

PRECISE- DYAD

Health trajectories for
mums and their children



PELVIC FLOOR DISTRESS INVENTORY MANUAL MASTER COPY

Version 1 – June 2021

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1. Introduction

The pelvic floor refers to the muscles and other tissues that support the bladder, rectum, uterus and other internal organs. Many women experience Pelvic Floor Disorders (PFDs) during and after pregnancy, the symptoms which include urinary and bowel incontinence, sagging of inner organs and other sensory and emptying abnormalities. These can all have a significant impact on women's quality of life.

Within this section of the questionnaire, we hope to learn the effect of pelvic floor disorders on the quality of life of women. These questions will ask participants if they have certain bowel, bladder, or pelvic symptoms and, if they do, how much it bothers them.

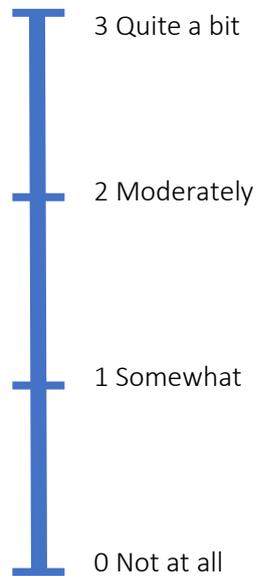
2. Tools

1. The **Pelvic Floor Distress Inventory** questionnaire is asked in DYAD visits 1 and 3 to participants who during PRECISE were in labour for more than 24 hours. We will also ask an equal number of women who were in labour for less than 12 hours to answer the questionnaire, these women will be randomly selected. For those participants who have been identified as part of this case-control subset, Pelvic Floor Distress Inventory form will appear automatically in Visit 1 and Visit 3.
2. The **Pelvic Floor Impact Questionnaire (PFIQ)** is asked in DYAD visit 3 to participants if they responded that they have experienced a symptom and it bothers her "*somewhat*", "*moderately*" or "*quite a bit*" in the PFDI questionnaire asked during that visit. If none of symptoms bother the women, the questionnaire will not be displayed.

2.1 Pelvic Floor Distress Inventory (PFDI)

The Pelvic Floor Distress Inventory (PFDI) includes 20 health-related quality of life questions, each one starting with a "Yes" or "No" response. If the participant responds "Yes" to a question, then you must ask her to indicate how much the symptom(s) have been bothering her in the past three months. There are four possible responses on a scale that ranges from "*Not at all*", "*Somewhat*", "*Moderately*" to "*Quite a Bit*". Hand flashcard #1 to the woman and ask her to use the scale of severity to indicate how much a symptom has been bothering her in the past three months.

Flashcard #1



Pelvic Floor Distress Inventory (PFDI)	
	Please consider your symptoms over the last 3 months:
1	Do you usually experience pressure in the lower abdomen?
2	Do you usually experience <i>heaviness or dullness</i> in the pelvic area?
3	Do you usually have a bulge or something falling out that you can see or feel in the vaginal area?
4	Do you usually have to push on the vagina or around the rectum to have or complete a bowel movement?
5	Do you usually experience a feeling of incomplete bladder emptying?
6	Do you ever have to push up on a bulge in the vaginal area with your fingers to start or complete urination?
7	Do you feel you need to strain too hard to have a bowel movement?
8	Do you feel you have not completely emptied your bowels at the end of a bowel movement?

9	Do you usually lose stool beyond your control if your stool is well formed?
10	Do you usually lose stool beyond your control if your stool is loose or liquid?
11	Do you usually lose gas from the rectum beyond your control?
12	Do you usually have pain when you pass your stool?
13	Do you experience a strong sense of urgency and have to rush to the bathroom to have a bowel movement?
14	Does a part of your bowel ever pass through the rectum and bulge outside during or after a bowel movement?
15	Do you usually experience frequent urination?
16	Do you usually experience urine leakage associated with a feeling of urgency, that is a strong sensation of needing to go to the bathroom?
17	Do you usually experience urine leakage related to coughing, sneezing, or laughing?
18	Do you usually experience small amounts of urine leakage (that is, drops)?
19	Do you usually experience difficulty emptying your bladder?
20	Do you usually experience <i>pain</i> or <i>discomfort</i> in the lower abdomen or genital region?

When answering these questions, ask the woman to consider her symptoms over the **last three months**.

1. Do you usually experience pressure in the lower abdomen?

Possible response options: yes, no.

Ask the woman if she usually feels pressure in her lower abdomen (below the belly button). Record the woman's response by selecting the appropriate option. If her answer to this question is "yes", ask her the following additional question:

- i) How much does this bother you? (*Possible response options: not at all, somewhat, moderately, quite a bit*). Record her answer by selecting the appropriate option.

2. Do you usually experience heaviness or dullness in the pelvic area?

Possible response options: yes, no.

Ask the woman if she usually feels a background ache or mild cramping in her pelvic area (i.e., a pain that is there most of the time and is uncomfortable, but not overwhelming). Record the woman's

response by selecting the appropriate option. If her answer to this question is “yes”, ask her the following additional question.

- i) How much does this bother you? (Possible response options: not at all, somewhat, moderately, quite a bit). Record her answer by selecting the appropriate option.

3. Do you usually have a bulge or something falling out that you can see or feel in the vaginal area?

Possible response options: yes, no.

Ask the woman if she usually feels or sees something bulging or coming out of her vaginal area. Record the woman’s response by selecting the appropriate option. If her answer to this question is “yes”, ask her the following additional question.

- i) How much does this bother you? (Possible response options: not at all, somewhat, moderately, quite a bit). Record her answer by selecting the appropriate option.

You can prompt the woman by asking her if the bulge is painful, uncomfortable or if it refrains her from doing certain activities.

4. Do you usually have to push on the vagina or around the rectum to have or complete a bowel movement?

Possible response options: yes, no.

Ask the woman if she must push hard on her vagina or rectum to pass stool. Record the woman’s response by selecting the appropriate option. If her answer to this question is “yes”, ask her the following additional question.

- i) How much does this bother you? (Possible response options: not at all, somewhat, moderately, quite a bit). Record her answer by selecting the appropriate option.

You can prompt the woman by asking her if pushing to complete a bowel movement is painful or uncomfortable.

5. Do you usually experience a feeling of incomplete bladder emptying?

Possible response options: yes, no.

Ask the woman if she has the sensation that her bladder is not completely empty after urinating. Record the woman’s response by selecting the appropriate option. If her answer to this question is “yes”, ask her the following additional question:

- i) How much does this bother you? (Possible response options: not at all, somewhat, moderately, quite a bit). Record her answer by selecting the appropriate option.

6. Do you ever have to push up on a bulge in the vaginal area with your fingers to start or complete urination?
Possible response options: yes, no.

Ask the women, if she must push on any bumps/bulges in the vaginal area before she is able to urinate. Record the woman's response by selecting the appropriate option. If her answer to this question is "yes", ask her the following additional question:

- i) How much does this bother you? (*Possible response options: not at all, somewhat, moderately, quite a bit*). Record her answer by selecting the appropriate option.

7. Do you feel you need to strain too hard to have a bowel movement?
Possible response options: yes, no.

Ask the woman if she feels like she must push too hard to pass stool. Record the woman's response by selecting the appropriate option. If her answer to this question is "yes", ask her the following additional question:

- i) How much does this bother you? (*Possible response options: not at all, somewhat, moderately, quite a bit*). Record her answer by selecting the appropriate option.

8. Do you feel you have not completely emptied your bowels at the end of a bowel movement?
Possible response options: yes, no.

Ask the woman if after passing stool, she feels like she is not quite finished. Record the woman's response by selecting the appropriate option. If her answer to this question is "yes", ask her the following additional question:

- i) How much does this bother you? (*Possible response options: not at all, somewhat, moderately, quite a bit*). Record her answer by selecting the appropriate option.

9. Do you usually lose stool beyond your control if your stool is well formed?
Possible response options: yes, no.

Ask the woman if she usually experiences an involuntary loss of stool (i.e. does not have time to get to the toilet), when her stool is solid. Record the woman's response by selecting the appropriate option. If her answer to this question is "yes", ask her the following additional question:

- i) How much does this bother you? (*Possible response options: not at all, somewhat, moderately, quite a bit*). Record her answer by selecting the appropriate option.

10. Do you usually lose stool beyond your control if your stool is loose or liquid?
Possible response options: yes, no.

Ask the woman if she usually experiences an involuntary loss of stool (i.e. does not have time to get to the toilet), when her stool is loose or liquid. Record the woman's response by selecting the appropriate option. If her answer to this question is "yes", ask her the following additional question:

- i) How much does this bother you? (Possible response options: not at all, somewhat, moderately, quite a bit). Record her answer by selecting the appropriate option.

11. Do you usually lose gas from the rectum beyond your control?

Possible response options: yes, no.

Ask the woman if she usually passes gas involuntarily. Record the woman's response by selecting the appropriate option. If her answer to this question is "yes", ask her the following additional question:

- i) How much does this bother you? (Possible response options: not at all, somewhat, moderately, quite a bit). Record her answer by selecting the appropriate option.

12. Do you usually have pain when you pass your stool?

Possible response options: yes, no.

Ask the woman if passing stool is usually painful. Record the woman's response by selecting the appropriate option. If her answer to this question is "yes", ask her the following additional question:

- i) How much does this bother you? (Possible response options: not at all, somewhat, moderately, quite a bit). Record her answer by selecting the appropriate option.

13. Do you experience a strong sense of urgency and have to rush to the bathroom to have a bowel movement?

Possible response options: yes, no.

Ask the woman if she feels a strong need to go to the bathroom quickly to pass stool. Record the woman's response by selecting the appropriate option. If her answer to this question is "yes", ask her the following additional question:

- i) How much does this bother you? (Possible response options: not at all, somewhat, moderately, quite a bit). Record her answer by selecting the appropriate option.

14. Does a part of your bowel ever pass through the rectum and bulge outside during or after a bowel movement?

Possible response options: yes, no.

Ask the woman if she has noticed that part of her intestine (bowel) has come through her rectum and bumps out while she is passing stool or afterwards. Record the woman's response by selecting the appropriate option. If her answer to this question is "yes", ask her the following additional question:

- i) How much does this bother you? (Possible response options: not at all, somewhat, moderately, quite a bit). Record her answer by selecting the appropriate option.

15. Do you usually experience frequent urination?

Possible response options: yes, no.

Ask the woman if she usually urinates frequently. You can prompt her by asking how many times in a day she usually urinates (the average number of times a person urinates in a day is between 6 – 7). Record the woman's response by selecting the appropriate option. If her answer to this question is "yes", ask her the following additional question:

- i) How much does this bother you? (Possible response options: not at all, somewhat, moderately, quite a bit). Record her answer by selecting the appropriate option.

16. Do you usually experience urine leakage associated with a feeling of urgency, that is a strong sensation of needing to go to the bathroom?

Possible response options: yes, no.

Ask the woman if she usually leaks urine, together with feeling a strong need to go to the bathroom. Record the woman's response by selecting the appropriate option. If her answer to this question is "yes", ask her the following additional question:

- i) How much does this bother you? (Possible response options: not at all, somewhat, moderately, quite a bit). Record her answer by selecting the appropriate option.

17. Do you usually experience urine leakage related to coughing, sneezing, or laughing?

Possible response options: yes, no.

Ask the woman if she leaks urine when she laughs, coughs or sneezes. Record the woman's response by selecting the appropriate option. If her answer to this question is "yes", ask her the following additional question:

- i) How much does this bother you? (Possible response options: not at all, somewhat, moderately, quite a bit). Record her answer by selecting the appropriate option.

18. Do you usually experience small amounts of urine leakage (that is, drops)?

Possible response options: yes, no.

Ask the woman if she usually leaks a few drops of urine throughout the day or night, in between going to the toilet. Record the woman's response by selecting the appropriate option. If her answer to this question is "yes", ask her the following additional question:

- i) How much does this bother you? (Possible response options: not at all, somewhat, moderately, quite a bit). Record her answer by selecting the appropriate option.
19. Do you usually experience difficulty emptying your bladder?
Possible response options: yes, no.

Ask the woman if she usually struggles to completely empty her bladder when urinating. Record the woman's response by selecting the appropriate option. If her answer to this question is "yes", ask her the following additional question:

- i) How much does this bother you? (Possible response options: not at all, somewhat, moderately, quite a bit). Record her answer by selecting the appropriate option.
20. Do you usually experience pain or discomfort in the lower abdomen or genital region?
Possible response options: yes, no.

Ask the woman if she usually feels pain or discomfort in the area below her belly button or near her vagina. Record the woman's response by selecting the appropriate option. If her answer to this question is "yes", ask her the following additional question:

- i) How much does this bother you? (Possible response options: not at all, somewhat, moderately, quite a bit). Record her answer by selecting the appropriate option.

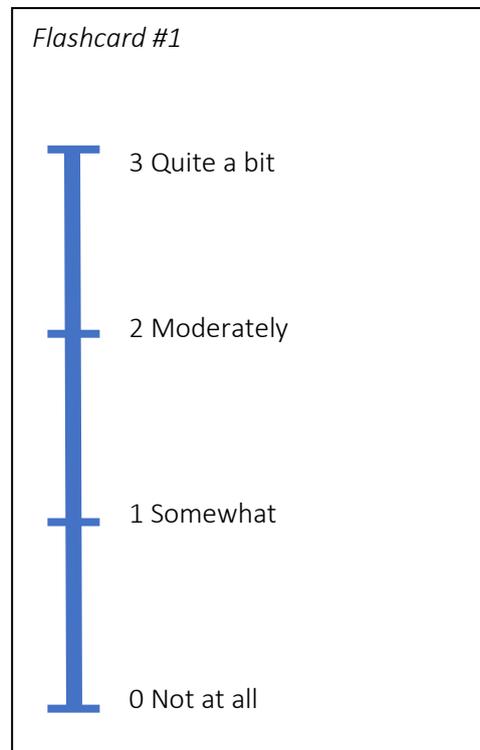
2.2 Pelvic Floor Impact Questionnaire (PFIQ)

With this questionnaire we want to learn how the experience of pelvic floor symptoms affects the participants activities, relationships, and feelings. The Pelvic Floor Impact Questionnaire (PFIQ) is asked to a subset of women at DYAD visit 3 if in the PFDI they responded that they have experienced a symptom and it bothers her "somewhat", "moderately" or "quite a bit".

The pelvic floor symptoms described in the PFDI are divided in three categories: bladder or urine, vagina or pelvis, and bowel or rectum. The PFIQ consists of questions relating to a particular scenario or area of the participants' life. For each question, the participant must consider how much her activities, relationships and feelings have been affected by the category of symptoms described in each question over the last 3 months.

The questions in the PFIQ questionnaire relate to the issues the woman reported have bothered her in the PFDI. For example, if the participant has experienced urinary symptoms only, the questions will display once and will only be related to her urinary/bladder symptoms. However, if she experienced urinary/bladder and bowel/rectum symptoms, each question will display twice: once for her to consider how her urinary/bladder symptoms affect her, and a second time for her to consider how her bowel/rectum symptoms affect her. It is important that you remind the woman to consider only the type of symptom that is described in each question.

Questions have four possible responses on a scale that ranges from “Not at all”, “Somewhat”, “Moderately” to “Quite a bit”. As with the PFDI, ask the woman to use the scale of severity in Flashcard #1 to indicate how much a symptom has affected her in the past three months.



Pelvic Floor Impact Questionnaire (PFIQ)	
	Please consider how much your activities, relationships or feelings have been affected by your bladder or urine symptoms or conditions over the last 3 months.
1	How do symptoms or conditions related to <i>bladder or urine / bowel or rectum / vagina or pelvis</i> usually affect your ability to do household chores (cooking, housecleaning, laundry)?
2	How do symptoms or conditions related to <i>bladder or urine / bowel or rectum / vagina or pelvis</i> usually affect your ability to do physical activities such as walking, swimming, or other exercise?
3	How do symptoms or conditions related to <i>bladder or urine / bowel or rectum / vagina or pelvis</i> usually affect your entertainment activities such as going to church or listen to a story?
4	How do symptoms or conditions related to <i>bladder or urine / bowel or rectum / vagina or pelvis</i> usually affect your ability to travel by car or bus for a distance greater than 30 minutes away from home?

5	How do symptoms or conditions related to <i>bladder or urine / bowel or rectum / vagina or pelvis</i> usually affect your participating in social activities outside your home?
6	How do symptoms or conditions related to <i>bladder or urine / bowel or rectum / vagina or pelvis</i> usually affect your emotional health (nervousness, depression, etc.)?
7	How do symptoms or conditions related to <i>bladder or urine / bowel or rectum / vagina or pelvis</i> usually affect your feeling frustrated?

You can probe the woman by saying something like: “You have previously mentioned that you have experienced XX and it bothers you. How does this affect your...”

Examples of *bladder or urine* symptoms are experiencing a feeling of incomplete bladder emptying, having trouble emptying her bladder, having to urinate frequently, experiencing urine leakage.

Examples of *bowel or rectum* symptoms are feeling that they have to push too hard to have a bowel movement, feeling that they have not completely emptied her bowels at the end of a bowel movement, losing gas or stool beyond her control, feeling pain when passing stool, experiencing a strong sense of urgency and having to rush to the bathroom to have a bowel movement.

Examples of *vagina or pelvic* symptoms are experiencing pain, discomfort or pressure in the pelvic area, lower abdomen or vagina, having a bulge in the vaginal area or having to push on a bulge around the vagina to complete a bowel movement or urination. Some of the vagina or pelvis symptoms overlap with symptoms from the other two categories. If a woman is bothered by symptoms that fall in two different categories, the PFIQ questions are displayed twice.

1. How do symptoms or conditions related to *bladder or urine / bowel or rectum / vagina or pelvis* usually affect your ability to do household chores (cooking, housecleaning, laundry)?

Possible response options: not at all, somewhat, moderately, quite a bit

We aim to know how the symptoms have affected the woman’s ability to do her usual household chores. You can probe the woman by asking her if she has experienced any difficulties in the past three months to do household chores. If she responds yes, you can follow-up by asking if her to what extent her symptoms have played a role. For example, it could be because she experiences pain, discomfort or involuntary loss of urine or stool when she strains herself.

2. How do symptoms or conditions related to *bladder or urine / bowel or rectum / vagina or pelvis* usually affect your ability to do physical activities such as walking, swimming, or other exercise?

Possible response options: not at all, somewhat, moderately, quite a bit

We aim to know how the symptoms have affected the woman’s ability to carry out physical activities. You can probe the woman by asking what sort of physical activities she usually does, and then ask her if the symptoms have affected her ability to do these in the past three months.

3. How do symptoms or conditions related to *bladder or urine / bowel or rectum / vagina or pelvis* usually affect your entertainment activities such as going to church or listen to a story?

Possible response options: not at all, somewhat, moderately, quite a bit

We aim to know how the symptoms have affected the woman's ability or desire to attend or take part in certain entertainment activities that take place in a public place over a somewhat extended period of time (around two hours). This could be because she is uncertain of the availability of toilet facilities or access to a private area, as well as the time it takes her to travel to the place where these activities take place

4. How do symptoms or conditions related to *bladder or urine / bowel or rectum / vagina or pelvis* usually affect your ability to travel by car or bus for a distance greater than 30 minutes away from home?

Possible response options: not at all, somewhat, moderately, quite a bit

We aim to learn how the symptoms have affected the woman's ability to cope with not having access to toilet facilities while traveling for more than 30 minutes.

5. How do symptoms or conditions related to *bladder or urine* usually affect your participating in social activities outside your home?

Possible response options: not at all, somewhat, moderately, quite a bit

We aim to learn how the symptoms have affected the woman's ability or desire to participate in social activities away from the comfort of her home. You can probe the woman by asking if she has attended a family or community gathering or celebration in the past three months. Then you can ask if her symptoms have affected her participation or enjoyment of the event in any way. You could also ask if in the past three months she has been mindful of her symptoms when planning to attend a social event or has avoided participating in social activities because of her symptoms.

6. How do symptoms or conditions related to *bladder or urine / bowel or rectum / vagina or pelvis* usually affect your emotional health (nervousness, depression, etc.)?

Possible response options: not at all, somewhat, moderately, quite a bit

We aim to learn how much the symptoms have played a part in her feeling stressed, anxious or depressed in the past three months.

7. How do symptoms or conditions related to *bladder or urine / bowel or rectum / vagina or pelvis* usually affect your feeling frustrated?

Possible response options: not at all, somewhat, moderately, quite a bit

We aim to learn whether these symptoms have caused the woman feelings of frustration or helplessness.