

Study of regulatory communication and risk awareness following the Article 31 referral of Combined Hormonal Contraceptives in relation to thromboembolism

**Semi-Structured Interview Topic Guide –
Women Version
(V1.1, UK/2017)**

Instructions

Preparation: Make sure the setting is private and quiet and that both you and the participant are comfortable.

Materials:

- This protocol, including the Socio-demographics form (i.e. ensure you use your country specific version)
- Audio recording equipment
- Patient information sheet and consent form

Label notes & recorded file: Your notes and the file with the recorded interview should be labelled as following: participant's initials and participant number; date of interview; your name; and location of interview.

Interview Strategy: This interview is meant to be an empathic conversation between you and the participant. It is best to start with an open-ended/relatively unstructured approach, and only impose structure if needed or the participant's answers become off-topic.

•Ask the participant to provide as many details as possible, using probes such as “anything else?”, “is there anything else you would like to add?”.

Introduction for the participant: The statement below includes the information that should be shared with participants prior to the interview and one example of how it can be verbalized.

“To facilitate our note-taking, our conversation will be audio-recorded. Only our research team will have access to the recordings, which will be destroyed after they are transcribed.

We encourage you not to mention any personal information during our conversation, but should you do so, we will remove it from the transcripts.

Before we start our conversation, it is important you take some time to read the participation information sheet. You may ask anything you want about the study and what your participation involves. If you agree with everything, we will ask you to sign a consent form confirming that you have accepted to participate in the study and understand what the study is about.

We would like to reassure you that your participation is completely voluntary. You are free to withdraw from our conversation at any time without any justification.

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PARTICIPANT ID

DATE

Whatever information you share with us will remain strictly confidential and will not be shared with any other party.

We have planned this interview to last approximately 30 minutes. During this time, we have several topics that we would like to cover, but you are free to provide any information you wish.”

PARTICIPANT ID

DATE

Interview Schedule

“There are currently thousands of women in the UK and abroad who are taking the pill but we do not know how and why people make that choice. During this conversation, we will talk about what you think about this and how you came to your decision about taking the pill.”

1. How do you make the choice about the type of contraceptive you take?
2. Did you consult any information source about contraceptives before making your choice?
3. Which information sources did you consult to make your contraceptive choice?
 - Health professionals
 - Internet websites
 - Written information in packs/leaflets
 - Other
4. All medications come with side-effects. Did you look for information about this?
5. Did you (and if so, how) discuss your contraceptive choice with your prescriber?
6. What makes you judge an information source as reliable?
7. Did the information you collected about the pill influence your choice?
8. Have you heard about any organisations that regulate medicines (such as the pill)?
9. Have you ever consulted any information provided by these regulators and how?
10. How did you become aware about these regulators and their information?
11. How would you like to be informed about the pros and cons of taking contraceptives?

(Stop the recording before moving to next section).

“Thank you for your time and help. Before we end the interview, we would just like to ask you some general questions for our statistics.”

PARTICIPANT ID

DATE

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Socio-demographics form

(To be completed by the researcher)

Age

1. Under 18 years old
2. 18-24 years old
3. 25-34 years old
4. 35-44 years old
5. 45-54 years old
6. 55-64 years old
7. 65-74 years old
8. 75 years or older

Ethnicity

*adapted from the Office for National Statistics (v3.3, May 2015)

1. White
 - a. English/ Welsh/ Scottish/ Northern Irish/ British
 - b. Irish
 - c. Gypsy, Traveller or Irish Traveller
 - d. Any other White background
2. Mixed/ Multiple ethnic groups
 - a. White and Black Caribbean
 - b. White and Black African
 - c. White and Asian
 - d. Any other Mixed/ Multiple ethnic background
3. Asian/ Asian British
 - a. Indian
 - b. Pakistani
 - c. Bangladeshi
 - d. Chinese
 - e. Any other Asian background
4. Black/ African/ Caribbean/ Black British
 - a. African
 - b. Caribbean
 - c. Any other Black/ African/ Caribbean background
5. Other ethnic group
 - a. Arab

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PARTICIPANT ID

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- b. Any other ethnic group

Employment status

1. Full time
 - a. Occupation _____
2. Part-time/casual
 - a. Occupation _____
3. Student
4. Unemployed
5. Other
 - a. Please specify _____

Education

- a. No qualification
- b. GCSE's / A levels
- c. Higher education diploma / degree
- d. Post-graduate education

PARTICIPANT ID

DATE