

Domain:	Reproductive Health
Measure:	Difficulty Getting Pregnant
Definition:	Methods to assess length of time male and female partners have been trying to get pregnant.
Purpose:	These methods ascertain whether a person and his or her partner are trying to become pregnant and how long they have been trying. Difficulty in conceiving may have genetic or epigenetic origins and is also related to lifestyle and environmental exposures.
Essential PhenX Measures:	Current Age Causes and Treatments of Known Infertility Gender Current Pregnancy Status
Related PhenX Measures:	Reproductive History, Contraceptive Methods, Hysterectomy and Oophorectomy, Prostate Symptoms
Keywords:	Reproductive health, difficulty conceiving, infertility, pregnancy, retrospective, prospective, PRESTO, subfertility, impaired fecundity
Measure Release Date:	February 26, 2010

Protocol Release Date:	February 26, 2010
PhenX Protocol Name:	Difficulty Getting Pregnant – Prospective
Protocol Name from Source:	PRESTO Study Female Screener and Baseline Questionnaire
Description:	<p>Depending on the aims of the project and feasibility, there are three widely used methods to assess difficulty getting pregnant or impaired fecundity. These include: retrospective assessment, prospective assessment, and the current duration approach.</p> <p>For the retrospective approach (also the approach used for cross-sectional studies), women or couples are asked if the pregnancy was planned and if yes, how many months it took to get pregnant. It is important to note that this approach can only be used with women/couples who planned their pregnancies.</p> <p>For prospective assessment, women/couples are followed over time as they try to get pregnant. Women/couples are asked to record exposure data, menstrual cycle data, intercourse, and pregnancy status prospectively over time. Again, this method can only be employed with women/couples who are planning a pregnancy.</p> <p>If investigators are interested in exposures among women/couples who are not</p>

	<p>planning a pregnancy, the current duration approach can be used. For this approach, women/couples are asked about the date that they last used contraception.</p>
<p>Specific Instructions:</p>	<p>The PhenX Expert Review Panel recommends this question be asked of either males or females, ages 15 and older.</p> <p>Women or couples who are trying to conceive are enrolled in a cohort study and followed over time so that time to pregnancy can be captured. For investigators interested in time-varying covariates, participants can be asked to complete daily diaries (see LIFE Study in general references). For those interested in more stable exposures, less frequent inquiry (e.g., every two months) is feasible. The following questions are from the PRESTO Study and administered less frequently. More details can be found in the referenced publications.</p>
<p>Protocol:</p>	<p><u> Screener and Baseline questions </u></p> <p>1. Are you currently in a stable relationship with a male partner? <input type="checkbox"/> YES...1 <input type="checkbox"/> NO...2 (END OF SCREENER)</p> <p>2. Are you currently pregnant? <input type="checkbox"/> YES...1 (END OF SCREENER) <input type="checkbox"/> NO...2 <input type="checkbox"/> Don't know...99</p> <p>3. Are you or your male partner currently using any form of birth control or protection against pregnancy? <input type="checkbox"/> YES...1 (Go to 5a) <input type="checkbox"/> NO...2</p> <p>4. Please give the approximate date when you stopped using all forms of birth control or protection against pregnancy: Month [Jan to Dec] (drop-down menu) Year [2010 to 2013] (drop-down menu)</p> <p>5. Are you currently trying to get pregnant? <input type="checkbox"/> YES...1 <input type="checkbox"/> NO...2 (Go to 5a)</p> <p>5a. When do you think you will start trying to become pregnant? (We will send you an invitation later to participate) About 1-2 months from now...1 (END OF SCREENER) About 3-4 months from now...2 (END OF SCREENER) About 5-6 months from now...3 (END OF SCREENER)</p> <p>5b. What is your e-mail address? _____</p>

6. For how many months? have you been trying to get pregnant?

|_|_| MONTHS

[If you have experienced a miscarriage before your current attempt to get pregnant, please state the number of months you have been trying since the miscarriage.]

7. Are you currently using any fertility treatments (e.g., clomiphene citrate (clomid), gonadotropins, donor insemination) or assisted reproductive technologies (e.g., in vitro fertilization)?

YES...1 **(END OF SCREENER)**

NO...2 **(go to next section)**

If respondent answers “NO (2)” to questions 1, or 5, “YES” to 2, 3 or 7, or is outside required age range, please write: “thank you for your interest – we are sorry, but you are not eligible for the present study at this time.” If 5a is completed, please write: “thank you for your interest – we will contact you in the near future and invite you to participate in our study.”

Baseline and Follow-up Questions

The next several questions are about your menstrual periods.

B1. Are you having your menstrual period right now?

YES ...1

NO 2(GO TO B3)

B2. What was the date it started?

Month [Jan to Dec] (drop-down menu)

Day [1 to 31] (drop-down menu)

Year [options: 2012, 2013, 2014] (drop-down menu:) (GO TO

B4)

[The first day of bleeding, not just spotting. If your period began yesterday or today, please provide yesterday or today’s date.]

DO NOT ALLOW FUTURE DATES. IF THEY GIVE A FUTURE DATE DO NOT LET WOMEN PROCEED WITH QUESTIONNAIRE.

B3. What was the date your last menstrual period started? (Please estimate exact date as best as you can)[The first day of bleeding, not just spotting.]

Month [Jan to Dec] (drop-down menu)

Day [1 to 31] (drop-down menu)

Year [2011, 2012, 2013, 2014—allow up to current year] (drop-down menu)

DO NOT ALLOW FUTURE DATES. IF THEY GIVE A FUTURE DATE DO NOT LET WOMEN PROCEED WITH QUESTIONNAIRE.

B4. How long do you expect it will be before you get your next period unless you become pregnant?

Less than 7 days...1

7-14 days...2

15-21 days...3

More than 21 days...4

B5. How many times have you had your menstrual period since you stopped using birth control or protection against pregnancy?

|_|_|

times

Don't Know...99

[Please only count the periods when you were actively trying to get pregnant. In addition, if you have experienced a miscarriage before your current attempt to get pregnant, please state the number of periods you have had since the miscarriage (subtracting off the periods when you weren't trying).]

B6. At what age did you have your first menstrual period?

____ (drop-down menu: range from 8 to 18)

AGE

B7. Did your period become regular on its own without the use of hormonal contraceptives like the pill, patch, implants, or injectables (regular in a way so you can usually predict about when the next period will start)?

YES...1

NO...2 (GO TO B12)

CANNOT SAY BECAUSE I WAS TAKING HORMONES MOST OF THE TIME...3 (GO TO B10)

B8. How old were you when your menstrual periods became regular?

|_|_| (drop-down: 8-21; GO TO B12)

AGE

Don't know...99 (GO TO B12)

Never became regular....90 (GO TO B12)

Deleted B9.

B10. What is the main reason you started using hormonal contraceptives?
(Check all that apply)

- To regulate my menstrual periods...1
- To prevent pregnancy...2
- To reduce menstrual pain...3
- To treat acne...4
- Other– What other reason?_____ ...5

Deleted B11.

B12. Within the past couple of years, has your menstrual period been regular?
Please think about those times you were **not** using hormonal
contraceptives?

- YES...1 (GO TO B14)
- NO...2 (GO TO B13)
- CANNOT SAY BECAUSE I WAS TAKING HORMONES MOST C
TIME...3 (GO TO B14)

[regular in a way that you could usually predict about when the next period
would start]

B13. What were the main reasons that your periods were irregular during this
time? (Check all that apply.)

I was not ovulating (GO TO B15)PCOS / Polycystic Ovary
Syndrome (GO TO B15)

- Hormonal abnormality (GO TO B15)
- Stress (GO TO B15)
- Exercise/Diet/Weight-related (GO TO B15)
- Pregnancy/Breastfeeding (GO TO B15)
- Other

Please Specify: _____ (GO TO B15)

- Don't Know (GO TO B15)

B14. Thinking about the time(s) when you have not used hormonal
contraceptives, what is your typical menstrual cycle length? That is,
the number of days from the **first day** of one menstrual period to the
first day of your next menstrual period?

DAYS ____ (GO TO B15) –
Don't Know...99 (GO TO B15)

[If you have a range of days, please pick midpoint of range. For example, if
your cycle ranges from 26-28 days, the midpoint would be 27 days.]

[If the number entered is less than 22 or above 40, the following will pop up:]
“Information on menstrual cycle length is very important for the accuracy of
this study. Please double check that you have entered your information

correctly.”]

B15. About how many menstrual periods do you have in one year (12 months)?

|_|_|
PERIODS

DON'T KNOW.....99

B16. How many days does your menstrual period usually flow (bleeding, not spotting)?

- Less than 3 days...1
- 3 days...2
- 4 days...3
- 5 days...4
- 6 days...5
- 7 or more days...6

B17. How would you classify the total amount of your menstrual flow?

- Light (10 or fewer pads or tampons per period)1
- Moderate (11 to 20 pads or tampons per period)2
- Moderate/heavy (21-30 pads or tampons per period)3
- Heavy (more than 30 pads or tampons per period)4

B18. Do you usually experience pain during your menstrual period? Please focus on the times when you were not using hormonal contraceptives.

- YES...1
- NO...2 (GO TO **END**)

B19. How much pain do you usually have with your menstrual period?

- Mild cramps, with medication seldom needed...1
- Moderate cramps, with medication usually needed...2
- Severe cramps, with medications and bed rest required...3

How to Calculate Time to Pregnancy

Time-to-pregnancy (TTP) was estimated by using data from the questionnaires completed by females (screening, baseline, and follow-up). Women reported their pregnancy attempt time (in months and in menstrual cycles) at baseline. Women who reported regular menstrual cycles (defined as being able to

	<p>“usually predict about when the next period will start”) were asked to report their usual menstrual cycle length. For women with irregular cycles, estimated cycle length was based on date of LMP at baseline and on prospectively-reported LMP dates during follow-up. TTP estimates were in cycles, using the following formula: [(menstrual cycles of attempt time at baseline) + [(LMP date from most recent follow-up questionnaire - date of baseline questionnaire)/cycle length] + 1].</p>
Selection Rationale:	These approaches were chosen to reflect the most modern widely accepted methods of measuring time to pregnancy.
Source:	Boston University PRESTO Study, Female Screener and Baseline Questionnaire
Life Stage:	Adolescent Adult
Language:	English
Participant:	Women age 21 to 45
Personnel and Training Required:	None
Equipment Needs:	If a computer-assisted instrument is used, computer software may be necessary to develop the instrument. The interviewer will require a laptop computer/handheld computer to administer a computer-assisted questionnaire.
General References:	<p>Buck Louis, G.M., Schisterman, E.F., Sweeney, A.M., Wilcosky, T.C., Gore-Langton, R.E., Lynch, C.D., Boyd Barr, D., Schrader, S.M., Kim, S., Chen, Z., Sundaram, R., on behalf of the LIFE Study. (2011). Designing prospective cohort studies for assessing reproductive and developmental toxicity during sensitive windows of human reproduction and development – the LIFE Study. <i>Paediatric and Perinatal Epidemiology</i>, 25(5): 413–424.</p> <p>Mikkelsen, E.M., Hatch, E.E., Wise, L.A., Rothman, K.J., Riis, A., Sørensen, H.T. (2009). Cohort Profile: The Danish Web-based Pregnancy Planning Study—“Snart-Gravid.” <i>International Journal of Epidemiology</i>, 38(4):938-943.</p> <p>Nguyen, R.H., Baird, D.D. (2005). Accuracy of men's recall of their partner's time to pregnancy. <i>Epidemiology</i>, 16(5):694-8.</p> <p>Slama R, Ballester F, Casas M, Cordier Set al., (2014). Epidemiologic tools to study the influence of environmental factors on fecundity and pregnancy-</p>

	<p>related outcomes. <i>Epidem Rev</i>, 36:148-64.</p> <p>Tingen, C., Stanford, J.B., Dunson, D.B. (2004). Methodologic and statistical approaches to studying human fertility and environmental exposure. <i>Environ Health Perspect</i>, 112(1):87-93.</p> <p>Weinberg, C.R., Baird, D.D., Wilcox, A.J. (1994). Sources of bias in studies of time to pregnancy. <i>Stat Med</i>. 13(5-7):671-81.</p>										
Mode of Administration:	Interviewer-administered questionnaire										
Derived Variables:	None										
Requirements:	<table border="1"> <thead> <tr> <th>Requirement Category</th> <th>Required</th> </tr> </thead> <tbody> <tr> <td>Major equipment</td> <td>No</td> </tr> <tr> <td>Specialized training</td> <td>No</td> </tr> <tr> <td>Specialized requirements for biospecimen collection</td> <td>No</td> </tr> <tr> <td>Average time of greater than 15 minutes in an unaffected individual</td> <td>No</td> </tr> </tbody> </table>	Requirement Category	Required	Major equipment	No	Specialized training	No	Specialized requirements for biospecimen collection	No	Average time of greater than 15 minutes in an unaffected individual	No
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	Specialized training	No									
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Annotations for Specific Conditions:	None at this time.										
Process and Review:	<p>The Expert Review Panel #5 (ERP 5) reviewed the measures in the Reproductive Health domain.</p> <p>Guidance from ERP 5 includes:</p> <ul style="list-style-type: none"> • Replaced the protocol (different source) <p>Not back-compatible, requires new Data Dictionary</p> <p>Previous version in Toolkit archive (link)</p>										