperative cut-off score for predicting improvement after surgery and identifying surgical candidates. In most cases, patients with higher scores preoperatively will report moderate to severe symptom severity and negative impacts on their quality of life with regard to their physical, social, and emotional functioning.[47] Hence, patient scores post-operatively will often report improved symptom severity and quality of life in terms of their physical, social, and emotional functioning.

Of note, compared with generic HRQOL measures, the application of condition-specific HRQOL PFDI-20 and PFIQ-7 instruments can provide a more in-depth assessment of issues specifically pertaining to pelvic floor dysfunction that are more responsive to change after treatment. For example, after a successful rectocele operation, bowel function can improve in some patients but not in others.[11]

Similar to clinical practice recommendations, the implementation of PFDI-20 and PFIQ-7 in a research setting is encouraged to standardise outcome evaluation. Furthermore, the availability of Norwegian PFDI-20 and PFIQ-7 instruments enables comparison between the health of the Norwegian population and other populations who have access to and use the same forms.

Validated Norwegian HRQOL PFDI-20 and PFIQ-7 instruments also can be used to provide accurate symptom-based prevalence data for women with symptomatic POP.[1] Nygaard et al[1] stated that symptom-based prevalence for POP is one of the most accurate measures of disease burden in the population. This accuracy is possible even though women often do not seek medical care for POP until symptoms arise. In addition, dissemination of research outcomes using the Norwegian PFDI-20 and PFIQ-7 will establish and provide a better evidence base for treatment outcomes within the field of pelvic floor dysfunction. Hence, the PFDI-20 and PFIQ-7 can measure the health of populations, particularly ageing female populations, and provide patient-reported outcome data for assessing the efficacy of health care practice and policy decisions in Norway.

Finally, the Norwegian PFDI-20 and PFIQ-7 can establish a benchmark for national and international standards. Thus, these questionnaires can be used to assess patient outcomes against national and international standards

7.5 RECOMMENDATIONS FOR FUTURE RESEARCH

The research reported in this thesis represents a starting point for research that can now be done in Norway, given the availability of Norwegian versions of the PFDI-20 and PFIQ-7, and their value in assessing the broader context of pelvic floor dysfunction. Summarised below are recommendations for future research.

Such research might include validation and interpretability studies, applicability studies of the Norwegian version PROMs PFDI-20 and PFIQ-7 in different settings, electronic administration, Patient-Reported Outcomes Measurement Information System (PROMIS®),[130] and translation methodology studies concerning the applicability and viability of the new translation method developed in this study compared to other existing methods.

7.5.1 STRUCTURAL VALIDITY

One future study might include an analysis of structural validity using confirmatory factor analysis to examine whether the scores of the Norwegian PFDI-20 and PFIQ-7 adequately reflect the dimensionality of the construct pelvic floor dysfunction. The PFDI-20 and PFIQ-7 questionnaires consist of three subscales (POP, bowel, and lower urinary tract), so there is a likely three-factor structure of the questionnaires. Therefore, the use of confirmatory factor analysis could show whether such an *a priori* hypothesised three-factor structure has an adequate fit in pelvic floor dysfunction patient populations or not.

Notably, in this current study, the PFDI-20 and PFIQ-7 were considered as separate instruments. However, they can arguably be viewed as one instrument. One study could analyse all 27 items together to determine whether they measure a unidimensional construct or multiple constructs, such as POP, bowel dysfunction, and lower urinary tract dysfunction.

7.5.2 ELECTRONIC ADMINISTRATION VERSIONS OF THE NORWEGIAN PFDI-20 AND PFIQ-7

In this program of research, the pencil-and-paper versions of the PFDI-20 and PFIQ-7 were employed as the mode of administration. As technology is becoming integral in the delivery of patient care and research, clinicians need to consider how to obtain data electronically while ensuring that this new format is equivalent to the pencil-and-paper questionnaires they currently use.[43,122,124] Touchscreen devices and smart phones have become more widespread across all different age groups[125] and smart phone subscribers is estimated to reach 5.9 billion by 2025, which is equal to approximately three quarters of the world's population.[126]

The United States has recently validated web-based PFDI-20 and PFIQ-7 questionnaires as an alternative to the paper-based versions. A Norwegian national information technology (IT) infrastructure is available for the secure electronic administration of PROMs in web browsers (University Centre for Information Technology at the University of Oslo, USIT).[127] This national IT infrastructure has recently been extended to offer smartphone app–based administration and delivery. Consequently, an additional recommendation for further research would be the validation of electronic (web-based and/or app-based) administration versions of the Norwegian HRQOL PFDI-20 and PFIQ-7 short forms in clinical and research

settings. A study could be conducted to assess and compare these electronic versions to the pencil-and-paper version and the source-language electronic and pencil-and-paper versions among women with pelvic floor dysfunction.

Data collection using web-based PFDI-20 and PFIQ-7 questionnaires is relevant and significant for clinics and hospitals treating these patients. For example, web-based questionnaires can result in substantial cost and time reductions and improve data quality by alerting patients when they enter incomplete answers.[122,128] Data collection (for clinical and research purposes) using web-based PRO questionnaires allows doctors to track the progress of study group outcomes easily. Healthcare personnel can immediately access data entered electronically by the participant, thus decreasing time and costs. This method of administration, in theory, improves the accuracy and quality of collected data while allowing more rapid data analysis.[128] Further, using electronic PROMS would enable patients to track and interact with their own data. Additionally, electronic questionnaire administration allows data entry at any time and place that is convenient for the patient. Electronic PROMS can also encourage higher survey response rates and reduce non-response bias.[128]

While this web-based PRO tool can determine and evaluate responsiveness regarding existing and new treatments, it can also assist policymakers to promote and improve patient management and healthcare-related decisions for patients with pelvic floor disorders.[1] Valid and reliable HRQL instruments like the web-based PFDI-20 and PFIQ-7 also can be used to measure the health of populations, including ageing female populations.

Future study aims could include the validation of electronic (web-based/ app-based or smartphone) administration of Norwegian PFDI-20 and PFIQ-7 condition-specific HRQOL questionnaires for women with pelvic floor dysfunction. This research would test measurement equivalence between the paper-based and web-based questionnaires.

As Coons et al[129] assert, because moderate alterations would be made to the electronic PRO (ePRO) PFDI-20 and PFIQ-7 questionnaires (e.g. changes in presentation) the level of evidence required would involve pilot testing, usability testing, and quantitative equivalence testing, which assesses the comparability between paper-based and web-based (ePRO) PFDI-20 and PFIQ-7 instruments.

Such an investigation could be a prospective validation study (i.e. testing for measurement equivalence) using a randomized parallel groups design.[129] Norwegian native speaking (bilingual/monolingual) women referred to the Department of Obstetrics and Gynaecology, Akershus University Hospital, and presenting with a pelvic floor dysfunction would be invited to participate. PFDI-20 and PFIQ-7 would be administered in paper-, web-, or app-based form using random assignment. The questionnaires would be given out regardless of the severity or extent of complaint. In addition, it would involve a reference population,[61] and sociodemographic information (e.g. age [61,118] and educational level[117,119,120,123]) would be collected to compare across the parallel groups.

7.5.3 PATIENT-REPORTED OUTCOMES MEASUREMENT INFORMATION SYSTEM (PROMIS®)

A subsequent phase in the development of PRO measurements in POP and pelvic floor dysfunction is the further development and/or validation of a set of person-centred (existing) item banks for HRQOL. The Patient-Reported Outcomes Measurement Information System (PROMIS®) offers an electronic system of person-centred item banks that can help measure patient-reported HRQOL for patients with different chronic conditions.[130] These conditions include POP and pelvic floor dysfunction.[130] The PROMIS® has self-reported health measures (based on a series of items banks) covering physical health,[131] mental health, and social health.[130,132,133]

PROMIS® was developed by the National Institutes of Health (NIH) in the United States and can be used for both individuals living with chronic conditions and the general population. Researchers and clinicians can assess these item banks (www.nihpromis.org).[130]

Item banks enable the Computer Adaptive Testing (CAT) software to adjust and fit the PRO evaluation of the individual patient[132,134] (for example, a patient with POP and pelvic floor dysfunction) by choosing a set of relevant questions based on patient replies to former questions.[135] One PROMIS® study assessed participants undergoing surgery for POP using the PFDI-20, Pelvic PFIQ-7, Patient Global Impression of Severity (PGI-S) Scale, and the PROMIS Profile questionnaire preoperatively. The study aimed to determine the relationship between POP and HRQOL dimensions including anxiety, fatigue, sleep disturbances, pain interference, and physical and social dysfunction.[135] Cross-sectional associations among the PFDI-20, PFIQ-7, PGI-S, and PROMIS® would be subsequently analysed. A study has shown

that the PROMIS® profile is an adequate adjunct in evaluating women undergoing pelvic reconstructive surgery.[135]

A precise measurement of health status would be obtained using the fewest possible questions based on the CAT software. The result is a reduced test burden for both clinicians and patients. PROMIS® also provides efficient, valid, and responsive instruments that can be adapted to various health conditions.[135,135] The development of PROMIS® is a novel system and seen as the next phase in the progression of PROMs.

7.5.4 EXTENSIVE INTERPRETABILITY STUDIES

The current study is the first to examine clinically meaningful cut-off scores of the validated, Norwegian PFDI-20 and PFIQ-7. It was conducted using the anchor-based MIC distribution and the ROC approach. Since the cut-offs for PROM scores are primarily based on a clinical judgement about is clinically meaningful and comparative data available from the general population and/or POP and pelvic floor dysfunction patients, further interpretability studies are recommended. One study could entail examining the interpretability of Norwegian PFDI-20 and PFIQ-7 total scores and subscales by combining distribution-based (using distributional characteristics of the sample) and anchor-based (using an external criterion) methods in a single study population. This approach would give a good overview and comparison of the categorisation of scores.[16]

7.5.5 VALIDATION AND APPLICABILITY STUDIES OF THE PFDI-20 AND PFIQ-7 IN DIFFERENT SETTINGS

The Norwegian translations of the PFDI-20 and PFIQ-7 provided adequate reliability, validity for women with symptomatic POP (with or without urinary or bowel dysfunction), and good responsiveness to change for women undergoing POP surgery. However, in future, validation and applicability studies of the Norwegian PFDI-20 and PFIQ-7 in different settings are recommended. As discussed in Chapters 2 and 6, studies should include assessing and validating the Norwegian PFDI-20 and PFIQ-7 questionnaires as accurate and reliable tools to identify suitable candidates for POP surgery and assessing factors (e.g. PFDI-20 and POPDI-6 scores, and POP-Q) affecting women's treatment choices for POP. Future studies assessing factors affecting women's treatment choices for POP could help to determine a threshold to standardise indications for conservative treatment and surgery.

Further studies could also entail validating and assessing these questionnaires as a tool to evaluate conservative treatments (such as pessaries and the improvement of pelvic floor muscle function and strength). A final suggested study might involve validating and assessing the Norwegian questionnaires as a tool for evaluating anal incontinence among post-partum women following obstetrical anal sphincter injury.

7.5.6 VALIDATION OF THE PFDI-20 AND PFIQ-7 ASSESSING WOMEN NOT REPRESENTED IN THIS STUDY.

The validation and applicability of the PFDI-20 and PFIQ-7 should be assessed in women who were not represented in this study (e.g. women with the inability to understand Norwegian, women with visual impairment, women with impairment of memory and other cognitive functions and/or intellectual functions). Furthermore, assessing the applicability of the PFDI-20 and PFIQ-7 questionnaires on women living in residential aged care. Different proxies (e.g. family carers, institutional carers, and healthcare professionals) could be required to assist such women in the completion of these questionnaires.

7.5.7 DEVELOPING A GOLD STANDARD AND EVALUATION OF THE DELPHI METHOD WITH AN EXPERT PANEL

As discussed in Chapter 3, further evaluation of the applicability and viability of the translation method using the Delphi method approach with an expert panel is recommended. Similarly, further research is needed to explore the appropriateness of this and other existing methods, and to develop a gold standard for translation, cross-cultural adaptation, and validation of HR PRO measures. In the absence of consensus of a preferred translation method or gold standard, a subsequent next step would be to establish a consensus-based method, such as an International Delphi study or task force, to form consensus on the translation and cross-cultural adaptation method of choice.

Groups such as the ISPOR TCA Task Force,[8] the PRO Consortium,[136] the ERIQA group,[9] and other groups have developed certain criteria and checklists on the principles of good practice of translation and cross-cultural adaptation. However, there is no preferred empirical based translation method or gold standard. The guidelines appear to be based on practices rather than empirical data. The ISPOR TCA Task Force,[8] the ERIQA Group,[9] IQOLA Group,[79] International Society for Quality of Life Research (ISOQOL) translation and cross-cultural adaptation special interest group (TCA-SIG),[137] and other groups (in particular,

groups outside the pharmaceutical sponsor context) could join to establish an International Delphi study or task force.

The aim of the International Delphi study or task force could be to assess existing and future translation methodologies and form empirically based recommendations and consensus on the translation and cross-cultural adaptation method of choice. Further, the International Delphi study or task group could encourage and assist such empirical research; few randomised studies have compared outcomes measured using, for example, a simple translation method (i.e. forward translation and reconciliation) versus a multistep translation approach, as recommended by the ISPOR TCA Task Force. Alternatively, a randomised study comparing outcomes measured in this study versus a multistep translation approach recommended by the ISPOR TCA Task Force could be undertaken. The item response theory (IRT) approach is another strategy recommended for evaluating the comparability of translations.[78] Over time, with more empirical research on appropriate translation methodologies, some approaches will come to be considered invalid or not highly recommended by this international regulatory body.[78]

As discussed in Chapter 3, there are several alternatives to the Delphi method approach with an expert panel, including the nominal group technique and multi-voting. However, the Delphi method was chosen for its unique iterative nature, system of anonymity, and statistical group response improving the cross-cultural adaptation between the voting rounds.

A further translation and cross-cultural adaptation study could include comparing one or more alternative methods (e.g. nominal group technique and multi-voting). This study would further assess whether the iterative nature and internal logic of the Delphi consensus method and, in particular, the system of anonymity, contributes to improving cross-cultural adaptation results.

7.5.8 VALIDATION OF A SEXUAL QUESTIONNAIRE IN NORWEGIAN

As discussed in Chapter 5, Stage 2 of this study and other studies,[32,138,139,140,141] identified sexual function and sexuality as important, challenging aspects for patients with pelvic floor dysfunction that were not covered in the PFDI-20 and PFIQ-7 instruments. Yet patients reported the importance of asking questions pertaining to partner-related issues, emotional

issues, and practical and physical issues related to sexual function. Employing a third measuring instrument to cover sexuality issues for women with pelvic floor dysfunction should be considered.[57]

A future research project could employ the method discussed in this thesis to translate a sexuality questionnaire into Norwegian and validate it for cross-cultural adaptation. The translation method developed and tested in this project could also be used for translating HR PRO instruments into any language.

7.6 CONCLUSION

POP and pelvic floor dysfunction are common conditions among Norwegian women of all ages, which can have a devastating impact on HRQOL. Before the commencement of this program of research, no validated PROM tools existed for POP and pelvic floor dysfunction in Norway. This research, therefore, undertook a cross-cultural adaptation of the ICI recommended Grade A PROMs PFDI-20 and PFIQ-7. The purpose was to provide evidence that these translated and cross-culturally adapted instruments are reliable, valid, responsive to change, and effective measures of symptom distress and QoL issues among Norwegian women with POP and pelvic floor dysfunction. Of importance, the Norwegian PFDI-20 captured change better than the PFIQ-7. Further evaluation studies will continue to provide evidence of the applicability of the PFDI-20 and PFIQ-7 and their viability in clinical and research settings. The dissemination and implementation of the Norwegian PFDI-20 and PFIQ-7 are important in the assessment of unmet needs in the clinical area and development of more evidence-based, effective Norwegian healthcare services.

Efforts to ensure a good translation and cross-cultural adaptation of the PFDI-20 and PFIQ-7 resulted in the development of a new study methodology, which used the Delphi method with a bilingual expert pelvic floor panel. To the author's knowledge, this research is original and significant as it developed a new multistep, cross-cultural adaptation method. The rigorous documentation process, controlled feedback approach (in the form of a quantitative statistical representation), iterative nature and internal logic of the Delphi consensus method appeared to contribute to improving translation results and ensuring good cross-cultural adaptation of the questionnaires. Finally, anonymity and statistical group

response improved the cross-cultural adaptation between rounds and ensured that every member of the panel was considered during the process and final response.

In conclusion, the PFDI-20 and PFIQ-7 instruments will provide improved, validated PRO assessment tools for effective measures of symptom distress and HRQOL among Norwegian women with POP and pelvic floor dysfunction. Application of these instruments in clinical and research settings will provide further data for promoting patient management and policy decisions in Norway.

APPENDIX 3.1

ORIGINAL ENGLISH SOURCE QUESTIONNAIRES OF THE PFDI-20 AND PFIQ-7

Pelvic Floor Distress Inventory- short form 20

Instructions

Please answer all of the questions in the following survey. These questions will ask you if you have certain bowel, bladder or pelvic symptoms and if you do how much they bother you. Answer these questions by putting a **X** in the appropriate box or boxes. If you are unsure about how to answer a question, give the best answer you can. While answering these questions, please consider your symptoms over the **last 3 months.**

EXAMPLE

For the following question:

If you do not usually have headaches just put an X in the "No" box.

Do you usually experience headaches?

☒ No ☐ Yes **If yes, how much does this bother you?**
0

☐ **1**		☐ **2**		☐ **3**		☐ **4**
Not at all	-	Somewhat	-	Moderately	-	Quite a bit

If you do usually have headaches just put an X in the "Yes" box and indicate how much the headaches bother you. (In this example, the headaches *moderately* bothersome)

Do you usually experience headaches?

☐ No ☒ Yes **If yes, how much does this bother you?**
0

☐ **1**		☐ **2**		☒ **3**		☐ **4**
Not at all	-	Somewhat	-	Moderately	-	Quite a bit

Pelvic Floor Distress Inventory - short form-20

1. Do you usually experience pressure in the lower abdomen?

☐ No; ☐ Yes
0

If yes, how much does this bother you?

☐ **1**		☐ **2**		☐ **3**		☐ **4**
Not at all	-	Somewhat	-	Moderately	-	Quite a bit

2. Do you usually experience heaviness or dullness in the pelvic area?

☐ No; ☐ Yes
0

If yes, how much does this bother you?

☐ **1**		☐ **2**		☐ **3**		☐ **4**
Not at all	-	Somewhat	-	Moderately	-	Quite a bit

3. Do you usually have a bulge or something falling out that you can see or feel in the vagina area?

☐ No; ☐ Yes
0

If yes, how much does this bother you?

☐ **1**		☐ **2**		☐ **3**		☐ **4**
Not at all	-	Somewhat	-	Moderately	-	Quite a bit

4. Do you usually have to push on the vagina or around the rectum to have or complete a bowel movement?

☐ No; ☐ Yes
0

If yes, how much does this bother you??

☐ **1**		☐ **2**		☐ **3**		☐ **4**
Not at all	-	Somewhat	-	Moderately	-	Quite a bit

5. Do you usually experience a feeling of incomplete bladder emptying?

☐ No; ☐ Yes
0

If yes, how much does this bother you?

☐ **1**		☐ **2**		☐ **3**		☐ **4**
Not at all	-	Somewhat	-	Moderately	-	Quite a bit

6. Do you ever have to push up on a bulge in the vagina area with your fingers to start or complete urination?

☐ No; ☐ Yes
0

If yes, how much does this bother you?

☐ **1**		☐ **2**		☐ **3**		☐ **4**
Not at all	-	Somewhat	-	Moderately	-	Quite a bit

7. Do you feel you need to strain too hard to have a bowel movement?

☐ No; ☐ Yes
0

If yes, how much does this bother you?

☐ **1**	☐ **2**	☐ **3**	☐ **4**
Not at all	Somewhat	Moderately	Quite a bit

8. Do you feel you have not completely emptied your bowels at the end of a bowel movement?

☐ No; ☐ Yes
0

If yes, how much does this bother you?

☐ **1**	☐ **2**	☐ **3**	☐ **4**
Not at all	Somewhat	Moderately	Quite a bit

9. Do you usually lose stool beyond your control if your stool is well formed?

☐ No; ☐ Yes
0

If yes, how much does this bother you?

☐ **1**	☐ **2**	☐ **3**	☐ **4**
Not at all	Somewhat	Moderately	Quite a bit

10. Do you usually lose stool beyond your control if your stool is loose or liquid?

☐ No; ☐ Yes
0

If yes, how much does this bother you?

☐ **1**	☐ **2**	☐ **3**	☐ **4**
Not at all	Somewhat	Moderately	Quite a bit

11. Do you usually lose gas from the rectum beyond your control?

☐ No; ☐ Yes
0

If yes, how much does this bother you?

☐ **1**	☐ **2**	☐ **3**	☐ **4**
Not at all	Somewhat	Moderately	Quite a bit

12. Do you usually have pain when you pass your stool?

☐ No; ☐ Yes
0

If yes, how much does this bother you?

☐ **1**	☐ **2**	☐ **3**	☐ **4**
Not at all	Somewhat	Moderately	Quite a bit

13. Do you experience a strong sense of urgency and have to rush to the bathroom to have a bowel movement?

☐ No; ☐ Yes
0

If yes, how much does this bother you?

☐ **1**	☐ **2**	☐ **3**	☐ **4**
Not at all	Somewhat	Moderately	Quite a bit

14. Does a part of your bowel ever pass through the rectum and bulge outside during or after a bowel movement?

☐ Nei; ☐ Yes
0

If yes, how much does this bother you?

☐ 1		☐ 2		☐ 3		☐ 4
Not at all	-	Somewhat	-	Moderately	-	Quite a bit

15. Do you usually experience frequent urination?

☐ No; ☐ Yes
0

If yes, how much does this bother you?

☐ 1		☐ 2		☐ 3		☐ 4
Not at all	-	Somewhat	-	Moderately	-	Quite a bit

16. Do you usually experience urin leakage associated with a feeling of urgency; that is, a strong sensation of needing to go to the bathroom?

☐ No; ☐ Yes
0

If yes, how much does this bother you?

☐ 1		☐ 2		☐ 3		☐ 4
Not at all	-	Somewhat	-	Moderately	-	Quite a bit

17. Do you usually experience urin leakage related to coughing, sneezing and laughing?

☐ No; ☐ Yes
0

If yes, how much does this bother you?

☐ 1		☐ 2		☐ 3		☐ 4
Not at all	-	Somewhat	-	Moderately	-	Quite a bit

18. Do you usually experience small amounts of urine leakage (that is, drops)?

☐ No; ☐ Yes
0

If yes, how much does this bother you?

☐ 1		☐ 2		☐ 3		☐ 4
Not at all	-	Somewhat	-	Moderately	-	Quite a bit

19. Do you usually experience difficulty emptying your bladder?

☐ No; ☐ Yes
0

If yes, how much does this bother you?

☐ 1		☐ 2		☐ 3		☐ 4
Not at all	-	Somewhat	-	Moderately	-	Quite a bit

20. Do you usually experience *pain* or *discomfort* in the lower abdomen or genital area?

☐ No; ☐ Yes
0

If yes, how much does this bother you?

☐ 1		☐ 2		☐ 3		☐ 4
Not at all	-	Somewhat	-	Moderately	-	Quite a bit

Thank-you for taking the time to complete this questionnaire

PFDI-20 Source version Side 4 av 4

INSTRUCTIONS
Some women find that bladder, bowel or vaginal symptoms affect their activities, relationships, and feelings. For each question, place an **X** in the response that best describes how much your activities, relationships or feelings have been affected by your bladder, bowel or vaginal symptoms or conditions **over the last 3 months**. You may or may not have symptoms in each of these three areas, but please be sure to mark an answer in **all 3 columns** for each question. If do not have symptoms in one of these areas, then the appropriate answer would be "Not at all" in the corresponding column for each question.

EXAMPLE
For the following question:

If your bladder symptoms interfere with your ability to drive a car *moderately*, and your bowel symptoms interfere with your ability to drive a car *somewhat*, but your vaginal or pelvic symptoms do not interfere with your ability to drive a car or you have no vaginal or pelvic symptoms then you should place an X in the corresponding boxes as indicated below:

How do symptoms or conditions related to the following usually affect your ↓ →→→→	***Bladder or urine***	***Bowel or rectum***	***Vagina or Pelvis***
1. ability to drive a car	☐ Not at all ☐ Somewhat ☒ Moderately ☐ Quite a bit	☐ Not at all ☒ Somewhat ☐ Moderately ☐ Quite a bit	☒ Not at all ☐ Somewhat ☐ Moderately ☐ Quite a bit

Please make sure to answer all 3 columns for each and every question.
Thank you for your cooperation

Pelvic Floor Impact Questionnaire – short form 7

Instructions: Some women find that bladder, bowel or vaginal symptoms affect their activities, relationships, and feelings. For each question, place an **X** in the response that best describes how much your activities, relationships or feelings have been affected by your bladder, bowel or vaginal symptoms or conditions **over the last 3 months**. Please be sure to mark an answer in **all 3 columns** for each question. Thank you for your cooperation.

How do symptoms or conditions related to the following →→→→ usually affect your ↓	***Bladder or urine***	***Bowel or rectum***	***Vagina or Pelvis***
1. ability to do household chores (cooking, housecleaning, laundry)?	☐ Not at all ☐ Somewhat ☐ Moderately ☐ Quite a bit	☐ Not at all ☐ Somewhat ☐ Moderately ☐ Quite a bit	☐ Not at all ☐ Somewhat ☐ Moderately ☐ Quite a bit
2. ability to do physical activities such as walking, swimming, or other exercise?	☐ Not at all ☐ Somewhat ☐ Moderately ☐ Quite a bit	☐ Not at all ☐ Somewhat ☐ Moderately ☐ Quite a bit	☐ Not at all ☐ Somewhat ☐ Moderately ☐ Quite a bit
3. entertainment activities such as going to a movie or concert?	☐ Not at all ☐ Somewhat ☐ Moderately ☐ Quite a bit	☐ Not at all ☐ Somewhat ☐ Moderately ☐ Quite a bit	☐ Not at all ☐ Somewhat ☐ Moderately ☐ Quite a bit
4. ability to travel by car or bus for a distance greater than 30 minutes away from home?	☐ Not at all ☐ Somewhat ☐ Moderately ☐ Quite a bit	☐ Not at all ☐ Somewhat ☐ Moderately ☐ Quite a bit	☐ Not at all ☐ Somewhat ☐ Moderately ☐ Quite a bit
5. participating in social activities outside your home?	☐ Not at all ☐ Somewhat ☐ Moderately ☐ Quite a bit	☐ Not at all ☐ Somewhat ☐ Moderately ☐ Quite a bit	☐ Not at all ☐ Somewhat ☐ Moderately ☐ Quite a bit
6. emotional health (nervousness, depression, etc.)?	☐ Not at all ☐ Somewhat ☐ Moderately ☐ Quite a bit	☐ Not at all ☐ Somewhat ☐ Moderately ☐ Quite a bit	☐ Not at all ☐ Somewhat ☐ Moderately ☐ Quite a bit
7. feeling frustrated?	☐ Not at all ☐ Somewhat ☐ Moderately ☐ Quite a bit	☐ Not at all ☐ Somewhat ☐ Moderately ☐ Quite a bit	☐ Not at all ☐ Somewhat ☐ Moderately ☐ Quite a bit

APPENDIX 3.2

NORWEGIAN INTERMEDIATE VERSION 1.0 PFDI-20 AND PFIQ-7

Please note: This Intermediate Version 1.0 was the same as the Single Forward Version (see tables 4.2a, 4.2b, 4.2c and 4.2d). No amendments to the Single Forward Version were made following the back-translations.

Spørreskjema om bekkenbunnsbesvær – kort skjema 20

Veiledning

Vennligst svar på alle spørsmålene i spørreskjemaet. Spørsmålene dreier seg om hvorvidt du har ulike symptomer i tarmen, blæren eller bekkenregionen, og i så fall i hvilken grad de plager deg. Svar på spørsmålene ved å krysse av i den eller de boksene som passer for deg. Hvis du er usikker på hva du skal svare, svarer du så godt du kan. Vennligst ta hensyn til symptomene du har hatt de siste tre månedene når du svarer på spørsmålene.

EKSEMPEL

Ved følgende spørsmål:

Hvis du ikke pleier å ha hodepine, setter du X i "Nei"- ruten.

Har du ofte *hodepine*?

☒ Nei ☐ Ja **Hvis ja, hvor mye plager det deg?**

☐ 1	☐ 2	☐ 3	☐ 4
Ikke det hele tatt	Litt	I noen grad	Ganske mye

Hvis du pleier å ha hodepine, setter du X i "Ja"-boksen og angir hvor mye du synes hodepinen plager deg. (I dette eksemplet plages vedkommende av hodepinen *i noen grad*)

Har du ofte *hodepine*?

☐ Nei ☒ Ja **Hvis ja, hvor mye plager det deg?**

☐ 1	☐ 2	☒ 3	☐ 4
Ikke det hele tatt	Litt	I noen grad	Ganske mye

Spørreskjema om bekkenbunnsbesvær – kort skjema 20

1.	Kjenner du vanligvis et *trykk* i den nedre delen av magen? ☐ Nei; ☐ Ja **0** **<u>Hvis ja</u>, hvor mye plager det deg?** **☐ 1** Ikke i det hele tatt - **☐ 2** Litt - **☐ 3** I noen grad - **☐ 4** Ganske mye
2.	Kjenner du vanligvis *tyngdefølelse i bekkenet*? ☐ Nei; ☐ Ja **0** **<u>Hvis ja</u>, hvor mye plager det deg?** **☐ 1** Ikke i det hele tatt - **☐ 2** Litt - **☐ 3** I noen grad - **☐ 4** Ganske mye
3.	Har du vanligvis noe som buler ut eller faller ut som du kan se eller kjenne i skjeden? ☐ Nei; ☐ Ja **0** **<u>Hvis ja</u>, hvor mye plager det deg?** **☐ 1** Ikke i det hele tatt - **☐ 2** Litt - **☐ 3** I noen grad - **☐ 4** Ganske mye
4.	Må du vanligvis presse i skjeden eller rundt endetarmsåpningen for å få avføring eller få tømt tarmen helt? ☐ Nei; ☐ Ja **0** **<u>Hvis ja</u>, hvor mye plager det deg?** **☐ 1** Ikke i det hele tatt - **☐ 2** Litt - **☐ 3** I noen grad - **☐ 4** Ganske mye
5.	Kjenner du vanligvis at urinblæren ikke blir tømt helt? ☐ Nei; ☐ Ja **0** **<u>Hvis ja</u>, hvor mye plager det deg?** **☐ 1** Ikke i det hele tatt - **☐ 2** Litt - **☐ 3** I noen grad - **☐ 4** Ganske mye
6.	Må du noen ganger trykke inn en bul i skjeden med fingrene for å begynne å tisse eller tømme blæren helt? ☐ Nei; ☐ Ja **0** **<u>Hvis ja</u>, hvor mye plager det deg?** **☐ 1** Ikke i det hele tatt - **☐ 2** Litt - **☐ 3** I noen grad - **☐ 4** Ganske mye

7. Føler du at du må presse for hardt for å ha avføringen?

☐ Nei; ☐ Ja
0

Hvis ja, hvor mye plager det deg?

☐ 1	☐ 2	☐ 3	☐ 4
Ikke i det hele tatt -	Litt -	I noen grad -	Ganske mye

8. Føler du at du ikke har tømt tarmen helt, når du har hatt avføring?

☐ Nei; ☐ Ja
0

Hvis ja, hvor mye plager det deg?

☐ 1	☐ 2	☐ 3	☐ 4
Ikke i det hele tatt -	Litt -	I noen grad -	Ganske mye

9. Har du vanligvis ufrivillig avføring hvis avføringen er fast?

☐ Nei; ☐ Ja
0

Hvis ja, hvor mye plager det deg?

☐ 1	☐ 2	☐ 3	☐ 4
Ikke i det hele tatt -	Litt -	I noen grad -	Ganske mye

10. Har du vanligvis ufrivillig avføring hvis avføringen er løs eller flytende?

☐ Nei; ☐ Ja
0

Hvis ja, hvor mye plager det deg?

☐ 1	☐ 2	☐ 3	☐ 4
Ikke i det hele tatt -	Litt -	I noen grad -	Ganske mye

11. Slipper du vanligvis luft fra tarmen uten kontroll?

☐ Nei; ☐ Ja
0

Hvis ja, hvor mye plager det deg?

☐ 1	☐ 2	☐ 3	☐ 4
Ikke i det hele tatt -	Litt -	I noen grad -	Ganske mye

12. Har du vanligvis smerter når du har avføring?

☐ Nei; ☐ Ja
0

Hvis ja, hvor mye plager det deg?

☐ 1	☐ 2	☐ 3	☐ 4
Ikke i det hele tatt -	Litt -	I noen grad -	Ganske mye

13. Opplever du stor trang og må løpe på toalettet for å tømme tarmen?

☐ Nei; ☐ Ja
0

Hvis ja, hvor mye plager det deg?

☐ 1	☐ 2	☐ 3	☐ 4
Ikke i det hele tatt -	Litt -	I noen grad -	Ganske mye

14. Hender det at en del av tarmen følger med ut under eller etter avføring?

☐ Nei; ☐ Ja
0

<u>Hvis ja</u>, hvor mye plager det deg?

☐ **1**	☐ **2**	☐ **3**	☐ **4**
Ikke i det hele tatt -	Litt -	I noen grad -	Ganske mye

15. Har du vanligvis hyppig vannlating?

☐ Nei; ☐ Ja
0

<u>Hvis ja</u>, hvor mye plager det deg?

☐ **1**	☐ **2**	☐ **3**	☐ **4**
Ikke i det hele tatt -	Litt -	I noen grad -	Ganske mye

16. Opplever du vanligvis urinlekkasje sammen med plutselig vannlatingstrang dvs en sterk følelse av at du må på toalettet?

☐ Nei; ☐ Ja
0

<u>Hvis ja</u>, hvor mye plager det deg?

☐ **1**	☐ **2**	☐ **3**	☐ **4**
Ikke i det hele tatt -	Litt -	I noen grad -	Ganske mye

17. Opplever du vanligvis urinlekkasje når du hoster, nyser eller ler?

☐ Nei; ☐ Ja
0

<u>Hvis ja</u>, hvor mye plager det deg?

☐ **1**	☐ **2**	☐ **3**	☐ **4**
Ikke i det hele tatt -	Litt -	I noen grad -	Ganske mye

18. Opplever du vanligvis urinlekkasjer i små mengder (dvs. dråper)?

☐ Nei; ☐ Ja
0

<u>Hvis ja</u>, hvor mye plager det deg?

☐ **1**	☐ **2**	☐ **3**	☐ **4**
Ikke i det hele tatt -	Litt -	I noen grad -	Ganske mye

19. Opplever du vanligvis problemer med å tømme blæren?

☐ Nei; ☐ Ja
0

<u>Hvis ja</u>, hvor mye plager det deg?

☐ **1**	☐ **2**	☐ **3**	☐ **4**
Ikke i det hele tatt -	Litt -	I noen grad -	Ganske mye

20. Kjenner du vanligvis *smerte* eller *ubehag* i den nedre delen av magen eller underlivet?

☐ Nei; ☐ Ja
0

<u>Hvis ja</u>, hvor mye plager det deg?

☐ **1**	☐ **2**	☐ **3**	☐ **4**
Ikke i det hele tatt -	Litt -	I noen grad -	Ganske mye

Spørreskjema om innvirkning på bekkenbunnen- kort skjema 7

Veiledning

Noen kvinner opplever at symptomer fra blære, endetarmen og skjede som påvirker deres aktiviteter, forhold og følelser. For hvert av spørsmålene ber vi deg krysse av for svaret som best beskriver hvordan dine aktiviteter, forhold eller dine følelser har blitt påvirket av symptomer eller plager fra blære, endetarm eller skjede **de tre siste månedene.**

Du kan ha, eller ikke ha symptomer innenfor hvert av disse tre områdene, men husk å svare i **alle tre kolonner** for hvert spørsmål. Hvis du ikke ha symptomer på et av områdene, svare du "ikke i det hele tatt" i den aktuelle kolonnen.

EKSEMPEL

Ved følgende spørsmål:
Hvis blærefunksjonen påvirker evnen din til å kjøre bil i noen grad, mens tarmfunksjonen bare påvirker evnen til å kjøre bil litt, og symptomer knyttet til skjede eller bekkenbunn ikke påvirker evnen til å kjøre bil i det hele tatt, skal du sette kryss (X) i boksene som vist nedenfor:

Hvordan pleier symptomer eller plager fra →→ å påvirke ↓	***Blære eller urin***	***Tarm eller endetarm***	***Skjede eller bekkenbunnen***
1. evne til å kjøre bil	☐ Ikke i det hele tatt ☐ Litt ☒ I noen grad ☐ Ganske mye	☐ Ikke i det hele tatt ☒ Litt ☐ I noen grad ☐ Ganske mye	☒ Ikke i det hele tatt ☐ Litt ☐ I noen grad ☐ Ganske mye

Vennligst husk å svare i alle tre kolonner for hvert spørsmål

Takk for hjelpen!

Spørreskjema om innvirkning på bekkenbunn – kort skjema 7

Veiledning: Noen kvinner opplever at symptomer fra blæren, endetarmen eller skjeden påvirker deres aktiviteter, forhold og følelser. For hvert av spørsmålene ber vi deg krysse av for svaret som best beskriver hvordan dine aktiviteter, forhold eller følelser har blitt påvirket av symptomer eller plager fra blære, endetarm eller skjede **de tre siste månedene**. Husk å krysse av i **alle de tre kolonnene** for hvert spørsmål.

Hvordan pleier symptomer eller plager fra →→ å påvirke ↓	***Blære eller urin***	***Tarm eller endetarm***	***Skjede eller bekkenbunnen***
1. evne til å utføre husarbeid (matlaging, rengjøring, klesvask)?	☐ Ikke i det hele tatt ☐ Litt ☐ I noen grad ☐ Ganske mye	☐ Ikke i det hele tatt ☐ Litt ☐ I noen grad ☐ Ganske mye	☐ Ikke i det hele tatt ☐ Litt ☐ I noen grad ☐ Ganske mye
2. evne til å være i fysisk aktivitet som turgåing, svømming eller annen mosjon?	☐ Ikke i det hele tatt ☐ Litt ☐ I noen grad ☐ Ganske mye	☐ Ikke i det hele tatt ☐ Litt ☐ I noen grad ☐ Ganske mye	☐ Ikke i det hele tatt ☐ Litt ☐ I noen grad ☐ Ganske mye
3. deltagelse i fritidsaktiviter som å gå på kino eller konsert?	☐ Ikke i det hele tatt ☐ Litt ☐ I noen grad ☐ Ganske mye	☐ Ikke i det hele tatt ☐ Litt ☐ I noen grad ☐ Ganske mye	☐ Ikke i det hele tatt ☐ Litt ☐ I noen grad ☐ Ganske mye
4. mulighet til å reise med bil eller buss lenger enn 30 minutter hjemmefra?	☐ Ikke i det hele tatt ☐ Litt ☐ I noen grad ☐ Ganske mye	☐ Ikke i det hele tatt ☐ Litt ☐ I noen grad ☐ Ganske mye	☐ Ikke i det hele tatt ☐ Litt ☐ I noen grad ☐ Ganske mye
5. deltagelse i sosiale aktiviteter utenfor hjemmet?	☐ Ikke i det hele tatt ☐ Litt ☐ I noen grad ☐ Ganske mye	☐ Ikke i det hele tatt ☐ Litt ☐ I noen grad ☐ Ganske mye	☐ Ikke i det hele tatt ☐ Litt ☐ I noen grad ☐ Ganske mye
6. følelsemessige helsetiltand (nervøsitet, engstelig, depresjon osv.)?	☐ Ikke i det hele tatt ☐ Litt ☐ I noen grad ☐ Ganske mye	☐ Ikke i det hele tatt ☐ Litt ☐ I noen grad ☐ Ganske mye	☐ Ikke i det hele tatt ☐ Litt ☐ I noen grad ☐ Ganske mye
7. følelse av frustrasjon?	☐ Ikke i det hele tatt ☐ Litt ☐ I noen grad ☐ Ganske mye	☐ Ikke i det hele tatt ☐ Litt ☐ I noen grad ☐ Ganske mye	☐ Ikke i det hele tatt ☐ Litt ☐ I noen grad ☐ Ganske mye

APPENDIX 3.3

INTERVIEW GUIDE FOR STAGE 1, ROUND 1 (EXPERT PANEL)

Content of questions and responses from the expert panel.

Faculty of Health Sciences, Flinders University

Ms Catherine Planke
Master of Science candidate
School of Medicine
Faculty of Health Sciences
Flinders University

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INTERVIEW GUIDE/ CONTENT OF QUESTIONS AND RESPONSES FROM THE EXPERT PANEL

Title of research project:

"Validating condition specific quality of life questionnaires for women with pelvic floor disorders in the Norwegian context"

After the provisional forward and back translation interviews with experts in Pelvic Floor Disorders will be conducted to comment on the translations.
During this process it is crucial that the translation produces questionnaires, which is both comparable in terms of semantic, idiomatic, experiential and conceptual equivalence. This will facilitate cross- cultural comparisons between the translations.

An interview guide/ content of questions and analysis of responses (table 1) will be used to document areas of agreement and disagreement between the clinicians. The interview guide/content of questions and analysis of responses will be re-circulated for clarification where consensus is not achieved, until a clear set of items that have cross-culture equivalence is identified for inclusion.

Table 1: Interview guide/table:
Decisions by the expert panel will be needed to achieve equivalence from the source (original document) and target version in four areas:
1. Semantic equivalence: Do words mean the same thing? Are there several meanings to a given item? Are there grammatical difficulties in the translation?

2. Idiomatic equivalence: Colloquialisms, or idioms are difficult to translate. The expert panel may have to formulate an similar expression in the target version

3. Experiential equivalence: Often items/words are seeking to capture an experience; however that particular country does not in fact, have that experience. For example- you ask a question about difficulty eating with a spoon. Perhaps that country does not a have spoon. These types of issues have to be addressed by the expert panel.

4. Conceptual equivalence: Often words hold different conceptual meanings in different cultures. The expert panel must examine the original document (English version) and find the appropriate meaning in Norwegian. The words and meaning should be understandable for a 12 year-old.

Faculty of Health Sciences, Flinders University

Ms Catherine Planke
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joyc0003@flinders.edu.au

Please read the Norwegian PFDI-20 and PFIQ-7 questionnaires and fill in Table 1 using a computer:
See attachment: PFDI-20 and PFIQ-7 Norwegian questionnaires

Round One	Have all four equivalences been met?	If 'No', which one(s) is/are not met?	Can you suggest a change?
PFDI-20 form Instructions			
Question 1			
Question 2			
Question 3			
Question 4			
Question 5			
Question 6			
Question 7			
Question 8			
Question 9			
Question 10			
Question 11			
Question 12			
Question 13			
Question 14			
Question 15			
Question 16			
Question 17			
Question 18			
Question 19			
Question 20			

Flinders UNIVERSITY ADELAIDE • AUSTRALIA

Faculty of Health Sciences, Flinders University

Ms Catherine Planke
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Round One	Have all four equivalences been met?	If 'No', which one(s) is/are not met?	Can you suggest a change?
PFIQ-7 form			
Instructions			
Question 1			
Question 2			
Question 3			
Question 4			
Question 5			
Question 6			
Question 7			

Thank you for your assistance.

Yours sincerely,

Ms Catherine Planke

Master of Science candidate
School of Medicine
Faculty of Health Sciences
Flinders University

APPENDIX 3.4

ETHICS APPROVAL FOR STAGES 1 - 4

Norwegian Regional Committees for Medical and Health Research Ethics (REK) approval for Stages One-Two:

3.4a Approval by The Regional Committees for Medical and Health Research Ethics (REK) for Stages One and Two. Project nr. 2011/1312. English version.

3.4b Approval by The Regional Committees for Medical and Health Research Ethics (REK) for Stages One and Two. Project nr. 2011/1312. Norwegian version.

3.4c Approval by The Regional Committees for Medical and Health Research Ethics (REK) for Stages One and Two. Project nr. 2011/1312. Extension. English version.

3.4d Approval by The Regional Committees for Medical and Health Research Ethics (REK) for Stages One and Two. Project nr. 2011/1312. Extension. Norwegian version.

Norwegian Regional Committees for Medical and Health Research Ethics (REK) approval for Stages Three-Four:

3.4e Approval by The Regional Committees for Medical and Health Research Ethics (REK) for Stages Three and Four. Project nr. 2011/1312 REK sør-øst D. English.

3.4f Approval by The Regional Committees for Medical and Health Research Ethics (REK) for Stages Three and Four. Project nr. 2011/1312 REK sør-øst D. Norwegian

Norwegian Akershus Hospital Ethics approval for Stages One-Four:

3.4g Approval by Akershus University Hospital Ethics Committee for Stages One, Two, Three and Four. Project nr. 11_60. English version.

Flinders University Social and Behavioural Research Ethics Committee (SBREC) approval for Stages One-Four:

3.4h Approval by Social and Behavioural Research Ethics Committee, Flinders University. Stages One, Two, Three and Four. Project nr. 5376. English version.

REK
REGIONAL COMMITTEES FOR MEDICAL AND HEALTH RESEARCH ETHICS

Region:	**Case officer:**	**Telephone:**	**Our date:**	**Our reference:**
REK South East	Ingrid Middelthon	22845515	07.09.11	2011/1312
			Your date:	**Your reference:**
			15.06.11	

Tom Øresland
Akershus University Hospital
N-1478 Lørenskog

Pelvic floor dysfunction in women: Translation and validation of questionnaires PFDI20 and PFIQ7 to Norwegian

With reference to the application of 15 June 2011 for the above-mentioned research project. The application was dealt with at the Committee meeting of 18 August 2011.

Project Leader is Professor Tom Øresland PhD.

Principle Investigator is Akershus University Hospital, top management.

Project subject:
The purpose of the study is to translate and validate questionnaires PFDI-20 and PFIQ-7 to Norwegian as well as to critically evaluate the Norwegian versions of PFDI-20 and PFIQ-7 as a tool for measuring symptoms and condition-related quality of life. The target group for the questionnaires are women with pelvic floor dysfunction. Twenty participants will be enrolled in the study. Consent will be obtained for all data.

Decision:
The Committee has considered the application and approves the project pursuant to the Act on Health Research Section10.

Permission is given conditional on the project being conducted as described in the application and protocol, and in compliance with the provisions pursuant to the Act on Health Research and associated regulations.

If any changes are made to the project concerning the information provided in the application, the Project Leader must submit an amendment notification to REK. We draw your attention to the fact that if the changes are substantial, the Project Leader must submit a new application, or REK can demand a new application.

The research project data must be stored securely, see the Regulations on processing personal data (Personal Data Regulations) Chapter 2, and the Norwegian Directorate of Health guidelines for «Personvern og informasjonssikkerhet i forskningsprosjekter innenfor helse- og omsorgssektoren» [Personal privacy and information security in research projects within the Health and Care Sector], http://www.norsk-helsenett.no/informasjonssikkerhet/bransjenormen/Personvern%20og%20informasjonssikkerhet%20i%20forskningsprosjekter%20v1.pdf

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PO Box 1130 Blindern
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Telephone: +47 22845511
Email: post@helseforskning.etikkom.no
Website: http://helseforskning.etikkom.no

Please submit all correspondence via our case portal or email. Please state our reference number in all correspondence.

The authorisation applies until 31 December 2012. However, due to documentation considerations, the data must be archived until 31 December 2013. The data must be stored with identification removed, i.e. separated in a key file and a data file. The data must subsequently be anonymised or destroyed.

The project must submit a completion notification to REK South East D no later than 31 June 2013.

The Committee's decision can be appealed to the National Research Ethics Committee for Medicine and Health Research, cf. The Public Administration Act 28 and following. Any appeal must be sent to REK South East D. The deadline for appeal is three (3) weeks from receipt of this letter.

Yours sincerely

Stein Evensen (sign.)
Professor
Chair

Ingrid Middelthon (sign.) Senior Advisor

Copy:
Akershus University Hospital

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Website: http://helseforskning.etikkom.no

Please submit all correspondence via our case portal or email. Please state our reference number in all correspondence.

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Region:	Saksbehandler:	Telefon:	Vår dato:	Vår referanse:
REK sør-øst	Ingrid Middelthon	22845515	07.09.11	2011/1312
			Deres dato:	Deres referanse:
			15.06.11	

Tom Øresland
Akershus Universitets Sykehus
1478 Lørenskog

Bekkenbunnsdysfunksjoner hos kvinner: Oversettelse og validering av spørreskjema PFDI20 og PFIQ7 til norsk

Vi viser til søknad av 15.06.11 for det ovenfor nevnte forskningsprosjekt. Søknaden ble behandlet i komiteens møte 18.08.11.

Prosjektleder er professor PhD Tom Øresland.

Forskningsansvarlig er Akershus universitetssykehus ved øverste administrative ledelse.

Prosjekttema:
Formålet med studien er å oversette og validere spørreskjemaene PFDI-20 og PFIQ-7 til norsk, samt og kritisk evaluere de norske versjonene av PFDI-20 og PFIQ-7 som verktøy for å måle symptomer og tilstandsrelatert livskvalitet. Målgruppen for spørreskjemaene er kvinner med bekkenbunnsdysfunksjoner. Det skal inkluderes 20 deltakere i studien. Samtykke skal innhentes for alle data.

Vedtak:
Komiteen har vurdert søknaden og godkjenner prosjektet med hjemmel i helseforskningsloven § 10.

Tillatelsen er gitt under forutsetning av at prosjektet gjennomføres slik det er beskrevet i søknaden, protokollen, og de bestemmelser som følger av helseforskningsloven med forskrifter.

Dersom det skal gjøres endringer i prosjektet i forhold til de opplysninger som er gitt i søknaden, må prosjektleder sende endringsmelding til REK. Vi gjør oppmerksom på at dersom endringene er vesentlige må prosjektleder sende ny søknad, eller REK kan pålegge at så gjøres.

Forskningsprosjektets data skal oppbevares forsvarlig, se personopplysningsforskriften kapittel 2, og Helsedirektoratets veileder for «Personvern og informasjonssikkerhet i forskningsprosjekter innenfor helse- og omsorgssektoren», http://www.norsk-helsenett.no/informasjonssikkerhet/bransjenormen/Personvern%20og%20informasjonssikkerhet%20i%20forskningsprosjekter%20v1.pdf

Postadresse:
Postboks 1130 Blindern
0318 Oslo

Telefon: 22845511
E-post: post@helseforskning.etikkom.no
Web: http://helseforskning.etikkom.no

Vi ber om at alle henvendelser sendes inn via vår saksportal eller på e-post. Vennligst oppgi vårt referansenummer i korrespondansen.

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Tillatelsen gjelder til 31.12.2012. Av dokumentasjonshensyn skal opplysningene likevel bevares inntil 31.12.2013. Opplysningene skal lagres avidentifisert, dvs. adskilt i en nøkkel- og en opplysningsfil. Opplysningene skal deretter anonymiseres eller slettes.

Prosjektet skal sende sluttmelding til REK Sør-Øst D senest 31.06.2013.

Komiteens vedtak kan påklages til Den nasjonale forskningsetiske komité for medisin og helsefag, jf. forvaltningsloven 28 flg. En eventuell klage sendes til REK Sør-Øst D. Klagefristen er tre uker fra mottak av dette brevet.

Med vennlig hilsen

Stein Evensen(sign.)
professor dr. med.
leder

Ingrid Middelthon(sign.)
seniorrådgiver

Kopi:
Akershus universitetssykehus

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Web: http://helseforskning.etikkom.no

Vi ber om at alle henvendelser sendes inn via vår saksportal eller på e-post. Vennligst oppgi vårt referansenummer i korrespondansen.

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Region:	Case officer:	Telephone:	Our date:	Our reference:
REC South East	Emil Lahlum	22845523	24.10.2013	2011/1312/REK sør-øst D
			Your date:	Your reference:
			16.10.2013	

Our reference must be included in all communications

To Tom Øresland

2011/1312 Pelvic floor dysfunctions in women: Translation and validation of questionnaires PFDI20 and PFIQ7 to Norwegian

Person or unit responsible for the study: Akershus University Hospital
Project Manager: Tom Øresland

We refer to your application for a project amendment dated 16.10.2013 for the above-mentioned research project. The application has been processed by the Chair of REC South East as authorised, pursuant to the Health Research Act section 11.

The amendments concern:
- extension of the study to 31.12.2013

Assessment
REC has assessed the amendment application and has no research ethical objections to the amendment to the project

Decision
REK approves the project in its current form, cf. the Health Research Act section 11(2).

Authorisation has been given conditional on implementation of the project as described in the application, the amendment application, the updated protocol and the provisions of the Health Research Act with regulations.

REC's decision can be appealed to The National Committee for Medical and Health Research Ethics, cf. The Health Research Act section 10(3) and the Public Administration Act section 28. Any appeal is to be sent to REC South East. The deadline for appeal is three weeks from receipt of this letter cf. the Public Administration Act section 29.

Please submit all communications using the correct form via our case portal: http://helseforskning.etikkom.no. If an appropriate form is not available, please submit the communication by email to: post@helseforskning.etikkom.no.

Please include our reference number in all correspondence.

Kind regards

Finn Wisløff
Emeritus Professor Dr.
Med. Chair

Emil Lahlum
Higher Executive Officer

Visiting address:
Gullhaugveien 1-3, 0484 Oslo

Telephone: 22845511
Email: post@helseforskning.etikkom.no
Website:
http://helseforskning.etikkom.no/

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Region:	Saksbehandler:	Telefon:	Vår dato:	Vår referanse:
REK sør-øst	Emil Lahlum	22845523	24.10.2013	2011/1312/REK sør-øst D
			Deres dato:	**Deres referanse:**
			16.10.2013	

Vår referanse må oppgis ved alle henvendelser

Til Tom Øresland

2011/1312 Bekkenbunns dysfunksjoner hos kvinner: Oversettelse og validering av spørreskjema PFDI20 og PFIQ7 til norsk

Forskningsansvarlig: Akershus universitetssykehus
Prosjektleder: Tom Øresland

Vi viser til søknad om prosjektendring datert 16.10.2013 for ovennevnte forskningsprosjekt. Søknaden er behandlet av leder for REK sør-øst på fullmakt, med hjemmel i helseforskningsloven § 11.

Endringene innebærer:
- forlengelse av studien til 31.12.2013

Vurdering
REK har vurdert endringssøknaden og har ingen forskningsetiske innvendinger mot endringen av prosjektet.

Vedtak
REK godkjenner prosjektet slik det nå foreligger, jfr. helseforskningsloven § 11, annet ledd.

Tillatelsen er gitt under forutsetning av at prosjektet gjennomføres slik det er beskrevet i søknaden, endringssøknad, oppdatert protokoll og de bestemmelser som følger av helseforskningsloven med forskrifter.

REKs vedtak kan påklages til Den nasjonale forskningsetiske komité for medisin og helsefag, jfr. helseforskningsloven § 10, 3 ledd og forvaltningsloven § 28. En eventuell klage sendes til REK sør-øst. Klagefristen er tre uker fra mottak av dette brevet, jfr. forvaltningsloven § 29.

Vi ber om at alle henvendelser sendes inn med korrekt skjema via vår saksportal: http://helseforskning.etikkom.no. Dersom det ikke finnes passende skjema kan henvendelsen rettes på e-post til: post@helseforskning.etikkom.no.

Vennligst oppgi vårt referansenummer i korrespondansen.

Med vennlig hilsen

Finn Wisløff
Professor em. dr. med.
Leder

Emil Lahlum
Førstekonsulent

Besøksadresse: Gullhaugveien 1-3, 0484 Oslo
Telefon: 22845511
E-post: post@helseforskning.etikkom.no
Web: http://helseforskning.etikkom.no/

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Region:	Contact:	Tel.:	Our date:	Our reference:
REK south-east	Gjøril Bergva	+4722845529	26.03.2014	2011/1312/REK south-east D
			Your date:	Your reference:
			04/03/2014	

Please state our reference in all correspondence

Tom Øresland
Akershus University Hospital
1478 Lørenskog

2011/1312 Pelvic floor dysfunction in women: Translation and validation of questionnaires PFDI20 and PFIQ7 to Norwegian

Research principal: Akershus University Hospital
Project Manager: Tom Øresland

With reference to your application for a change dated 04.03.2014 to the above research project. The application has been considered by the head of REK south east under proxy, in accordance with Section 11 of the Health Research Act.

The changes entail:
- An extension of the project period to 31.12.2015
- An increase in the number of participants: N=420
- A change in the inclusion and exclusion criteria: Women with intestinal, urinal, vaginal and uterus prolapse, degree II-IV to be included
- Change in recruitment procedure
- New/revised enquiry for participation and declaration of consent
- Further validation of PFDI-20 and PFIQ-7

Evaluation
REK has evaluated the application for change, and has no objections on research ethics grounds to changing the project. The changes applied for are in line with the original objective of the study in the committee's opinion.

Ruling
REK approves the project in its current format, in accordance with Section 11 (2) of the Health Research Act.

Permission is granted on condition that the project is completed as described in the application, change application updated protocol and the provisions arising from the Health Research Act and its regulations.

Complaints
You can complain about the committee's according to Section 28 of the Public Administration Act. Complaints should be sent to REK south-east D. The deadline for complaints is three weeks from receipt of this letter. If the ruling is upheld by REK south-east D, it will be referred to the National Research Ethics Committee for Medicine and Healthcare for final evaluation.

Please submit all enquiries with the correct form via our portal: http://helseforskning.etikkom.no. If there is no suitable form, enquiries can be made by e-mail to: post@helseforskning.etikkom.no.

Office address: Gullhaugveien 1-3, 0484 Oslo
Tel.: 22845511
E-post: post@helseforskning.etikkom.no
Web: http://helseforskning.etikkom.no/

All post og e-post som inngår i saksbehandlingen, bes adressert til REK sør-øst og ikke til enkelte personer

Kindly address all mail and e-mails to the Regional Ethics Committee, REK sør-øst, not to individual staff

Please state our reference number in all correspondence.

Yours sincerely

Dr Finn Wisløff
Professor em.
Chairman

Gjøril Bergva
Consultant

Copy to: *pål.wiik@ahus.no, catherineplanke@yahoo.com, postmottak@ahus.no*

REK
REGIONALE KOMITEER FOR MEDISINSK OG HELSEFAGLIG FORSKNINGSETIKK

Region:	Saksbehandler:	Telefon:	Vår dato:	Vår referanse:
REK sør-øst	Gjøril Bergva	22845529	26.03.2014	2011/1312/REK sør-øst D
			Deres dato:	**Deres referanse:**
			04.03.2014	

Vår referanse må oppgis ved alle henvendelser

Tom Øresland
Akershus universitetssykehus
1478 Lørenskog

2011/1312 Bekkenbunns dysfunksjoner hos kvinner: Oversettelse og validering av spørreskjema PFDI20 og PFIQ7 til norsk

Forskningsansvarlig: Akershus universitetssykehus
Prosjektleder: Tom Øresland

Vi viser til søknad om prosjektendring datert 04.03.2014 for ovennevnte forskningsprosjekt. Søknaden er behandlet av leder for REK sør-øst på fullmakt, med hjemmel i helseforskningsloven § 11.

Endringene innebærer:
- Forlengelse av prosjektperioden til 31.12.2015
- Økning i antall forskningsdeltakere: N=420
- Endring i inklusjons- og eksklusjonskriterier: Kvinner med tarm, urin og vaginal- og uterusprolaps grad II-IV som skal inkluderes
- Endring i rekrutteringsprosedyre
- Ny/endret forespørsel om deltakelse og samtykkeerklæring
- Videre validering av PFDI-20 og PFIQ-7

Vurdering
REK har vurdert endringssøknaden og har ingen forskningsetiske innvendinger mot endringen av prosjektet. De omsøkte endringer er, etter komiteens syn, i tråd med det opprinnelige formålet med studien.

Vedtak
REK godkjenner prosjektet slik det nå foreligger, jfr. helseforskningsloven § 11, annet ledd.

Tillatelsen er gitt under forutsetning av at prosjektet gjennomføres slik det er beskrevet i søknaden, endringssøknad, oppdatert protokoll og de bestemmelser som følger av helseforskningsloven med forskrifter.

Klageadgang
Du kan klage på komiteens vedtak, jf. forvaltningslovens § 28 flg. Klagen sendes til REK sør-øst D. Klagefristen er tre uker fra du mottar dette brevet. Dersom vedtaket opprettholdes av REK sør-øst D, sendes klagen videre til Den nasjonale forskningsetiske komité for medisin og helsefag for endelig vurdering.

Vi ber om at alle henvendelser sendes inn med korrekt skjema via vår saksportal: http://helseforskning.etikkom.no. Dersom det ikke finnes passende skjema kan henvendelsen rettes på e-post til: post@helseforskning.etikkom.no.

Besøksadresse: Gullhaugveien 1-3, 0484 Oslo
Telefon: 22845511
E-post: post@helseforskning.etikkom.no
Web: http://helseforskning.etikkom.no/

Vennligst oppgi vårt referansenummer i korrespondansen.

Med vennlig hilsen

Finn Wisløff
Professor em. dr. med.
Leder

Gjøril Bergva
Rådgiver

Kopi til: *pål.wiik@ahus.no*, *catherineplanke@yahoo.com*; *postmottak@ahus.no*

AKERSHUS UNIVERSITY HOSPITAL

To whom it may concern

Their ref.:	Our ref.:	Officer		Date:7 th.november 2016
ReferanseNr	Document 11/060	Name: Ingrid Ursin	e-mail: personvern@ahus.no	DokumentDato:

Confirmation

Research project "Validating condition-specific quality of life questionnaires for women with pelvic floor disorders in the Norwegian context"

Project manager: Catherine Planke

Research objectives

1. *Translate and validate the PFDI-20 and PFIQ-7 self-administered questionnaires in Norwegian.*
2. *Critically evaluate the Norwegian PFIQ-20 and PFIQ-7 questionnaire as tools for measuring condition-specific QOL*

According the EU direktiv 95/46 EF guidelines the identifiable data and consent forms will only be stored at Akershus University Hospital. De-indentified data (de-identified questionnaires) will be stored at Flinders University server for a period of 5 years.

Project periode: 1 st of December 2011 – 31 st of December 2015. The project was approved by the Data protection Official 25 th November 2011 and 13 th may 2014.

We hereby confirm that the project has been approved by the Data protection Official at Akershus University Hospital, Norway.

Best regards

Ingrid Ursin

Ingrid Ursin
Data protection Official
Akershus University Hospital
Norway

Post address: Akershus universitetssykehus HF 1478 LØRENSKOG
Office addresse: Sykehusveien 25 Nordbyhagen
Phone: +47 02900 Telefax: +47 67968861 E-mail: postmottak@ahus.no
Bank: 1503.27.07499 Org.nr: 983 971 636 Web: www.ahus.no
UiO : University of Oslo

FINAL APPROVAL NOTICE

Project No.: **5376**

Project Title: Validating condition-specific quality of life questionnaires for women with pelvic floor disorders in the Norwegion context

Principal Researcher: Ms Catherine Planke

Email: Catherine.Planke@ahus.no

Address: School of Medicine

Approval Date: 18 March 2012 Ethics Approval Expiry Date: **1 December 2012**

The above proposed project has been **approved** on the basis of the information contained in the application, its attachments and the information subsequently provided.

RESPONSIBILITIES OF RESEARCHERS AND SUPERVISORS

1. Participant Documentation

Please note that it is the responsibility of researchers and supervisors, in the case of student projects, to ensure that:

- all participant documents are checked for spelling, grammatical, numbering and formatting errors. The Committee does not accept any responsibility for the above mentioned errors.
- the Flinders University logo is included on all participant documentation (e.g., letters of Introduction, information Sheets, consent forms, debriefing information and questionnaires – with the exception of purchased research tools) and the current Flinders University letterhead is included in the header of all letters of introduction. The Flinders University international logo/letterhead should be used and documentation should contain international dialling codes for all telephone and fax numbers listed for all research to be conducted overseas.

- the SBREC contact details, listed below, are included in the footer of all letters of introduction and information sheets.

This research project has been approved by the Flinders University Social and Behavioural Research Ethics Committee (Project Number 'INSERT PROJECT No. here following approval'). For more information regarding ethical approval of the project the Executive Officer of the Committee can be contacted by telephone on 8201 3116, by fax on 8201 2035 or by email human.researchethics@flinders.edu.au.

2. Annual Progress / Final Reports

In order to comply with the monitoring requirements of the *National Statement on Ethical Conduct in Human Research (March 2007)* an annual progress report must be submitted each year on the **18 March** (approval anniversary date) for the duration of the ethics approval using the annual progress / final report pro forma.

Please retain this notice for reference when completing annual progress or final reports.

If the project is completed *before* ethics approval has expired please ensure a final report is submitted immediately. If ethics approval for your project expires please submit either (1) a final report; or (2) an extension of time request and an annual report.

Your first report is due on **18 March 2013** or on completion of the project, whichever is the earliest.

3. Modifications to Project

Modifications to the project must not proceed until approval has been obtained from the Ethics Committee. Such matters include:

- proposed changes to the research protocol;
- proposed changes to participant recruitment methods;
- amendments to participant documentation and/or research tools;
- extension of ethics approval expiry date; and
- changes to the research team (addition, removals, supervisor changes).

To notify the Committee of any proposed modifications to the project please submit a Modification Request Form to the Executive Officer. Please note that extension of time requests should be submitted prior to the Ethics Approval Expiry Date listed on this notice.

Change of Contact Details
Please ensure that you notify the Committee if either your mailing or email address changes to ensure that correspondence relating to this project can be sent to you. A modification request is not required to change your contact details.

4. Adverse Events and/or Complaints
Researchers should advise the Executive Officer of the Ethics Committee on 08 8201-3116 or human.researchethics@flinders.edu.au immediately if:

- any complaints regarding the research are received;
- a serious or unexpected adverse event occurs that effects participants;
- an unforseen event occurs that may affect the ethical acceptability of the project.

Andrea Mather
Executive Officer
Social and Behavioural Research Ethics Committee

c.c A/Prof Malcolm Bond, malcolm.bond@flinders.edu.au
Dr Angelita Martini, angelita.martini@flinders.edu.au

Andrea Mather
Executive Officer, Social and Behavioural Research Ethics Committee
Research Services Office |Union Building Basement
Flinders University
Sturt Road, Bedford Park | South Australia | 5042
GPO Box 2100 | Adelaide SA 5001
P: +61 8 8201-3116 | F: +61 8 8201-2035 |Web: Social and Behavioural Research Ethics Committee

APPENDIX 3.5

RESEARCH MATERIAL FOR STAGE 1 (EXPERT PANEL)

Ms Catherine Planke

Faculty of Health Sciences, Flinders University

INTRODUCTION LETTER – FOR EXPERT PANEL

Invitation to a research project:

"Validating condition specific quality of life questionnaires for women with pelvic floor disorders in the Norwegian context"

I am undertaking research on the subject of translating and testing a new set of questionnaires in Norwegian to assess pelvic floor disorders. The questionnaires aims to measure patients' bowel, urine and prolapse symptoms and the impact of these symptoms on Norwegian women's quality of life. The Purpose of the research project is to translate a well-established set of pelvic floor disorder questionnaires from English to Norwegian and pilot test the questionnaires on 20 Norwegian women. Before pilot-testing the questionnaires it will be reviewed by a expert panel.

The expert panel will review all the versions of the questionnaires and consider the pre-final version of the questionnaires for pilot testing. The pelvic floor experts will comprise of gynaecologists, urologists, a colorectal surgeons, physiotherapists and a specialist nurse.

The Norwegian translation will be circulated by e-mail and/or a meeting organised among the experts for comments about the questionnaire's items. Three to four rounds will be recommended to reach consensus among the seven PDF experts. The questionnaires will be re-circulated for clarification where consensus is not achieved, until a clear set of items that have cross-cultural equivalence is achieved.

I am most grateful for your assistance in this project.

For more information see attachments: PFDI-20 PFIQ-7 questionnaires and interview guide.

Yours sincerely,
Ms Catherine Planke
Master of Science candidate
School of Medicine
Faculty of Health Sciences
Flinders University

inspiring achievement

APPENDIX 4.1

DATA EXTRACTION TABLES FOR STAGE 1 (TRANSLATIONS)

Forward translations and reconciliation phase of PFDI-20 and PFIQ-7:

Table 4.1a Forward translations and reconciliation phase of PFDI-20 instructions and PFDI-20 example — producing a single forward version in Norwegian.

Table 4.1b Forward translations and reconciliation phase of PFDI-20 title, opening question, example, questions 1–20 and responses — producing a single forward version in Norwegian.

Table 4.1c Forward translations and reconciliation phase of PFIQ-7 instructions and PFIQ-7 example — producing a single forward version in Norwegian.

Table 4.1d Forward translations and reconciliation phase of PFIQ-7 title, opening question, example, questions 1–7 and responses — producing a single forward version in Norwegian.

Back-translations and back-translation review of PFDI-20 and PFIQ-7 (First interim report):

Table 4.1e Back-translations and back-translation review of PFDI-20 instructions and PFDI-20 example (First interim report — producing a Norwegian Intermediate Version 1.0).

Table 4.1f Back-translations and back-translation review of PFDI-20 title, opening question, example, questions 1–20 and responses (First interim report — producing a Norwegian Intermediate Version 1.0).

Table 4.1g Back-translations and back-translation review of PFIQ-7 instructions and PFIQ-7 example (First interim report — producing a Norwegian Intermediate Version 1.0).

Table 4.1h Back-translations and back-translation review of PFIQ-7 title, opening question, example, questions 1–7 and responses (First interim report — producing a Norwegian Intermediate Version 1.0).

Table 4.1a Forward translations and reconciliation phase of PFDI-20 instructions and example — producing a single forward translation

Forward translations and reconciliation phase of PFDI-20 – Instructions
Source Text
INSTRUCTIONS Please answer all of the questions in the following survey. These questions will ask you if you have certain bowel, bladder or pelvic symptoms and if you do how much they bother you. Answer these questions by putting an X in the appropriate box or boxes. If you are unsure about how to answer a question, give the best answer you can. While answering these questions, please consider your symptoms over the last 3 months.
Forward Translation One (FT1)
INSTRUKSJONER: Alle spørsmålene i skjemaet må besvares. Spørsmålene dreier seg om hvorvidt du har visse symptomer i forbindelse med tarm-, blære- eller bekkenbunnfunksjon, og i så fall hvor mye du plages av dem. Svar på spørsmålene ved å sette en X i den aktuelle boksen eller boksene. Hvis du er usikker på hvordan du skal besvares et spørsmål, svarer du bare så godt du kan. La eventuelle symptomer de siste 3 månedene være utgangspunkt for svarene du gir.
Forward translation Two (FT2)
VEILEDNING: Vennligst svar på alle spørsmålene i spørreskjemaet. Spørsmålene dreier seg om hvorvidt du har bestemte symptomer i tarmen, blæren eller bekkenregionen, og hvis du har de i hvilken grad de plager deg. Svar på spørsmålene ved å krysse X i den eller de boksene som passer for deg. Hvis du er usikker på hva du skal svare, svarer du så godt du kan. Vennligst ta i betraktning symptomene dine i løpet av de siste tre månedene når du svarer på spørsmålene.
Equivalence: Equivalence includes: semantic, idiomatic, conceptual or experiential equivalence
FT2 retained slightly better semantic, idiomatic, conceptual equivalence.
Comments: Comments include Specific domain terminology (STD), equivalence and clear wording
The second translation (FT2) was selected with some minor amendments. *Ulike* replaces *bestemte*; *i så fall* replaces *hvis du hadde det;* and *ta hensyn til* replaces *ta i betraktning*. Amendments were made due to lack of semantic equivalence and clear wording. Both translators agreed to use FT2 and approved of the amendments.
Outcome: Single forward translation
VEILEDNING: Vennligst svar på alle spørsmålene i spørreskjemaet. Spørsmålene dreier seg om hvorvidt du har ulike symptomer i tarmen, blæren eller bekkenregionen, og i så fall i hvilken grad de plager deg. Svar på spørsmålene ved å krysse av i den eller de boksene som passer for deg. Hvis du er usikker på hva du skal svare, svarer du så godt du kan. Vennligst ta hensyn til symptomene du har hatt de siste tre månedene når du svarer på spørsmålene.

Forward translations and reconciliation phase of PFDI-20 – Example
Source Text
Example For the following question: Do you usually experience headaches? (1) If you do not usually have headaches just put an **X** in the "No" box. (2) If you do usually have headaches, put an X in the "Yes" box and indicates how much the headaches bother you, (In this example, the headaches were moderately bothersome).
Forward translation (first translator)
EKSEMPEL *Ved følgende spørsmål:* *Har du ofte hodepine?* *(1) Hvis du ikke pleier å ha hodepine, setter du **X** i "Nei"-ruten.* *(2) Hvis du pleier å ha hodepine, setter du **X** i "Ja"-boksen og angir hvor mye du synes hodepinen plager deg. (I dette eksemplet plages vedkommende av hodepinen i noen grad).*
Forward translation (second translator)
EKSEMPEL *For følgende spørsmål:* *Pleier du å ha hodepine?* *(1) Dersom du ikke pleier å ha hodepine, setter du en **X** i "Nei"-boksen.* *(2) Dersom du pleier å ha hodepine, setter du en **X** i "Ja"-boksen og angir hvilken grad hodepinen plager deg. (I dette eksemplet er hodepinen plagsom i moderat grad).*
Equivalence Equivalence includes semantic, idiomatic, conceptual or experiential equivalence
Both translations were very similar and retained equivalence in all four areas.
Comments[a] Comments include specific domain terminology (STD), equivalence and clear wording
First translation was selected due to slightly clearer wording. Second translator approved of the selection.
Outcome: Single forward translation
EKSEMPEL *Ved følgende spørsmål:* *Har du ofte hodepine?* *(1) Hvis du ikke pleier å ha hodepine, setter du **X** i "Nei"-ruten.* *(2) Hvis du pleier å ha hodepine, setter du **X** i "Ja"-boksen og angir hvor mye du synes hodepinen plager deg. (I dette eksemplet plages vedkommende av hodepinen i noen grad).*
[a] Where differences arose between the two forward translations, the principal researcher (using some recommendations from the pelvic floor advisory team) resolved these through discussions with the two forward translators to produce a single forward version or a provisional forward translation.

Table 4.1b Forward translations and reconciliation phase of PFDI-20 title, example, questions 1–20 and responses — producing a single forward translation

Forward translations and reconciliation phase of PFDI-20 (bold text pertains to the text being reviewed)						
Question	**Source Text**	**First Forward Translation (FT 1)**	**Second Forward Translation (FT 2)**	**Equivalence** **Semantic** **Conceptual** **Idiomatic** **Experiential**	**Comments[a]** **Equivalence** **Specific domain terminology (STD)** **Clear wording** *First and second translators agreed to the following proposals and amendments*	**Outcome Single forward translation (SFT)**
Title	Pelvic Floor Distress Inventory- short form 20	*Oversikt over bekkenbunnspla ger- kort skjema 20*	*Detaljert spørreskjema om bekkenbunns-plager - kort skjema 20*	Both the first translation (FT1) and second translation (FT2) achieved equivalence between the original source and Norwegian version of the questionnaire in all four areas. However, the title needed further discussion.	The second translation (FT2) was selected due to specific domain terminology. *Besvær* replaces *plager. Detaljert* was removed from the text.	*Spørreskjema om bekkenbunns-besvær- kort skjema 20*
For instructions and example - See Table 3.3a						
This section discusses idiomatic equivalence concerning the PFDI-20 questions 1-20.						
3 4 9 10 11 12	Idiom Do you usually…	*Har du ofte* *Må du ofte*	*Pleier du* *Pleier det*	Both FT1 and FT2 achieved equivalence between the original source and Norwegian version in all four areas. However, the idiom needed further discussion.	The principal researcher aim was to find one idiom (or phrase) that would be suitable for all the questions (i.e. question 3, 4, 9, 10, 11 and 12). The Translation Advisory Group (TAG) proposed three alternative idioms *har du vanligvis* or *må du vanligvis* or *slipper du vanligvis.* These phrases were flagged for discussion in the pilot test	*Har du vanligvis* or *Må du vanligvis* or *Slipper du vanligvis*

Forward translations and reconciliation phase of PFDI-20 (bold text pertains to the text being reviewed)						
Question	**Source Text**	**First Forward Translation (FT 1)**	**Second Forward Translation (FT 2)**	**Equivalence** **Semantic** **Conceptual** **Idiomatic** **Experiential**	**Comments[a]** **Equivalence** **Specific domain terminology (STD)** **Clear wording** *First and second translators agreed to the following proposals and amendments*	**Outcome Single forward translation (SFT)**
1 2 5 15 16 17 18 19 20	Do you usually experience...	*Føler du ofte* *Føler du deg ofte* *Opplever du ofte* *Har du ofte* *Opplever du*	*Pleier du å kjenne* *Pleier du å ha en følelse* *Pleier du*	Both FT1 and FT2 achieved equivalence between the original source and Norwegian version in all four areas. However, the idiom needed further discussion.	The principal researcher aim was to find one idiom (or phrase) that would be suitable for all the questions (i.e. question 1, 2, 5, 15-20). The TAG proposed two alternative idioms *kjenner du vanligvis* and *opplever du vanligvis*. These phrases were flagged for discussion in the pilot test.	*Kjenner du vanligvis* or *Opplever du vanligvis*
7 8	Do you feel...	*Føler du at du*	*Synes du at du* *Føles det som*	Both FT1 and FT2 achieved equivalence between the original source and Norwegian version in all four areas.	FT1 was selected.	*Føler du at du*
13	Do you experience...	*Opplever du*	*Pleier du å kjenne*	FT1 retained equivalence between the original source and Norwegian version in all four areas.	FT1 was selected.	*Opplever du*
14	Ever	*Noen gang*	*Hender det at*	Both FT1 and FT2 achieved equivalence between the original source and Norwegian version in all four areas.	FT2 was selected. Even though both idioms had idiomatic equivalence, FT2 was more accurate in relation to the question.	*Hender det at*
6	Do you ever have to...	*Må du noen ganger*	*Hender det at*	Both FT1 and FT2 achieved equivalence between the original source and Norwegian version in all four areas.	FT1 was selected. Even though both idioms had idiomatic equivalence, FT1 was more accurate in relation to the question.	*Må du noen ganger*

Forward translations and reconciliation phase of PFDI-20 (bold text pertains to the text being reviewed)						
Question	**Source Text**	**First Forward Translation (FT 1)**	**Second Forward Translation (FT 2)**	**Equivalence** **Semantic** **Conceptual** **Idiomatic** **Experiential**	**Comments[a]** **Equivalence** **Specific domain terminology (STD)** **Clear wording** *First and second translators agreed to the following proposals and amendments*	**Outcome Single forward translation (SFT)**
This section discusses idiomatic, semantic, conceptual and experiential equivalence concerning the PFDI-20 questions 1-20.						
1	Do you usually have pressure in the lower abdomen?	*Føle du ofte et press i underlivet?*	*Pleier du å kjenne en trykkende følelse nederst i buken?*	Both first translation (FT1) and second translation (FT2) lacked semantic equivalence.	The first translation (FT1) and second translation (FT2) lacked specific domain terminology and semantic equivalence. FT2 was selected with some amendments.	*Kjenne du vanligvis et trykk i den nedre delen av magen?*
2	Do you usually experience heaviness or dullness in pelvic area pressure in the lower abdomen?	*Føler du deg ofte tung eller nummen i bekken-området?*	*Pleier du å kjenne en treg eller tung følelse i bekkenet?*	FT2 achieved equivalence between the original source and Norwegian version in all four areas. FT1 lacked conceptual and semantic equivalence.	FT2 was selected. FT2 is closer to a semantic equivalence and specific domain terminology. Some amendments were made to FT2. *Tyngde* replaces *Tung*. Word *Treg* removed.	*Kjenner du vanligvis tyngdefølelse i bekkenet?*
3	Do you usually have a bulge or something falling out that you can see or feel in the vaginal area?	*Har du ofte en utposning eller noe som faller ned, som du kan se eller kjenne?*	*Pleier du å kjenne en kul eller noe som faller ut, som du kan se eller kjenne i skjeden?*	Both FT1 and FT2 achieved equivalence between the original source and Norwegian version in all four areas. However, the wording needed further discussion.	FT2 was selected. FT2 is closer to a semantic equivalence and specific domain terminology. However, the principal researcher was concerned that the wording *have a bulge* was not clear and lacked specific domain terminology. The wording was amended. This item was flagged for discussion in the pilot test.	*Har du vanligvis noe som buler ut eller faller ut som du kan se eller kjenne i skjeden?*
4	Do you usually have to push on the vagina or around the rectum to have or complete a bowel movement?	*Må du ofte trykke i skjeden eller rundt endetarmåpningen for få avføring eller få tømt tarmen helt?*	*Pleier du å måtte presse mot skjeden eller rundt endetarmen for å bli ferdig med avføringen?*	FT1 achieved equivalence between the original source and Norwegian version in all four areas. FT2 lacked semantic equivalence.	FT1 was selected with some amendments. *Vanligvis presse* replaces *ofte trykke*.	*Må du vanligvis presse i skjeden eller rundt endetarms-åpningen for å få avføring eller få tømt tarmen helt?*

Forward translations and reconciliation phase of PFDI-20 (bold text pertains to the text being reviewed)						
Question	**Source Text**	**First Forward Translation (FT 1)**	**Second Forward Translation (FT 2)**	**Equivalence** **Semantic** **Conceptual** **Idiomatic** **Experiential**	**Comments[a]** **Equivalence** **Specific domain terminology (STD)** **Clear wording** *First and second translators agreed to the following proposals and amendments*	**Outcome Single forward translation (SFT)**
5	Do you usually experience a feeling of incomplete bladder emptying?	*Føler du ofte urinblæren ikke er blitt tømt fullstendig?*	*Pleier du å ha en følelse av at blæren ikke tømmes helt?*	FT1 and FT2 achieved equivalence between the original source and Norwegian version in all four areas. However, wording needed further discussion.	FT1 was selected. FT1 was closer to specific domain terminology. Some amendments were made to FT1. The sentence was change to presence tense og *helt* replaced *fullstendig*.	*Kjenner du vanligvis* ***at urinblæren ikke blir tømt helt?***
6	Do you ever have to push to up on a bulge in the vaginal area with your fingers to start or complete urination?	*Må du noen ganger trykke på en utposning i skjedeområdet med fingrene for å kunne late vannet eller tømme blæren helt?*	*Hender det at du må skyve opp en slags kul i skjeden med fingrene for å begynne eller bli ferdig med å late vannet?*	FT1 and FT2 achieved equivalence between the original source and Norwegian version in all four areas.	FT1 was selected with several amendments. FT1 was closer to specific domain terminology. *bul* replaced *utposning.* *skjeden* replaced *skjedeområdet* and *for å begynne å tisse eller tømme blæren helt* replaced *for å kunne late vannet eller tømme blæren helt.*	*Må du noen ganger* ***trykke inn en bul i skjeden med fingrene for å begynne å tisse eller tømme blæren helt?***
7	Do you feel you need to strain too hard to have a bowel movement?	*Føler du at du presser for hardt når du skal tømme magen?*	*Synes du at du må anstrenge deg veldig for å ha avføring?*	FT1 and FT2 achieved equivalence between the original source and Norwegian version in all four areas.	A combination of both (FT1) and (FT2) were selected with amendments.	*Føler du at du* ***må presse for hardt for å ha avføring?***
8	Do you feel you have not completely emptied your bowels at the end of a bowel movement?	*Føler du at du ikke har tømt magen helt, når du har hatt avføring?*	*Føles det som om du ikke er helt ferdig etter at du har hatt avføring?*	FT1 and FT2 lacked semantic equivalence between the original source and Norwegian version.	FT1 was selected since it was closer to semantic equivalence. The principal researcher proposed that *tarmen* replaced *magen.*	*Føler du at du ikke har tømt tarmen helt, når du har hatt avføring?*

Forward translations and reconciliation phase of PFDI-20 (bold text pertains to the text being reviewed)						
Question	**Source Text**	**First Forward Translation (FT 1)**	**Second Forward Translation (FT 2)**	**Equivalence** **Semantic** **Conceptual** **Idiomatic** **Experiential**	**Comments[a]** **Equivalence** **Specific domain terminology (STD)** **Clear wording** *First and second translators agreed to the following proposals and amendments*	**Outcome Single forward translation (SFT)**
9	Do you usually lose stool beyond your control if your stool is well formed?	*Har du ofte ufrivillig avføring hvis konsistensen er normal?*	*Pleier du å få avføring uten at du ønsker det, når avføringen er fast og fin?*	FT1 and FT2 lacked semantic equivalence between the original source and Norwegian version.	A combination of both FT1 and FT2 were selected with amendments.	*Har du vanligvis **ufrivillig avføring, hvis avføring er fast?***
10	Do you usually lose stool beyond your control if your stool is loose or liquid?	*Har du ofte ufrivillig avføring hvis konsistensen er løs eller flytende?*	*Pleier du å få avføring uten at du ønsker det, når avføringen er løs eller flytende?*	FT1 and FT2 lacked semantic equivalence between the original source and Norwegian version.	FT1 was selected with some amendments. *Vanligvis* replaced *ofte* and *avføringen* replaced *konsistensen.*	*Har du vanligvis ufrivillig avføring hvis avføringen er løs eller flytende?*
11	Do you usually lose gas from your rectum beyond your control?	*Har du ofte ufrivillig lekkasje av luft fra endetarmen?*	*Pleier du ufrivillig å slippe ut luft fra endetarmen?*	FT1 and FT2 lacked semantic equivalence between the original source and Norwegian version.	A combination of both (FT1) and (FT2) were selected with amendments.	*Slipper du vanligvis luft fra tarmen uten kontroll?*
12	Do you usually have pain when you pass your stool?	*Har du ofte smerte ved avføring?*	*Pleier det å gjøre vondt når du har avføring?*	FT1 lacked semantic equivalence between the original source and Norwegian version.	Second translation FT2 was selected with some amendments. The phrase *smerte* replaced *vondt.*	*Har du vanligvis smerte når du har avføring?*
13	Do you experience a strong sense of urgency and have to rush to the bathroom to have a bowel movement?	*Opplever du at det haster veldig, og at du må løpe på toalettet for å tømme magen?*	*Pleier du å kjenne at det haster veldig og må skynde deg på toalettet når du har avføring?*	FT1 lacked semantic equivalence between the original source and Norwegian version.	Second translation (FT2) was selected with some amendments. The wording was slightly modified due to specific domain terminology. *Tarmen* replaced *magen.* This item was flagged for discussion in the pilot test	*Opplever du stor trang og må løpe på toalettet for å tømme tarmen?*

Forward translations and reconciliation phase of PFDI-20 (bold text pertains to the text being reviewed)						
Question	**Source Text**	**First Forward Translation (FT 1)**	**Second Forward Translation (FT 2)**	**Equivalence** **Semantic** **Conceptual** **Idiomatic** **Experiential**	**Comments[a]** **Equivalence** **Specific domain terminology (STD)** **Clear wording** *First and second translators agreed to the following proposals and amendments*	**Outcome Single forward translation (SFT)**
14	Does part of your bowel ever pass through the rectum and bulge outside during or after a bowel movement?	*Stikker noen grad av tarmen noen gang ut av endetarmen når du har, eller hatt avføring?*	*Hender det at deler av tarmen følger med ut av endetarmen ved avføring eller etterpå?*	FT1 lacked semantic equivalence between the original source and Norwegian version.	FT2 was selected with some amendments. The wording was slightly modified due to semantic equivalence and specific domain terminology. En del replaced deler av. Endetarmen removed. *Under eller etter avføring* replaced *ved avføring eller etterpå.*	*Hender det at en del av tarmen følger med ut under eller etter avføring?*
15	Do you usually experience frequent urination?	*Opplever du at du må late vannet ofte?*	*Pleier du å måtte late vannet ofte?*	FT1 and FT2 lacked semantic equivalence between the original source and Norwegian version.	FT1 and FT2 translations lacked both semantic equivalence and precise specific domain terminology. The TAG proposed an alternative wording *hyppig vannlatning*.	*Har du vanligvis hyppig vannlatning?*
16	Do you usually experience urine leakage associated with a feeling of urgency; that is, a strong sense of needing to go to the bathroom?	*Har du ofte urinlekkasje i forbindelse med en sterk trang til å late vannet; det vil si at det haster veldig med å komme på toalettet?*	*Pleier du å ha urinlekkasje sammen med en sterk trang til å late vannet; dvs en følelse av at det haster med å gå på toalettet?*	FT1 and FT2 lacked semantic equivalence between the original source and Norwegian version.	The principal researcher was concerned that FT1 and FT2 translations lacked both semantic equivalence and precise specific domain terminology. A combination of both (FT1) and (FT2) were selected with amendments. This item was flagged for discussion in the pilot test.	*Opplever du vanligvis* ***urinlekkasje sammen med plutselig vannlatningstrang dvs en sterk følelse av at du må på toalettet?***
17	Do you usually experience urine leakage related to coughing, sneezing or laughing?	*Har du ofte urinlekkasje når du hoster, nyser eller ler?*	*Pleier du å ha urin -lekkasje når du hoster, nyser eller ler?*	FT1 and FT2 achieved equivalence between the original source and Norwegian version in all four areas.	Both FT1 and FT2 were both selected. The translations were very similar.	*Opplever du vanligvis urinlekkasje når du hoster, nyser og ler?*

Forward translations and reconciliation phase of PFDI-20 (bold text pertains to the text being reviewed)						
Question	**Source Text**	**First Forward Translation (FT 1)**	**Second Forward Translation (FT 2)**	**Equivalence** **Semantic** **Conceptual** **Idiomatic** **Experiential**	**Comments[a]** **Equivalence** **Specific domain terminology (STD)** **Clear wording** *First and second translators agreed to the following proposals and amendments*	**Outcome Single forward translation (SFT)**
18	Do you usually experience small amounts of urine leakage (that is, drops)?	*Har du ofte **urinlekkasje. I små mengder (det vil si, i form av dråper)?***	*Pleier du å ha urin-lekkasjer i små mengder (det vil si, dråper)?*	FT1 and FT2 achieved equivalence between the original source and Norwegian version in all four areas.	FT2 was selected.	*Opplever du vanligvis urinlekkasje i små mengder (dvs ,dråper)?*
19	Do you usually experience difficulty emptying your bladder?	*Opplever du ofte at det er vanskelig å få tømt blæren?*	*Pleier du å ha problemer med å tømme blæren?*	FT1 and FT2 achieved equivalence between the original source and Norwegian version in all four areas.	FT2 was selected.	*Opplever du vanligvis problemer med å tømme blæren?*
20	Do you usually experience pain or discomfort in the lower abdomen or genital region?	*Opplever du ofte smerte eller ubehag i underlivet eller området rundt kjønns-organene?*	*Pleier du å kjenne smerte eller ubehag nederst i buken eller i området rundt kjønnsorganene ?*	FT1 and FT2 lacked conceptual and semantic equivalence between the original source and Norwegian version.	FT1 and FT2 translations lacked conceptual equivalence, semantic equivalence and precise specific domain terminology. The second translation FT2 was selected with some amendments. *Nedre delen av magen* replaced *nederst i buken* and *i området rundt kjønnsorganene.*	*Kjenner du vanligvis smerte eller ubehag i den nedre delen av magen eller underlivet?*
This section discusses idiomatic, semantic, conceptual and experiential equivalence concerning the responses to the PFIQ-7 example and questions 1-20.						
Response question	If yes, how much does it bother you?	*Hvis svare er ja, hvor mye plager det deg?*	*Hvis ja, i hvilken grad plager det deg?*	FT1 and FT2 achieved equivalence between the original source and Norwegian version in all four areas.	Both FT1 and FT2 were selected.	*Hvis ja, hvor mye plager det deg?*

Forward translations and reconciliation phase of PFDI-20 (bold text pertains to the text being reviewed)						
Question	**Source Text**	**First Forward Translation (FT 1)**	**Second Forward Translation (FT 2)**	**Equivalence** **Semantic** **Conceptual** **Idiomatic** **Experiential**	**Comments[a]** **Equivalence** **Specific domain terminology (STD)** **Clear wording** *First and second translators agreed to the following proposals and amendments*	**Outcome Single forward translation (SFT)**
Response	Not at all	*Overhodet ikke*	*Ikke det hele tatt*	FT1 and FT2 achieved equivalence between the original source and Norwegian version in all four areas.	FT1 was selected because it was important to choose a response that would be distinctive enough, so the rater would differentiate between the choices.	*Ikke i det hele tatt*
Response	Somewhat	*Litt*	*Noe*	FT1 and FT2 achieved equivalence between the original source and Norwegian version in all four areas.	FT1 was selected because it was important to choose a response that would be distinctive enough, so the rater would differentiate between the choices.	*Litt*
Response	Moderately	*I noen grad*	*Moderat*	FT1 and FT2 achieved equivalence between the original source and Norwegian version in all four areas.	FT1 was selected because it was important to choose a response that would be distinctive enough, so the rater would differentiate between the choices.	*I noen grad*
Response	Quite a bit	*Ganske mye*	*Ganske mye*	FT1 and FT2 achieved equivalence between the original source and Norwegian version in all four areas.	Both FT1 and FT2 were both selected. The translations were very similar.	*Ganske mye*

[a] Where differences arose between the two forward translations, the principal researcher (using some recommendations from the pelvic floor advisory team) resolved these through discussions with the two forward translators to produce a single forward version or a provisional forward translation.

Table 4.1c Forward translations and reconciliation phase of PFIQ-7 instructions and example — producing a single forward translation

Instructions: Source Text
Instructions for page one and two: Instructions: Some women find that bladder, bowel or vaginal symptoms affect their activities, relationships and feelings. For each question, place an X in the response that best describes how much your activities, relationships or feelings have been affected by your bladder, bowel or vaginal symptoms or conditions over the last 3 months. Please be sure to mark an answer in **all 3 columns** for each question. Thank you for your cooperation. Instructions for page two only: You may or may not have had symptoms, in each of these three areas, but please be sure to mark an answer in **all 3 columns** for each question. If you do not have symptoms in one of these areas, then the appropriate answer for the corresponding column for each question.
Forward translation (first translator) (FT1)
Instructions for page one and two: *Veiledning: Noen kvinner opplever at symptomer til blære-, tarmfunksjon eller skjede påvirker deres aktiviteter, forhold og følelsesliv. Sett X ved det svaret på hvert spørsmål som best beskriver i hvilken grad dine aktiviteter og forhold eller ditt følelsesliv kan har blitt påvirket av symptomer eller plager fra blære, endetarm eller skjede de tre siste månedene. Husk å krysse av i **alle de tre kolonnene** for hvert spørsmål.* **Instructions for page one only:** D*et kan være at du har eller ikke har symptomer i hvert av disse områdene, men du må uansett markere ett svar i **hver av de tre kolonnene** for hvert spørsmål. Dersom du ikke har symptomer i ett av disse områdene, krysser du av for svaret "Ikke i det hele tatt" i den aktuelle kolonnen for hvert spørsmål.*
Forward translation (second translator) (FT2)
Instructions for page one and two: ***Forklaring:** Noen kvinner har symptomer fra blære, tarmen og skjede som påvirker aktivitetsnivå, forhold og følelser. For hvert av spørsmålene setter du en X krysse av for svaret som best beskriver hvordan dine aktiviteter, forhold eller dine følelser har blitt påvirket av symptomer eller plager fra blære, endetarm eller skjede de tre siste månedene. Husk å krysse av i **alle de** tre kolonnene for hvert spørsmål.* **Instructions for page one only:** *Du kan ha, eller ikke ha symptomer innenfor hvert av disse tre områdene, men husk å svare i **alle tre kolonner** for hvert spørsmål. Hvis du ikke ha symptomer på et av områdene, svare du "ikke I det hele tatt" I den aktuelle kolonnen.*
Equivalence:
The first and second translations were very similar however they both lacked semantic equivalence.
Comments[a]: Comments included equivalence, specific domain terminology (STD) and clear wording
The second translation (FT2) was selected. The following amendments were made: *Veiledning* replaces *Forklaring; opplever at* replaces *har*; *endetarmen* replaces *tarmen;* and *For hvert av spørsmålene ber vi deg krysse av for svaret som best beskriver* replaces *For hvert av spørsmålene setter du en X krysse av for svaret som best beskriver.* The amendments were made due to specific domain terminology and semantic equivalence. First and Second translator approved of amendments and selection.

Outcome: Single forward translation
Instructions for page one and two: ***Veiledning:*** *Noen kvinner opplever at symptomer fra blære, endetarmen og skjede som påvirker deres aktiviteter, forhold og følelser. For hvert av spørsmålene ber vi deg krysse av for svaret som best beskriver hvordan dine aktiviteter, forhold eller dine følelser har blitt påvirket av symptomer eller plager fra blære, endetarm eller skjede* ***de tre siste månedene.*** Instructions for page two only: *Du kan ha, eller ikke ha symptomer innenfor hvert av disse tre områdene, men husk å svare i* ***alle tre kolonner*** *for hvert spørsmål. Hvis du ikke ha symptomer på et av områdene, svare du "ikke I det hele tatt" I den aktuelle kolonnen.*
Example: Source Text
EXAMPLE: For the following question: If your bladder symptoms interfere with your ability to drive a car *moderately*, and your bowel symptoms interfere with your ability to drive a car *somewhat*, but your vaginal or pelvic symptoms do not interfere with your ability to drive a car or you have no vaginal or pelvic symptoms then you should place an X in the corresponding boxes as indicated below: Make sure to answer all 3 columns for each and every question. Thank you for your cooperation.
Forward translation (first translator)
EKSEMPEL: Ved følgende spørsmål: Hvis du har symptomer tilknyttet blærefunksjonen, som påvirker evnen din til å kjøre bil i noen grad, og symptomene knyttet til tarmfunksjonene påvirker evnen til å kjøre bil litt, men symptomer knyttet til skjede eller bekkenbunn ikke påvirker evnen til å kjøre bil, skal du sette kryss (X) i boksene som vist nedenfor: *Husk å krysse av for et svar i alle tre kolonner for hvert spørsmål. Takk for hjelpen!*
Forward translation (second translator)
EKSEMPEL: For følgende spørsmål: Dersom blæresymptomene forstyrrer din evne til å kjøre bil i moderat grad, og tarmsymptomene forstyrrer din evne til å kjøre bil i noen grad, mens symptomer i skjede eller bekken ikke forstyrrer din evne til å kjøre bil eller di ikke har noen symptomer i skjede eller bekken, krysser du av for svarene slik det vises nedenfor: *Vennligst husk å svare i alle tre kolonner for hvert spørsmål. Takk for hjelpen!*
Equivalence: Equivalence includes semantic, idiomatic, conceptual or experiential
First forward translation (FT1) achieved equivalence between the original source and Norwegian version in all four areas. Second forward translation (FT2) lacked semantic equivalence.
Comments[a]: Comments include specific domain terminology (STD). Clear wording.
First translation (FT1) was selected. Minor amendments made. Second translator approved of the selection.
Outcome: Single forward translation
EKSEMPEL: Ved følgende spørsmål: *Hvis blærefunksjonen påvirker evnen din til å kjøre bil i noen grad, mens tarmfunksjonen bare påvirker evnen til å kjøre bil litt, og symptomer knyttet til skjede eller bekkenbunn ikke påvirker evnen til å kjøre bil i det hele tatt, skal du sette kryss (X) i boksene som vist nedenfor:* *Vennligst husk å svare i alle tre kolonner for hvert spørsmål. Takk for hjelpen!*
[a] Where differences arose between the two forward translations, the principal researcher (using some recommendations from the pelvic floor advisory team) resolved these through discussions with the two forward translators to produce a single forward version or a provisional forward translation.

Table 4.1d Forward translations and reconciliation phase of PFIQ-7 title, example, questions 1–7 and responses — producing a single forward translation

Forward translations and reconciliation phase of PFIQ-7						
PFIQ-7	**Source Text**	**First Forward translation (FT 1)**	**Second Forward translation (FT 2)**	**Equivalence** Semantic Conceptual Idiomatic Experiential	**Comments**[b] Equivalence Specific domain terminology (STD) Clear wording *First and second translators agreed to the following proposals and amendments.*	**Outcome** **Single Forward Translation**
Title	Pelvic Floor Impact Questionnaire- short form 7	*Oversikt over bekkenbunns-plager. kort form 7*	*Spørreskjema om innvirkning av Bekkenbunnsplager - kort form 7*	First translation (FT1) and second translation (FT2) achieved equivalence between the original source and Norwegian version in all four areas. However, the wording needed further discussion.	FT2 was selected due to specific domain terminology. *Plager* removed from the text.	*Spørreskjema om innvirkning av Bekkenbunn - kort form 7*
For Instructions and example see Table 3.3c.						
This section discusses idiomatic, semantic, conceptual and experiential equivalence concerning the opening questions for the PFIQ-7 example and questions 1-7.						
Opening Question for example and questions 1-7.	How does your symptoms or conditions related to the following usually affect your bladder or urine Bowel or rectum Vagina or Pelvis?	*Hvordan påvirker symptomer eller tilstander knyttet til følgende* *-Blære eller urinveier* *-Tarm eller endetarm* *-Skjede eller bekkenbunn* *vanligvis din:*	*I hvilken grad påvirker symptomer eller plager relatert til følgende område vanligvis?* *-Blære eller urinveier* *-Tarm eller endetarm* *-Skjede eller bekkenbunn*	FT1 and FT2 achieved equivalence between the original source and Norwegian version in all four areas. However, the wording needed further discussion.	FT1 was selected with som amendments. The amendments were made due to semantic equivalence and precise specific domain terminology. *Plager* replaced *tilstander. Fra* replaced *knyttet til følgende*. *Din* placed in the opening question instead of at the beginning of question 1-7.	*Hvordan påvirker symptomer eller plager fra-* *-Blære eller urinveier* *-Tarm eller endetarm* *-Skjede eller bekkenbunn* *vanligvis din:*

Forward translations and reconciliation phase of PFIQ-7						
PFIQ-7	**Source Text**	**First Forward translation (FT 1)**	**Second Forward translation (FT 2)**	**Equivalence** Semantic Conceptual Idiomatic Experiential	**Comments**[b] Equivalence Specific domain terminology (STD) Clear wording *First and second translators agreed to the following proposals and amendments.*	**Outcome** **Single Forward Translation**
Question for example	Ability to drive a car?	*Din evne å kjøre bil?*	*Din evne å kjøre bil?*	FT1 and FT2 achieved equivalence between the original source and Norwegian version in all four areas.	Both FT1 and FT2 were selected. *Din* removed from the sentence.	*Evne å kjøre bil?*
Question 1	Ability to do house work chores (cooking, cleaning, laudry)?	*Din evne til å utføre husarbeid (matlaging, rengjøring, klesvask)?*	*Din evne til å utføre husarbeid (matlaging, rengjøring, klesvask)?*	Both FT1 and FT2 achieved equivalence in all four areas.	Both FT1 and FT2 were selected. *Din* removed from the sentence.	*Evne til å utføre husarbeid (matlaging, rengjøring, klesvask)?*
Question 2	Ability to do physical activities such as walking, swimming, or other exercise?	*Din evne til å drive fysiske aktivitet, som turgåing, svømming eller annenform for trening?*	*Din evne til å være fysisk aktiv, for eksempel gå , svømme eller andre former for trening?*	FT1 achieved equivalence between the original source and Norwegian version in all four areas. FT2 lacked semantic equivalence.	FT1 was selected with some amendments. *Være* replaced *drive* and *for eksempel* replaced *som.* *Din* removed from the sentence.	*Evne til å være i fysisk aktivitet, for eksempel turgåing , svømming eller annen mosjon?*

Forward translations and reconciliation phase of PFIQ-7						
PFIQ-7	**Source Text**	**First Forward translation (FT 1)**	**Second Forward translation (FT 2)**	**Equivalence** Semantic Conceptual Idiomatic Experiential	**Comments**[b] Equivalence Specific domain terminology (STD) Clear wording *First and second translators agreed to the following proposals and amendments.*	**Outcome** **Single Forward Translation**
Question 3	Entertain-ment or activities such as going to a movie or concert?	*Dine fritids-aktiviteter som å gå på kino eller konsert?*	*Din mulighet er for å gå på kino eller konserter og lignende?*	FT1 achieved equivalence between the original source and Norwegian version in all four areas. FT2 lacked semantic equivalence.	FT1 was selected with some amendments. The principal researcher checked other alternatives in Norwegian for the word entertainment. The principal researcher used the recommendation from Translation Advisory Group (TAG) and selected *fritidsaktiviter* based on the use of common language. Further, *deltagelse i* was placed at the beginning of the sentence. *Din* removed from the sentence.	*Deltagelse i fritidsaktivitet er som å gå på kino eller konsert?*
Question 4	Ability to travel by car or bus for a distance greater than 30 minutes from home?	*Din mulighet til å reise med bil eller buss lenger enn 30 minutter hjemmefra?*	*Din muligheter til å kjøre bil eller buss i mer enn 30 minutter hjemmefra?*	FT1 and FT2 achieved equivalence between the original source and Norwegian version in all four areas.	FT1 was selected. FT1 had a slightly better semantic equivalence. *Din* removed from the sentence.	*Mulighet til å reise med bil eller buss lenger enn 30 minutter hjemmefra?*
Question 5	Participat-ing in social activities outside your home?	*Din deltakelse i sosiale aktiviteter utenfor hjemmet?*	*Dine muligheter for å delta i sosiale aktiviter utenfor hjemmet?*	FT1 and FT2 achieved equivalence between the original source and Norwegian version in all four areas.	FT1 was selected. FT1 had a slightly better semantic equivalence. *Din* removed from the sentence.	*Deltakelse i sosiale aktiviteter utenfor hjemmet?*

Forward translations and reconciliation phase of PFIQ-7						
PFIQ-7	**Source Text**	**First Forward translation (FT 1)**	**Second Forward translation (FT 2)**	**Equivalence** Semantic Conceptual Idiomatic Experiential	**Comments**[b] Equivalence Specific domain terminology (STD) Clear wording *First and second translators agreed to the following proposals and amendments.*	**Outcome** **Single Forward Translation**
Question 6	Emotional health* (nervous-ness, depression, etc.?)	*Din følelsemessig-tilstand (nervøsitet, depresjon osv.)?*	*Din psykiske helse (nervøsitet, depresjon og lignende)?*	FT1 achieved equivalence between the original source and Norwegian version in all four areas. However, the title needed further discussion.	FT1 was selected. FT1was chosen because conceptual and semantic equivalence would be retained in forward and back-translations. *Din* removed from the sentence. The principal researcher used the health specialists on the advisory team to discuss the alternatives and agreed that the decision should be based on the use of common language	*Følelses-messige helsetilstand?*
Question 7	Feeling frustrated?	*Din følelse av frustrasjon?*	*Din følelse av å være frustert og lei?*	FT1 achieved equivalence between the original source and Norwegian version in all four areas.	FT1 was selected. *Din* removed from the sentence.	*Følelse av frustrasjon?*
This section discusses idiomatic, semantic, conceptual and experiential equivalence for the responses to the PFIQ-7 example and questions 1-7 .						
Response	Not at all	*Overhodet ikke*	*Ikke i det hele tatt*	FT1 and FT2 achieved equivalence between the original source and Norwegian version in all four areas.	FT2 was selected because it was important in choosing the Norwegian phrasing to make the choices distinctive enough so the rater can differentiate between the choices.	*Ikke i det hele tatt*

Forward translations and reconciliation phase of PFIQ-7						
PFIQ-7	**Source Text**	**First Forward translation (FT 1)**	**Second Forward translation (FT 2)**	**Equivalence** Semantic Conceptual Idiomatic Experiential	**Comments**[b] Equivalence Specific domain terminology (STD) Clear wording *First and second translators agreed to the following proposals and amendments.*	**Outcome** **Single Forward Translation**
Response	Somewhat	*Litt*	*Noe*	FT1 and FT2 achieved equivalence between the original source and Norwegian version in all four areas.	FT1 was selected because it was important in choosing the Norwegian phrasing to make the choices distinctive enough so the rater can differentiate between the choices.	*Litt*
Response	Moderately	*I noen grad*	*Moderat*	FT1 and FT2 achieved equivalence between the original source and Norwegian version in all four areas.	FT1 was selected because it was important in choosing the Norwegian phrasing to make the choices distinctive enough so the rater can differentiate between the choices.	*I noen grad*
Response	Quite a bit	*Ganske mye*	*Ganske mye*	FT1 and FT2 achieved equivalence between the original source and Norwegian version in all four areas.	Both FT1 and FT2 were selected.	*No change*

[b] Where differences arose between the two forward translations, the principal researcher (using some recommendations from the pelvic floor Translation Advisory Group (TAG)) resolved these through discussions with the two forward translators to produce a single forward version

Table 4.1e Back-translations and back-translation review of PFDI-20 instructions and PFDI-20 example (First interim report) producing an Intermediate Version 1.0)

Instructions: Source text
See source text. Table 4.3c
Instructions: Single Forward Translation
VEILEDNING: *Vennligst svar på alle spørsmålene i spørreskjemaet. Spørsmålene dreier seg om hvorvidt du har ulike symptomer i tarmen, blæren eller bekkenregionen, og i så fall i hvilken grad de plager deg. Svar på spørsmålene ved å krysse av i den eller de boksene som passer for deg. Hvis du er usikker på hva du skal svare, svarer du så godt du kan. Vennligst ta hensyn til symptomene du har hatt de siste tre månedene når du svarer på spørsmålene.*
First Back-translation
INSTRUCTIONS Please answer all questions in the questionnaire. The questions concern whether you have different symptoms in the colon, the bladder and the pelvic area, and if so how much they affect you. Answer the questions by putting a cross in the box(es) that apply to you. If you are unsure what to answer, answer as well as you can. When you answer the questions please consider the symptoms you have had in **the last three months.**
Second Back-translation
INSTRUCTIONS Please answer all the questions in the questionnaire. The questions relate to any symptoms you may have in the bowel, bladder or pelvic area and if so, how troublesome they are. Answer the questions by marking the alternative which is most appropriate with an X. If you are unsure how to answer, an approximate answer is sufficient. Please keep in mind that your answers relate to symptoms experienced over **the past three months.**
Checking Equivalence (by identifying major discrepancies or misinterpretations in the translation.)
Both translations FT1 and FT2 were very similar and no major discrepancies or misinterpretations were identified in the translation.
Comments Comments include: specific domain terminology (STD) and Clear wording. *Both Translators agreed with proposals.*
No major discrepancies or misinterpretations were identified, so no amendments were made to the Single Forward translation.
Outcome: Intermediate Version 1.0
VEILEDNING: *Vennligst svar på alle spørsmålene i spørreskjemaet. Spørsmålene dreier seg om hvorvidt du har ulike symptomer i tarmen, blæren eller bekkenregionen, og i så fall i hvilken grad de plager deg. Svar på spørsmålene ved å krysse av i den eller de boksene som passer for deg. Hvis du er usikker på hva du skal svare, svarer du så godt du kan. Vennligst ta hensyn til symptomene du har hatt de siste tre månedene når du svarer på spørsmålene.*
Example: Source Text
See source text 4.3.c
Example: Single forward translation
EKSEMPEL *Ved følgende spørsmål:* *(1) Hvis du ikke pleier å ha hodepine, setter du **X** i "Nei"-ruten.* *(2) Hvis du pleier å ha hodepine, setter du **X** i "Ja"-boksen og angir hvor mye du synes hodepinen plager deg. (I dette eksemplet plages vedkommende av hodepinen i noen grad)*

Back-translation (first translator) (BT1)
Example **For the following question:** **(1) If you normally do not have headaches put an X in the "No" box.** **(2) If you normally do have headaches, put an X in the "Yes" box and indicate how much you feel the headache bothers you. (In this example, the person is bothered by headaches to some extent)**
Back-translation (second translator) (BT2)
Example **For the following questions:** **(1) If you do not normally have headaches, you enter an X in the "No" box.** **(2) If you normally have a headache, enter an X in the "Yes" box and state how much you think the headaches bother you. (In this example, the headaches bother the person responding to a certain extent).**
Checking Equivalence[a] (by identifying major discrepancies or misinterpretations in the translation.)
Both translations FT1 and FT2 were very similar and no major discrepancies or misinterpretations were identified in the translation.
Comments[b] Comments include specific domain terminology (STD), equivalence and clear wording
No major discrepancies or misinterpretations were identified in the translation, so no amendments were made to the single forward translation.
Outcome: Single forward translation
EKSEMPEL *Ved følgende spørsmål:* *(1) Hvis du ikke pleier å ha hodepine, setter du **X** i "Nei"-ruten.* *(2) Hvis du pleier å ha hodepine, setter du **X** i "Ja"-boksen og angir hvor mye du synes hodepinen plager deg. (I dette eksemplet plages vedkommende av hodepinen i noen grad)*
Equivalence[a] includes: semantic, idiomatic, conceptual or experiential equivalence Comments[b] included: equivalence, specific domain terminology (STD) and clear wording. Where differences arose, the principal researcher (using some recommendations from the Translation Advisory Group) resolved these by a discussion with the two back-translators to produce an Intermediate Version 1.0.

Table 4.1f Back-translations and back-translation review (First interim report) of PFDI-20 title, example, questions 1–20 and responses — producing an Intermediate Version 1.0)

Back-translations and back-translation review of PFDI-20							
Question	**Source Text**	**Single Forward Version (SFV)**	**First Back-translation By First Translator (BT1)**	**Second Back Translation By Second Translator (BT2)**	**Checking Equivalence[a] by identifying major discrepancies**	**Comments in Back-translation review[b] Both translators agreed to the following proposals:**	**Outcome Intermediate Version 1.0 ready for the expert panel review**
Title	Pelvic Floor Distress Inventory-short form 20	*Spørreskjema om bekkenbunns - besvær- kort skjema 20*	Questionnaire on pelvic floor problems – short form 20	Questionnaire regarding pelvic floor problems– abbreviated questionnaire 20	No major discrepancies .	No comments	No amendments. *Spørreskjema om bekkenbunns-besvær- kort skjema 20*
PFDI-20 Instructions and example. See 4.3e							
This section discusses idiomatic, semantic, conceptual and experiential equivalence concerning the PFDI-20 questions 1-20.							
1	Do you usually have pressure in the lower abdomen?	*Kjenner du vanligvis et trykk i den nedre delen av magen?*	Do you normally experience a pressing sensation in the lower part of the abdomen?	Do you normally feel pressure in the lower part of your abdomen?	No major discrepancies	No comments	No amendments. *Kjenner du vanligvis et trykk i den nedre delen av magen?*

Back-translations and back-translation review of PFDI-20							
Question	**Source Text**	**Single Forward Version (SFV)**	**First Back-translation By First Translator (BT1)**	**Second Back Translation By Second Translator (BT2)**	**Checking Equivalence[a] by identifying major discrepancies**	**Comments in Back-translation review[b] Both translators agreed to the following proposals:**	**Outcome Intermediate Version 1.0 ready for the expert panel review**
2	Do you usually experience heaviness or dullness in pelvic area pressure in the lower abdomen?	*Kjenner du vanligvis tyngdefølelse i bekkenet?*	*Do you normally have a heavy sensation in the pelvis?*	Do you normally feel heavy in the pelvic area?	Lack of semantic and idiomatic equivalence in the translation.	The principal researcher (PR) was concerned that the idiom heaviness or dullness in the pelvic area" in both back-translations was not clear. The Translation Advisory Group (TAG) recommended two new options in Norwegian: *Tyngdefølelse* or *tunghets-følelse i bekkenet.*	No amendments. Suggestions for the expert panel to review in the Intermediate version 1.0: *Tyngdefølelse I bekkenet*
3	Do you usually have a bulge or something falling out that you can see or feel in the vaginal area?	*Har du vanligvis noe som buler ut eller faller ut som du kan se eller kjenne i skjeden?*	Do you normally have something that bulges or 'falls out' that you can see or feel in the vagina?	Do you normally experience bulges or protrusions in the vagina which you can see or feel?	No major discrepancies	None	No amendments. *Har du vanligvis noe som buler ut eller faller ut som du kan se eller kjenne i skjeden?*
4	Do you usually have to push on the vagina or around the rectum to have or complete a bowel movement? .	*Må du vanligvis presse i skjeden eller rundt endetarm-åpningen for å få avføring eller få tømt tarmen helt?*	Do you normally have to press in the vagina or around the anus when you have a bowel movement, or to empty the bowels completely?	Do you normally have to press with your vagina or anus in order to completely empty your bowel or complete a motion?	Lack of semantic equivalence in the translation.	The PR was concerned that this wording "to push on" was not clear. Translation Advisory Group recommended the SFV in Norwegian – *press i.*	No amendments.

Back-translations and back-translation review of PFDI-20							
Question	**Source Text**	**Single Forward Version (SFV)**	**First Back-translation By First Translator (BT1)**	**Second Back Translation By Second Translator (BT2)**	**Checking Equivalence[a] by identifying major discrepancies**	**Comments in Back-translation review[b] Both translators agreed to the following proposals:**	**Outcome Intermediate Version 1.0 ready for the expert panel review**
5	Do you usually experience a feeling of incomplete bladder emptying?	*Kjenner du vanligvis at urinblæren ikke blir tømt helt?*	Do you normally feel that your bladder does not empty completely?	Do you normally feel like you are not able to completely empty your bladder?	No major discrepancies	None	No amendments. *Kjenner du vanligvis at urinblæren ikke blir tømt helt?*
6	Do you ever have to push to up on a bulge in the vaginal area with your fingers to start or complete urination?	*Må du noen ganger trykke inn en bul i skjeden med fingrene for å begynne å tisse eller tømme blæren helt?*	Do you sometimes have to push in a bulge in your vagina with your fingers in order to start urinating or to empty your bladder completely?	Do you sometimes have to press a bulge in your vagina in with your fingers before you are able to urinate or completely empty your bladder?	No major discrepancies	The PR asked the translators to confirm that "Do you sometimes" is equivalent "to Do you ever".	No amendments. *Må du noen ganger trykke inn en bul i skjeden med fingrene for å begynne å tisse eller tømme blæren helt?*
7	Do you feel you need to strain too hard to have a bowel movement?	*Føler du at du må presse for hardt for å ha avføring?*	Do you feel that you have to press too hard to have a bowel movement?	Do you feel that you have to press too hard to empty your bowel?	No major discrepancies	None	No amendments. *Føler du at du må presse for hardt for å ha avføring?*
8	Do you feel you have not completely emptied your bowels at the end of a bowel movement?	*Føler du at du ikke har tømt tarmen helt når du har hatt avføring?*	Do you feel that you haven't emptied your bowel completely when you have had a bowel movement?	Do you feel that you have not managed to completely empty your bowel once you have had a motion?	No major discrepancies	None	No amendments. *Føler du at du ikke har tømt tarmen helt når du har hatt avføring?*
9	Do you usually lose stool beyond your control if your stool is well formed?	*Har du vanligvis ufrivillig avføring hvis avføringen er fast?*	Do you normally have involuntary bowel movements if the stools are hard?	Do you normally have involuntary faecal soiling if your stools are hard?	No major discrepancies	None	No amendments. *Har du vanligvis ufrivillig avføring hvis avføringen er fast?*

Back-translations and back-translation review of PFDI-20							
Question	**Source Text**	**Single Forward Version (SFV)**	**First Back-translation By First Translator (BT1)**	**Second Back Translation By Second Translator (BT2)**	**Checking Equivalence[a] by identifying major discrepancies**	**Comments in Back-translation review[b] Both translators agreed to the following proposals:**	**Outcome Intermediate Version 1.0 ready for the expert panel review**
10	Do you usually lose stool beyond your control if your stool is loose or liquid?	*Har du vanligvis ufrivillig avføring hvis avføringen er løs eller flytende?*	Do you normally have involuntary bowel movements if the stools are loose or liquid?	Do you normally have involuntary faecal soiling if your stools are loose or liquid?	No major discrepancies	None	No amendments. *Har du vanligvis ufrivillig avføring hvis avføringen er løs eller flytende?*
11	Do you usually lose gas from your rectum beyond your control?	*Slipper du vanligvis luft fra tarmen uten kontroll?*	Do you normally pass wind uncontrolled from the colon?	Do you normally experience wind from your bowel which you cannot control?	No major discrepancies	None	No amendments. *Slipper du vanligvis luft fra tarmen uten kontroll?*
12	Do you usually have pain when you pass your stool?	*Har du vanligvis smerter når du har avføring?*	Do you normally have pain when you have a bowel movement?	Do you normally experience pain during motions?	No major discrepancies	None	No amendments. *Har du vanligvis smerter når du har avføring?*
13	Do you experience a strong sense of urgency and have to rush to the bathroom to have a bowel movement?	*Opplever du stor trang og må løpe på toalettet for å tømme tarmen?*	Do you experience a strong urge and have to run to the toilet to have a bowel movement?	Do you suddenly have to run to the toilet to empty your bowel?	No major discrepancies	None	No amendments. *Opplever du stor trang og må løpe på toalettet for å tømme tarmen?*
14	Does part of your bowel ever pass through the rectum and bulge outside during or after a bowel movement?	*Hender det at en del av tarmen følger med ut under eller etter avføring?*	Does part of the colon sometimes move out during or after a bowel movement?	Have you experienced that part of your bowel/intestines protrude during or after a motion?	No major discrepancies	None	No amendments. *Hender det at en del av tarmen følger med ut under eller etter avføring?*

Back-translations and back-translation review of PFDI-20							
Question	**Source Text**	**Single Forward Version (SFV)**	**First Back-translation By First Translator (BT1)**	**Second Back Translation By Second Translator (BT2)**	**Checking Equivalence[a] by identifying major discrepancies**	**Comments in Back-translation review[b] Both translators agreed to the following proposals:**	**Outcome Intermediate Version 1.0 ready for the expert panel review**
15	Do you usually experience frequent urination?	*Har du vanligvis hyppig vannlating?*	Do you normally have a frequent urge to urinate?	Do you normally experience a frequent need to urinate?	Some discrepancy with the wording "frequent urination".	The PR was concerned that the specific domain terminology was poor. The Translation Advisory Group recommended *hyppig vannlatnings trang.* .	No amendments. Suggestion for the expert panel to review in Intermediate Version 1.0: *Hyppig vannlatning.*
16	Do you usually experience urine leakage associated with a feeling of urgency; that is, a strong sense of needing to go to the bathroom?	*Opplever du vanligvis urinlekkasje sammen med plutselig vannlatingstr ang, dvs. en sterk følelse av at du må på toalettet?*	Do you normally experience urine leakage and a sudden urge to urinate i.e. a strong feeling that you have to go to the toilet?	Do you normally experience leakages of urine and a sudden need to urinate, i.e. a strong urge to go to the toilet?	Some discrepancy with the wording "associated with a feeling of urgency". Lack of semantic equivalence in the translation.	The PR was concerned that the equivalence, specific domain terminology and clear wording was poor. It was agreed among the principal researcher, translators and TAG that this item was sent to pilot testing.	No amendments. *Opplever du vanligvis urinlekkasje sammen med plutselig vannlatings-trang, dvs. en sterk følelse av at du må på toalettet?*
17	Do you usually experience urine leakage related to coughing, sneezing or laughing?	*Opplever du vanligvis urinlekkasje når du hoster, nyser eller ler?*	Do you normally experience urine leakage when you cough, sneeze or laugh?	Do you normally experience leakages of urine when you cough, sneeze or laugh?	No major discrepancies	None	No amendments. *Opplever du vanligvis urinlekkasje når du hoster, nyser eller ler?*

Back-translations and back-translation review of PFDI-20							
Question	**Source Text**	**Single Forward Version (SFV)**	**First Back-translation By First Translator (BT1)**	**Second Back Translation By Second Translator (BT2)**	**Checking Equivalence[a] by identifying major discrepancies**	**Comments in Back-translation review[b] Both translators agreed to the following proposals:**	**Outcome Intermediate Version 1.0 ready for the expert panel review**
18	Do you usually experience small amounts of urine leakage (that is, drops)?	*Opplever du vanligvis urinlekkasjer i små mengder (dvs. dråper)?*	Do you normally experience small amounts of urine leakage (i.e. drops)?	Do you normally experience a small amount of urine leakage (i.e. small drops of urine)?	No major discrepancies .	None	No amendments. *Opplever du vanligvis urinlekkasjer i små mengder (dvs. dråper)?*
19	Do you usually experience difficulty emptying your bladder?	*Opplever du vanligvis problemer med å tømme blæren?*	Do you normally experience problems with emptying your bladder?	Do you normally have problems emptying your bladder?	No major discrepancies	None	No amendments. *Opplever du vanligvis problemer med å tømme blæren?*
20	Do you usually experience pain or discomfort in the lower abdomen or genital region?	*Kjenner du vanligvis smerte eller ubehag i den nedre delen av magen eller underlivet?*	Do you normally experience pain or discomfort in the lower part of your abdomen or pelvis?	Do you normally feel pain or discomfort in the lower part of your stomach or in your abdomen?	Some discrepancy with the wording "lower abdomen or genital region". Lack of conceptual equivalence in the translation.	Norway does not often use Latin medical expressions with patients. Important to identify correct specific domain terminology for "- the lower abdomen or genital region".	No amendments. *Kjenner du vanligvis smerte eller ubehag i den nedre delen av magen eller underlivet?*
This section discusses idiomatic, semantic, conceptual and experiential equivalence concerning the PFDI-20 questions and responses 1-20.							
Response question	If yes, how much does it bother you?	*Hvis ja, hvor mye plager det deg?*	If yes, how much does this bother you?	If yes, how much does this bother you?	No major discrepancies	No comment.	No amendments. *Hvis ja, hvor mye plager det deg?*

Back-translations and back-translation review of PFDI-20							
Question	**Source Text**	**Single Forward Version (SFV)**	**First Back-translation By First Translator (BT1)**	**Second Back Translation By Second Translator (BT2)**	**Checking Equivalence[a] by identifying major discrepancies**	**Comments in Back-translation review[b] Both translators agreed to the following proposals:**	**Outcome Intermediate Version 1.0 ready for the expert panel review**
Response	Not at all	*Ikke i det hele tatt*	Not at all	Not at all	No major discrepancies .	It was agreed among the principal researcher, translators and TAG that the conceptual equivalence was retained in the back-translation.	No amendments. *Ikke i det hele tatt*
Response	Somewhat	*Litt*	A little	A little	No major discrepancies	It was agreed among the principal researcher, translators and advisory group that the conceptual equivalence was retained in the back-translation.	No amendments. *Litt*
Response	Moderately	*I noen grad*	To some extent	To a certain extent	No major discrepancies .	It was agreed among the principal researcher, translators and advisory group that the conceptual equivalence was retained in the back-translation.	No amendments. *I noen grad*

Back-translations and back-translation review of PFDI-20							
Question	**Source Text**	**Single Forward Version (SFV)**	**First Back-translation By First Translator (BT1)**	**Second Back Translation By Second Translator (BT2)**	**Checking Equivalence[a] by identifying major discrepancies**	**Comments in Back-translation review[b] Both translators agreed to the following proposals:**	**Outcome Intermediate Version 1.0 ready for the expert panel review**
Response	Quite a bit	*Ganske mye*	Quite a lot	Quite a lot	No major discrepancies	It was agreed among the principal researcher, translators and advisory group that the conceptual equivalence was retained in the back-translation.	No amendments. *Ganske mye*

Equivalence[a] includes: semantic, idiomatic, conceptual or experiential equivalence
Comments[b] included: equivalence, specific domain terminology (STD) and clear wording. Where differences arose, the principal researcher (using some recommendations from the Translation Advisory Group) resolved these by a discussion with the two back-translators to produce an Intermediate Version 1.0.

Table 4.1g Back-translations and back-translation review (First interim report) of PFIQ-7 instructions and example — producing a Norwegian Intermediate Version 1.0

Back-translations and back-translation review of PFIQ-7
Instructions: Source text
See source text. Table 4.3d
Instructions: Single Forward Translation
Instructions for page one and two: ***Veiledning:*** *Noen kvinner opplever at symptomer fra blære, endetarmen og skjede som påvirker deres aktiviteter, forhold og følelser. For hvert av spørsmålene ber vi deg krysse av for svaret som best beskriver hvordan dine aktiviteter, forhold eller dine følelser har blitt påvirket av symptomer eller plager fra blære, endetarm eller skjede* ***de tre siste månedene.*** **Instructions for page two only:** *Du kan ha, eller ikke ha symptomer innenfor hvert av disse tre områdene, men husk å svare i* ***alle tre kolonner*** *for hvert spørsmål. Hvis du ikke ha symptomer på et av områdene, svare du "ikke I det hele tatt" I den aktuelle kolonnen.* ***Vennligst husk å svare i alle tre kolonner for hvert spørsmål.***
Back-translation (first translator)
Instructions for page one and two: **Instructions:** Some women experience that symptoms from the bladder, anus or vagina have a negative effect on their activities, relationships and emotions. For each of the questions we ask you to put a cross for the answer that is most applicable to how your activities and relationships or your emotions have been affected by symptoms or problems from your bladder, anus or vagina during **the last three months**. Remember to put a cross for each question in **all three columns**. Instructions for page two only: You may or may not have had symptoms, in each of these three areas, but please be sure to mark an answer in **all 3 columns** for each question. If you do not have symptoms in one of these areas, then the appropriate answer for the corresponding column for each question. **Make sure to answer all 3 columns for every question. Thank you for your cooperstion**
Back-translation (second translator)
Instructions for page one and two: **Guidelines**: Some women find that symptoms from their bladders, bowel or vagina have a negative impact on their level of activity, relationships and emotions. Please answer each question by marking the most appropriate answer with an X. These relate to how your level of activity, relationships or emotions have been affected by symptoms or problems with your bladder, bowel or vagina **over the past three months**. Please remember to mark an X **in all three columns** for each question. Instructions for page two only: You may or may not have have symptoms, in each of these three areas, but please be sure to mark an answer in **all 3 columns** for each question. If you do not have symptoms in one of these areas, then the appropriate answer for the corresponding column for each question. **Make sure to answer all 3 columns for each and every question. Thank you for your cooperation**

Checking Equivalence (by identifying major discrepancies or misinterpretations in the translation.)
Both translations FT1 and FT2 were very similar and no major discrepancies or misinterpretations were identified in the translation.
Comments[a] Comments include: specific domain terminology (STD), equivalence and clear wording.
No major discrepancies or misinterpretations were identified in the translation, so no amendments were made to the Single Forward translation.
Outcome: Intermediate Version 1.0 ready for expert panel
Instructions for page one and two: ***Veiledning:*** *Noen kvinner opplever at symptomer fra blære, endetarmen og skjede som påvirker deres aktiviteter, forhold og følelser. For hvert av spørsmålene ber vi deg krysse av for svaret som best beskriver hvordan dine aktiviteter, forhold eller dine følelser har blitt påvirket av symptomer eller plager fra blære, endetarm eller skjede* ***de tre siste månedene.*** **Instructions for page two only:** *Du kan ha, eller ikke ha symptomer innenfor hvert av disse tre områdene, men husk å svare i* ***alle tre kolonner*** *for hvert spørsmål. Hvis du ikke ha symptomer på et av områdene, svare du "ikke I det hele tatt" I den aktuelle kolonnen.* ***Vennligst husk å svare i alle tre kolonner for hvert spørsmål.***
Example: Source text
See source text. Table 4.3d
Example: Single Forward Translation
EKSEMPEL: Ved følgende spørsmål: *Hvis blærefunksjonen påvirker evnen din til å kjøre bil i noen grad, mens tarmfunksjonen bare påvirker evnen til å kjøre bil litt, og symptomer knyttet til skjede eller bekkenbunn ikke påvirker evnen til å kjøre bil i det hele tatt, skal du sette kryss (X) i boksene som vist nedenfor:* *Vennligst husk å svare i alle tre kolonner for hvert spørsmål. Takk for hjelpen!*
Back-translation (first translator) (BT1)
EXAMPLE: If your bladder symptoms affect your ability to drive a car *to some extent*, and your bowel or anus symptoms affect your ability to drive a car *a little*, but your vaginal or pelvic floor symptoms do not affect your ability to drive a car *at all* then you should put an X in the corresponding boxes as shown below: Make sure to answer all 3 columns for each question. Thank you for your cooperation!
Back-translation (second translator) (BT2)
EXAMPLE: If your bladder symptoms affect your capacity to drive a car *to a certain extent*, and your bowel symptoms affect your capacity to drive a car *a little*, however your vaginal and pelvic floor symptoms do not affect your capacity to drive a car *not at all* then you should mark an X in the boxes as indicated below: Be sure to answer all 3 columns for each question. Thank you for your help!

Checking Equivalence[a] (by identifying major discrepancies or misinterpretations in the translation.)
No discrepancies or misinterpretations in the translation.
Comments[b] Comments include specific domain terminology (STD), equivalence and clear wording
No discrepancies or misinterpretations in the translation, so no amendments were made to the single forward translation.
Outcome: Single forward translation
EKSEMPEL: Ved følgende spørsmål: *Hvis blærefunksjonen påvirker evnen din til å kjøre bil i noen grad, mens tarmfunksjonen bare påvirker evnen til å kjøre bil litt, og symptomer knyttet til skjede eller bekkenbunn ikke påvirker evnen til å kjøre bil i det hele tatt, skal du sette kryss (X) i boksene som vist nedenfor:* *Vennligst husk å svare i alle tre kolonner for hvert spørsmål. Takk for hjelpen!*
Equivalence[a] includes: semantic, idiomatic, conceptual or experiential equivalence Comments[b] included: equivalence, specific domain terminology (STD) and clear wording. Where differences arose, the principal researcher (using some recommendations from the Translation Advisory Group) resolved these by a discussion with the two back-translators to produce an Intermediate Version 1.0.

Table 4.1h Back-translations and back-translation review (First interim report) of the PFIQ-7 — producing an Intermediate Version 1.0

Back-translations and back-translation review of the PFIQ-7							
PFIQ-7 Questions	**Source Text**	**Single Forward Version (SFV)**	**First Back-trans-lation (BT1)**	**Second Back-translation (BT2)**	**Checking Equivalence[a] By identifying any major discrepancies**	**Comments[b] The translators approved of the proposals and amend-ments**	**Outcome Intermediate Version 1.0 ready for expert panel**
Title	Pelvic Floor Impact Questionnaire- short form 7	*Spørreskjema om innvirkning på bekkenbunnen – kort skjema 7*	Questionnaire on the effects on the pelvic floor – short form 7	Questionnaire regarding impact of pelvic floor problems – abbreviated questionnaire 7	No major discrepancies	No comments	No amendments. *Spørreskjema om innvirkning på bekkenbunnen – kort skjema 7*
For PFIQ-7 instructions and example see Table 4.3g.							
This section discusses idiomatic, semantic, conceptual and experiential equivalence concerning the PFIQ-7 opening question, question for example and questions 1-7.							
Opening question for example and questions 1-7	How do symptoms or conditions related to the following usually affect your: Bladder or urine Bowel or rectum Vagina or pelvic	*Hvordan påvirker symptomer eller plager fra? Vanligvis din:* *Blære eller urin* *Tarm eller endetarm* *Skjede eller bekkenbunnen*	How do the symptoms from or problems with - Bladder or urine Colon or rectum Vagina or pelvic floor - normally affect your-	How do symptoms or problems with your - Bladder or urine Bowel or intestines Vagina or pelvic floor -normally affect your -	No major discrepancies	No comments	No amendments. *Hvordan påvirker symptomer eller plager fra? Vanligvis din:* *Blære eller urin* *Tarm eller endetarm* *Skjede eller bekkenbunnen*
Question for example	Ability to drive a car?	*Evne til å kjøre bil?*	ability to drive a car?	capacity to drive a car?	No major discrepancies	No comments	No amendments *Evne til å kjøre bil?*
Question 1	Ability to do household chores (cooking, house-cleaning, laundry)?	*Evne til å utføre husarbeid (matlaging, rengjøring, klesvask)?*	Ability to do house work (preparing meals, cleaning, laundry)?	Capacity to do the housework (cooking, cleaning, laundry)?	No major discrepancies	No comments	No amendments. *Evne til å utføre husarbeid (matlaging, rengjøring, klesvask)?*
Question 2	Ability to do physical activities such as walking, swimming or other exercise?	*Evne til å være i fysisk aktivitet som turgåing, svømming eller annen mosjon?*	Ability to be physically active such as walking, swimming or other exercise?	Capacity for physical activities such as walking, swimming or other activity?	No major discrepancies	No comments	No amendments. *Evne til å være i fysisk aktivitet som turgåing, svømming eller annen mosjon?*

Back-translations and back-translation review of the PFIQ-7							
PFIQ-7 Questions	**Source Text**	**Single Forward Version (SFV)**	**First Back-trans-lation (BT1)**	**Second Back-translation (BT2)**	**Checking Equivalence[a] By identifying any major discrepancies**	**Comments[b] The translators approved of the proposals and amend-ments**	**Outcome Intermediate Version 1.0 ready for expert panel**
Question 3	Entertainment activities such as going to a movie or concerts?	*Deltagelse i fritidsaktiviteter som å gå på kino eller konsert?*	Participation in leisure activities such as going to the cinema or concerts?	Participation in leisure activities, such as going to the cinema or a concert?	No major discrepancies	No comments	No amendments. *Deltagelse i fritidsaktiviteter som å gå på kino eller konsert?*
Question 4	Ability to travel by car or bus for a distance greater than 30 minutes away from home?	*Mulighet til å reise med bil eller buss lenger enn 30 minutter hjemmefra?*	Possibility to travel by car or bus longer than 30 minutes from home?	Capacity to travel by car or bus for longer than 30 minutes from home?	No major discrepancies	No comments	No amendments. *Mulighet til å reise med bil eller buss lenger enn 30 minutter hjemmefra?*
Question 5	Participating in social activities outside your home?	*Deltagelse i sosiale aktiviteter utenfor hjemmet?*	Participation in social activities outside the home?	Participation in social activities outside of the home?	No major discrepancies	No comments	No amendments. *Deltagelse i sosiale aktiviteter utenfor hjemmet?*
Question 6	Emotional health (nervous-ness, depression, etc.)?	*Følelsesmessige helsetilstand (nervøsitet, engstelig, depresjon osv.)?*	Emotional health (nervous-ness, depression, etc.)?	Emotional health (nervous-ness, depression etc.)?	No major discrepancies	The PR was concerned that the psychological health item *"følelses-messig helsetilstand"* was not clear. It was agreed among the principal researcher, translators and TAG that this item would be discussed in the pilot test.	No amendments. *Følelsesmessige helsetilstand (nervøsitet, engstelig, depresjon osv.)?*
Question 7	Feeling frustrated?	*Følelse av frustrasjon?*	Feelings of frustration?	Feelings of frustration?	No major discrepancies	No comments	No amendments. *Følelse av frustrasjon?*
This section discusses semantic equivalence concerning the formulation and wording for the PFIQ-7 Questions 1-7.							

Back-translations and back-translation review of the PFIQ-7							
PFIQ-7 Questions	**Source Text**	**Single Forward Version (SFV)**	**First Back-trans-lation (BT1)**	**Second Back-translation (BT2)**	**Checking Equivalence[a] By identifying any major discrepancies**	**Comments[b] The translators approved of the proposals and amend-ments**	**Outcome Intermediate Version 1.0 ready for expert panel**
Questions 1-7	Your	*Din*	Your	Your	No major discrepancies	The PR and TAG agreed that *Din* should be in front of every question. The wording *Din* was sent to the pilot test for review.	No amendments. However *Din* was sent to the pilot test for review.
This section discusses idiomatic, semantic, conceptual and experiential equivalence concerning the responses in the PFIQ-7 questionnaire.							
Response	Not at all	*Ikke i det hele tatt*	Not at all	Not at all	No major discrepancies	No comments.	No amendments. *Ikke i det hele tatt*
Response	Somewhat	*Litt*	A little	A little	No major discrepancies	No comments	No amendments. *Litt*
Response	Moderately	*I noen grad*	To some extent	To a certain extent	No major discrepancies		No amendments. *I noen grad*
Response	Quite a bit	*Ganske mye*	Quite a lot	Quite a lot	No major discrepancies	No comments.	No amendments. *Ganske mye*
Equivalence[a] includes: semantic, idiomatic, conceptual or experiential equivalence Comments[b] included: equivalence, specific domain terminology (STD) and clear wording. Where differences arose, the principal researcher (using some recommendations from the Translation Advisory Group) resolved these by a discussion with the two back-translators to produce an Intermediate Version 1.0.							

APPENDIX 4.2

DATA EXTRACTION TABLES FOR STAGE 1, ROUND 1 (EXPERT PANEL):

Summary results from Round 1

The Intermediate Version 1.0, reviewed by the expert panel, was the same as the Single Forward Version. No amendments to the Single Forward Version were made following the back-translations.

Table 4.2a PFDI-20 expert panel review (using the modified Delphi method) summary results from Round 1 (Second interim report).

Table 4.2b PFIQ-7 expert panel review (using the modified Delphi method) summary results from Round 1 (Second interim report)

Table 4.2a PFDI-20 summary results from Round 1 (expert panel)

Stage 1 - expert panel review using the modified Delphi method PFDI-20 summary results from Round 1					
PFDI-20 items	**Lack of equivalence between the source and Norwegian version in all the four areas -Idiomatic -Conceptual -Semantic -Experiential**	**Achieved equivalence between the source and Norwegian version in all the four areas -Idiomatic -Conceptual -Semantic -Experiential**	Reason for disagreement If no, which area(s) of equivalence are not met? why?	Number of suggestions for alternative wording Some panellists disagreed, however did not make any suggestions for alternative wording.	Suggestion for alternative wording Can you suggest a change?
Title	0	8	-	No suggestions	No comments
Instructions	2	6	Semantic	1 suggestion	Alternative 1: *Vennligst svar på alle spørsmålene i spørreskjemaet. Spørsmålene dreier seg om hvorvidt du har visse symptomer i tarmen, blæren eller bekkenregionen, og i så fall i hvilken grad de plager deg.* *Svar på spørsmålene ved å krysse av i den eller de boksene som passer for deg. Hvis du er usikker på hva du skal svare, svarer du så godt du kan.* *Vennligst svar på spørsmålene ut fra de symptomene du har hatt* ***de siste tre månedene.***
Example	1	7	Semantic	1 suggestion	Alternative 1: *Hvis du pleier å ha hodepine, setter du X i "Ja"-boksen og angir hvor mye hodepinen plager deg. (I dette eksemplet plages vedkommende av hodepinen i noen grad)*
Response question	0	8	-	No suggestions	No comments
Question 1	5	3	Idiomatic Semantic	1 suggestion	Alternative 1: *Kjenner du ofte trykk i den nedre delen av magen?* (*Ofte* replaces *vanligvis* and remove *et*)
Question 2	5	3	Idiomatic Semantic Specific domain terminology	4 suggestions	Alternative 1: *Har du ofte tyngdefornemmelse i bekkenet?* Alternative 2: *Kjenner du ofte tyngdefølelse i bekkenet?* Alternative 3: *Kjenner du ofte en vissenhet i bekkenet?* Alternative 4: *Har du ofte tyngdefølelse i bekkenet?*

Stage 1 - expert panel review using the modified Delphi method PFDI-20 summary results from Round 1					
PFDI-20 items	**Lack of equivalence between the source and Norwegian version in all the four areas** **-Idiomatic** **-Conceptual** **-Semantic** **-Experiential**	**Achieved equivalence between the source and Norwegian version in all the four areas** **-Idiomatic** **-Conceptual** **-Semantic** **-Experiential**	Reason for disagreement If no, which area(s) of equivalence are not met? why?	Number of suggestions for alternative wording Some panellists disagreed, however did not make any suggestions for alternative wording.	Suggestion for alternative wording Can you suggest a change?
Question 3	5	3	Idiomatic	3 suggestions	Alternative 1: *Kjenner eller ser du noen gang noe som buler ut eller "faller ut", i skjeden?* Alternative 2. *Kjenner eller ser du noen gang noe som "buler ut" eller faller ut i skjeden?* Alternative 3: *Kjenner eller ser du vanligvis noe som "buler ut" eller faller ut i skjeden?*
Question 4	5	3	Idiomatic Semantic Grammatical	2 suggestions	Alternative 1: *Må du ofte presse med fingre i skjeden eller rundt endetarmsåpningen for å få ut avføring eller å få tømt tarmen helt?* Alternative 2: *Må du ofte presse i skjeden eller rundt endetarmsåpningen for å få avføring eller å få tømt tarmen helt?*
Question 5	5	3	Conceptual Semantic Idiomatic	5 suggestions	Alternative 1: *Kjennes det vanligvis som om urinblæren ikke er helt tømt etter vannlating?* Alternative 2: *Føler du ofte at du ikke ha tømt blæren helt etter vannlating?* Alternative 3: *Føler du ofte at du ikke får tømt blæren helt?* Alternative 4: *Føler du vanligvis at urinblæren ikke blir helt tømt?* Alternative 5: *Føler du at du ikke får tømt blæren helt når du late vannet?*
Question 6	3	5	Conceptual Semantic	1 suggestion	Alternative 1: *Hender det noen gang at du må trykke inn med fingrene noe som buler i skjeden, for å få tisset eller tømt blæren helt?*
Question 7	2	6	Semantic Specific domain terminology	1 suggestion	Alternative 1: *Føler du at du må presse for hardt for å få ut avføringen?*
Question 8	0	8	-	No suggestion	No comments.

Stage 1 - expert panel review using the modified Delphi method PFDI-20 summary results from Round 1					
PFDI-20 items	**Lack of equivalence between the source and Norwegian version in all the four areas** **-Idiomatic** **-Conceptual** **-Semantic** **-Experiential**	**Achieved equivalence between the source and Norwegian version in all the four areas** **-Idiomatic** **-Conceptual** **-Semantic** **-Experiential**	Reason for disagreement If no, which area(s) of equivalence are not met? why?	Number of suggestions for alternative wording Some panellists disagreed, however did not make any suggestions for alternative wording.	Suggestion for alternative wording Can you suggest a change?
Question 9	4	4	Idiomatic Specific domain terminology	2 suggestions	Alternative 1: *Har du ofte avføringslekkasje når avføringen er fast?* Alternative 2: *Har du vanligvis avføringslekkasje når avføringen er fast?*
Question 10	5	3	Idiomatic	2 suggestions	Alternative 1: *Har du ofte avføringslekkasje når avføringen er løs eller flytende?* Alternative 2: *Har du vanligvis avføringslekkasje når avføringen er løs eller flytende?*
Question 11	5	3		3 suggestions	Alternative 1: *Slipper du ofte luft fra tarmen uten kontroll?* Alternative 2: *Lekker du ofte ufrivillig luft fra tarmen?* Alternative 3: *Har du ofte ufrivillige lekkasje av luft fra tarmen?*
Question 12	5	3	Idiomatic	1 suggestion	Alternative 1: *Har du ofte smerter mens du har avføring?*
Question 13	6	2	Idiomatic Specific domain terminology	4 suggestions	Alternative 1: *Opplever du ved avføringstrang at det haster, så du må løpe til toalettet for å tømme tarmen?* Alternative 2: *Opplever du ofte så sterk avføringstrang og må løper på toalettet?* Alternative 3: *Opplever du sterk trang og må løper på toalettet for å ha avføring?* Alternative 4: *Opplever du plutselig avføringstrang, slik at du må løpe til toalettet?*
Question 14	3	5	Idiomatic Specific Domain terminology	2 suggestions	Alternative 1: *Hender det at en del av tarmen følger med ut gjennom endetarmsåpningen under eller etter avføring?* Alternative 2: *Hender det at en del av tarmen buler ut gjennom endetarmsåpningen under eller etter avføring?*
Question 15	0	8	-	No suggestion	No comments.

Stage 1 - expert panel review using the modified Delphi method PFDI-20 summary results from Round 1					
PFDI-20 items	**Lack of equivalence between the source and Norwegian version in all the four areas** **-Idiomatic** **-Conceptual** **-Semantic** **-Experiential**	**Achieved equivalence between the source and Norwegian version in all the four areas** **-Idiomatic** **-Conceptual** **-Semantic** **-Experiential**	Reason for disagreement If no, which area(s) of equivalence are not met? why?	Number of suggestions for alternative wording Some panellists disagreed, however did not make any suggestions for alternative wording.	Suggestion for alternative wording Can you suggest a change?
Question 16	7	1	Idiomatic Semantic Conceptual Specific domain terminology	1 suggestion	Alternative 1: *Har du ofte urinlekkasje under så sterk følelse av hast at du straks må på toalettet?*
Question 17	4	4	Idiomatic	2 suggestions	Alternative 1: *Opplever du ofte urinlekkasje når du hoster, nyser eller ler?* Alternative 2: *Har du ofte urinlekkasje når du hoster, nyser eller ler?*
Question 18	6	2	Idiomatic	2 suggestions	Alternative 1: *Opplever du ofte små urinlekkasjer (dvs. dråper)?* Alternative 2: *Har du ofte små urinlekkasjer (dvs. dråper)?*
Question 19	5	3	Idiomatic	1 suggestion	Alternative 1: *Har du ofte problemer med å tømme blæren?*
Question 20	5	3	Idiomatic	2 suggestions	Alternative 1: *Kjenner du ofte smerte eller ubehag i nedre del av magen eller underlivet?* Alternative 2: *Har du ofte smerte eller ubehag i nedre del av magen eller underlivet?*
Responses	0	8	-	-	No comments

Table 4.2b PFIQ-7 Summary Results from Round 1 (expert panel)

Stage 1 - expert panel review using the modified Delphi method **PFIQ-7 summary results from Round 1**					
PFIQ-7 items	**Lack of equivalence between the source and Norwegian version in all the four areas** **-Idiomatic** **-Conceptual** **-Semantic** **-Experiential**	**Achieved equivalence between the source and Norwegian version in all the four areas** **-Idiomatic** **-Conceptual** **-Semantic** **-Experiential**	**Reason for disagreement** **If no, which area(s) of equivalence are not met? why?**	**Number of suggestions for alternative wording** Some panellists disagreed, however did not make any suggestions for alternative wording.	**Suggestion for alternative wording** Can you suggest a change?
Title	0	8		No suggestions	No comments
Instructions-Page one and two	4	4	Idiomatic	1 suggestion	Alternative 1: *Noen kvinner opplever at symptomer fra blæren, endetarmen eller skjeden påvirker deres gjøremål,* ***samliv*** *og følelser. For hvert av spørsmålene ber vi deg krysse av for svaret som best beskriver hvordan dine gjøremål,* ***samliv*** *eller følelser har blitt påvirket av symptomer eller plager fra blære, endetarm eller skjede de tre siste månedene.*
Example	1	7		1 suggestion	Alternative 1: Remove *"i det hele tatt"* in Example text.
Opening Question	4	4		No suggestions	No comments
Responses	0	8		No suggestions	No comments
Question 1	3	5	Semantic	1 suggestion	Alternative 1: *din evne til å utføre husarbeid (matlaging, rengjøring, klesvask)?* *(Din* included in text*)*
Question 2	3	5	Idiomatic Semantic	2 suggestions	Alternative 1: *din fysiske aktivitet som turgåing, svømming eller annen mosjon?* Alternative 2: *din fysiske aktivitet som å gå tur, svømming eller annen mosjon?*
Question 3	2	6	Semantic	1 suggestion	Alternative 1: *din deltagelse i fritidsaktiviteter som å gå på kino eller konsert?* (*Din* included in text)
Question 4	3	5	Semantic	1 suggestion	Alternative 1: *din mulighet til å reise med bil eller buss lenger enn 30 minutter hjemmefra?* (*Din* included in text)
Question 5	3	5	Semantic	1 suggestion	Alternative 1: din deltagelse i sosiale aktiviteter utenfor hjemmet? (*Din* included in text)

Stage 1 - expert panel review using the modified Delphi method PFIQ-7 summary results from Round 1					
PFIQ-7 items	**Lack of equivalence between the source and Norwegian version in all the four areas** **-Idiomatic** **-Conceptual** **-Semantic** **-Experiential**	**Achieved equivalence between the source and Norwegian version in all the four areas** **-Idiomatic** **-Conceptual** **-Semantic** **-Experiential**	**Reason for disagreement** **If no, which area(s) of equivalence are not met? why?**	**Number of suggestions for alternative wording** Some panellists disagreed, however did not make any suggestions for alternative wording.	**Suggestion for alternative wording** Can you suggest a change?
Question 6	3	5	Idiomatic	3 suggestions	Alternative 1: Følelsesmessige helse (nervøsitet, engstelig, depresjon osv.)? Alternative 2: Psykiske helsetilstand (nervøsitet, engstelig, depresjon osv.)? Alternative 3: din følelsesmessige helsetilstand (nervøsitet, engstelig, depresjon osv.)? (*Din* included in text)
Question 7	3	5	Semantic	1 suggestion	Alternative 1: din følelse av frustrasjon? (Din included in text)

APPENDIX 4.3

INTERVIEW GUIDE FOR STAGE 1, ROUND 2 - 4 (EXPERT PANEL)

Expert panel review using the modified Delphi method:

Rounds 2, 3 and 4

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EXPERT PANEL
INTERVIEW GUIDE FOR ROUND TWO; THREE; FOUR

Title of research project:

"Validating condition specific quality of life questionnaires for women with pelvic floor disorders in the Norwegian context"
Round one is completed and the subsequent rounds will commence. During this process it is crucial that the translation produces questionnaires, which has specific domain terminology and is both comparable in terms of semantic, idiomatic, experiential and conceptual equivalence. This will facilitate cross- cultural comparisons between the translations.

An interview guide/ content of questions and analysis of responses (table 1) will be used to document areas of agreement and disagreement between the clinicians. The interview guide/content of questions and analysis of responses will be re-circulated for clarification where consensus is not achieved, until a clear set of items that have cross-culture equivalence is identified for inclusion. Consensus is defined as 75% - 6/8 panellists must score > 3.

Table 1: Interview guide/table:

Decisions by the expert panel will be needed to achieve equivalence from the source (original document) and target version in four areas and assess specific domain terminology:

1. Semantic equivalence: Do words mean the same thing? Are there several meanings to a given item? Are there grammatical difficulties in the translation?

2. Idiomatic equivalence: Colloquialisms, or idioms are difficult to translate. The expert panel may have to formulate an similar expression in the target version

3. Experiential equivalence: Often items/words are seeking to capture an experience; however that particular country does not in fact, have that experience. For example- you ask a question about difficulty eating with a spoon. Perhaps that country does not a have spoon. These types of issues have to be addressed by the expert panel.

4. Conceptual equivalence: Often words hold different conceptual meanings in different cultures. The expert panel must examine the original document (English version) and find

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the appropriate meaning in Norwegian. The words and meaning should be understandable for a 12 year-old.

Round two: Please read the question below and comments in the attachment: PFDI-20 and PFIQ-7 Norwegian questionnaires from round one. Rate the alternatives (1-5) proposed by the panellists from round one.
Round three: Please read the question below and comments in the attachment: PFDI-20 and PFIQ-7 Norwegian questionnaires from round one. Rate the alternatives (1-5) proposed by the panellists from round two.
Round four: Please read the question below and comments in the attachment: PFDI-20 and PFIQ-7 Norwegian questionnaires from round one. Rate the alternatives (1-5) proposed by the panellists from round three.

Question: Have all the equivalences being met and do you believe the item should be selected in the final PFIQ-20 and PFIQ-7 questionnaires?- state the degree of agreement with specific domain terminology and four areas of equivalence

Likert scale: 1 strongly agree – 2 disagree – 3 undecided – 4 agree – 5 strongly agree.

Round two, Round three Round four	Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree	Comments
PFDI-20 form Instructions						
Question 1						
Question 2						
Question 3						
Question 4						
Question 5						

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Round two, Round three Round four	Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree	Comments
Question 6						
Question 7						
Question 8						
Question 9						
Question 10						
Question 11						
Question 12						
Question 13						
Question 14						
Question 15						
Question 16						
Question 17						
Question 18						
Question 19						
Question 20						
PFIQ-7 form						
Instructions						
Question 1						
Question 2						
Question 3						
Question 4						

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Round two, Round three Round four	Strongly Disagree	Disagree	Undecided	Agree	Strongly Agree	Comments
Question 5						
Question 6						
Question 7						

Thank you for your assistance.

Yours sincerely,

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APPENDIX 4.4

DATA EXTRACTION TABLES FOR STAGE 1, ROUNDS 2 - 4 (EXPERT PANEL)

Expert panel review using the modified Delphi method:

Summary results from Rounds 2, 3 and 4.

Table 4.4a PFDI-20 expert panel review summary results from Round 2

Stage 1 - expert panel review using the modified Delphi method **PFDI-20 summary results from Round 2**					
PFDI-20 Items	**Single Forward Version** *(SFV)*	**Alternatives from Round 1** *The alternatives from Round 1 are voted on in Round 2.*	**Outcome**	**Consensus[a] % (Median)**	**Comment**
Title	Single Forward Version: *Spørreskjema om bekkenbunnsbesvær kort skjema 20*	None	Single Forward version (SFV)	**SFV 75% (4,5)**	Three suggested *Spørreskjema om bekkenbunnsplager skjema PFDI-20*
PFDI-20 instructions and example					
Instruction:	Single Forward Version: *Vennligst svar på alle spørsmålene i spørreskjemaet. Spørsmålene dreier seg om hvorvidt du har ulike symptomer i tarmen, blæren eller bekkenregionen, og i så fall i hvilken grad de plager deg.* *Svar på spørsmålene ved å krysse av i den eller de boksene som passer for deg. Hvis du er usikker på hva du skal svare, svarer du så godt du kan.* *Vennligst ta hensyn til symptomene du har hatt de siste tre månedene når du svarer på spørsmålene.*	Alternative 1: *Vennligst svar på alle spørsmålene i spørreskjemaet. Spørsmålene dreier seg om hvorvidt du har visse symptomer i tarmen, blæren eller bekkenregionen, og i så fall i hvilken grad de plager deg. Svar på spørsmålene ved å krysse av i den eller de boksene som passer for deg. Hvis du er usikker på hva du skal svare, svarer du så godt du kan.* *Vennligst svar på spørsmålene ut fra de symptomene du har hatt **de siste tre månedene.***	Alternative 1 (A1)	Consensus research **A1 100% (5)**	Two suggested *Vær snill og svar på spørsmålene ut fra de symptomene du har hatt **de siste tre månedene.***
Example	Single Forward Version: *Hvis du pleier å ha hodepine, setter du X i "Ja"-boksen og angir hvor mye du synes hodepinen plager deg. (I dette eksemplet plages vedkommende av hodepinen i noen grad).* *Hvis ja, hvor mye plager det deg?*	Alternative 1: *Hvis du pleier å ha hodepine, setter du X i "Ja"-boksen og angir hvor mye hodepinen plager deg. (I dette eksemplet plages vedkommende av hodepinen i noen grad)* *Hvis ja, hvor mye plager det deg?*	Alternative 1 (A1)	**A1 100% (5)**	No comments
PFDI-20 response question, questions 1-20 and responses.					
Responses question and responses	Single Forward Version: *Hvis ja, hvor mye plager det deg?* *Ikke det hele tatt* *Litt-* *I noen grad* *Ganske mye*	No alternatives	Single Forward Version	**SVF 100%(5)**	No comments
1	Single Forward Version: *Kjenner du vanligvis et trykk i den nedre delen av magen?*	Alternative 1: *Kjenner du ofte trykk i den nedre delen av magen?*	Alternative 1 (A1)	**A1 100% (5)**	Two suggested *et trykk* is more grammatically

Stage 1 - expert panel review using the modified Delphi method PFDI-20 summary results from Round 2					
PFDI-20 Items	**Single Forward Version** *(SFV)*	**Alternatives from Round 1** *The alternatives from Round 1 are voted on in Round 2.*	**Outcome**	**Consensus[a] % (Median)**	**Comment**
					correct. New alternative: *Kjenner du ofte et trykk i den nedre delen av magen?*
2	Single Forward Version: *Kjenner du vanligvis tyngdefølelse i bekkenet?*	Alternative 1: *Har du ofte tyngdefornemmelse i bekkenet?* Alternative 2: *Kjenner du ofte tyngdefølelse i bekkenet?* Alternative 3: *Kjenner du ofte en vissenhet i bekkenet?* Alternative 4: *Har du ofte tyngdefølelse i bekkenet?*	Alternative 1 (A1)	**A1 100% (5)**	No comments
3	Single Forward Version: *Har du vanligvis noe som buler ut eller "faller ut", som du kan se eller kjenne i skjeden?*	Alternative 1: *Kjenner eller ser du noen gang noe som buler ut eller "faller ut", i skjeden?* Alternative 2. *Kjenner eller ser du noen gang noe som "buker ut" eller faller ut i skjeden?* Alternative 3: *Kjenner eller ser du vanligvis noe som "buler ut" eller faller ut i skjeden?*	Alternative 3 (A3)	**A3 100%(4,5)**	Alternative 3 chosen with comments: One suggested *ofte* replaces *vanligvis*. Two suggested *kul* replaces *bul*.
4	Single Forward Version: *Må du vanligvis presse i skjeden eller rundt endetarmsåpningen for å få avføring eller få tømt tarmen helt?*	Alternative 1: *Må du ofte presse med fingre i skjeden eller rundt endetarmsåpningen for å få ut avføring eller å få tømt tarmen helt?* Alternative 2: *Må du ofte presse i skjeden eller rundt endetarmsåpningen for å få ut avføring eller å få tømt tarmen helt?*	Alternative 1	**A1 87,5% (4,5)**	Alternative 1: Seven suggested proposed to remove *med fingre.*
5	Single Forward Version: *Kjenner du vanligvis at urinblæren ikke blir helt tømt?*	Alternative 1: *Kjennes det vanligvis som om urinblæren ikke er helt tømt etter vannlating?* Alternative 2: *Føler du ofte at du ikke ha tømt blæren helt etter vannlating?* Alternative 3: *Føler du ofte at du ikke får tømt blæren helt?* Alternative 4: *Føler du vanligvis at urinblæren ikke blir helt tømt?* Alternative 5: *Føler du at du ikke får tømt blæren helt når du late vannet?*	Alternative 3	**A3 100% (4)**	Alternative 3: One suggested *fullstendig* replaces *helt*. One suggested *under vannlatning* at the end of the sentence.
6	Single Forward Version: *Må du noen ganger trykke inn en bul i skjeden med fingrene for å begynne å tisse eller tømme blæren helt?*	Alternative 1: *Hender det noen gang at du må trykke inn med fingrene noe som buler i skjeden, for å få tisset eller tømt blæren helt?*	Alternative 1	**A1 87,5% (4)**	Two panellists suggested removing *noen gang.*
7	Single Forward Version: *Føler du at du må*	Alternative 1: *Føler du at du må presse for hardt for å få ut*	Alternative 1	**A1 87,5% (5**)	No comments

Stage 1 - expert panel review using the modified Delphi method PFDI-20 summary results from Round 2					
PFDI-20 Items	**Single Forward Version** *(SFV)*	**Alternatives from Round 1** *The alternatives from Round 1 are voted on in Round 2.*	**Outcome**	**Consensus[a] % (Median)**	**Comment**
	presse for hardt for å ha avføring?	*avføringen?*			
8	Single Forward Version: *Føler du at du ikke har tømt tarmen helt, når du har hatt avføring?*	No new suggestions	Original version	**SFV 100%(5)**	One suggested *Føler du etter avføring at du ikke har klart å tømme tarmen helt*
9	Single Forward Version: *Har du vanligvis ufrivillige avføring hvis avføringen er fast?*	Alternative 1: *Har du ofte avføringslekkasje når avføringen er fast?* Alternative 2: *Har du vanligvis avføringslekkasje når avføringen er fast?*	Alternative 1	**A1 100% (5)**	One suggested *formet* replaced *fast*
10	Single Forward Version: *Har du vanligvis ufrivillig avføring hvis avføringen løs eller flytende?*	Alternative 1: *Har du ofte avføringslekkasje når avføringen er løs eller flytende?* Alternative 2: *Har du vanligvis avføringslekkasje når avføringen er løs eller flytende?*	Alternative 1	**A1 100% (5)**	No comments
11	Single Forward Version: *Slipper du vanligvis luft fra tarmen uten kontroll?*	Alternative 1: *Slipper du ofte luft fra tarmen uten kontroll?* Alternative 2: *Lekker du ofte ufrivillig luft fra tarmen?* Alternative 3: *Har du ofte ufrivillige lekkasje av luft fra tarmen?*	Alternative 3	**A3 100% (5)**	No comments
12	Single Forward Version: *Har du vanligvis smerter når du har avføring?*	Alternative 1: *Har du ofte smerter mens du har avføring?*	Alternative 1	**A1 100% (4)**	Alternative 1: 6 suggested *når*
13	Single Forward Version: *Opplever du stor trang og må løpe på toalettet for å tømme tarmen?*	Alternative 1: *Opplever du ved avføringstrang at det haster, så du må løpe til toalettet for å tømme tarmen?* Alternative 2: *Opplever du ofte så sterk avføringstrang og må løper på toalettet?* Alternative 3: *Opplever du sterk trang og må løper på toalettet for å ha avføring?* Alternative 4: *Opplever du plutselig avføringstrang, slik at du må løpe til toalettet?*	Alternative 2	**A2 100% (4)**	Alternative 2: Eight suggested removing *ofte* and one suggested *til toalettet.*
14	Single Forward Version: *Hender det at en del av tarmen følger med ut under eller etter avføring?*	Alternative 1: Hender det at en del av tarmen følger med ut gjennom endetarmsåpningen under eller etter avføring? Alternative 2: Hender det at en del av tarmen buler ut gjennom endetarmsåpningen under eller etter avføring?	Alternative 2	**A2 100%(4,5)**	No comments
15	Single Forward Version: *Har du vanligvis hyppig vannlating?*	No new suggestions	Original version	**SFV 100%(5)**	Original version: One suggested *har du som oftest*
16	Single Forward Version:	Alternative 1: *Har du ofte*	No consensus.	No	3 new

Stage 1 - expert panel review using the modified Delphi method PFDI-20 summary results from Round 2					
PFDI-20 Items	**Single Forward Version** *(SFV)*	**Alternatives from Round 1** *The alternatives from Round 1 are voted on in Round 2.*	**Outcome**	**Consensus[a] % (Median)**	**Comment**
	Opplever du vanligvis urinlekkasje sammen med plutselig vannlatningstrang dvs en sterk følelse av at du må på toalettet?	*urinlekkasje under så sterk følelse av hast at du straks må på toalettet?*	No alternative given.	consensus. A1 25% (3) SFV 0% (3)	alternatives given for Round 3
17	Single Forward Version: *Opplever du vanligvis urinlekkasje når du hoster, nyser eller ler?*	Alternative 1: *Opplever du ofte urinlekkasje når du hoster, nyser eller ler?* Alternative 2: *Har du ofte urinlekkasje når du hoster, nyser eller ler?*	Alternative 2	**A2 87,5% (5)**	No comments
18	Single Forward Version: *Opplever du vanligvis urinlekkasje i små mengder (dvs. dråper)?*	Alternative 1: *Opplever du ofte små urinlekkasjer (dvs. dråper)?* Alternative 2: *Har du ofte små urinlekkasjer (dvs. dråper)?*	Alternative 2	**A2 75% (5)**	No comments
19	Single Forward Version: *Opplever du vanligvis problemer med å tømme blæren?*	Alternative 1: *Har du ofte problemer med å tømme blæren?*	Alternative 1	**A1 100% (5)**	No comments
20	Single Forward Version: *Kjenner du vanligvis smerte eller ubehag i den nedre delen av magen eller underlivet?*	Alternative 1: *Kjenner du ofte smerte eller ubehag i nedre del av magen eller underlivet?* Alternative 2: *Har du ofte smerte eller ubehag i nedre del av magen eller underlivet?*	Alternative 1 and Alternative 2	No consensus A1 87.5 % (4) A2 87,5 % (4) SFV 0% (2)	No consensus reached. A1 87.5% A2 87.5% To be discussed and voted on in Round 3.

[a]Letters and Numbers in bold means that consensus has been reached with no further comments or rounds required. Consensus is defined as those items rated as median >4 by at least 75% of the expert panellists with no additional comments.

Table 4.4b PFIQ-7 expert panel review summary results from Round 2.

Stage 1 - expert panel using the modified Delphi method PFIQ-7 summary results from Round 2					
PFIQ-7 Items	**Single Forward Version** *(SFV)*	**Alternatives from Round 1** *The alternatives are voted on in Round 2*	**Outcome**	**Consensus[a] % (Median)**	**Comment**
Title-	Single Forward Version: *Spørreskjema om innvirkning på bekkenbunnen – kort skjema 7*	No new alternatives	No consensus	**SFV 62.5% (5)**	Three comments: Alternative 1: *Spørreskjema om virkning på dagliglivet- skjema PFIQ-7* Alternative 2: *Hvordan påvirker din bekkenbunn deg- skjema PFIQ-7* Alternative 3: *Spørreskjema om bekkenbunnsplager og innvirkning på dagliglivet- skjema PFIQ-7*
PFIQ-7 instructions and example					
Instructions For Page one and page two	Single Forward Version: *Veiledning: Noen kvinner opplever at symptomer fra blæren, endetarmen eller skjeden påvirker deres aktiviteter, forhold og følelser. For hvert av spørsmålene ber vi deg krysse av for svaret som best beskriver hvordan dine aktiviteter, forhold eller følelser har blitt påvirket av symptomer eller plager fra blære, endetarm eller skjede **de tre siste månedene**. Du kan ha, eller ikke ha symptomer innenfor hvert av disse tre områdene, men husk å svare i alle tre kolonner for hvert spørsmål. Hvis du ikke har symptomer på et av områdene, svarer du "ikke i det hele tatt" i den aktuelle kolonnen.*	Alternative 1: *Noen kvinner opplever at symptomer fra blæren, endetarmen eller skjeden påvirker deres **gjøremål, samliv** og følelser. For hvert av spørsmålene ber vi deg krysse av for svaret som best beskriver hvordan dine **gjøremål, samliv** eller følelser har blitt påvirket av symptomer eller plager fra blære, endetarm eller skjede de tre siste månedene. Du kan ha, eller ikke ha symptomer innenfor hvert av disse tre områdene, men husk å svare i alle tre kolonner for hvert spørsmål. Hvis du ikke har symptomer på et av områdene, svarer du "ikke i det hele tatt" i den aktuelle kolonnen.*	Alternative 1 (A1)	**A1 100% (5)**	No comments

Stage 1 - expert panel using the modified Delphi method PFIQ-7 summary results from Round 2					
PFIQ-7 Items	**Single Forward Version** *(SFV)*	**Alternatives from Round 1** *The alternatives are voted on in Round 2*	**Outcome**	**Consensus[a] % (Median)**	**Comment**
Example	Single Forward Version: *Ved følgende spørsmål: Hvis du har symptomer tilknyttet blærefunksjonen, som påvirker evnen din til å kjøre bil i noen grad, og symptomene knyttet til tarmfunksjonen påvirker evnen til å kjøre bil litt, men symptomer knyttet til skjede eller bekkenbunn ikke påvirker evnen til å kjøre bil i det hele tatt, skal du sette kryss **(X)** i boksene som vist nedenfor:* *Evne til å kjøre bil?*	Alternative 1: Remove *i det hele tatt* in the example section.	SFV	**SFV 75% (5)**	One suggested to rewrite and shorten the paragraph.
PFIQ-7 response question, questions 1-7 and responses					
Opening question for 1-7	*Hvordan pleier symptomer eller plager fra-* *-Blære eller urinveier* *-Tarm eller endetarm* *-Skjede eller bekkenbunn* *å påvirke:* *Vennligst husk å svare i alle tre kolonner for hvert spørsmål*	No comments	SFV	**SFV 100% (5)**	No comments
Responses	Single Forward Version: *Ikke det hele tatt* *Litt* *I noen grad* *Ganske mye*	No alternatives	SFV	**SFV 100% (5)**	No comments
Question 1	Single Forward Version: *Evne til å utføre husarbeid (matlaging, rengjøring, klesvask)?*	Alternative 1: *din evne til å utføre husarbeid (matlaging, rengjøring, klesvask)?*	Alternative 1	**A1 100% (5)**	No comments
Question 2	Single Forward Version: *Evne til å være i fysisk aktivitet som turgåing, svømming eller annen mosjon?*	Alternative 1: *din fysiske aktivitet som turgåing, svømming eller annen mosjon?* Alternative 2: *din fysiske aktivitet som å gå tur, svømming eller annen mosjon?*	No consensus.	A1 50% % (4) A2 62.5% (4) SFV 0% (2)	Two panellists suggested that Alternative 2 corresponds well with question 1
Question 3	Single Forward Version: *Deltagelse i fritidsaktiviteter som å gå på kino eller konsert?*	Alternative 1: *dine fritidsaktiviteter som å gå på kino eller konsert?*	Alternative 1.	**A1 100% (5)**	No comments

Stage 1 - expert panel using the modified Delphi method PFIQ-7 summary results from Round 2					
PFIQ-7 Items	**Single Forward Version** *(SFV)*	**Alternatives from Round 1** *The alternatives are voted on in Round 2*	**Outcome**	**Consensus[a] % (Median)**	**Comment**
Question 4	Single Forward Version: *Mulighet til å reise med bil eller buss lenger enn 30 minutter hjemmefra?*	Alternative 1: *din mulighet til å reise med bil eller buss lenger enn 30 minutter hjemmefra?*	Alternative 1.	**A1 100% (5)**	No comments
Question 5	Single Forward Version: *Deltagelse i sosiale aktiviteter utenfor hjemmet?*	Alternative 1: *din deltagelse i sosiale aktiviteter utenfor hjemmet?*	Alternative 1	**A1 100% (5)**	No comments
Question 6	Single Forward Version: *Følelsesmessige helsetilstand (nervøsitet, engstelig, depresjon osv.)?*	Alternative 1: *følelsesmessige helse (nervøsitet, engstelig, depresjon osv.)?* Alternative 2: *din psykiske helsetilstand (nervøsitet, engstelig, depresjon osv.)?* Alternative 3: *psykiske helsetilstand (nervøsitet, engstelig, depresjon osv.)?*	Alternative 2	**A2 100% (5)**	No comments
Question 7	Single Forward Version: *Følelse av frustrasjon?*	Alternative 1: *din følelse av frustrasjon?*	Alternative 1	**A1 100% (5)**	No comments
[a] Consensus is defined as those items rated as median >4 by at least 75% of the expert panellists with no additional comments.					

Table 4.4c PFDI-20 expert panel review summary results from Round 3

Stage 1 - expert panel using the modified Delphi method PFDI-20 summary results from Round 3					
PFDI-20 Items	**Round 2 Version**	**New alternatives and suggestions made during Round 2** *These alternatives made in Round 2 are voted on in Round 3*	**Outcome**	**Consensus[a]**	**Comments**
Title	Single Forward Version: *Spørreskjema om bekkenbunnsbesvær – kort skjema 20*	Alternative 1: *Spørreskjema om bekkenbunnsplager – skjema PFDI-20*	Discussed but not voted on. To be discussed and voted on in Round 4	No consensus	No further comments
Instruction:	Alternative 1: *Vennligst svar på alle spørsmålene i spørreskjemaet. Spørsmålene dreier seg om hvorvidt du har visse symptomer i tarmen, blæren eller bekkenregionen, og i så fall i hvilken grad de plager deg.* *Svar på spørsmålene ved å krysse av i den eller de boksene som passer for deg. Hvis du er usikker på hva du skal svare, svarer du så godt du kan.* *Vennligst svar på spørsmålene ut fra de symptomene du har hatt* ***de siste tre månedene.***	Alternative 1A: *Vennligst svar på alle spørsmålene i spørreskjemaet. Spørsmålene dreier seg om hvorvidt du har visse symptomer i tarmen, blæren eller bekkenregionen, og i så fall i hvilken grad de plager deg.* *Svar på spørsmålene ved å krysse av i den eller de boksene som passer for deg. Hvis du er usikker på hva du skal svare, svarer du så godt du kan.* *Vær snill og svar på spørsmålene ut fra de symptomene du har hatt* ***de siste tre månedene.***	Discussed but not voted on. To be discussed and voted on in Round 4	No consensus	No further comments
Example			Consensus reached in Round 2		
Response Question and Responses			Consensus reached in Round 2		
1	Alternative 1: *Kjenner du ofte trykk i den nedre delen av magen?*	Alternative 1A: *Kjenner du ofte et trykk i den nedre delen av magen?*	Discussed but not voted on. To be discussed and voted on in Round 4	No consensus	No further comments
2			Consensus reached in Round 2		
3	Alternative 3: *Kjenner eller ser du vanligvis noe som "buler ut" eller faller ut i skjeden?*	Alternative 3A: *Kjenner eller ser du ofte noe som buler eller faller ut i skjeden?* Alternative 3B: *Kjenner eller ser du en kul eller noe som kommer ut i skjeden?*	Discussed but not voted on. To be discussed and voted on in Round 4	No consensus	No further comments
4	Alternative 1: *Må du ofte presse med fingre i skjeden eller rundt endetarmsåpningen for å få ut avføring eller å få tømt*	Alternative 1A: *Må du ofte presse i skjeden eller rundt endetarmsåpningen for å få ut avføring eller å få tømt tarmen helt?*	Discussed but not voted on. To be discussed and voted on in Round 4	No consensus	No further comments

Stage 1 - expert panel using the modified Delphi method PFDI-20 summary results from Round 3					
PFDI-20 Items	**Round 2 Version**	**New alternatives and suggestions made during Round 2** *These alternatives made in Round 2 are voted on in Round 3*	**Outcome**	**Consensus[a]**	**Comments**
	tarmen helt?				
5	Alternative 3: *Føler du ofte at du ikke får tømt blæren helt?*	Alternative 3A with comment *"fullstendig": Føler du ofte at du ikke får tømt blæren fullstendig?* Alternative 3B with comment *"under vannlatning": Føler du ofte at du ikke får tømt blæren helt under vannlatning?*	Discussed but not voted on. To be discussed and voted on in Round 4	No consensus	No further comments
6	Alternative 1: *Hender det noen gang at du må trykke inn med fingrene noe som buler i skjeden, for å få tisset eller tømt blæren helt?*	Alternative 1A with comment remove *"noen gang": Hender det at du må trykke inn med fingrene noe som buler i skjeden, for å få tisset eller tømme blæren helt?*	Discussed but not voted on. To be discussed and voted on in Round 4	No consensus	No further comments
7	Alternative 1: *Føler du at du må presse for hardt for å få ut avføringen?*	None	Consensus reached in Round 2	No consensus	No further comments
8	Single Forward Version: *Føler du at du ikke har tømt tarmen helt, når du har hatt avføring?*	Alternative 1: *Føler du etter avføring at du ikke har klart å tome tarmen helt?*	Discussed but not voted on. To be discussed and voted on in Round 4	No consensus	No further comments
9	Alternative 1: *Har du ofte avføringslekkasje når avføringen er fast?*	Alternative 1A with comment *"formet": Har du ofte avføringslekkasje når avføringen er formet?*	Discussed but not voted on. To be discussed and voted on in Round 4	No consensus	No further comments
10			Consensus reached in Round 2		
11			Consensus reached in Round 2		
12	Alternative 1: *Har du ofte smerter mens du har avføring?*	Alternative 1A with comment *"når": Har du ofte smerter når du har avføring?*	Discussed but not voted on. To be discussed and voted on in Round 4	No consensus	No further comments
13	Alternative 2: *Opplever du ofte så sterk avføringstrang og må løper på toalettet?*	Alternative 2A: *Opplever du så sterk avføringstrang og må løper til toalettet?* Alternative 2B: *Opplever du ved avføringstrang at det haster veldig?*	Discussed but not voted on. To be discussed and voted on in Round 4	No consensus	No further comments
14			Consensus reached in Round 2		
15	Single Forward Version: *Har du vanligvis hyppig vannlating?*	Alternative 1: *Har du som oftest hyppig vannlating?*	Discussed but not voted on. To be discussed and voted on in Round 4	No consensus	No further comments
16	Single Forward Version: *Opplever du vanligvis urinlekkasje sammen med plutselig*	Alternative 1: *Har du ofte urinlekkasje og plutselig vannlatningstrang: dvs så sterk følelse av du må på toalettet?* Alternative 2: *Har du ofte urinlekkasje under så sterk følelse av hast at du må*	Voted on however no consensus reached. SFV 0% (3)	No consensus	Voted on however no consensus reached.

Stage 1 - expert panel using the modified Delphi method PFDI-20 summary results from Round 3					
PFDI-20 Items	**Round 2 Version**	**New alternatives and suggestions made during Round 2** *These alternatives made in Round 2 are voted on in Round 3*	**Outcome**	**Consensus[a]**	**Comments**
	vannlatningstrang dvs en sterk følelse av at du må på toalettet?	*på toalettet?* Alternative 3: *Opplever du ofte kraftig vannlatnings trang etterfulgt av urinlekkasje: dvs så sterk vannlatningstrang at du straks vil oppsøke toalettet?* Alternative 4: *Opplever du ofte så sterk vannlatningstrang at du ikke rekker til toalettet før du får lekkasje?*	A1 25% (3) A2 0% (3) A3 0% (3) A4 0% (3) To be further discussed and voted on in Round 4		Four new alternatives given: A5 A6 A7 A8 To be discussed and voted on in Round 4
17			Consensus reached in Round 2		
18			Consensus reached in Round 2		
19			Consensus reached in Round 2		
20	Alternative 1: *Kjenner du ofte smerte eller ubehag i nedre del av magen eller underlivet?* Alternative 2: *Har du ofte smerte eller ubehag i nedre del av magen eller underlivet?*	No new alternatives	Voted on however no consensus reached. A1 87.5% A2 87.5% To be discussed and voted on in Round 4.	No consensus 87,5 % (4) for both	No further comments

[a] Consensus is defined as those items rated as median >4 by at least 75% of the expert panellists with no additional comments.

Table 4.4d PFIQ-7 expert panel review summary results from Round 3.

Stage 1 - expert panel using Delphi method PFIQ-7 Delphi Summary Results from Round 3					
PFIQ-7 Items	**Round 2 Version**	**New Alternatives and Suggestions Made During Round 2** *These alternatives made in Round 2 are voted on in Round 3*	**Outcome**	**Consensus (Median)**	**Comment**
Title-	Single Forward Version: *Spørreskjema om innvirkning på bekkenbunnen – kort skjema 7*	Alternative 1: *Spørreskjema om virkning på dagliglivet- skjema PFIQ-7* Alternative 2: *Hvordan påvirker din bekkenbunn deg- skjema PFIQ-7* Alternative 3: *Spørreskjema om bekkenbunnsplager og innvirkning på dagliglivet- skjema PFIQ-7*	Voted on however no consensus reached. To be discussed and voted on in Round 4.	SFV 62.5% (5) A1 62.5% (5) A2 62.5% (5) A3 62.5% (5)	No further comments
Instruction Page 1 and 2			Consensus reached in Round 2		
Example			Voted on however no consensus reached. To be discussed and voted on in Round 4.		One suggested to rewrite and shorten the paragraph.
Response question and responses			Consensus reached in Round 2		
Opening Question for 1-7			Consensus reached in Round 2		
Question 1			Consensus reached in Round 2		
Question 2	Single Forward Version: *Evne til å være i fysisk aktivitet som turgåing, svømming eller annen mosjon?*	Alternative 1: *Din fysiske aktivitet som turgåing, svømming eller annen mosjon?* Alternative 2: *Din fysisk aktivitet som å gå tur, svømming eller annen mosjon?*	Consensus.	**A1 75% (5) A2 50% (4) SFV 0% (2)**	No further comments
Question 3			Consensus reached in Round 2		
Question 4			Consensus reached in Round 2		
Question 5			Consensus reached in Round 2		
Question 6			Consensus reached in Round 2		
Question 7			Consensus reached in Round 2		
[a] Consensus is defined as those items rated as median >4 by at least 75% of the expert panellists with no additional comments.					

Table 4.4e PFDI-20 expert panel review summary results from Round 4.

Numbers highlighted = consensus has been reached and no further comments or further rounds

Stage 1 - expert panel using the modified Delphi method **PFDI-20 summary results from Round 4**					
PFDI-20 Items	**Round 3 Version (R3V)** *Few changes have made been made from Round 2*	**New Alternatives and Suggestions Made During Round 3** *These alternatives made in Round 3 are voted on in Round 4*	**Outcome**	**Consensus[a] (Median)**	**Comments**
Title	Single Forward Version: *Spørreskjema om bekkenbunnsbesvær – skjema PFDI-20*	Alternative 1: *Spørreskjema om bekkenbunnsplager – skjema PFDI-20*	Alternative 1	**Alt. 1: 100% (5)**	No further comments
Instruction:	Alternative 1: V*ennligst svar på alle spørsmålene i spørreskjemaet. Spørsmålene dreier seg om hvorvidt du har visse symptomer i tarmen, blæren eller bekkenregionen, og i så fall i hvilken grad de plager deg.* *Svar på spørsmålene ved å krysse av i den eller de boksene som passer for deg. Hvis du er usikker på hva du skal svare, svarer du så godt du kan.* *Vennligst svar på spørsmålene ut fra de symptomene du har hatt* ***de siste tre månedene.***	Alternative 1A: *Vennligst svar på alle spørsmålene i spørreskjemaet. Spørsmålene dreier seg om hvorvidt du har visse symptomer i tarmen, blæren eller bekkenregionen, og i så fall i hvilken grad de plager deg.* *Svar på spørsmålene ved å krysse av i den eller de boksene som passer for deg. Hvis du er usikker på hva du skal svare, svarer du så godt du kan.* *Vær snill og svar på spørsmålene ut fra de symptomene du har hatt* ***de siste tre månedene.***	Alternative 1A	Alt 1: 0%(2) **Alt.1A: 100%(5)**	No further comments
Example			Consensus reached in Round 2		
Response questions and Responses			Consensus reached in Round 2		
1	Alternative 1: *Kjenner du vanligvis trykk i den nedre delen av magen?*	Alternative 1A: *Kjenner du ofte et trykk i den nedre delen av magen?*		Alt. 1: 0% (2) **Alt. 1A: 100% (5)**	No further comments
2			Consensus reached in Round 2		
3	Alternative 3: *Kjenner eller ser du vanligvis noe som "buler ut" eller faller ut i skjeden som du kan se eller kjenner I skjeden?*	Alternative 3A: *Kjenner eller ser du ofte noe som buler eller faller ut i skjeden?* Alternative 3B: *Kjenner eller ser du en kul eller noe som kommer ut i skjeden?*	Alternative 3A	**Alt. 3A 100% (5)** Alt. 3B 0% (2)	No further comments
4	Alternative 1: *Må du ofte presse med fingre* i *skjeden eller rundt*	Alternative 1A: *Må du ofte presse i skjeden eller rundt endetarmsåpningen*	Alternative 1	**Alt. 1 75 % (4,5)** Alt. 1A 25%	No further comments

Stage 1 - expert panel using the modified Delphi method PFDI-20 summary results from Round 4					
PFDI-20 Items	**Round 3 Version (R3V)** *Few changes have made been made from Round 2*	**New Alternatives and Suggestions Made During Round 3** *These alternatives made in Round 3 are voted on in Round 4*	**Outcome**	**Consensus[a] (Median)**	**Comments**
	endetarmsåpningen for å få ut avføring eller å få tømt tarmen helt?	*for å få ut avføring eller å få tømt tarmen helt?*		(2)	
5	Alternative 3: *Føler du ofte at du ikke får tømt blæren helt?*	Alternative 3A with comment *"fullstendig": Føler du ofte at du ikke får tømt blæren fullstendig?* Alternative 3B with comment *"under vannlatning": Føler du ofte at du ikke får tømt blæren helt under vannlatning?*	No change from Round 2 and Three	**Alt. 3 100% (5)** Alt. 3A 0% (2) Alt. 3B 0% (2)	No further comments
6	Alternative 1: *Hender det noen gang at du må trykke inn med fingrene noe som buler i skjeden, for å få tisset eller tømt blæren helt?*	Alternative 1A with comment remove *"noen gang": Hender det at du må trykke inn med fingrene noe som buler i skjeden, for å få tisset eller tømme blæren helt?*	Alternative 1A	A1 12.5% (2) **Alt. 1A 87.5%(4)**	No further comments
7	Alternative 1: *Kjenner Føler du at du må presse for hardt for å få ut avføringen?*	None	No change from Round 2 and Three	**Alt. 1: 87,5% (5)**	No further comments
8	Single Forward Version: *Føler du at du ikke har tømt tarmen helt, når du har hatt avføring?*	Alternative 1: *Føler du etter avføring at du ikke har klart å tome tarmen helt?*	No change from Round 2 and Three	**SVF. 100% (5)** Alt. 1 0% (2)	No further comments
9	Alternative 1: *Har du ofte avføringslekkasje når avføringen er fast?*	Alternative 1A with comment "formet": Har du ofte avføringslekkasje når avføringen er formet?	No change from Round 2 and Three	**Alt.1 100% (5)** Alt.1A: 0% (2**)**	No further comments
10			Consensus reached in Round 2		
11			Consensus reached in Round 2		
12	Alternative 1: *Har du ofte smerter mens du har avføring?*	Alternative 1A with comment *"når": Har du ofte smerter når du har avføring?*	Alternative 1A	Alt.1 0% (2) **Alt. 1A100% (5)**	No further comments
13	Alternative 2: *Opplever du ofte så sterk avføringstrang og må løper på toalettet?*	Alternative 2A with comments remove *"ofte"* and *"til": Opplever du så sterk avføringstrang og må løper til toalettet? Alternative 2B: Opplever du ved avføringstrang at det haster veldig?*	Alternative 2A	Alt.2 0% (2) **Alt. 2A:100% (4.5)** Alt.2B 12.5% (2)	No further comments
14			Consensus reached in Round 2		

Stage 1 - expert panel using the modified Delphi method PFDI-20 summary results from Round 4					
PFDI-20 Items	**Round 3 Version (R3V)** *Few changes have made been made from Round 2*	**New Alternatives and Suggestions Made During Round 3** *These alternatives made in Round 3 are voted on in Round 4*	**Outcome**	**Consensus[a] (Median)**	**Comments**
15	Single Forward Version: *Har du vanligvis hyppig vannlating?*	Alternative 1: *Har du som oftest hyppig vannlating?*	Alternative 1	Orig. 25% (2) **Alt. 1: 100%(5)**	No further comments
16	Single Forward Version: *Opplever du vanligvis urinlekkasje sammen med plutselig vannlatningstrang dvs en sterk følelse av at du må på toalettet?* Alternative 1: *Har du ofte urinlekkasje og plutselig vannlatningstrang: dvs så sterk følelse av du må på toalettet?* Alternative 2: *Har du ofte urinlekkasje under så sterk følelse av hast at du må på toalettet?* Alternative 3: *Opplever du ofte kraftig vannlatnings trang etterfulgt av urinlekkasje: dvs så sterk vannlatningstrang at du straks vil oppsøke toalettet?* Alternative 4: *Opplever du ofte så sterk vannlatningstrang at du ikke rekker til toalettet før du får lekkasje?*	Alternative 5: *Har du ofte urinlekkasje og kraftig trang til vannlatning: dvs så sterk følelse av hast at du må på toalettet?* Alternative 6: *Har du ofte urinlekkasje og plutselig vannlatningstrang: dvs så sterk følelse av du må til toalettet?* Alternative 7: *Har du ofte urinlekkasje under så sterk følelse av hast at du må straks på toalettet?* Alternative 8: *Har du ofte urinlekkasje før du når toalettet ved kraftig trang til vannlatning: dvs så sterk følelse av hast at du må på toalettet?*	Alternative 7	Orig. 0% (2) A1 0% (2) A2 12.5% (2) A3 37.5% (3) A4 0% (2) A5 0% (2) A6 12.5% (2) **A7 100% (5)** A8 0% (2)	
17			Consensus reached in Round 2		
18			Consensus reached in Round 2		
19			Consensus reached in Round 2		
20	Alternative 1: *Kjenner du ofte smerte eller ubehag i nedre del av magen eller underlivet?* *Alternative 2: Har du ofte smerte eller ubehag i nedre del av magen eller underlivet?*	No new alternatives	Alternative 2	A1 62.5% (4) **A2 100% (4)**	No further comments

[a] Consensus is defined as those items rated as median >4 by at least 75% of the expert panellists with no additional comments.

Table 4.4f PFIQ-7 expert panel review summary results from Round 4.

Stage 1 - expert panel using the modified Delphi method PFIQ-7 summary results from Round 4					
PFIQ-7 Items	**Round 3 Version**	**New alternatives and suggestions made during Round 3** *These alternatives made in Round 3 are voted on in Round 4*	**Outcome**	**Consensus[a] (median)**	**Comment**
Title-	Single Forward Version: *Spørreskjema om innvirkning på bekkenbunnen – kort skjema 7*	Alternative 1: *Spørreskjema om virkning på dagliglivet- skjema PFIQ-7* Alternative 2: *Hvordan påvirker din bekkenbunn deg- skjema PFIQ-7* Alternative 3: *Spørreskjema om bekkenbunnsplager og innvirkning på dagliglivet- skjema PFIQ-7*	Alternative 3	**A3 87.5% (5)**	No further comments
Instruction Page 1 and 2		Voted on however no consensus reached. To be discussed and voted on in Round 4.	Consensus reached in Round 2		
Example	Single Forward Version:		Suggested to rewrite and shorten the paragraph rejected.	**SFV 87.5% (5)**	No further comments
Opening question for 1-7			Consensus reached in Round 2		
Responses			Consensus reached in Round 2		
Question 1			Consensus reached in Round 2		
Question 2			Consensus reached in Round 3		
Question 3			Consensus reached in Round 2		
Question 4			Consensus reached in Round 2		
Question 5			Consensus reached in Round 2		
Question 6			Consensus reached in Round 2		
Question 7			Consensus reached in Round 2		
[a] Consensus is defined as those items rated as median >4 by at least 75% of the expert panellists with no additional comments.					

APPENDIX 5.1

NORWEGIAN INTERMEDIATE VERSION 2.0

Spørreskjema om bekkenbunnsplager - skjema PFDI-20

Veiledning

Vennligst svar på alle spørsmålene i spørreskjemaet. Spørsmålene dreier seg om hvorvidt du har visse symptomer i tarmen, blæren eller bekkenregionen, og i så fall hvor mye de plager deg. Svar på spørsmålene ved å krysse av i den eller de boksene som passer for deg. Hvis du er usikker på hva du skal svare, svarer du så godt du kan. Vær snill og svar på spørsmålene ut fra de symptomer du har hatt gjennom de **siste tre månedene.**

EKSEMPEL

Ved følgende spørsmål:

Hvis du ikke pleier å ha hodepine, setter du X i "Nei"- ruten.

Har du ofte *hodepine*?

☒ Nei ☐ Ja **Hvis ja, hvor mye plager det deg?**

☐ 1	☐ 2	☐ 3	☐ 4
Ikke det hele tatt	Litt	I noen grad	Ganske mye

Hvis du pleier å ha hodepine, setter du X i "Ja"-boksen og angir hvor mye hodepinen plager deg. (I dette eksemplet plages vedkommende av hodepinen *i noen grad*)

Har du ofte *hodepine*?

☐ Nei ☒ Ja **Hvis ja, hvor mye plager det deg?**

☐ 1	☐ 2	☒ 3	☐ 4
Ikke det hele tatt	Litt	I noen grad	Ganske mye

Spørreskjema om bekkenbunnsplager - skjema PFDI-20

1.	Kjenner du ofte et *trykk* i nedre del av magen? ☐ Nei; ☐ Ja **0** **<u>Hvis ja</u>, hvor mye plager det deg?** **☐ 1** Ikke i det hele tatt - **☐ 2** Litt - **☐ 3** I noen grad - **☐ 4** Ganske mye
2.	Har du ofte *tyngdefornemmelse i bekkenet*? ☐ Nei; ☐ Ja **0** **<u>Hvis ja</u>, hvor mye plager det deg?** **☐ 1** Ikke i det hele tatt - **☐ 2** Litt - **☐ 3** I noen grad - **☐ 4** Ganske mye
3.	Kjenner eller ser du ofte noe som buler eller faller ut i skjeden? ☐ Nei; ☐ Ja **0** **<u>Hvis ja</u>, hvor mye plager det deg?** **☐ 1** Ikke i det hele tatt - **☐ 2** Litt - **☐ 3** I noen grad - **☐ 4** Ganske mye
4.	Må du ofte presse med fingre i skjeden eller rundt endetarmsåpningen for å få ut avføring eller få tømt tarmen helt? ☐ Nei; ☐ Ja **0** **<u>Hvis ja</u>, hvor mye plager det deg?** **☐ 1** Ikke i det hele tatt - **☐ 2** Litt - **☐ 3** I noen grad - **☐ 4** Ganske mye
5.	Føler du ofte at du ikke får tømt blæren helt? ☐ Nei; ☐ Ja **0** **<u>Hvis ja</u>, hvor mye plager det deg?** **☐ 1** Ikke i det hele tatt - **☐ 2** Litt - **☐ 3** I noen grad - **☐ 4** Ganske mye
6.	Hender det at du må trykke inn med fingrene noe som buler i skjeden, for å få tisset eller tømt blæren helt? ☐ Nei; ☐ Ja **0** **<u>Hvis ja</u>, hvor mye plager det deg?** **☐ 1** Ikke i det hele tatt - **☐ 2** Litt - **☐ 3** I noen grad - **☐ 4** Ganske mye

7. Føler du at du må presse for hardt for å få ut avføringen?

☐ Nei; ☐ Ja
0

Hvis ja, hvor mye plager det deg?

☐ 1	☐ 2	☐ 3	☐ 4
Ikke i det hele tatt -	Litt -	I noen grad -	Ganske mye

8. Føler du at du ikke har tømt tarmen helt, når du har hatt avføring?

☐ Nei; ☐ Ja
0

Hvis ja, hvor mye plager det deg?

☐ 1	☐ 2	☐ 3	☐ 4
Ikke i det hele tatt -	Litt -	I noen grad -	Ganske mye

9. Har du ofte avføringslekkasje når avføringen er fast?

☐ Nei; ☐ Ja
0

Hvis ja, hvor mye plager det deg?

☐ 1	☐ 2	☐ 3	☐ 4
Ikke i det hele tatt -	Litt -	I noen grad -	Ganske mye

10. Har du ofte avføringslekkasje når avføringen er løs eller flytende?

☐ Nei; ☐ Ja
0

Hvis ja, hvor mye plager det deg?

☐ 1	☐ 2	☐ 3	☐ 4
Ikke i det hele tatt -	Litt -	I noen grad -	Ganske mye

11. Har du ofte ufrivillig lekkasje av luft fra tarmen?

☐ Nei; ☐ Ja
0

Hvis ja, hvor mye plager det deg?

☐ 1	☐ 2	☐ 3	☐ 4
Ikke i det hele tatt -	Litt -	I noen grad -	Ganske mye

12. Har du ofte smerter når du har avføring?

☐ Nei; ☐ Ja
0

Hvis ja, hvor mye plager det deg?

☐ 1	☐ 2	☐ 3	☐ 4
Ikke i det hele tatt -	Litt -	I noen grad -	Ganske mye

13. Opplever du så sterk avføringstrang at du må løpe til toalettet?

☐ Nei; ☐ Ja
0

Hvis ja, hvor mye plager det deg?

☐ 1	☐ 2	☐ 3	☐ 4
Ikke i det hele tatt -	Litt -	I noen grad -	Ganske mye

14. Hender det at en del av tarmen følger med ut gjennom endetarmsåpningen under eller etter avføring?

☐ Nei; ☐ Ja
0

<u>Hvis ja</u>, hvor mye plager det deg?

☐ **1**	☐ **2**	☐ **3**	☐ **4**
Ikke i det hele tatt -	Litt -	I noen grad -	Ganske mye

15. Har du som oftest hyppig vannlating?

☐ Nei; ☐ Ja
0

<u>Hvis ja</u>, hvor mye plager det deg?

☐ **1**	☐ **2**	☐ **3**	☐ **4**
Ikke i det hele tatt -	Litt -	I noen grad -	Ganske mye

16. Opplever du så sterk vannlatingstrang at du ikke rekker til toalettet før du får lekkasje?

☐ Nei; ☐ Ja
0

<u>Hvis ja</u>, hvor mye plager det deg?

☐ **1**	☐ **2**	☐ **3**	☐ **4**
Ikke i det hele tatt -	Litt -	I noen grad -	Ganske mye

17. Har du ofte urinlekkasje når du hoster, nyser eller ler?

☐ Nei; ☐ Ja
0

<u>Hvis ja</u>, hvor mye plager det deg?

☐ **1**	☐ **2**	☐ **3**	☐ **4**
Ikke i det hele tatt -	Litt -	I noen grad -	Ganske mye

18. Har du ofte små urinlekkasjer (dvs. dråper)?

☐ Nei; ☐ Ja
0

<u>Hvis ja</u>, hvor mye plager det deg?

☐ **1**	☐ **2**	☐ **3**	☐ **4**
Ikke i det hele tatt -	Litt -	I noen grad -	Ganske mye

19. Har du ofte problemer med å tømme blæren?

☐ Nei; ☐ Ja
0

<u>Hvis ja</u>, hvor mye plager det deg?

☐ **1**	☐ **2**	☐ **3**	☐ **4**
Ikke i det hele tatt -	Litt -	I noen grad -	Ganske mye

20. Har du ofte *smerte* eller *ubehag* i nedre del av magen eller underlivet?

☐ Nei; ☐ Ja
0

<u>Hvis ja</u>, hvor mye plager det deg?

☐ **1**	☐ **2**	☐ **3**	☐ **4**
Ikke i det hele tatt -	Litt -	I noen grad -	Ganske mye

Spørreskjema om bekkenbunnsplager og innvirkning på dagliglivet - skjema PFIQ-7

Veiledning

Noen kvinner opplever at symptomer fra blæren, endetarmen eller skjeden påvirker deres gjøremål, samliv og følelser. For hvert av spørsmålene ber vi deg krysse av for svaret som best beskriver hvordan dine gjøremål, samliv eller følelser har blitt påvirket av symptomer eller plager fra blære, endetarm eller skjede **de tre siste månedene**.

Du kan ha, eller ikke ha symptomer innenfor hvert av disse tre områdene, men husk å svare i **alle tre kolonner** for hvert spørsmål. Hvis du ikke har symptomer på et av områdene, svarer du "ikke i det hele tatt" i den aktuelle kolonnen.

EKSEMPEL

Ved følgende spørsmål:
Hvis blærefunksjonen påvirker evnen din til å kjøre bil i noen grad, mens tarmfunksjonen bare påvirker evnen til å kjøre bil litt, og symptomer knyttet til skjede eller bekkenbunn ikke påvirker evnen til å kjøre bil i det hele tatt, skal du sette kryss (X) i boksene som vist nedenfor:

Hvordan pleier symptomer eller plager fra →→ å påvirke ↓	***Blære eller urin***	***Tarm eller endetarm***	***Skjede eller bekkenbunnen***
1. din evne til å kjøre bil	☐ Ikke i det hele tatt ☐ Litt ☒ I noen grad ☐ Ganske mye	☐ Ikke i det hele tatt ☒ Litt ☐ I noen grad ☐ Ganske mye	☒ Ikke i det hele tatt ☐ Litt ☐ I noen grad ☐ Ganske mye

Vennligst husk å svare i alle tre kolonner for hvert spørsmål

Takk for hjelpen!

Spørreskjema om bekkenbunnsplager og innvirkning på dagliglivet - skjema PFIQ-7

Veiledning: Noen kvinner opplever at symptomer fra blæren, endetarmen eller skjeden påvirker deres gjøremål, samliv og følelser. For hvert av spørsmålene ber vi deg krysse av for svaret som best beskriver hvordan dine gjøremål, samliv eller følelser har blitt påvirket av symptomer eller plager fra blære, endetarm eller skjede **de tre siste månedene**. Husk å krysse av i **alle de tre kolonnene** for hvert spørsmål.

Hvordan pleier symptomer eller plager fra →→ å påvirke ↓	***Blære eller urin***	***Tarm eller endetarm***	***Skjede eller bekkenbunnen***
1. din evne til å utføre husarbeid (matlaging, rengjøring, klesvask)?	☐ Ikke i det hele tatt ☐ Litt ☐ I noen grad ☐ Ganske mye	☐ Ikke i det hele tatt ☐ Litt ☐ I noen grad ☐ Ganske mye	☐ Ikke i det hele tatt ☐ Litt ☐ I noen grad ☐ Ganske mye
2. din fysiske aktivitet, som turgåing, svømming eller annen mosjon?	☐ Ikke i det hele tatt ☐ Litt ☐ I noen grad ☐ Ganske mye	☐ Ikke i det hele tatt ☐ Litt ☐ I noen grad ☐ Ganske mye	☐ Ikke i det hele tatt ☐ Litt ☐ I noen grad ☐ Ganske mye
3. dine fritidsaktiviteter som å gå på kino eller konsert?	☐ Ikke i det hele tatt ☐ Litt ☐ I noen grad ☐ Ganske mye	☐ Ikke i det hele tatt ☐ Litt ☐ I noen grad ☐ Ganske mye	☐ Ikke i det hele tatt ☐ Litt ☐ I noen grad ☐ Ganske mye
4. din mulighet til å reise med bil eller buss i lenger enn 30 minutter hjemmefra?	☐ Ikke i det hele tatt ☐ Litt ☐ I noen grad ☐ Ganske mye	☐ Ikke i det hele tatt ☐ Litt ☐ I noen grad ☐ Ganske mye	☐ Ikke i det hele tatt ☐ Litt ☐ I noen grad ☐ Ganske mye
5. din deltakelse i sosiale aktiviteter utenfor hjemmet?	☐ Ikke i det hele tatt ☐ Litt ☐ I noen grad ☐ Ganske mye	☐ Ikke i det hele tatt ☐ Litt ☐ I noen grad ☐ Ganske mye	☐ Ikke i det hele tatt ☐ Litt ☐ I noen grad ☐ Ganske mye
6. din psykiske helsetilstand (nervøsitet, depresjon osv.)?	☐ Ikke i det hele tatt ☐ Litt ☐ I noen grad ☐ Ganske mye	☐ Ikke i det hele tatt ☐ Litt ☐ I noen grad ☐ Ganske mye	☐ Ikke i det hele tatt ☐ Litt ☐ I noen grad ☐ Ganske mye
7. din følelse av frustrasjon?	☐ Ikke i det hele tatt ☐ Litt ☐ I noen grad ☐ Ganske mye	☐ Ikke i det hele tatt ☐ Litt ☐ I noen grad ☐ Ganske mye	☐ Ikke i det hele tatt ☐ Litt ☐ I noen grad ☐ Ganske mye

APPENDIX 5.2

RESEARCH MATERIALS FOR STAGE 2 (PILOT TESTING)

5.2a: Verbal script for health personnel (English)

5.2b: Verbal script for health personnel (Norwegian)

5.2c: Verbal script for principal researcher (English)

5.2d: Verbal script for principal researcher (Norwegian)

5.2e: Letter of Introduction (English)

5.2f: Information Sheet (English)

5.2g: Consent Form - Consent for participation (English)

5.2h: *Samtykke* (Letter of Introduction, Information sheet and Consent Form) (Norwegian)

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VERBAL SCRIPT FOR HEALTH PERSONNEL

Title of research project:

"Validating condition-specific quality of life questionnaires for women with pelvic floor disorders in the Norwegian context"

"We have a Master student Catherine Planke from the Faculty of Medicine at Flinders University, Australia. She is also employed as the Administrative Manager at our Pelvic Floor Center here at the Hospital. She is undertaking research leading to the production of a thesis and publications on the subject of "Validating condition-specific quality of life questionnaires for women with pelvic floor disorders in the Norwegian context"
The questionnaire has originally been devised in English and is now translated into Norwegian. We want to be sure that these translated questionnaires ask the right questions in the right way. She is available to see you now if you wish to participate"

Thank- you for your assistance.

Faculty of Health Sciences, Flinders University

Ms Catherine Planke
Master of Science candidate
School of Medicine
Faculty of Health Sciences
Flinders University

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Adelaide SA 5001, Australia

Tel: +47 4800 3263
joyc0003@flinders.edu.au

VERBAL SCRIPT FOR HEALTH PERSONNEL

Vi har en Master student Catherine Planke fra Det Medisinske Fakultet ved Flinders University, Australia. Hun er også ansatt som administrativ leder på Bekkensenteret her på Akershus universitetssykehus. Hun jobber med et forskningsprosjekt som oversetter to bekkbunnsspørreskjemaene fra engelsk til norsk.
Spørreskjemaene tar sikte på å måle pasientens tarm, urin og vaginal- og uterusprolaps symptomer og innvirkningen av disse symptomene på pasienters livskvalitet før og etter vaginal kirurgi. Vi ønsker å være sikker på at disse oversatte spørreskjemaer stiller de riktige spørsmålene på riktig måte på norsk. Hun er tilgjengelig for å se deg nå hvis du ønsker å delta.

Thank- you for your assistance.

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VERBAL SCRIPT FOR PRINCIPAL RESEARCHER

Title of research project:
"Validating condition specific quality of life questionnaires for women with pelvic floor disorders in the Norwegian context"

"My name is Catherine Planke and I am a Master student at the Faculty of Medicine at Flinders University, Australia and Administrative Manager for the Pelvic Floor Centre at Akershus University Hospital. I am undertaking research on the subject of translating and testing a new set of questionnaires in Norwegian to assess pelvic floor disorders. The questionnaires aims to measure patients' bowel, urine and prolapse symptoms and the impact of these symptoms on Norwegian women's quality of life. The Purpose of the research project is to translate a well-established set of pelvic floor disorder questionnaires from English to Norwegian and test the questionnaires on 20 Norwegian women.
I would be most grateful if you would volunteer to assist in this project, by filling out two self-administered questionnaires that include a total of 27 questions and permit me a short interview. The interview would include 13 questions. No more than 50 minutes would be required. Would you be interested in participating in this study?"

The participant is shown the questionnaires and interview guide.

If the participant is willing, they will read the introduction letter and information sheet, fill out the consent form and proceed to complete the questionnaires and comment by interview.

The questionnaires and interview would either take place on the same day as the consultation or the gynaecologist or the researcher would make a future appointment with the participant.

If the participants decline they will be thanked for considering the request.

Please note that these verbal scripts will be translated into Norwegian

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VERBALT MANUS FOR PROSJEKT LEDER

"Mitt navn er Catherine Planke og jeg er en PhD student fra Det Medisinske Fakultet ved Flinders University, Australia. Jeg er også ansatt som administrativ leder på Bekkensenteret her på Akershus universitetssykehus. Jeg tar doktorgrad i Bekkenbunnslidelser hos kvinner: Oversettelse og validering av to bekkbunnsspørreskjema til norsk.

Spørreskjemaene tar sikte på å måle pasientens tarm, urin og vaginal- og uterusprolaps symptomer og innvirkningen av disse symptomene på pasienters livskvalitet før og etter vaginal kirurgi. Vi ønsker å være sikker på at disse oversatte spørreskjemaer stiller de riktige spørsmålene på riktig måte på norsk.

Du vil bli bedt om å besvare to spørreskjemaer på egenhånd og deretter delta i et intervju. Intervjuet inkluderer 13 spørsmål. Det vil ikke ta mer enn 50 minutter. Vil du være interessert i å delta i denne studien? "

Deltakeren er vist spørreskjemaene og intervjuguide.

Hvis deltakeren er villig etter konsultasjonen, skal de fylle ut samtykkeskjema og deretter fylle ut spørreskjemaene.

Dersom deltakere svarer nei, vil de bli takket for å vurdere forespørselen.

Takk for din hjelp.

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Discipline of General Practice, School of Medicine
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Associate Professor Malcolm Bond
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LETTER OF INTRODUCTION
INTERVIEW

Dear Madam,

This letter is to introduce Ms Catherine Planke who is a Masters student in the School of Medicine at Flinders University and Administrative Manager at Akershus University Hospital Pelvic Care Center. She will produce her student card, which carries a photograph, as proof of identity.

She is undertaking research leading to the production of a dissertation or other publications on the subject of "Validating condition specific quality of life questionnaires for women with pelvic floor disorders in the Norwegian context"

The questionnaires are called Pelvic Floor Distress Inventory and the Pelvic Floor Impact Questionnaire (PFDI-20 and PFIQ-7). These are self-administered questionnaires that ask about you and your health. We know that these questionnaires are of value for patients who suffer from pelvic floor disorders.

The questionnaires have originally been devised in English and are now translated into Norwegian. We want to be sure that these translated questionnaires ask the right questions in the right way. For that purpose, we are now asking for your help.

The PFDI-20 PFIQ-7 self-administered questionnaires will firstly be translated from English into Norwegian using several professional translators and a pelvic floor expert panel. The translation will be then pre-tested in a pilot study on 20 patients at the gynecological department, Akershus University Hospital with a pelvic floor dysfunction diagnosis (bowel, urinary or prolapse). There is an outline of the research attached.

She would be most grateful if you would volunteer to assist in this project, by completing the questionnaires and then granting a brief recorded interview which makes sure we asked these questions in a proper way and covers certain aspects of this topic. No more than 50 minutes would be required.

The questionnaires aims to measure patients' bowel, urine and prolapse symptoms and the impact of these symptoms on patients' quality of life. The questionnaires will also be available in Norway for use by patients to measure the effectiveness of treatments for prolapse, urine and bowel symptoms.

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Be assured that any information provided will be treated in the strictest confidence and none of the participants will be individually identifiable in the resulting thesis, report or other publications. You are, of course, entirely free to discontinue your participation at any time or to decline to answer particular questions.

Since she intends to make a tape recording of the interview, Ms Planke will seek your consent, on the attached form to record the interview and to use the recording or a transcription in preparing the thesis, report or other publications. Faculty of Health Sciences, Flinders University

This will be on the condition that your name or identity is not revealed, and that the recording may be made available to other researchers on the same conditions. It may be necessary to make the recording available to authorised administrative staff for transcription, in which case you may be assured that such persons will be advised of the requirement that your name or identity not be revealed and that the confidentiality of the material is respected and maintained.

The tool is being used for research purposes only and is not a clinical assessment. If any of the questions cause you concerns about your health we strongly advise you to take this up with your gynaecologist.

Any enquiries you may have concerning this project should be directed to me at the contact detail above.

Thank you for your attention and assistance.

Yours sincerely,

Associate Professor Malcolm Bond
Discipline of General Practice
School of Medicine
Faculty of Health Sciences
Flinders University

This research project has been approved by the Flinders University Social and Behavioural Research Ethics Committee (Project Number 5376). For more information regarding ethical approval of the project the Executive Officer of the Committee can be contacted by telephone on 8201 3116, by fax on 8201 2035 or by email human.researchethics@flinders.edu.au..

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INFORMATION SHEET

Title:
"Validating condition specific quality of life questionnaires for women with pelvic floor disorders in the Norwegian context"

Investigator:
Ms Catherine Planke
Master of Science candidate
School of Medicine
Faculty of Health Sciences
Flinders University

Description of the study:
This study is part of the project entitled "Validating condition specific quality of life questionnaires for women with pelvic floor disorders in the Norwegian context"
The questionnaires are called the Pelvic Floors Distress Inventory and the Pelvic Floor Impact Questionnaires (PFDI-20 and PFIQ-7).
This research project involves translating well-established pelvic floor disorder questionnaires (PFDI-20 and PFIQ-7) from English into Norwegian and testing the questionnaires on 20 Norwegian Woman with pelvic floor disorders.
This project is supported and funded by Flinders University, School of Prevention, Promotion and Primary Health Care, General Practice.

Purpose of the study:
This questionnaires aims to measure:

- patients bowel, urine and prolapse symptoms and the impact of these symptoms on patients' quality of life.
- the effectiveness of treatments on Norwegian female patients with prolapse, urine and bowel symptoms.

What will I be asked to do?
You are invited to attend a one-on-one interview with the investigator who will ask you to fill out two self-administered questionnaires that include a total of 27 questions, followed by a short interview. The interview would include 13 questions. No more than 50 minutes would be required. The interview will be recorded using a digital voice recorder to help with the processing of the results. Once you have completed the questionnaires and the interview, you will have finished the study.

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What benefit will I gain from being involved in this study?
The information that we get from you will help us properly translate and adapt the questionnaires into Norwegian and help measure patients' bowel symptoms and the impact of these symptoms on patients' quality of life. The questionnaires can also be used to measure the effectiveness of treatments and improve patient health care management for you and others with pelvic floor disorders.

Will I be identifiable by being involved in this study?
No name or information that identifies you will be written on the questionnaires. This will ensure anonymity and confidentiality. Your comments will not be linked directly to you. In addition, the data (coded questionnaires, interview guide, information sheet, consent forms and transcripts of the interview) will be stored in a secure collection box at the Akershus University Hospital.
As mentioned, the interview will also be recorded using a digital voice recorder to help with the processing of the results. Once recorded, the interview will be transcribed (typed up) and stored as a computer file.
The electronic data (excel file with patient name and birth date and transcriptions) containing sensitive data will also be stored in the secure zone on the hospital server for five years. This enables the participants and the pelvic floor expert panel to have access to the data for several years after the completion of study.
Be assured that none of the participants will be individually identifiable in the resulting thesis, report or other publications.

Are there any risks or discomforts if I am involved?
The investigator anticipates few risks from your involvement in this study. However, we would like to bring it to your attention that the questions in the questionnaires can involve sensitive personal issues, gender identity, depression and anxiety issues and specific health problems. If you have any concerns regarding anticipated or actual risks or discomforts, please raise them with the investigator.
The tool is being used for research purposes only and is not a clinical assessment. If any of the questions cause you concerns about your health we strongly advise you to take this up with your gynaecologist.

How do I agree to participate?
Participation is voluntary. You may answer 'no comment' or refuse to answer any questions and you are free to withdraw from the interview at any time without effect or consequences. A consent form accompanies this information sheet. If you agree to participate, please read and sign the form.

How will I receive feedback?
Outcomes from the project will be summarised and given to you by the investigator if you would like to see them.

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Thank you for taking the time to read this information sheet and we hope that you will accept our invitation to be involved.

Yours sincerely,

Ms Catherine Planke
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School of Medicine
Faculty of Health Sciences
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Consent for participation in the

Pelvic floor disorders in Norwegian Women: Validating the PFDI20 and PDIQ7 self-administered questionnaires for the Norwegian context.

I am willing to participate in the study

_____

(Signed by the project participant, date)

I have confirmed that I have given information about the study

_____

(Signed, role in the study, date)

Thank you for your assistance.

Catherine Planke
Title …….

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Bekkenbunns dysfunksjoner hos kvinner – Hoveddel – 15/6/2011]

SAMTYKKE

Forespørsel om deltakelse i forskningsprosjektet

"Bekkenbunns dysfunksjoner hos kvinner: Oversettelse og validering av spørreskjema PDF120 og PFIQ7 til norsk"

Bakgrunn og hensikt

Dette er et spørsmål til deg om å delta i en forskningsstudie for å oversette to bekkenbunns spørreskjema fra USA, kalt henholdsvis PDF120 og PFIQ7, til norsk. Spørreskjemaene tar sikte på å måle pasientens tarm, urin og vaginal- og uterusprolaps symptomer og innvirkningen av disse symptomene på pasienters livskvalitet. Tilgjengeligheten av slike skjemaer i Norge vil kunne forbedre evnen til å måle effektiviteten av klinisk behandling av bekkenbunns dysfunksjoner. Foruten å oversette spørreskjemaene til norsk vil denne studien hvorvidt skjemaene er dekkende for norske forhold.

Hva innebærer studien?

Du vil bli bedt om å besvare to spørreskjema på egenhånd, totalt 27 spørsmål om urin, tarm og vaginal- og uterusprolaps. I tillegg vil det bli gjennomført et kort intervju av deg. Spørreskjemaene tar sikte på å måle pasientens tarm, urin, vaginal- uterusprolaps symptomer og virkningen av disse symptomene på pasienters livskvalitet. Intervjuet omfatter 14 spørsmål og vil bli tatt opp på lydbånd eller digitalt. Samlet tidsforbruk anslås til maksimalt 50 minutter.

Mulige fordeler og ulemper
Spørreskjemaene som skal prøves ut i prosjektet er utformet for å avdekke og evaluere pasienters respons på eksisterende og nye behandlingsmetoder for dysfunksjoner i bekkenbunnen. Spørsmålene i skjemaene kan omhandle ømtålige personlige anliggender, kjønnsidentitet, problemer med depresjon og angst samt spesifikke helseproblemer.
Spørreskjemaet brukes til forskningsfomål og ikke til klinisk vurdering. Hvis noen spørsmål føre til bekrymminger rundt din helse, vil vi anbefaler at du diskutere dette med din gynekolog.

Hva skjer med informasjonen om deg?
Informasjonen som registreres om deg skal kun brukes slik som beskrevet i hensikten med studien. Alle opplysningene og prøvene vil bli behandlet uten navn og fødselsnummer eller andre direkte gjenkjennende opplysninger. En kode knytter deg til dine opplysninger og prøver gjennom en navneliste.

Det er kun autorisert personell knyttet til prosjektet som har adgang til navnelisten og som kan finne tilbake til deg. Det vil ikke være mulig å identifisere deg i resultatene av studien når disse publiseres.

Frivillig deltakelse
Det er frivillig å delta i studien. Du kan når som helst og uten å oppgi noen grunn trekke ditt samtykke til å delta i studien. Dette vil ikke få konsekvenser for din videre behandling. Dersom du ønsker å delta, undertegner du samtykkeerklæringen på siste side. Om du nå sier ja til å delta, kan du senere trekke tilbake ditt samtykke uten at det påvirker din øvrige behandling. Dersom du senere ønsker å trekke deg eller har spørsmål til studien, kan du kontakte Kvinneklinikken, Akershus universitets sykehus, Marie Ellstrøm Engh: m.e.engh@medisin.uio.no

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Kapittel A- utdypende forklaring av hva studien innebærer

Kriterier for deltakelse
For å kunne inkluderes i undersøkelsen må du være kvinne med dysfunksjon i bekkenbunnen (tarm, urin eller prolaps) og henvist til Kvinneklinikken, Ahus samt ha returnert ditt skriftlige samtykke. Vi ønsker at du skal ha norsk som morsmål.

Bakgrunnsinformasjon om studien
Konsekvenser av urin- og fekal inkontinens blir vanligvis vurdert i henhold til graden av ulempe og ut fra skalaer som måler innvirkningen av inkontinens og prolaps på funksjonell tilstand og livskvalitet. Dysfunksjoner i bekkenbunnen kan ha negative konsekvenser på livsstil og mental velvære, sosial og emosjonell funksjon, helsetilstand, funksjonsevne, tilfredshet med livet, sosial støtte samt levestandard. Kvinner opplever slike dysfunksjoner som smertefulle, disruptive, emosjonelt belastende og sjokkerende.

Mulige fordeler
Spørreskjemaene som evalueres i studien kan ha stor verdi i å måle helsetilstanden i den kvinnelige delen av befolkningen. Den kan støtte beslutningstakere i å argumentere for forbedringer i pasientadministrasjonen og andre helserelaterte spørsmål angående pasienter med bekkenbunnsdysfunksjoner. De norske utgavene av spørreskjemaene "The Pelvic Floor Distress Inventory" (PFDI-20) og "The Pelvic Floor Impact Inventory" (PFIQ-7) som vil bli resultatet av dette prosjektet vil støtte klinisk personell i hospitalene samt kliniske forskere i Norge. Man vil kunne oppnå et bredere klinisk utfallsrom som vil inkludere omtanke for kvinnelige pasienters psykologiske, sosiale og materielle velferd. Disse spørreskjemaene er også nyttige for å identifisere konsekvenser og barrierer i dagliglivet (for eksempel som følge av fekal inkontinens) som kvinnelige pasienter vanligvis ikke ville ha fått diskutert under en poliklinisk konsultasjon.

Mulige ubehag/ulemper
Det forventes ingen spesielle ubehag for det skal ikke anvendes noen legemidler i studien og det skal heller ikke tas blodprøver eller gjøres fysiske tester av deg.

Pasientens/studiedeltakerens ansvar
Den enkeltes ansvar er begrenset til å besvare alle spørsmål etter beste evne. Videre er det viktig å gi så korrekte opplysninger som mulig.

Kriterier for ikke å få være med
Eksklusjonskriterier er alder under 18 år, samt ikke fullstendig beherskelse av norsk språk.

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Kompensasjon/dekning av utgifter til deltakelse
I denne studien har man ikke budsjettert med dekning av utgifter til prosjektdeltakerne, og vi kan ikke betale deg noe for å delta i prosjektet.

Pasientens/studiedeltakerens ansvar
Den enkeltes ansvar er begrenset til å opplyse om forhold som kan tenkes å ha betydning for deltakelse i studien. Det er også viktig å gi så korrekte opplysninger som mulig i spørreskjema og under intervjuet.

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Kapittel B - Personvern, biobank, økonomi og forsikring

Personvern

Følgende prinsipper og rutiner vil bli fulgt: Den enkelte vil ikke kunne identifiseres gjennom kodede data. Det vil ikke bli opprettet egne pasientjournaler for prosjektet. Det vil ikke være mulig å koble seg inn på de registrerte opplysninger for noen utenfra da de maskiner som benyttes i lagring av data er beskyttet via sykehusets sikkerhetsrutiner. Opplysninger du gir vil registreres på et skjema. Det som registreres vil bli gitt en tallkode før det legges inn på PC. Opplysningene vil bli lagret nedlåst hos Bekkensenteret/Kvinneklinikken ved Akershus Universitetssykehus i inntil 5 år etter at undersøkelsen er avsluttet.

Akershus Universitetssykehus ved administrerende direktør er databehandlingsansvarlig.

Utlevering av materiale og opplysninger til andre

Hvis du sier ja til å delta i studien, gir du også ditt samtykke til at avidentifiserte opplysninger blir tilgjengelige for personer som er tilknyttet prosjektet som medarbeidere. Dette gjelder også min studieveileder Angelita Martini og Malcolm Bond Flinders University, Australia. Opplysninger som kan identifisere deg direkte vil imidlertid ikke bli utlevert til personer utenfor sykehuset eller til personell ved Ahus som ikke har noen rolle i prosjektet.

Rett til innsyn og sletting av opplysninger om deg og sletting av prøver

Hvis du sier ja til å delta i studien, har du rett til å få innsyn i hvilke opplysninger som er registrert om deg. Du har videre rett til å få korrigert eventuelle feil i de opplysningene vi har registrert. Dersom du trekker deg fra studien, kan du kreve å få slettet innsamlede prøver og opplysninger, med mindre opplysningene allerede er inngått i analyser eller brukt i vitenskapelige publikasjoner.

Økonomi

Studien er finansiert i sin helhet via driftsmidler ved Kirurgisk divisjon ved Akershus Universitetssykehus.

Forsikring

I og med at studien er gjennomført i regi av Akershus Universitetssykehus gjelder ordningen med Norsk pasientskadeerstatning for deg ved behov.

Informasjon om utfallet av studien

Utfallet av studien vil bli forsøkt publisert i fagtidsskrifter. Ut over dette vil man på forespørsel kunne presentere sammendrag av resultatene for interesserte parter.

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Samtykke til deltakelse i studien

Jeg er villig til å delta i studien

(Signert av prosjektdeltaker, dato)

Stedfortredende samtykke når berettiget, enten i tillegg til personen selv eller istedenfor

---

(Signert av nærstående, dato)

Jeg bekrefter å ha gitt informasjon om studien

(Signert, rolle i studien, dato)

This research project has been approved by the Flinders University Social and Behavioural Research Ethics Committee (Project Number 5376). For more information regarding ethical approval of the project the Executive Officer of the Committee can be contacted by telephone on 8201 3116, by fax on 8201 2035 or by email human.researchethics@flinders.edu.au..

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APPENDIX 5.3

INTERVIEW GUIDE FOR STAGE 2 (PILOT TESTING)

5.3a Interview guide for patient interview – Part One: Each item interviewed separately and Part Two: General Questions (English)

5.3b *Pasientintervju* (Interview guide for patient interview) – Part One: Each item interviewed separately and Part Two: General Questions (Norwegian)

Table 5.3c *Pasientintervju* (Interview guide for pilot test) – Part Three: Alternative phrasings in question items solicited during the pilot test (Norwegian and English)

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INTERVIEW GUIDE FOR PATIENT INTERVIEW

Title of research project:

"Validating condition specific quality of life questionnaires for women with pelvic floor disorders in the Norwegian context"

The semi- structured interview

The interview will firstly be directed to each module item separately (question a-g), then the patient will be asked general questions (1-6). The interview will also be taped recorded.

Interview directed to each module item separately:

Interview directed to each module item separately:

a) Did you have difficulty in replying to this question?
(probe: can you tell me what you found difficult?)

b) Did you find this question confusing?
(probe: can you tell me what you found confusing?)

c) Have words been used that you found difficult to understand? (probe: can you tell me which words you found difficult to understand?)

d).Did you find the way this question was worded to be upsetting or offensive in anyway?
(probe: can you tell me which words you found upsetting/offensive?)

e). How would you have asked the question?

General questions:

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1.Does the questionnaires cover all issues related to bowel, urine and prolapse that you consider to be important? If not, why?

2.Do you feel that further items should be added to the questionnaires to assess additional issues or to assess those already covered in more depth? If so, what issues?

3. Are there any items that cover issues that you feel are irrelevant or unimportant? If so, which ones and why?

4.Where any of the response categories unclear, inappropriate or inadequate to allow you to express what you felt? If so, which ones and why?

5. Were the instructions and examples clear? If not, which ones and why?

6. Are there further comments you would like to make or items you would like to ask about?

Thank- you for your assistance!

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Faculty of Health Sciences, Flinders University

PAS 01

PASIENTINTERVJU

Intervju rettet mot hvert spørsmål separat:

a) Hadde du vanskeligheter med å svare på dette spørsmålet?

b) Syns du dette spørsmålet var forvirrende?
(utprøving: kan du si meg hva du syns var forvirrende?)

c) Er det blitt brukt ord som du syns er vanskelig å forstå?
(utprøving: kan du si meg hvilke ord du syns var vanskelig å forstå?)

d) Syns du måten dette spørsmålet var uttrykt på i ord var opprørende eller støtende på en eller annen måte?
(utprøving: kan du si meg hvilke ord du syns var opprørende/støtende?)

e) Hvordan ville du stilt spørsmålet?

Rett oversettelse bekreftes:

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Oversettelse fra engelsk:

Generelle spørsmål:

1. Dekker spørreskjemaet alle spørsmålene som gjelder tarm, urin og prolaps som du mener er viktige? Hvis ikke, hvorfor?

2. Føler du at spørreskjemaet burde ha flere punkter slik at flere ting blir tatt opp, eller slik at de tingene som allerede er tatt opp, dekkes mer i dybden? Hvis så, hvilke ting?

3. Er det punkter som dekker ting du føler er irrelevante eller uviktige? Hvis så, hvilke og hvorfor?

4. Var noen av svarkategoriene uklare, uegnet eller ikke helt treffende for at du kunne uttrykke det du føler? Hvis så, hvilke og hvorfor?

5. Var instruksene og eksemplene klare? Hvis ikke, hvilke og hvorfor?

6. Har du andre kommentarer du gjerne vil komme med eller ting du gjerne vil spørre om?

Takk for hjelpen!

Rett oversettelse bekreftes:

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Table 5.3c. Part 3 of Interview: Alternative phrasings in question items solicited during the pilot test (Norwegian and English).

QUESTIONS	ORIGINAL PHRASINGS IN QUESTION ITEMS	SOURCE VERSION (ENGLISH)	ALTERNATIVE PHRASINGS IN QUESTION ITEMS	ANSWERS; NUMBER OF PATIENTS THAT PREFER ALTERNATIVE(S)
PFDI-20				
Questions 1–2	Phrase: “Kjenner du ofte”	Do you usually	“Kjenner du vanligvis”	1
Question 3	Phrase: “Buler ut eller faller ut av skjeden”	A bulge or something falling out	“En kul eller noe som faller ut av skjeden?”	5
Questions 9–12	Phrase: “Har du ofte”	Do you usually	“Har du vanligvis”	1
Question 13	Phrase: “så sterk avføringstrang at du må løpe til toilettet”	A strong sense of urgency and have to rush to the bathroom to have a bowel movement	“ved avføringstrang at det haster veldig”	8
Question 16	“Opplever du så sterk vannlatingstrang at du ikke rekker til toalettet før du får lekkasje?”	Do you normally experience urine leakage associated with a feeling of urgency, that is, a strong sensation of needing to go to the bathroom?	“Har du ofte urinlekkasje ved kraftig trang til vannlatning:, dvs. så sterk følelse av hast at du må på toalettet?”	2
Questions 17–19	Phrase: “Har du ofte”	Do you usually	“Opplever du ofte” “Opplever du vanligvis?”	4
Question 20	Phrase: “Har du ofte”	Do you usually	“Kjenner du ofte?” “Kjenner du vanligvis”	4
PFIQ-7				
Instructions	Term “Gjøremål”	Activities	“Aktiviteter”	6
Instructions	Term “Samliv”	Relationship	“Forhold”	1
Questions 1–7	Term “Din”	Your	(Remove term “din”)	2
Question 6	Term “Psykiske helsetilstand”	Emotional health	“Emosjonelle helsetilstand”	1

APPENDIX 5.4

DATE EXTRACTION TABLES FOR STAGE 2 (PILOT TESTING)

Table 5.4 Pilot test hesitations and total time to fill in forms PFDI-20 and PFIQ-7.

Table 5.4 Pilot test hesitations and total time to fill in forms PFDI-20 and PFIQ-7.

Patient	Approx. time (min) to fill in PFDI-20 and PFIQ-7	Hesitations
1	12	No hesitations. Filled inn example PFDI-20 and PFIQ-7
2	13	No hesitations. Enlarge word example
3	11	No hesitations. Filled inn example PFDI-20 and PFIQ-7
4	14	No hesitations. Filled inn example PFDI-20 and PFIQ-7
5	11	Hesitated with PFDI-20 Question 2
6	12	Hesitated with PFDI-20 Questions 1 and 2
7	13	No hesitations. Filled in example PFDI-20 and PFIQ-7
8	13	No hesitations. Filled in example PFDI-20 and PFIQ-7
9	12	No hesitations. Filled in example PFDI-20 and PFIQ-7
10	14	No hesitations. Filled in example PFDI-20 and PFIQ-7
11	13	No hesitations. Filled in example PFDI-20 and PFIQ-7
12	15	No hesitations. Filled in example PFDI-20 and PFIQ-7
13	14	No hesitations. Filled in example PFDI-20 and PFIQ-7
14	13	No hesitations. Filled in example PFDI-20 and PFIQ-7
15	17	Hesitated with PFDI-20 Question 2
16	16	Hesitated with PFDI-20 Question 1
17	12	Hesitated with PFDI-20 Question 2
18	14	Hesitated with PFDI-20 Question 2. Enlarged word Example
19	13	No hesitations. Filled in example PFDI-20 and PFIQ-7
20	12	No hesitations. Filled in example PFDI-20 and PFIQ-7

APPENDIX 5.5

NORWEGIAN INTERMEDIATE VERSION 3.0 PFDI-20 AND PFIQ-7

Version after pilot testing no amendments were made between the Intermediate Version 3.0 PFDI-20 and PFIQ-7 and the Norwegian final version PFDI-20 and PFIQ-7. Please refer to Appendix 6.1 for the document versions.

APPENDIX 6.1

RESEARCH MATERIAL FOR STAGES 3 AND 4

(TESTING MEASUREMENT PROPERTIES)

Patient Health Information Forms for non-surgery and surgery patients

6.1a Patient Health Information Form for non-surgery patients (English)

6.1b Patient Health Information Form for surgery patients (English)

6.1c *Pasient Helse opplysning spørreskjema* (Patient Health Information Form for non-surgery patient) (Norwegian)

6.1d *Pasient Helse opplysning spørreskjema* (Patient Health Information Form for surgery patients) (Norwegian)

6.1e Retest Questionnaire (English)

6.1f *Retest spørreskjema* (Retest Questionnaire) (Norwegian)

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PASIENT HEALTH INFORMATION
NON-SURGERY PATIENTS

PATIENT CODE: _____ DATO:_____

THIS SECTION IS TO BE COMPLETED BY PATIENTS:

AGE:_____
BIRTH DATE:_____

WEIGHT(BMI):_____

NUMBER OF PREGNACIES:_____

BIRTHS:
NUMBER OF BIRTHS:_____
DATE:_____

HAVE YOU STOPPED MENSTRATING ? YES _____ NO_____
IF YES, DATE _____

HYSTERECTOMY: YES_____ NO_____

PREVIOUS PELVIC FLOOR RECONSTRUCTIVE SURGERY JA _____ NO_____
IF YES; WHICH SURGICAL PROCEDURE: _____

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PLACE A CROSS IN THE RING BELOW BY THE WORD/PHRASE THAT BEST DESCRIBES YOUR CONDITION **THE LAST THREE MONTHS:** :

GENERAL QUESTION					
”In your opinion how severe is your vaginal prolapse in the last three months?”	Not severe O	Mild O	Moderate O	Severe O	Highly severe O

PLACE A CROSS IN THE RING BELOW BY THE WORD/PHRASE THAT BEST DESCRIBES YOUR CONDITION **THE LAST THREE MONTHS:**

GENERAL QUESTION					
My vaginal prolapse causes physical complaints	Never O	Seldom O	Sometimes O	Often O	Always O
My vaginal prolapse negatively affects my daily activities or interaction with others	Never O	Seldom O	Sometimes O	Often O	Always O
My vaginal prolapse negatively affects my mood or feelings	Never O	Seldom O	Sometimes O	Often O	Always O
My vaginal prolapse negatively affects my overall quality of life	Never O	Seldom O	Sometimes O	Often O	Always O

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This research project has been approved by the Flinders University Social and Behavioral Research Ethics Committee (Project Number – insert here), the Regional Ethics Committee in Southern Norway REK (Project Number 2011/1312-21 and 2014/418 REK south-east D) and Akershus University Hospital Ethics Committee (Project number 11_60 change notification and 14-060). For more information regarding ethical approval of the project the Executive Officer of the Committee can be contacted by telephone on 8201 3116, by fax on 8201 2035 or by email human.researchethics@flinders.edu.au

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PATIENT HEALTH INFORMATION
Surgery patients

PATIENT CODE: _____ DATE:_____

THIS SECTION IS TO BE COMPLETED BY THE PATIENT

AGE:_____
BIRTH DATE:_____

WEIGHT (BMI):_____
HEIGHT _____

NUMBER OF PREGNACIES:_____

BIRTHS:
NUMBER OF BIRTHS:_____
DATE:_____

HAVE YOU STOPPED MENSTRUATING? YES _____ NO_____
IF YES, DATE _____

HYSTERECTOMY: YES_____ NO_____

PREVIOUS PELVIC FLOOR RECONSTRUCTIVE SURGERY YES _____ NO_____
IF YES; WHICH SURGICAL PROCEDURE: _____

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PLACE A CROSS IN THE RING BELOW BY THE WORD/PHRASE THAT BEST DESCRIBES YOUR CONDITION **THE LAST THREE MONTHS**:

GENERAL QUESTION					
”In your opinion how severe is your vaginal prolapse in the last three months?”	Not severe O	Mild O	Moderate O	Severe O	Highly severe O

PLACE A CROSS IN THE RING BELOW BY THE WORD/PHRASE THAT BEST DESCRIBES YOUR CONDITION **THE LAST THREE MONTHS:**

GENERAL QUESTION					
My vaginal prolapse causes physical complaints	Never O	Seldom O	Sometimes O	Often O	Always O
My vaginal prolapse negatively affects my daily activities or interaction with others	Never O	Seldom O	Sometimes O	Often O	Always O
My vaginal prolapse negatively affects my mood or feelings	Never O	Seldom O	Sometimes O	Often O	Always O
My vaginal prolapse negatively affects my overall quality of life	Never O	Seldom O	Sometimes O	Often O	Always O

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PLACE A CROSS IN THE RING BELOW BY THE WORD/PHRASE THAT BEST DESCRIBES YOUR CONDITION AFTER THE OPERATION:

QUESTION						
In general, how much did the treatment improve your pelvic organ prolapse?	Much worse O	Slightly worse O	No change O	A little improved O	Much improved O	Very much improved O

THIS SECTION IS COMPLETED BY HEALTH PERSONNEL:

POP GRADE:

Grade II: YES NO

Grade III: YES NO

Grade IV: YES NO

POP-Q TEST RESULT BEFORE OPERATION:

_____

POP-Q TEST RESULT 6 MONTHS AFTER POP OPERATION:

_____

This research project has been approved by the Flinders University Social and Behavioral Research Ethics Committee (Project Number 5376), the Regional Ethics Committee in Southern Norway REK (Project Number 2011/1312-21 and 2014/418 REK south-east D) and Akershus University Hospital Ethics Committee (Project number 11_60 change notification and 14-060). For more information regarding ethical approval of the project the Executive Officer of the Committee can be contacted by telephone on 8201 3116, by fax on 8201 2035 or by email human.researchethics@flinders.edu.au

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PASIENT HELSEOPPLYSNING SPØRRESKJEMA

PASIENT KODE: _____ DATO:_____

DENNE DELEN SKAL FYLLES INN AV PASIENTEN

ALDER:_____

VEKT (BMI):_____

ANTALL SVANGERSKAP:_____

FØDSLER:_____
Dato:_____
Antall:_____

HAR DU SLUTTET Å MENSTRUERE ? NEI _____ JA_____
Hvis Ja, Når _____

FJERNET LIVMOR: JA NEI

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TIDLIGERE VAGINAL PROLAPS KIRURGI

JA NEI

Hvis JA, Hvilken: _____

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PASIENT HELSEOPPLYSNING SPØRRESKJEMA FØR OG ETTER VAGINAL (POP) KIRURGI

PASIENT KODE: _____ DATO:_____

DENNE DELEN SKAL FYLLES UT AV PASIENTEN FØR OPERASJONEN

ALDER:_____ VEKT (BMI):_____

ANTALL SVANGERSKAP:_____

FØDSLER:_____
Dato:_____
Antall:_____

HAR DU SLUTTET Å MENSTRUERE ? NEI _____ JA_____
Hvis Ja, Når _____

FJERNET LIVMOR: JA NEI

TIDLIGERE VAGINAL (POP) KIRURGI
JA NEI
Hvis JA, Hvilken: _____

POP-Q RESULTATER

DENNE DELEN SKAL FYLLES UT AV HELSEPERSONELL FØR OPERASJONEN

POP GRADERING:

Grad I:	JA	NEI	Grad II:	JA	NEI
Grad III:	JA	NEI	Grad IV:	JA	NEI

DENNE DELEN SKAL FYLLES UT AV HELSEPERSONELL FØR OPERASJONEN

POP-Q TEST RESULTAT FØR OPERASJON: (se POP-Q skjema)

_____

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Akershus universitetssykehus

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DENNE DELEN SKAL FYLLES UT AV PASIENTEN ETTER OPERASJON

VI VIL STILLE DEG ET SPØRSMÅL ETTER KIRURGI. SETT ET X HVOR DET BEST BESKRIVER DIN TILSTAND ETTER OPERASJONEN.

SPØRSMÅL: TOTALT SETT, I HVILKEN GRAD HJALP DEN BEHANDLINGEN DU HAR FÅTT FOR DITT FRAMFALL?

O 1 HJALP SVÆRT MYE

O 2 HJALP MYE

O 3 HJALP LITT

O 4 HJALP IKKE

O 5 GJORDE ALT VERRE

O 6 GJORDE ALT MYE VERRE

DENNE DELEN SKAL FYLLES UT AV HELSEPERSONELL ETTER OPERASJONEN

POP GRADERING:
Grad II: JA NEI
Grad III: JA NEI
Grad IV: JA NEI

DENNE DELEN SKAL FYLLES UT AV HELSEPERSONELL ETTER OPERASJONEN

POP-Q TEST RESULTAT 6 MÅNEDER ETTER OPERASJONEN: Se skjema

This research project has been approved by the Flinders University Social and Behavioral Research Ethics Committee (Project Number –5376), the Regional Ethics Committee in Southern Norway REK (Project Number 2011/1312-21 and 2014/418 REK south-east D) and Akershus University Hospital Ethics Committee (Project number 11_60 change notification and 14-060). For more information regarding ethical approval of the project the Executive Officer of the Committee can be contacted by telephone on 8201 3116, by fax on 8201 2035 or by email human.researchethics@flinders.edu.au..

Akershus universitetssykehus

RE - TEST

Name: _____ Date: ____/____/_____

Thank you for participating in the re-test part of this study and completing these questionnaires again. The aim of a re-test after 1-4 weeks is to ensure that the formulations of the questionnaires are both accurate and reliable.

Please fill in the following questionnaires:

- PFDI-20 questionnaire
- PFIQ-7 questionnaire
- SF-36 questionnaire

Please also answer the additional question below. Check the box that best describes your situation.

"Compared to the first time you completed the questionnaires, has your genital prolapse condition changed? "

O Changed for the worse

O Unchanged

O Improved somewhat

O Improved moderately

O Improved quite a bit

O Completely disappeared

Please fill in the questionnaires (approx. 15 min.) and hand them in at the main desk at the Womens Outpatient Clinic. Any enquires you may have should be directed to Catherine Planke mob: 4800 3263.

Thank you for your assistance.

Akershus universitetssykehus

RE - TEST

Navn: _____ Dato: ____/____/_____

Takk for at du deltar på re- test delen av studien og fyller ut disse tre spørreskjemaene igjen. Hensikten med en slik "re-test" noen uker etter at du fylte ut skjemaene første gang er å sikre utformingen av spørreskjemaene slik at de gir pålitelige resultater. Følgene skjemaer fylles ut:

- PFDI-20 skjema
- PFIQ-7 skjema
- SF-36 skjema

Vi ønsker også at du besvarer et tilleggsspørsmål før du fyller ut skjemaene. Sett et kryss ved svaralternativet som best beskriver din tilstand akkurat nå.

I hvilken grad har ditt vaginal fremfall problem endret seg siden du ble inkludert i studien?

O Endret seg til det verre

O Er uforandret

O Bedret seg en del

O Bedret seg nokså mye

O Bedret seg svært mye

O Forsvunnet helt

Vi ber deg om å besvare spørreskjemaene på **egenhånd** (ca.15 min). Deretter **leverer du spørreskjemaene til sekretærene** i resepsjonen på Kvinneklinikken.

Ved spørsmål, ta kontakt med *Catherine Planke Teig mob: 4800 3263*

Tusen takk for at du tok deg tid til å hjelpe oss!

APPENDIX 6.2

RESEARCH MATERIAL FOR STAGE 3 (TESTING MEASUREMENT PROPERTIES)

Verbal script, Information sheets and consent form for non-surgery patients

6.2a Verbal script for health personnel - non-surgery patients (English)

6.2b *Verbalt manus for helsepersonell* (Verbal script for health personnel - non-surgery patients) (Norwegian)

6.2c Letter of Introduction non-surgery patients (English)

6.2d Information sheet non-surgery patients (English)

6.2e Consent form for non-surgery patients (English)

6.2f *Samtykke* Introduction letter, Information sheet and consent form - non-surgery patients (Norwegian)

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VERBAL SCRIPT FOR HEALTH PERSONNEL
Non- surgery patients

Title of research project:

"Validating condition-specific health related quality of life pelvic floor disorder (PFD) questionnaires and measuring the impact on quality of life of women with PFD in the Norwegian context"

"We have a PhD student Catherine Planke from the Faculty of Medicine at Flinders University, Australia. She is also employed as the Administrative Manager at our Pelvic Floor Centre here at the Hospital. She is undertaking research leading to the production of a thesis and publications on the subject of "Translating and validating quality of life questionnaires for women with pelvic floor disorders in the Norwegian population"

The questionnaires aims to measure patients' bowel, urine and prolapse symptoms and the impact of these symptoms on Norwegian women's quality of life. The Purpose of the research project is to translate a well-established set of pelvic floor disorder questionnaires from English to Norwegian and test the questionnaires on 270 Norwegian women. The questionnaires aims to measure patients' bowel, urine and prolapse symptoms and the impact of these symptoms on Norwegian women's quality of life. We want to be sure that these translated questionnaires ask the right questions in the right way.

We would be most grateful if you would volunteer to assist in this project, by filling out health-related question (for example age and weight,) and three self-administered questionnaires that include a total of 63 questions. No more than 20 minutes would be required. In some cases we will ask you to return to the hospital within 1-4 weeks and fill-out these questionnaires again.

Would you be interested in participating in this study?"

The participant is shown the questionnaires.

If the participant is willing, they will read the Introduction Letter and Information Sheet, fill out the Consent Form and proceed to complete the questionnaires and return to the nursing staff at the out patients clinic.

The questionnaires would take place on the same day as the consultation.

If the participants decline they will be thanked for considering the request.

Please note that these verbal scripts will be translated into Norwegian

Thank-you for your assistance.

This research project has been approved by the Flinders University Social and Behavioral Research Ethics Committee (Project Number 5376), the Regional Ethics Committee in Southern Norway REK (Project Number 2011/1312 REK south-east D) and Akershus University Hospital Ethics Committee (Project number 11_60 change notification). For more information regarding ethical approval of the project the Executive Officer of the Committee can be contacted by telephone on 8201 3116, by fax on 8201 2035 or by email human.researchethics@flinders.edu.au..

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VERBALT MANUS FOR HELSEPERSONELL

"Vi har en PhD student Catherine Planke fra Det Medisinske Fakultet ved Flinders University, Australia . Hun er også ansatt som administrativ leder på Bekkensenteret her på Ahus. Hun tar doktorgrad I Bekkenbunnslidelser hos kvinner: Oversettelse og validering av et bekkbunnsspørreskjema til norsk.

Har du lyst å delta i en forskningsstudie for å oversette to bekkenbunns spørreskjema fra USA, kalt henholdsvis PFDI- 20 og PFIQ-7, til norsk? Spørreskjemaene tar sikte på å måle pasientens tarm, urin og vaginal- og uterusprolaps symptomer og innvirkningen av disse symptomene på pasienters livskvalitet før og etter vaginal kirurgi. Vi ønsker å være sikker på at disse oversatte spørre stille de riktige spørsmålene på riktig mate på norsk.

Du vil bli bedt om å besvare tre spørreskjema på **egenhånd**. To spørreskjema handler om urin, tarm og vaginal- og uterusprolaps og virkningen av disse symptomene på pasienters livskvalitet. Det tredje spørreskjemaet, SF-36, har totalt 36 spørsmål om generell helse. Du vil også bli bedt om å fylle inn opplysninger om alder og andre helse opplysninger. Det vil ikke ta mer enn 20 minutter. Vil du være interessert i å delta i denne studien ? "

Deltakeren er vist spørreskjemaene. Hvis deltakeren er villig etter konsultasjonen, skal de fylle ut samtykkeskjema og deretter fylle ut spørreskjemaene.

Dersom deltakerne svare nei, vil de bli takket for å vurdere forespørselen.

This research project has been approved by the Flinders University Social and Behavioural Research Ethics Committee (Project Number 5376), the Regional Ethics Committee in Southern Norway REK (Project Number 2011/1312 REK south-east D) and Akershus University Hospital Ethics Committee (Project number 11_60). For more information regarding ethical approval of the project the Executive Officer of the Committee can be contacted by telephone on 8201 3116, by fax on 8201 2035 or by email human.researchethics@flinders.edu.au..

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LETTER OF INTRODUCTION
Non- Surgery Patients

Dear Madam,

This letter is to introduce Ms Catherine Planke who is a Doctor of Philosophy (PhD) student in the School of Medicine at Flinders University, South Australia. Catherine is also the Administrative Manager at Akershus University Hospital, Pelvic Care Center, Norway. She will produce her student card, which carries a photograph, as proof of identity.

Catherine is undertaking research leading to the production of a dissertation or other publications on the subject of the quality of life of Norwegian women with pelvic floor disorders. Her study is titled; "Validating condition-specific health related quality of life pelvic floor disorder (PFD) questionnaires and measuring the impact on quality of life of women with PFD in the Norwegian context"

The study firstly involved translating the questionnaires called Pelvic Floor Distress Inventory and the Pelvic Floor Impact Questionnaire (PFDI-20 and PFIQ-7). These are self-administered questionnaires that ask about you and your health. We know that these questionnaires are of value for patients who suffer from pelvic floor disorders.

The questionnaires have originally been devised in English and are now translated into Norwegian. We want to be sure that these translated questionnaires ask the right questions in the right way. For that purpose, we are now asking for your help.

PFDI-20 PFIQ-7 self-administered questionnaires were translated from English into Norwegian using professional translators, pre-tested in a pilot study and will now be tested on 270 patients at the gynecological department, Akershus University Hospital with a pelvic floor dysfunction diagnosis (bowel, urinary or prolapse). There is an outline of the research attached.

She would be most grateful if you would volunteer to assist in this project, by filling out health-related question (for example age and weight,) and three self-administered questionnaires that include a total of 63 questions. No more than 20 minutes would be required. In some cases we will ask you to return to the hospital within 1-4 weeks and fill-out these questionnaires again.

The questionnaires aims to measure patients' bowel, urine and prolapse symptoms and the impact of these symptoms on patients' quality of life. The data collected in this study can be used to examine quality of life aspects among women with pelvic organ prolapse.

2011

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The questionnaires will also be available in Norway for use by patients to measure the effectiveness of treatments for prolapse, urine and bowel symptoms.

Be assured that any information provided will be treated in the strictest confidence and none of the participants will be individually identifiable in the resulting thesis, report or other publications. You are, of course, entirely free to discontinue your participation at any time or to decline to answer particular questions.

This will be on the condition that your name or identity is not revealed, and that the recording may be made available to other researchers on the same conditions. It may be necessary to make the recording available to authorised administrative staff for transcription, in which case you may be assured that such persons will be advised of the requirement that your name or identity not be revealed and that the confidentiality of the material is respected and maintained.

The tool is being used for research purposes only and is not a clinical assessment. If any of the questions cause you concerns about your health we strongly advise you to take this up with your gynaecologist.

Any enquiries you may have concerning this project should be directed to me at the contact detail above.

Thank you for your attention and assistance.

Yours sincerely,

Ms Catherine Planke
PhD candidate
School of Medicine
Faculty of Medicine, Nursing and Health Sciences,
Flinders University

This research project has been approved by the Flinders University Social and Behavioral Research Ethics Committee (Project Number 5376), the Regional Ethics Committee in Southern Norway REK (Project Number 2011/1312 REK south-east D) and Akershus University Hospital Ethics Committee (Project number 11_60 change notification). For more information regarding ethical approval of the project the Executive Officer of the Committee can be contacted by telephone on 8201 3116, by fax on 8201 2035 or by email human.researchethics@flinders.edu.au

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INFORMATION SHEET

Non- surgery patients

Title: ""Validating condition-specific health related quality of life pelvic floor disorder (PFD) questionnaires and measuring the impact on quality of life of women with PFD in the Norwegian context"

Investigator:
Ms Catherine Planke
PhD candidate
School of Medicine,
Faculty of Medicine, Nursing and Health Sciences,
Flinders University

Description of the study:
This study is part of the project entitled "Validating condition-specific health related quality of life pelvic floor disorder (PFD) questionnaires and measuring the impact on quality of life of women with PFD in the Norwegian context". So far, the study has translated well-established pelvic floor disorder questionnaires called the Pelvic Floors Distress Inventory and the Pelvic Floor Impact Questionnaires (PFDI-20 and PFIQ-7) from English into Norwegian using professional translators, then pre-tested in a pilot study.
This study will now test the questionnaires (PFDI-20 and PFIQ-7) with 270 patients who have a pelvic organ prolapse (with co-existing bowel, urinary or prolapse) at the Women's Department of Obstetrics and Gynaecology at Akershus University Hospital.

This project is supervised by Flinders University, School of Medicine, Faculty of Medicine, Nursing and Health Sciences and has ethics approval from the Social and Behavioural Research Ethics Committee at Flinders University (SBREC)

Purpose of the study:
These PFDI and PFIQ questionnaires aims to measure:

- Patient's prolapse, urine and bowel symptoms and the impact of these symptoms on patients' quality of life.
- The effectiveness of treatments on Norwegian female patients with prolapse, urine and bowel symptoms.
- The data collected in this study can be used to examine quality of life aspects among women with pelvic organ prolapse

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What will I be asked to do?
You are invited to fill out three self-administered questionnaires that include a total of 63 questions related to pelvic floor disorders and general health issues. You will also be asked to answer some health-related questions (for example age and weight). No more than 20 minutes would be required. In some cases we will ask you to return to the hospital within 1-4 weeks and fill-out these questionnaires again.

Once you have completed the questionnaires, you will have finished the study.

What benefit will I gain from being involved in this study?
The information that we get from you will help us properly translate and adapt the questionnaires into Norwegian and help measure patients' prolapse urinary or bowel symptoms and the impact of these symptoms on patients' quality of life. The questionnaires can also be used to measure the effectiveness of treatments and improve patient health care management for you and others with pelvic floor disorders.

Will I be identifiable by being involved in this study?
No name or information that identifies you will be written on the questionnaires. This will ensure anonymity and confidentiality. Your comments will not be linked directly to you. In addition, the data (coded questionnaires, information sheet and consent forms) will be stored in a secure collection box at the Akershus University Hospital for five years. This enables the participants to have access to the data for several years after the completion of study.
Be assured that none of the participants will be individually identifiable in the resulting thesis, report or other publications.

Are there any risks or discomforts if I am involved?
The investigator anticipates no risk from your involvement in this study. However, we would like to bring it to your attention that the questions in the questionnaires can involve sensitive personal issues, gender identity, depression and anxiety issues and specific health problems.
If you have any concerns regarding anticipated or actual risks or discomforts, please raise them with attending gynaecologist.
The tool is being used for research purposes only and is not a clinical assessment. If any of the questions cause you concerns about your health we strongly advise you to take this up with your gynaecologist.

How do I agree to participate?
Participation is voluntary. You may answer 'no comment' or refuse to answer any questions and you are free to withdraw from the interview at any time without effect or consequences. A consent form accompanies this information sheet. If you agree to participate, please read and sign the form.

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How will I receive feedback?
Outcomes from the project will be summarised and given to you by the investigator if you would like to see them.

Thank you for taking the time to read this information sheet and we hope that you will accept our invitation to be involved.

Yours sincerely,

Ms Catherine Planke
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Faculty of Medicine, Nursing and Health Sciences,
Flinders University

This research project has been approved by the Flinders University Social and Behavioral Research Ethics Committee (Project Number 5376), the Regional Ethics Committee in Southern Norway REK (Project Number 2011/1312 REK south-east D) and Akershus University Hospital Ethics Committee (Project number 11_60 change notification). For more information regarding ethical approval of the project the Executive Officer of the Committee can be contacted by telephone on 8201 3116, by fax on 8201 2035 or by email human.researchethics@flinders.edu.au

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Consent for participation in the PFDI-20 and PFIQ-7 study

Project title: "Validating condition-specific quality of life pelvic floor disorder (PFD) questionnaires and measuring the impact on quality of life of women with PFD in the Norwegian context"

I am willing to participate in the study

(Signed by the project participant, date)

Proxy consent when it is warranted, either in addition or in place of the participant's consent.

(Signed by representative, date)

I have confirmed that I have given information about the study

---

(Signed, role in the study, date)

Thank you for your assistance.

This research project has been approved by the Flinders University Social and Behavioral Research Ethics Committee (Project Number 5376), the Regional Ethics Committee in Southern Norway REK (Project Number 2011/1312 REK south-east D) and Akershus University Hospital Ethics Committee (Project number 11_60 change notification). For more information regarding ethical approval of the project the Executive Officer of the Committee can be contacted by telephone on 8201 3116, by fax on 8201 2035 or by email human.researchethics@flinders.edu.au

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SAMTYKKE

Forespørsel om deltakelse i forskningsprosjektet

"Bekkenbunns dysfunksjoner hos kvinner: Oversettelse og validering av spørreskjema PFDI-120 og PFIQ-7 til norsk"

Bakgrunn og hensikt

Dette er et spørsmål til deg om å delta i en forskningsstudie for å oversette to bekkenbunns spørreskjema fra USA, kalt henholdsvis PFDI-20 og PFIQ7, til norsk. Spørreskjemaene tar sikte på å måle pasientens tarm, urin og vaginal- og uterusprolaps symptomer og innvirkningen av disse symptomene på pasienters livskvalitet. Tilgjengeligheten av slike skjemaer i Norge vil kunne forbedre evnen til å måle effektiviteten av klinisk behandling av bekkenbunns dysfunksjoner. Foruten å oversette spørreskjemaene til norsk vil denne studien hvorvidt skjemaene er dekkende for norske forhold.

Studien vil også innebære å se på livskvalitet og dagligliv-aspekter blant kvinner med vaginal-uterusprolaps. Innhentede data kan også benyttes i forskning på livskvalitet blant kvinner med vaginal- uterusprolaps. I tillegg til alder vil andre helserelaterte opplysninger rundt livskvalitet også være en del av denne studien (for eksempel vekt, tidligere operasjoner og lignende).

Hva innebærer studien?

Du vil bli bedt om å besvare tre spørreskjema på **egenhånd.** To av skjemaene har totalt 27 spørsmål om urin, tarm og vaginal- og uterusprolaps. Spørreskjemaene, kalt henholdsvis PDF1-20 og PFIQ-7, tar sikte på å måle pasienters tarm, urin, vaginal- uterusprolaps symptomer og virkningen av disse symptomene på pasienters livskvalitet. Det tredje spørreskjemaet, SF-36, har totalt 36 spørsmål om generell helse. Du vil også bli bedt om å fylle inn opplysninger om alder og andre helse opplysninger. Samlet tidsforbruk anslås til maksimalt 20 minutter.
Re-test:
Du kan kanskje bli invitert til å fylle ut disse spørreskjemaene igjen på nytt om 1-4 uker (såkalt "re-test"). Hensikten med et slikt tidsintervall er å sikre at utformingen av spørreskjemaene gjør dem pålitelige. Vi regner med at tilstanden til POP pasienter endrer seg svært lite i løpet av perioden mellom utfylling av skjemaene. For å holde omstendighetene under prosjektet så like som mulig vil pasientene bli bedt om å fylle ut spørreskjemaene på sykehuset både under test og re-test.
Helsepersonell kan eventuelt ringe eller sende deg en SMS til å minne deg om å besøke klinikken og fylle ut spørreskjemaer i løpet av 1-4 uker. Du vil bli kompensert for parkeringsutgifter. Samlet tidsforbruk for et re-test besøk anslås til maksimalt 20 minutter.

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2011

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Mulige fordeler og ulemper
Spørreskjemaene som skal prøves ut i prosjektet er utformet for å avdekke og evaluere pasienters respons på eksisterende og nye behandlingsmetoder for dysfunksjoner i bekkenbunnen. Spørsmålene i skjemaene kan omhandle ømtålige personlige anliggender, kjønnsidentitet, problemer med depresjon og angst samt spesifikke helseproblemer.
Spørreskjemaet brukes til forskningsformål og ikke til klinisk vurdering. Hvis noen spørsmål føre til bekymringer rundt din helse, vil vi anbefaler at du diskutere dette med din gynekolog.

Hva skjer med informasjonen om deg?
Informasjonen som registreres om deg skal kun brukes slik som beskrevet i hensikten med studien. Alle opplysningene og prøvene vil bli behandlet uten navn og fødselsnummer eller andre direkte gjenkjennende opplysninger. En kode knytter deg til dine opplysninger og prøver gjennom en navneliste.

Det er kun autorisert personell knyttet til prosjektet som har adgang til navnelisten og som kan finne tilbake til deg. Det vil ikke være mulig å identifisere deg i resultatene av studien når disse publiseres.

Frivillig deltakelse
Det er frivillig å delta i studien. Du kan når som helst og uten å oppgi noen grunn trekke ditt samtykke til å delta i studien. Dette vil ikke få konsekvenser for din videre behandling. Dersom du ønsker å delta, undertegner du samtykkeerklæringen på siste side. Om du nå sier ja til å delta, kan du senere trekke tilbake ditt samtykke uten at det påvirker din øvrige behandling. Dersom du senere ønsker å trekke deg eller har spørsmål til studien, kan du kontakte Bekkensenteret, Akershus universitetssykehus Catherine Planke: chpl@ahus.no eller Kvinneklinikken, Akershus universitets sykehus, Marie Ellstrøm Engh: m.e.engh@medisin.uio.no

Ytterligere informasjon om studien finnes i kapittel *A* – *utdypende forklaring av hva studien innebærer*.
Ytterligere informasjon om biobank, personvern og forsikring finnes i kapittel B – *Personvern, biobank, økonomi og forsikring*.

Samtykkeerklæring følger etter kapittel B

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Kapittel A- utdypende forklaring av hva studien innebærer

Kriterier for deltakelse

For å kunne inkluderes i undersøkelsen må du være kvinne med symptomer av fremfall med eller uten samtidlige problemer med (tarm, urin) og henvist til Kvinneklinikken, Ahus samt ha returnert ditt skriftlige samtykke. Vi ønsker at du skal ha norsk som morsmål.

Bakgrunnsinformasjon om studien

Konsekvenser av dine symptomer blir vanligvis vurdert i henhold til graden av ulempe og ut fra skalaer som måler innvirkningen av og prolaps og inkontinens på funksjonell tilstand og livskvalitet. Dysfunksjoner i bekkenbunnen kan ha negative konsekvenser på livsstil og mental velvære, sosial og emosjonell funksjon, helsetilstand, funksjonsevne, tilfredshet med livet, sosial støtte samt levestandard. Kvinner opplever slike dysfunksjoner som smertefulle, disruptive, kan ikke vare et vanlig norsk ord emosjonelt belastende og sjokkerende.

Mulige fordeler

Spørreskjemaene som evalueres i studien kan ha stor verdi i å måle helsetilstanden i den kvinnelige delen av befolkningen. Den kan støtte beslutningstakere i å argumentere for forbedringer i pasientadministrasjonen og andre helserelaterte spørsmål angående pasienter med bekkenbunnsdysfunksjoner. De norske utgavene av spørreskjemaene "The Pelvic Floor Distress Inventory" (PFDI-20) og "The Pelvic Floor Impact Inventory" (PFIQ-7) som vil bli resultatet av dette prosjektet vil støtte klinisk personell i hospitalene samt kliniske forskere i Norge. Man vil kunne oppnå et bredere klinisk utfallsrom som vil inkludere omtanke for kvinnelige pasienters psykologiske, sosiale og materielle velferd. Disse spørreskjemaene er også nyttige for å identifisere konsekvenser og barrierer i dagliglivet (for eksempel som følge av fekal inkontinens) som kvinnelige pasienter vanligvis ikke ville ha fått diskutert under en poliklinisk konsultasjon.

Mulige ubehag/ulemper

Det forventes ingen spesielle ubehag for det skal ikke anvendes noen legemidler i studien og det skal heller ikke tas blodprøver eller gjøres fysiske tester av deg.

Pasientens/studiedeltakerens ansvar

Den enkeltes ansvar er begrenset til **å besvare alle spørsmål etter beste evne**. Du skal besvare spørsmålene uten assistanse fra helsepersonell. Videre er det viktig å gi så korrekte opplysninger som mulig.

Kriterier for ikke å få være med

Eksklusjonskriterier er personer med alder under 18 år, personer ute av stand til å fylle ut skjemaene på egen hånd samt personer som ikke fullstendig behersker norsk.

Kompensasjon/dekning av utgifter til deltakelse

I denne studien vi har man budsjettert med dekning av parkeringsutgifter til prosjektdeltakerne for test og re-test delen. Ellers vi kan ikke betale deg noe for å delta i prosjektet.

Pasientens/studiedeltakerens ansvar

Den enkeltes ansvar er begrenset til å opplyse om forhold som kan tenkes å ha betydning for deltakelse i studien. Det er også viktig å gi så korrekte opplysninger som mulig i spørreskjema.

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Kapittel B - Personvern, biobank, økonomi og forsikring

Personvern

Følgende prinsipper og rutiner vil bli fulgt: Den enkelte vil ikke kunne identifiseres gjennom kodede data. Det vil ikke bli opprettet egne pasientjournaler for prosjektet. Det vil ikke være mulig å koble seg inn på de registrerte opplysninger for noen utenfra da de maskiner som benyttes i lagring av data er beskyttet via sykehusets sikkerhetsrutiner. Opplysninger du gir vil registreres på et skjema. Det som registreres vil bli gitt en tallkode før det legges inn på PC. Opplysningene vil bli lagret nedlåst hos Bekkensenteret/Kvinneklinikken ved Akershus Universitetssykehus i inntil 5 år etter at undersøkelsen er avsluttet.

Akershus Universitetssykehus ved administrerende direktør er databehandlingsansvarlig.

Utlevering av materiale og opplysninger til andre

Hvis du sier ja til å delta i studien, gir du også ditt samtykke til at avidentifiserte opplysninger blir tilgjengelige for personer som er tilknyttet prosjektet som medarbeidere. Dette gjelder også min studieveileder Angelita Martini og Malcolm Bond Flinders University, Australia. Opplysninger som kan identifisere deg direkte vil imidlertid ikke bli utlevert til personer utenfor sykehuset eller til personell ved Ahus som ikke har noen rolle i prosjektet.

Rett til innsyn og sletting av opplysninger om deg og sletting av prøver

Hvis du sier ja til å delta i studien, har du rett til å få innsyn i hvilke opplysninger som er registrert om deg. Du har videre rett til å få korrigert eventuelle feil i de opplysningene vi har registrert. Dersom du trekker deg fra studien, kan du kreve å få slettet innsamlede prøver og opplysninger, med mindre opplysningene allerede er inngått i analyser eller brukt i vitenskapelige publikasjoner.

Økonomi

Studien er finansiert i sin helhet via driftsmidler ved Kirurgisk divisjon ved Akershus Universitetssykehus.

Forsikring

I og med at studien er gjennomført i regi av Akershus Universitetssykehus gjelder ordningen med Norsk pasientskadeerstatning for deg ved behov.

Informasjon om utfallet av studien

Utfallet av studien vil bli publisert i fagtidsskrifter. Ut over dette vil man på forespørsel kunne presentere sammendrag av resultatene for interesserte parter.

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Samtykke til deltakelse i studien

Jeg er villig til å delta i studien

(Signert av prosjektdeltaker, dato)

Stedfortredende samtykke når berettiget, enten i tillegg til personen selv eller istedenfor

---

(Signert av nærstående, dato)

Jeg bekrefter å ha gitt informasjon om studien

(Signert, rolle i studien, dato)

This research project has been approved by the Flinders University Social and Behavioural Research Ethics Committee (Project Number 5376), the Regional Ethics Committee in Southern Norway REK (Project Number 2011/1312 REK south-east D) and Akershus University Hospital Ethics Committee (Project number 11_60 change notification). For more information regarding ethical approval of the project the Executive Officer of the Committee can be contacted by telephone on 8201 3116, by fax on 8201 2035 or by email human.researchethics@flinders.edu.au..

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APPENDIX 6.3

RESEARCH MATERIAL FOR STAGE 4 (TESTING MEASUREMENT PROPERTIES)

Verbal script, Letter of introduction, Information sheet for surgery patients

6.3a Verbal script for health personnel - surgery patients (English)

6.3b *Verbalt manus for helsepersonell* (Verbal script for health personnel – surgery patients) (Norwegian)

6.3c Letter of Introduction -surgery patients (English)

6.3d Information sheet surgery patients (English)

6.3e Consent form for surgery patients (English)

6.3f *Samtykke* (Introduction letter, Information sheet and Consent form) – surgery patients (Norwegian)

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VERBAL SCRIPT FOR HEALTH PERSONNEL
Surgery patients

Title of research project:

"Validating condition-specific health related quality of life pelvic floor disorder (PFD) questionnaires and measuring the impact on quality of life of women with PFD in the Norwegian context"

"We have a PhD student Catherine Planke from the Faculty of Medicine at Flinders University, Australia. She is also employed as the Administrative Manager at our Pelvic Floor Centre here at the Hospital. She is undertaking research leading to the production of a thesis and publications on the subject of translating and validating quality of life questionnaires for women with pelvic floor disorders in the Norwegian population."

The Purpose of the research project is to translate a well-established set of pelvic floor disorder questionnaires from English to Norwegian and test the questionnaires on Norwegian women. The questionnaires aims to measure patients' bowel, urine and prolapse symptoms and the impact of these symptoms on Norwegian women's quality of life. We want to be sure that these translated questionnaires ask the right questions in the right way.

We would be most grateful if you would volunteer to assist in this project, by filling out health-related question (for example age and weight,) and three self-administered questionnaires that include a total of 63 questions before and after surgery.
The first two questionnaires, PFDI-20 and PFIQ-7 has a total of 27 questions and asks about patients' bowel, urine and prolapse symptoms and the impact of these symptoms on your quality of life. The third questionnaire, SF-36 has a total of 36 questions and asks about your general health. No more than 20 minutes would be required. In some cases we will ask you to return to the hospital within 1-4 weeks and fill-out these questionnaires again.
Would you be interested in participating in this study?"

The participant is shown the questionnaires.

If the participant is willing, they will read the Introduction Letter and Information Sheet, fill out the Consent Form and proceed to complete the questionnaires and return to the nursing staff at the out patients clinic.

The questionnaires would take place on the same day as the consultation.

If the participants decline they will be thanked for considering the request.

Please note that these verbal scripts will be translated into Norwegian

Thank-you for your assistance.

This research project has been approved by the Flinders University Social and Behavioral Research Ethics Committee (Project Number 5376), the Regional Ethics Committee in Southern Norway REK (Project Number 2011/1312 REK south-east D) and Akershus University Hospital Ethics Committee (Project number 11_60 change notification). For more information regarding ethical approval of the project the Executive Officer of the Committee can be contacted by telephone on 8201 3116, by fax on 8201 2035 or by email human.researchethics@flinders.edu.au

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VERBALT MANUS FOR HELSEPERSONELL

KIRURGI PASIENTER

"Vi har en PhD student Catherine Planke fra Det Medisinske Fakultet ved Flinders University, Australia . Hun er også ansatt som administrativ leder på Bekkensenteret her på Ahus. Hun tar doktorgrad i Bekkenbunnslidelser hos kvinner: Oversettelse og validering av et bekkbunnsspørreskjema til norsk.

Har du lyst å delta i en forskningsstudie for å oversette to bekkenbunns spørreskjema fra USA, kalt henholdsvis PFDI-20 og PFIQ-7, til norsk? Spørreskjemaene tar sikte på å måle pasientens tarm, urin og vaginal- og uterusprolaps symptomer og innvirkningen av disse symptomene på pasienters livskvalitet før og etter vaginal kirurgi. Vi ønsker å sikre at disse oversatte spørreskjemaene stiller de riktige spørsmålene på riktig måte på norsk.

Du vil bli bedt om å besvare tre spørreskjema på **egenhånd før og etter kirurgi**. To spørreskjema handler om urin, tarm og vaginal- og uterusprolaps og virkningen av disse symptomene på pasienters livskvalitet. Det tredje spørreskjemaet, SF-36, har totalt 36 spørsmål om generell helse. Du vil også bli bedt om å fylle inn opplysninger om alder og andre helse opplysninger. Det vil ikke ta mer enn 20 minutter. Vil du være interessert i å delta i denne studien ? "

Deltakeren er vist spørreskjemaene. Hvis deltakeren er villig etter konsultasjonen, skal de fylle ut samtykkeskjema og deretter fylle ut spørreskjemaene.

Dersom deltakerne svare nei, vil de bli takket for å vurdere forespørselen.

This research project has been approved by the Flinders University Social and Behavioural Research Ethics Committee (Project Number 5376), the Regional Ethics Committee in Southern Norway REK (Project Number 2011/1312 REK south-east D) and Akershus University Hospital Ethics Committee (Project number 11_60 change notification). For more information regarding ethical approval of the project the Executive Officer of the Committee can be contacted by telephone on 8201 3116, by fax on 8201 2035 or by email human.researchethics@flinders.edu.au..

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LETTER OF INTRODUCTION
Surgery Patients

Dear Madam,

This letter is to introduce Ms Catherine Planke who is a Doctor of Philosophy (PhD) student in the School of Medicine at Flinders University, South Australia. Catherine is also the Administrative Manager at Akershus University Hospital, Pelvic Care Center, Norway. She will produce her student card, which carries a photograph, as proof of identity.

Catherine is undertaking research leading to the production of a dissertation or other publications on the subject of the quality of life of Norwegian women with pelvic floor disorders. Her study is titled; "Validating condition-specific health related quality of life pelvic floor disorder (PFD) questionnaires and measuring the impact on quality of life of women with PFD in the Norwegian context"

The study firstly involved translating the questionnaires called Pelvic Floor Distress Inventory and the Pelvic Floor Impact Questionnaire (PFDI-20 and PFIQ-7). These are self-administered questionnaires that ask about you and your health. We know that these questionnaires are of value for patients who suffer from pelvic floor disorders.

The questionnaires have originally been devised in English and are now translated into Norwegian. We want to be sure that these translated questionnaires ask the right questions in the right way. For that purpose, we are now asking for your help.

PFDI-20 PFIQ-7 self-administered questionnaires were translated from English into Norwegian using professional translators, pre-tested in a pilot study and will now be tested on 150 patients at the gynecological department, Akershus University Hospital with a pelvic floor dysfunction diagnosis (bowel, urinary or prolapse). There is an outline of the research attached.

She would be most grateful if you would volunteer to assist in this project, by filling out - related question (for example age and weight,) and three self-administered questionnaires that include a total of 63 questions before and 6-months after surgery. No more than 20 minutes would be required. In some cases we will ask you to return to the hospital within 1-4 weeks and fill-out these questionnaires again.
POP-Q information would also be collected from a POP-Q examination (pelvic organ prolapse examination) that patients currently undergo before and 6 months after reconstructive prolapse surgery at the Women´s Department of Obstetrics and Gynecology at Akershus University Hospital.

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The questionnaires aims to measure patients' bowel, urine and prolapse symptoms and the impact of these symptoms on patients' quality of life. The data collected in this study can be used to examine quality of life aspects among women with pelvic organ prolapse. The questionnaires will also be available in Norway for use by patients to measure the effectiveness of treatments for prolapse, urine and bowel symptoms.

Be assured that any information provided will be treated in the strictest confidence and none of the participants will be individually identifiable in the resulting thesis, report or other publications. You are, of course, entirely free to discontinue your participation at any time or to decline to answer particular questions.

This will be on the condition that your name or identity is not revealed, and that the recording may be made available to other researchers on the same conditions. It may be necessary to make the recording available to authorised administrative staff for transcription, in which case you may be assured that such persons will be advised of the requirement that your name or identity not be revealed and that the confidentiality of the material is respected and maintained.

The tool is being used for research purposes only and is not a clinical assessment. If any of the questions cause you concerns about your health we strongly advise you to take this up with your gynaecologist.

Any enquiries you may have concerning this project should be directed to me at the contact detail above.

Thank you for your attention and assistance.

Yours sincerely,

Ms Catherine Planke
PhD candidate
School of Medicine
Faculty of Medicine, Nursing and Health Sciences,
Flinders University

This research project has been approved by the Flinders University Social and Behavioral Research Ethics Committee (Project Number 5376), the Regional Ethics Committee in Southern Norway REK (Project Number 2011/1312 REK south-east D) and Akershus University Hospital Ethics Committee (Project number 11_60 change notification). For more information regarding ethical approval of the project the Executive Officer of the Committee can be contacted by telephone on 8201 3116, by fax on 8201 2035 or by email human.researchethics@flinders.edu.au

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INFORMATION SHEET

Surgery patients

Title: ""Validating condition-specific health related quality of life pelvic floor disorder (PFD) questionnaires and measuring the impact on quality of life of women with PFD in the Norwegian context"

Investigator:
Ms Catherine Planke
PhD candidate
School of Medicine,
Faculty of Medicine, Nursing and Health Sciences,
Flinders University

Description of the study:
This study is part of the project entitled "Validating condition-specific health related quality of life pelvic floor disorder (PFD) questionnaires and measuring the impact on quality of life of women with PFD in the Norwegian context". So far, the study has translated well-established pelvic floor disorder questionnaires called the Pelvic Floors Distress Inventory and the Pelvic Floor Impact Questionnaires (PFDI-20 and PFIQ-7) from English into Norwegian using professional translators, then pre-tested in a pilot study.
This study will now test the questionnaires (PFDI-20 and PFIQ-7) with 150 patients undergoing pelvic organ prolapse surgery at the Women's Department of Obstetrics and Gynaecology at Akershus University Hospital.

This project is supervised by Flinders University, School of Medicine, Faculty of Medicine, Nursing and Health Sciences and has ethics approval from the Social and Behavioural Research Ethics Committee at Flinders University (SBREC).

Purpose of the study:
These PFDI and PFIQ questionnaires aims to measure:

- Patient's prolapse, urine and bowel symptoms and the impact of these symptoms on patients' quality of life.
- The effectiveness of surgical treatments on Norwegian female patients with prolapse, urine and bowel symptoms.

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- The data collected in this study can be used to examine quality of life aspects among women with pelvic organ prolapse

What will I be asked to do?
You are invited to fill out three self-administered questionnaires that include a total of 63 questions related to pelvic floor disorders and general health issues before and 6-months after pelvic organ prolapse (POP) surgery. You will also be asked to answer some health-related questions (for example age and weight). No more than 20 minutes would be required. In some cases we will ask you to return to the hospital within 1-4 weeks and fill-out these questionnaires again.
We will be collecting data from your POP-Q (a simple pelvic organ prolapse examination) at baseline and 6 months POP surgery. The POP-Q system is currently used for pre-and post prolapse reconstructive surgery at the Women's Department of Obstetrics and Gynaecology at Akershus University Hospital.

Once you have completed the questionnaires, before and after 6-month pelvic organ prolapse, you will have finished the study.

What benefit will I gain from being involved in this study?
The information that we get from you will help us properly translate and adapt the questionnaires into Norwegian and help measure patients' prolapse urinary or bowel symptoms and the impact of these symptoms on patients' quality of life. The questionnaires can also be used to measure the effectiveness of surgical treatments and improve patient health care management for you and others with pelvic floor disorders.

Will I be identifiable by being involved in this study?
No name or information that identifies you will be written on the questionnaires. This will ensure anonymity and confidentiality. Your comments will not be linked directly to you. In addition, the data (coded questionnaires, information sheet and consent forms) will be stored in a secure collection box at the Akershus University Hospital for five years. This enables the participants to have access to the data for several years after the completion of study.
Be assured that none of the participants will be individually identifiable in the resulting thesis, report or other publications.

Are there any risks or discomforts if I am involved?
The investigator anticipates no risk from your involvement in this study. However, we would like to bring it to your attention that the questions in the questionnaires can involve sensitive personal issues, gender identity, depression and anxiety issues and specific health problems. The POP-Q examination, before and 6 months after surgery, may cause slight discomfort. If you have any concerns regarding anticipated or actual risks or discomforts, please raise them with attending gynaecologist.

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The tool is being used for research purposes only and is not a clinical assessment. If any of the questions cause you concerns about your health we strongly advise you to take this up with your gynaecologist.

How do I agree to participate?
Participation is voluntary. You may answer 'no comment' or refuse to answer any questions and you are free to withdraw from the interview at any time without effect or consequences. A consent form accompanies this information sheet. If you agree to participate, please read and sign the form.

How will I receive feedback?
Outcomes from the project will be summarised and given to you by the investigator if you would like to see them.

Thank you for taking the time to read this information sheet and we hope that you will accept our invitation to be involved.

Yours sincerely,

Ms Catherine Planke
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Flinders University

This research project has been approved by the Flinders University Social and Behavioral Research Ethics Committee (Project Number 5376), the Regional Ethics Committee in Southern Norway REK (Project Number 2011/1312 REK south-east D) and Akershus University Hospital Ethics Committee (Project number 11_60 change notification). For more information regarding ethical approval of the project the Executive Officer of the Committee can be contacted by telephone on 8201 3116, by fax on 8201 2035 or by email human.researchethics@flinders.edu.au

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Consent for participation in the PFDI-20 and PFIQ-7 study

Project title: "Validating condition-specific quality of life pelvic floor disorder (PFD) questionnaires and measuring the impact on quality of life of women with PFD in the Norwegian context"

I am willing to participate in the study

(Signed by the project participant, date)

Proxy consent when it is warranted, either in addition or in place of the participant's consent.

(Signed by representative, date)

I have confirmed that I have given information about the study

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(Signed, role in the study, date)

Thank you for your assistance.

This research project has been approved by the Flinders University Social and Behavioral Research Ethics Committee (Project Number 5376), the Regional Ethics Committee in Southern Norway REK (Project Number 2011/1312 REK south-east D) and Akershus University Hospital Ethics Committee (Project number 11_60 change notification). For more information regarding ethical approval of the project the Executive Officer of the Committee can be contacted by telephone on 8201 3116, by fax on 8201 2035 or by email human.researchethics@flinders.edu.au

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SAMTYKKE

Forespørsel om deltakelse i forskningsprosjektet

"Bekkenbunns dysfunksjoner hos kvinner: Oversettelse og validering av spørreskjema PDF120 og PFIQ7 til norsk"

Kirurgi pasienter

Bakgrunn og hensikt

Dette er et spørsmål til deg om å delta i en forskningsstudie for å oversette to bekkenbunns spørreskjema fra USA, kalt henholdsvis PDF1-20 og PFIQ-7, til norsk. Spørreskjemaene tar sikte på å måle pasientens tarm, urin og vaginal- og uterusprolaps symptomer og innvirkningen av disse symptomene på pasienters livskvalitet. Skjema også er brukt for å måle pasientens tarm, urin og vaginal- og uterusprolaps symptomer og innvirkningen av disse symptomene på pasienters livskvalitet før og etter vaginal kirurgi. Tilgjengeligheten av slike skjemaer i Norge vil kunne forbedre evnen til å måle effektiviteten av klinisk behandling av bekkenbunns dysfunksjoner. Foruten å oversette spørreskjemaene til norsk vil denne studien hvorvidt skjemaene er dekkende for norske forhold.

Studien vil også innebære å se på livskvalitet og dagligliv-aspekter blant kvinner med vaginal-uterusprolaps. Innhentede data kan også benyttes i forskning på livskvalitet før og etter vaginal kirurgi. I tillegg til alder vil andre helserelaterte opplysninger rundt livskvalitet også være en del av denne studien (for eksempel vekt, tidligere operasjoner og lignende).

Hva innebærer studien?

Du vil bli bedt om å besvare tre spørreskjema på **egenhånd før og 6 måneder etter din vaginal prolapskirurgi**. To av skjemaene har totalt 27 spørsmål om urin, tarm og vaginal- og uterusprolaps. Spørreskjemaene, kalt henholdsvis PDF1-20 og PFIQ-7, tar sikte på å måle pasienters tarm, urin, vaginal- uterusprolaps symptomer og virkningen av disse symptomene på pasienters livskvalitet. Det tredje spørreskjemaet, SF-36, har totalt 36 spørsmål om generell helse. Du vil også bli bedt om å fylle inn opplysninger om alder og andre helse opplysninger. Andre helseopplysninger inkluderer POP-Q informasjon. POP-Q-undersøkelsen er en enkel underlivsundersøkelse som tar 1-2 minutter, og brukes i dag regelmessig før og etter vaginal prolapskirurgi ved Kvinneklinikken, Akershus universitetssykehus.
Samlet tidsforbruk anslås til maksimalt 20 minutter.

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Mulige fordeler og ulemper
Spørreskjemaene som skal prøves ut i prosjektet er utformet for å avdekke og evaluere pasienters respons på eksisterende og nye behandlingsmetoder for dysfunksjoner i bekkenbunnen.

Spørsmålene i skjemaene kan omhandle ømtålige personlige anliggender, kjønnsidentitet, problemer med depresjon og angst samt spesifikke helseproblemer.
Spørreskjemaet brukes til forskningsformål og ikke til klinisk vurdering. Hvis noen spørsmål føre til bekymringer rundt din helse, vil vi anbefale at du diskuterer dette med din gynekolog.
Hvis POP-Q undersøkelsen fører til noe ubehag eller bekymringer, vil vi også anbefale at du diskuterer dette med gynekologen som utfører undersøkelsen

Hva skjer med informasjonen om deg?
Informasjonen som registreres om deg skal kun brukes slik som beskrevet i hensikten med studien. Alle opplysningene og prøvene vil bli behandlet uten navn og fødselsnummer eller andre direkte gjenkjennende opplysninger. En kode knytter deg til dine opplysninger og prøver gjennom en navneliste.

Det er kun autorisert personell knyttet til prosjektet som har adgang til navnelisten og som kan finne tilbake til deg. Det vil ikke være mulig å identifisere deg i resultatene av studien når disse publiseres.

Frivillig deltakelse
Det er frivillig å delta i studien. Du kan når som helst og uten å oppgi noen grunn trekke ditt samtykke til å delta i studien. Dette vil ikke få konsekvenser for din videre behandling. Dersom du ønsker å delta, undertegner du samtykkeerklæringen på siste side. Om du nå sier ja til å delta, kan du senere trekke tilbake ditt samtykke uten at det påvirker din øvrige behandling. Dersom du senere ønsker å trekke deg eller har spørsmål til studien, kan du kontakte Kvinneklinikken, Akershus universitets sykehus, Catherine Planke chpl@ahus.no eller Marie Ellstrøm Engh: m.e.engh@medisin.uio.no

Ytterligere informasjon om studien finnes i kapittel *A* – *utdypende forklaring av hva studien innebærer*.
Ytterligere informasjon om biobank, personvern og forsikring finnes i kapittel B – *Personvern, biobank, økonomi og forsikring*.

Samtykkeerklæring følger etter kapittel B.

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Kapittel A- utdypende forklaring av hva studien innebærer

Kriterier for deltakelse

For å kunne inkluderes i undersøkelsen må du være kvinne med symptomer av fremfall med eller uten samtidlige problmerer med (tarm, urin) og henvist til Kvinneklinikken, Ahus samt ha returnert ditt skriftlige samtykke. Vi ønsker at du skal ha norsk som morsmål.

Bakgrunnsinformasjon om studien

Konsekvenser av dine symptomer blir vanligvis vurdert i henhold til graden av ulempe og ut fra skalaer som måler innvirkningen av og prolaps og inkontinens på funksjonell tilstand og livskvalitet. Dysfunksjoner i bekkenbunnen kan ha negative konsekvenser på livsstil og mental velvære, sosial og emosjonell funksjon, helsetilstand, funksjonsevne, tilfredshet med livet, sosial støtte samt levestandard. Kvinner opplever slike dysfunksjoner som smertefulle, disruptive, kan ikke vare et vanlig norsk ord emosjonelt belastende og sjokkerende.

Mulige fordeler

Spørreskjemaene som evalueres i studien kan ha stor verdi i å måle helsetilstanden i den kvinnelige delen av befolkningen. Den kan støtte beslutningstakere i å argumentere for forbedringer i pasientadministrasjonen og andre helserelaterte spørsmål angående pasienter med bekkenbunnsdysfunksjoner. De norske utgavene av spørreskjemaene "The Pelvic Floor Distress Inventory" (PFDI-20) og "The Pelvic Floor Impact Inventory" (PFIQ-7) som vil bli resultatet av dette prosjektet vil støtte klinisk personell i hospitalene samt kliniske forskere i Norge. Man vil kunne oppnå et bredere klinisk utfallsrom som vil inkludere omtanke for kvinnelige pasienters psykologiske, sosiale og materielle velferd. Disse spørreskjemaene er også nyttige for å identifisere konsekvenser og barrierer i dagliglivet (for eksempel som følge av fekal inkontinens) som kvinnelige pasienter vanligvis ikke ville ha fått diskutert under en poliklinisk konsultasjon.

Mulige ubehag/ulemper

Det forventes ingen spesielle ubehag for det skal ikke anvendes noen legemidler i studien og det skal heller ikke tas blodprøver eller gjøres fysiske tester av deg.

Pasientens/studiedeltakerens ansvar

Den enkeltes ansvar er begrenset til **å besvare alle spørsmål etter beste evne**. Du skal besvare spørsmålene uten assistanse fra helsepersonell. Videre er det viktig å gi så korrekte opplysninger som mulig.

Kriterier for ikke å få være med

Eksklusjonskriterier er personer med alder under 18 år, personer ute av stand til å fylle ut skjemaene på egen hånd samt personer som ikke fullstendig behersker norsk.

Kompensasjon/dekning av utgifter til deltakelse

I denne studien vi har man budsjettert med dekning av parkeringsutgifter til prosjektdeltakerne for test og re-test delen. Ellers vi kan ikke betale deg noe for å delta i prosjektet.

Pasientens/studiedeltakerens ansvar

Den enkeltes ansvar er begrenset til å opplyse om forhold som kan tenkes å ha betydning for deltakelse i studien. Det er også viktig å gi så korrekte opplysninger som mulig i spørreskjema.

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Kapittel B - Personvern, biobank, økonomi og forsikring

Personvern

Følgende prinsipper og rutiner vil bli fulgt: Den enkelte vil ikke kunne identifiseres gjennom kodede data. Det vil ikke bli opprettet egne pasientjournaler for prosjektet. Det vil ikke være mulig å koble seg inn på de registrerte opplysninger for noen utenfra da de maskiner som benyttes i lagring av data er beskyttet via sykehusets sikkerhetsrutiner. Opplysninger du gir vil registreres på et skjema. Det som registreres vil bli gitt en tallkode før det legges inn på PC. Opplysningene vil bli lagret nedlåst hos Bekkensenteret/Kvinneklinikken ved Akershus Universitetssykehus i inntil 5 år etter at undersøkelsen er avsluttet. Akershus Universitetssykehus ved administrerende direktør er databehandlingsansvarlig.

Utlevering av materiale og opplysninger til andre

Hvis du sier ja til å delta i studien, gir du også ditt samtykke til at avidentifiserte opplysninger blir tilgjengelige for personer som er tilknyttet prosjektet som medarbeidere. Dette gjelder også min studieveileder Angelita Martini og Malcolm Bond Flinders University, Australia. Opplysninger som kan identifisere deg direkte vil imidlertid ikke bli utlevert til personer utenfor sykehuset eller til personell ved Ahus som ikke har noen rolle i prosjektet.

Rett til innsyn og sletting av opplysninger om deg og sletting av prøver

Hvis du sier ja til å delta i studien, har du rett til å få innsyn i hvilke opplysninger som er registrert om deg. Du har videre rett til å få korrigert eventuelle feil i de opplysningene vi har registrert. Dersom du trekker deg fra studien, kan du kreve å få slettet innsamlede prøver og opplysninger, med mindre opplysningene allerede er inngått i analyser eller brukt i vitenskapelige publikasjoner.

Økonomi

Studien er finansiert i sin helhet via driftsmidler ved Kirurgisk divisjon ved Akershus

Universitetssykehus

Forsikring

I og med at studien er gjennomført i regi av Akershus Universitetssykehus gjelder ordningen med Norsk pasientskadeerstatning for deg ved behov.

Informasjon om utfallet av studien

Utfallet av studien vil bli publisert i fagtidsskrifter. Ut over dette vil man på forespørsel kunne presentere sammendrag av resultatene for interesserte parter.

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Samtykke til deltakelse i studien

Jeg er villig til å delta i studien

(Signert av prosjektdeltaker, dato)

Stedfortredende samtykke når berettiget, enten i tillegg til personen selv eller istedenfor

---

(Signert av nærstående, dato)

Jeg bekrefter å ha gitt informasjon om studien

(Signert, rolle i studien, dato)

This research project has been approved by the Flinders University Social and Behavioural Research Ethics Committee (Project Number 5376), the Regional Ethics Committee in Southern Norway REK (Project Number 2011/1312 REK south-east D) and Akershus University Hospital Ethics Committee (Project number 11_60 change notification). For more information regarding ethical approval of the project the Executive Officer of the Committee can be contacted by telephone on 8201 3116, by fax on 8201 2035 or by email human.researchethics@flinders.edu.au..

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APPENDIX 6.4

NORWEGIAN FINAL VERSION PFDI-20 AND PFIQ-7

Version after extensive validation

No amendments were made between the Intermediate Version 3.0 PFDI-20 and PFIQ-7 and the Norwegian final version PFDI-20 and PFIQ-7.

Spørreskjema om bekkenbunnsplager - skjema PFDI-20

Veiledning

Vennligst svar på alle spørsmålene i spørreskjemaet. Spørsmålene dreier seg om hvorvidt du har visse symptomer i tarmen, blæren eller bekkenregionen, og i så fall hvor mye de plager deg. Svar på spørsmålene ved å krysse av i den eller de boksene som passer for deg. Hvis du er usikker på hva du skal svare, svarer du så godt du kan. Vær snill og svar på spørsmålene ut fra de symptomer du har hatt gjennom de **siste tre månedene.**

EKSEMPEL

Ved følgende spørsmål:

Hvis du ikke pleier å ha hodepine, setter du X i "Nei"- ruten.

Har du ofte *hodepine*?

☒ Nei ☐ Ja **Hvis svaret er ja, hvor mye plager det deg?**

☐ 1	☐ 2	☐ 3	☐ 4
Ikke det hele tatt	Litt	I noen grad	Ganske mye

Hvis du pleier å ha hodepine, setter du X i "Ja"-boksen og angir hvor mye hodepinen plager deg. (I dette eksemplet plages vedkommende av hodepinen *i noen grad*)

Har du ofte *hodepine*?

☐ Nei ☒ Ja **Hvis svaret er ja, hvor mye plager det deg?**

☐ 1	☐ 2	☒ 3	☐ 4
Ikke det hele tatt	Litt	I noen grad	Ganske mye

Spørreskjema om bekkenbunnsplager - skjema PFDI-20

1.	Kjenner du ofte *trykk* i nedre del av magen? ☐ Nei; ☐ Ja **0** **<u>Hvis ja</u>, hvor mye plager det deg?** **☐ 1** Ikke i det hele tatt - **☐ 2** Litt - **☐ 3** I noen grad - **☐ 4** Ganske mye
2.	Har du ofte *tyngdefølelse i bekkenet*? ☐ Nei; ☐ Ja **0** **<u>Hvis ja</u>, hvor mye plager det deg?** **☐ 1** Ikke i det hele tatt - **☐ 2** Litt - **☐ 3** I noen grad - **☐ 4** Ganske mye
3.	Kjenner eller ser du ofte noe som buler eller faller ut i skjeden? ☐ Nei; ☐ Ja **0** **<u>Hvis ja</u>, hvor mye plager det deg?** **☐ 1** Ikke i det hele tatt - **☐ 2** Litt - **☐ 3** I noen grad - **☐ 4** Ganske mye
4.	Må du ofte presse med fingre i skjeden eller rundt endetarmsåpningen for å få ut avføring eller få tømt tarmen helt? ☐ Nei; ☐ Ja **0** **<u>Hvis ja</u>, hvor mye plager det deg?** **☐ 1** Ikke i det hele tatt - **☐ 2** Litt - **☐ 3** I noen grad - **☐ 4** Ganske mye
5.	Føler du ofte at du ikke får tømt blæren helt? ☐ Nei; ☐ Ja **0** **<u>Hvis ja</u>, hvor mye plager det deg?** **☐ 1** Ikke i det hele tatt - **☐ 2** Litt - **☐ 3** I noen grad - **☐ 4** Ganske mye
6.	Hender det at du må trykke inn med fingrene noe som buler i skjeden, for å få tisset eller tømt blæren helt? ☐ Nei; ☐ Ja **0** **<u>Hvis ja</u>, hvor mye plager det deg?** **☐ 1** Ikke i det hele tatt - **☐ 2** Litt - **☐ 3** I noen grad - **☐ 4** Ganske mye

7. Føler du at du må presse for hardt for å få ut avføringen?

☐ Nei; ☐ Ja
0

Hvis ja, hvor mye plager det deg?

☐ 1	☐ 2	☐ 3	☐ 4
Ikke i det hele tatt -	Litt -	I noen grad -	Ganske mye

8. Føler du at du ikke har tømt tarmen helt, når du har hatt avføring?

☐ Nei; ☐ Ja
0

Hvis ja, hvor mye plager det deg?

☐ 1	☐ 2	☐ 3	☐ 4
Ikke i det hele tatt -	Litt -	I noen grad -	Ganske mye

9. Har du ofte avføringslekkasje når avføringen er fast?

☐ Nei; ☐ Ja
0

Hvis ja, hvor mye plager det deg?

☐ 1	☐ 2	☐ 3	☐ 4
Ikke i det hele tatt -	Litt -	I noen grad -	Ganske mye

10. Har du ofte avføringslekkasje når avføringen er løs eller flytende?

☐ Nei; ☐ Ja
0

Hvis ja, hvor mye plager det deg?

☐ 1	☐ 2	☐ 3	☐ 4
Ikke i det hele tatt -	Litt -	I noen grad -	Ganske mye

11. Har du ofte ufrivillig lekkasje av luft fra tarmen?

☐ Nei; ☐ Ja
0

Hvis ja, hvor mye plager det deg?

☐ 1	☐ 2	☐ 3	☐ 4
Ikke i det hele tatt -	Litt -	I noen grad -	Ganske mye

12. Har du ofte smerter når du har avføring?

☐ Nei; ☐ Ja
0

Hvis ja, hvor mye plager det deg?

☐ 1	☐ 2	☐ 3	☐ 4
Ikke i det hele tatt -	Litt -	I noen grad -	Ganske mye

13. Opplever du så sterk avføringstrang at du må løpe til toalettet?

☐ Nei; ☐ Ja
0

Hvis ja, hvor mye plager det deg?

☐ 1	☐ 2	☐ 3	☐ 4
Ikke i det hele tatt -	Litt -	I noen grad -	Ganske mye

14. Hender det at en del av tarmen følger med ut gjennom endetarmsåpningen under eller etter avføring?

☐ Nei; ☐ Ja
0

Hvis ja, hvor mye plager det deg?

☐ 1	☐ 2	☐ 3	☐ 4
Ikke i det hele tatt -	Litt -	I noen grad -	Ganske mye

15. Har du vanligvis hyppig vannlating?

☐ Nei; ☐ Ja
0

Hvis ja, hvor mye plager det deg?

☐ 1	☐ 2	☐ 3	☐ 4
Ikke i det hele tatt -	Litt -	I noen grad -	Ganske mye

16. Opplever du så sterk vannlatingstrang at du ikke rekker til toalettet før du får lekkasje?

☐ Nei; ☐ Ja
0

Hvis ja, hvor mye plager det deg?

☐ 1	☐ 2	☐ 3	☐ 4
Ikke i det hele tatt -	Litt -	I noen grad -	Ganske mye

17. Har du ofte urinlekkasje når du hoster, nyser eller ler?

☐ Nei; ☐ Ja
0

Hvis ja, hvor mye plager det deg?

☐ 1	☐ 2	☐ 3	☐ 4
Ikke i det hele tatt -	Litt -	I noen grad -	Ganske mye

18. Har du ofte små urinlekkasjer (dvs. dråper)?

☐ Nei; ☐ Ja
0

Hvis ja, hvor mye plager det deg?

☐ 1	☐ 2	☐ 3	☐ 4
Ikke i det hele tatt -	Litt -	I noen grad -	Ganske mye

19. Har du ofte problemer med å tømme blæren?

☐ Nei; ☐ Ja
0

Hvis ja, hvor mye plager det deg?

☐ 1	☐ 2	☐ 3	☐ 4
Ikke i det hele tatt -	Litt -	I noen grad -	Ganske mye

20. Har du ofte *smerte* eller *ubehag* i nedre del av magen eller underlivet?

☐ Nei; ☐ Ja
0

Hvis ja, hvor mye plager det deg?

☐ 1	☐ 2	☐ 3	☐ 4
Ikke i det hele tatt -	Litt -	I noen grad -	Ganske mye

Spørreskjema om bekkenbunnsplager og innvirkning på dagliglivet - skjema PFIQ-7

Veiledning

Noen kvinner opplever at symptomer fra blæren, endetarmen eller skjeden påvirker deres gjøremål, forhold og følelser. For hvert av spørsmålene ber vi deg krysse av for svaret som best beskriver hvordan dine gjøremål, forhold eller følelser har blitt påvirket av symptomer eller plager fra blære, endetarm eller skjede **de tre siste månedene**.

Du kan ha, eller ikke ha symptomer innenfor hvert av disse tre områdene, men husk å svare i alle tre kolonner for hvert spørsmål. Hvis du ikke har symptomer på et av områdene, svarer du "ikke i det hele tatt" i den aktuelle kolonnen.

EKSEMPEL

Ved følgende spørsmål:
Hvis blærefunksjonen påvirker evnen din til å kjøre bil i noen grad, mens tarmfunksjonen bare påvirker evnen til å kjøre bil litt, og symptomer knyttet til skjede eller bekkenbunn ikke påvirker evnen til å kjøre bil i det hele tatt, skal du sette kryss (X) i boksene som vist nedenfor:

Hvordan pleier symptomer eller plager fra å påvirke → → → → ↓	***Blære eller urin***	***Tarm eller endetarm***	***Skjede eller bekkenbunnen***
1. din evne til å kjøre bil	☐ Ikke i det hele tatt ☐ Litt ☒ I noen grad ☐ Ganske mye	☐ Ikke i det hele tatt ☒ Litt ☐ I noen grad ☐ Ganske mye	☒ Ikke i det hele tatt ☐ Litt ☐ I noen grad ☐ Ganske mye

Vennligst husk å svare i alle tre kolonner for hvert spørsmål

Takk for hjelpen!

Spørreskjema om bekkenbunnsplager og innvirkning på dagliglivet - skjema PFIQ-7

Veiledning: Noen kvinner opplever at symptomer fra blæren, endetarmen eller skjeden påvirker deres gjøremål, forhold og følelser. For hvert av spørsmålene ber vi deg krysse av for svaret som best beskriver hvordan dine gjøremål, forhold eller følelser har blitt påvirket av symptomer eller plager fra blære, endetarm eller skjede **de tre siste månedene**. Husk å krysse av i **alle de tre kolonnene** for hvert spørsmål.

Hvordan pleier symptomer eller plager fra →→→→ å påvirke ↓	***Blære eller urin***	***Tarm eller endetarm***	***Skjede eller bekkenbunnen***
1. din evne til å gjøre husarbeid (matlaging, rengjøring, klesvask)?	☐ Ikke i det hele tatt ☐ Litt ☐ I noen grad ☐ Ganske mye	☐ Ikke i det hele tatt ☐ Litt ☐ I noen grad ☐ Ganske mye	☐ Ikke i det hele tatt ☐ Litt ☐ I noen grad ☐ Ganske mye
2. din fysiske aktivitet, som turgåing, svømming eller annen mosjon?	☐ Ikke i det hele tatt ☐ Litt ☐ I noen grad ☐ Ganske mye	☐ Ikke i det hele tatt ☐ Litt ☐ I noen grad ☐ Ganske mye	☐ Ikke i det hele tatt ☐ Litt ☐ I noen grad ☐ Ganske mye
3. dine fritidsaktiviteter som å gå på kino eller konsert?	☐ Ikke i det hele tatt ☐ Litt ☐ I noen grad ☐ Ganske mye	☐ Ikke i det hele tatt ☐ Litt ☐ I noen grad ☐ Ganske mye	☐ Ikke i det hele tatt ☐ Litt ☐ I noen grad ☐ Ganske mye
4. din mulighet til å reise med bil eller buss i mer enn 30 minutter hjemmefra?	☐ Ikke i det hele tatt ☐ Litt ☐ I noen grad ☐ Ganske mye	☐ Ikke i det hele tatt ☐ Litt ☐ I noen grad ☐ Ganske mye	☐ Ikke i det hele tatt ☐ Litt ☐ I noen grad ☐ Ganske mye
5. din deltakelse i sosiale aktiviteter utenfor hjemmet?	☐ Ikke i det hele tatt ☐ Litt ☐ I noen grad ☐ Ganske mye	☐ Ikke i det hele tatt ☐ Litt ☐ I noen grad ☐ Ganske mye	☐ Ikke i det hele tatt ☐ Litt ☐ I noen grad ☐ Ganske mye
6. din psykiske helsetilstand (nervøsitet, depresjon osv.)?	☐ Ikke i det hele tatt ☐ Litt ☐ I noen grad ☐ Ganske mye	☐ Ikke i det hele tatt ☐ Litt ☐ I noen grad ☐ Ganske mye	☐ Ikke i det hele tatt ☐ Litt ☐ I noen grad ☐ Ganske mye
7. din følelse av frustrasjon?	☐ Ikke i det hele tatt ☐ Litt ☐ I noen grad ☐ Ganske mye	☐ Ikke i det hele tatt ☐ Litt ☐ I noen grad ☐ Ganske mye	☐ Ikke i det hele tatt ☐ Litt ☐ I noen grad ☐ Ganske mye

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