

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

Final report

December 2017

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# **PASS** information

| Title                             | Study of regulatory communication and risk awareness following        |  |  |  |
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| Joint PASS                        | Νο  |  |  |  |
| Research question and             | Do women and prescribers consider the risks of venous                 |  |  |  |
| objectives                        | thromboembolism when making decisions about the use of                |  |  |  |
|                                   | combined hormonal contraceptives and what sources of                  |  |  |  |
|                                   | information inform their assessments?                                 |  |  |  |
|                                   | Objectives  |  |  |  |
|                                   | 1. To consider the extent to which women and health                   |  |  |  |
|                                   | professionals are aware of the risks of venous                        |  |  |  |
|                                   | thromboembolism (VTE) in users of combined hormonal                   |  |  |  |
|                                   | contraceptives (CHC)  |  |  |  |
|                                   | 2. To document awareness, knowledge, attitudes and                    |  |  |  |
|                                   | practices related to recommendations from regulatory                  |  |  |  |
|                                   | authorities   |  |  |  |
|                                   | 3. To understand how advice from regulators concerning                |  |  |  |
|                                   | CHC, and specifically how the risks of VTE are                        |  |  |  |
|                                   | perceived? Is advice clearly communicated? Is it seen                 |  |  |  |
|                                   | as helpful? How could it be improved?                                 |  |  |  |
|                                   | <ol> <li>To document ways in which communications aimed at</li> </ol> |  |  |  |
|                                   | women and health care professionals from regulatory                   |  |  |  |
|                                   | authorities could be improved in the future                           |  |  |  |
|                                   |   |  |  |  |

| Country(-ies) of study | UK, Denmark, Germany, Slovakia, Netherlands, Spain |
|------------------------|--|
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# Marketing authorisation holder(s)

| Marketing authorisation holder(s) | Not applicable |
|-----------------------------------|----------------|
| MAH contact person                | Not applicable |

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# 1. Abstract

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

**Keywords:** Combined hormonal contraceptives; venous thromboembolism; information sources; patient-doctor communication.

**Rationale and background:** Research has demonstrated an increased risk of venous thromboembolism (VTE) in women using combined hormonal contraceptives (CHC) compared with non-users who are not pregnant. In spite of this, international regulators, such as the European Medicines Agency, have recommended that the benefits of using CHC outweigh its risks. Little is known about how this recommendation is translated into practice, namely, discussed between health professionals and women using CHC.

**Research question and objectives:** We aimed to explore to what extent women and prescribers of CHC consider the risks of venous thromboembolism when opting for CHC, as well investigating the information sources used during this process, the awareness and knowledge about the recommendations of regulatory authorities and how the communication between these authorities and women / health professionals could be improved.

**Study design:** This project followed a mixed-methods approach. The work comprised (i) an internet search of websites providing information about CHC and their risks, with particular reference to VTE; (ii) a qualitative study employing semi-structured interviews and (iii) a cross-sectional survey, conducted with women and health professionals.

**Setting:** Data was collected in six EU countries, namely, Denmark, Germany, the Netherlands, Slovakia, Spain and the United Kingdom. The internet search study was conducted online using the Google Search Engine. For the interviews and the survey, participants were recruited via social and professional networks in the six participating countries.

**Subjects and study size:** During the internet search study, 357 websites were identified and selected for review across the 6 EU countries; for the qualitative study, a total of 16 women and 16 health professionals were recruited in the UK and Denmark; and for the cross-sectional survey, a total of 1092 women and 51 health professionals were recruited from the UK, Denmark, Spain and Slovakia.

**Results:** Women tend to consider CHC to be safe in relation to VTE, however there are aspects (e.g. side-effects, how CHC work, what to do if a dose of CHC is missed) about which they would like to receive further information from their health professionals. Women tend to seek information prior to choosing CHC but most have never heard about health regulatory bodies. Health professionals tend to consider VTE an unlikely event following the use of CHC. They tend to use local and/or national documents to guide their clinical practice and consider communicating the risks of CHC to women to be a challenge, particularly during short appointments.

**Discussion:** Our findings suggest that health professionals can play a key role in communicating with women about CHC and its risks and that they need further support in this task. The dissemination of international guidance on CHC, such as that produced by EMA, could also be improved, to ensure that women across Europe are provided with similar standards of health care when it comes to contraception choices.

### Marketing Authorisation Holder(s): Not applicable.

Names and affiliations of principal investigators: Dr Fiona Stevenson, University College London.

# 2. List of abbreviations

| Abbreviation used | Full description                 |  |
|-------------------|----------------------------------|--|
| VTE               | venous thromboembolism           |  |
| СНС               | combined hormonal contraceptives |  |
| WP                | work packages                    |  |
| DVT               | deep vein thrombosis             |  |
| ЕМА               | European Medicines Agency        |  |
| EU                | European Union                   |  |

# 3. Investigators

| Country           | Local Research Teams   | Institution   |
|-------------------|--|---|
| ик                | Dr Paula Alves (research associate<br>for the project, RA); Dr Irene<br>Petersen |   |
| Denmark / Germany | Dr Vera Ehrenstein; Miss<br>Henriette Kristoffersen                              | Aarhus University   |
| Netherlands       | Dr Astrid Hylckama Vlieg   | Leiden University Medical Center                              |
| Spain             | Dr Maria del Mar Garcia Gil  | Sistema d' Informació per a la<br>Recerca en Atenció Primària |
| Slovakia          | Dr Iveta Rajničová Nagyová; Dr<br>Zuzana Katreniaková                            | Univerzita Pavla Jozefa Šafárika v<br>Košiciach               |

# 4. Other responsible parties

Not applicable.

# 5. Milestones

| Milestones               | Planned date | Actual date | Comments  |
|--------------------------|--------------|-------------|---|
| Start of data collection | January      | March       | This was due to the   |
|                          | 2017         | 2017        | research associate<br>contract with UCL starting<br>in January 2017, which<br>led to ethics approval<br>being granted at the end<br>of February 2017. |

| End of data collection        | August<br>2017   | December<br>2017 | This was due to delays in<br>obtaining ethical approval<br>in:<br>1)Slovakia (for the<br>interviews and the online<br>survey)<br>Expected approval date:<br>May 2017<br>Actual approval date:<br>October 2017<br>2)Spain (for the online<br>survey)<br>Expected approval date:<br>October 2017<br>Actual approval date: |
|-------------------------------|------------------|------------------|---|
| Registration in the EU        | October 2017     | October 2017     | November 2017<br>None.  |
| PAS register                  |                  |                  |   |
| Final report of study results | December<br>2017 | January<br>2018  | Agreed extension due to<br>contract being signed in<br>August 2016 when<br>academic lead was on<br>annual leave.  |

# 6. Rationale and background

Research has demonstrated an increased risk of venous thromboembolism (VTE) in women using combined hormonal contraceptives (CHC) compared with non-users who are not pregnant. A review from the European Medicines Agency (EMA) conducted in 2013 reported that the risk of VTE associated with the use of CHCs varies with the type of progesterone in the CHC. Despite the risks identified, the EMA Committee for Medicinal Products for Human Use (CHMP) concluded that the benefits of CHC in preventing unwanted pregnancy continue to outweigh the risks and also that these well-known risks are small.

The risks and the benefits associated with use of CHC have long been established. What is less clear is the extent to which this information is being used to give advice in practice. For instance, research suggests that women tended to have negative views about CHCs, but still chose them due to familiarity in comparison with other contraceptive methods (1,2,3). Research has also shown that women tend to be unable to identify non-contraceptive benefits of CHC or its severe health risks (4). Younger users of CHCs report feeling uncertain, anxious and afraid of using contraceptives (5). Previous studies have revealed, however, that providing counselling and/or information about CHCs to women are likely to improve their knowledge and support their decision-making process in relation to contraceptive choices and that over 30% of women select a different contraceptive method from that originally considered after receiving counselling (6,7).

There is a gap in evidence relating to awareness of the recommendations of EMA about the risk of VTE in users of CHC provided in 2013 and understanding of information sources, both formal and informal, used by women and practitioners. We also need to know the perceived influence of different information sources on both prescribing and use of CHC.

# 7. Research question and objectives

Our main research question was to explore to what extent women and prescribers consider the risks of venous thromboembolism when making decisions about the use of combined hormonal contraceptives and what sources of information inform their assessments. Our specific goals were as follows:

- To consider the extent to which women and health professionals are aware of the risks of venous thromboembolism (VTE) in users of combined hormonal contraceptives (CHC)
- To document awareness, knowledge, attitudes and practices related to recommendations from regulatory authorities
- To understand how advice from regulators concerning CHC, and specifically how the risks of VTE are perceived? Is advice clearly communicated? Is it seen as helpful? How could it be improved?
- To document ways in which communications aimed at women and health care professionals from regulatory authorities could be improved in the future

| Number | Date            | Section<br>of study<br>protocol | Amendment<br>or update   | Reason   |
|--------|-----------------|---------------------------------|--|--|
| 1      | October<br>2017 | 9.1                             | The survey was not<br>conducted in the<br>Netherlands and<br>Germany.  | We contacted our local research team in the<br>Netherlands in early October 2017 to<br>implement the survey. However, the local team<br>pointed out that the timeframe needed to<br>obtain approval from local ethics committee<br>was not compatible with our project deadlines.<br>In Germany, between September and<br>December 2017 several organisations were<br>contacted by the local and the UK research<br>team. However, no response was obtained by<br>any of these organisations.  |
| 2      | October<br>2017 | 9.1                             | For women, we<br>exceeded the<br>overall expected<br>sample size;<br>however, the<br>sample size for<br>health professionals<br>was below<br>expected. | Sample of women:<br>We expected to recruit approximately 100<br>respondents from each country. However in<br>Slovakia, Spain and the UK the response rate<br>was low, despite advertisements being sent to<br>universities, family planning associations and<br>online social networks. On the other hand,<br>there was recently a national study about<br>contraceptives in Denmark that draw attention<br>to this topic, which potentially resulted in a<br>very good response rate in this country (>800<br>women). As a result, even though we did not<br>achieve the expected sample per country, our |

# 8. Amendments and updates

|  | final aggregated sample was satisfactory.  |
|--|--|
|  | Health professionals sample:   |
|  | The expected sample size per country and<br>overall was low, despite invitations being sent<br>to several professional networks and national<br>organisations. For instance, in the UK, the<br>survey was advertised in the newsletter of the<br>Royal College of General Practitioners, which<br>reaches over 1000 professionals. To increase<br>the dissemination, the survey was also<br>distributed among social networks. |

# 9. Research methods

## 9.1. Study design

This project involved four main tasks; i) a literature review concerning communication between health professionals and women about the risks of CHC; ii) an internet search to establish the sources of information available to both health professionals and women concerning the risks of VTE associated with the use of CHC; iii) interviews with health professionals and women to explore knowledge of VTE related to use of CHC and views of sources of information about the risks of VTE associated with CHC and how this affects choices in relation to prescribing and use of CHC; and iv) an online survey aimed at women of childbearing age and health professionals to understand the range of information accessed and consider how regulators can help to ensure access to the most up to date evidence for both prescribing and use of CHC.

# 9.2. Setting

The aforementioned tasks were operationalised into seven work packages (WP):

#### WP1 – Literature review

The aim of this review was to assess current research evidence relating to the awareness of the risk of VTE among prescribers, potential users and users of CHC and how they communicate about these risks. This review was conducted by the UK research team, at UCL, between 26<sup>th</sup> January and 16<sup>th</sup> February 2017. For this, a search strategy was designed in collaboration with a librarian from the Royal Free Hospital UCL campus (where the UK research team is based).

#### WP2 – Internet search

The aim of this internet search was to identify the major online information sources that are available to women when they search for information about CHC and their risks. The internet search was conducted across six European Union Member States (Denmark, Germany, UK, Slovakia, The Netherlands and Spain), using the Google Search Engine, by the UK research team with the assistance of three additional research assistants, between 27<sup>th</sup> February and 6<sup>th</sup> March 2017. A specialised programme was used meaning that although the researchers were physically based in the UK, the search was conducted as if they were geographically located in the counties in which

they were conducting the search. A standardised internet search strategy was developed and used to ensure consistency across the searches in the different counties. This consisted of a step-by-step guide for the research assistants to follow, including relevant key words. The RA in London (PA) worked closely with the three research assistants to provide support and maximise the validity and comparability of the searches. The research assistants were all women aged over 18 years old with previous experience of using contraceptives and fluent in both English and one of the other languages relevant for this study (see below).

| Researcher II | Languages |         |         |         |           |         |
|---------------|-----------|---------|---------|---------|-----------|---------|
|               | Danish    | Dutch   | English | German  | Slovakian | Spanish |
| #1            | Native    |         | Native  | Fluent  |           |         |
|               | speaker   |         | speaker | speaker |           |         |
| #2            |           | Native  | Fluent  |         |           |         |
|               |           | speaker | speaker |         |           |         |
| #3            |           |         | Fluent  |         | Native    |         |
|               |           |         | speaker |         | speaker   |         |
| #4            |           |         | Fluent  |         |           | Fluent  |
|               |           |         | speaker |         |           | speaker |

#### WP3 – Semi-structured interview study with women

The aim of this study was to gather the perspectives of women of reproductive age regarding their contraceptive choice, the reasons for their choices and the information, if any, they had used to inform their choice. We also explored if they were familiar with regulators (such as EMA). As per our protocol, the interviews were conducted in Denmark and the UK between the 9th May and 7th August. Slovakia delivered the results in January 2018, which was too late for the report but will be included in publications.

#### WP4 – Semi-structured interview study with health professionals

The aim of this study was to gather the perspectives of health professionals who are prescribers of combined hormonal contraceptives regarding the sources of information they utilise and specifically about their familiarity with information from regulators such as the EMA. As per our protocol, the interviews were conducted in Denmark and the UK between the 9<sup>th</sup> May and 7<sup>th</sup> August. Slovakia failed to deliver results for interviews with health professionals and we are in negotiations as to whether this will be possible for inclusion in publications.

#### WP5 – Online survey with women

The aim of this study was to understand if women of reproductive age sought information when making decisions about CHC, and if so from where; their perceptions of risk in response to short scenarios based on previously collected interview data (WP3), awareness of information from the regulators such as the EMA and what optimal communication from regulators would look like. The survey was conducted in Denmark, UK, Slovakia and Spain between the 19<sup>th</sup> October and 15<sup>th</sup> December.

#### WP6 – Online survey with health professionals

The aim of this study was to understand the awareness of health professionals about regulatory communication about CHC, as well as to explore scenarios and suggestions for improvement in communication by regulatory authorities, based on previously collected interview data (WP4). The survey was conducted in Denmark, UK, Slovakia and Spain between the 19<sup>th</sup> October and 15<sup>th</sup> December.

#### WP7 – Preparation of project outputs

The aim of this final WP was to combine the findings of the previous 6 packages and to reflect on the awareness, perceptions and use of regulatory communication among health professionals and users of combined hormonal contraceptives, with a specific focus on the risks of venous thromboembolism. For this, we have prepared this final report and we are also working on two manuscripts for publication in peer-review journals.

#### 9.3. Subjects

This project involved the recruitment of various groups of people from the population to meet the requirements of each WP. These were as follows:

**WP1** – **Literature review** – Not applicable, since the study was a literature review which did not involve the participation of subjects.

**WP2** – **Internet search** – Not applicable, since the study was an internet search for websites about CHC and its risk.

**WP3 and WP5 – Interviews and survey with women –** The interviews and the online survey within these work packages involved the recruitment of women of childbearing age (between 16 and 49 years of age) who were users of CHC. For the interview study, women were recruited via social networks (e.g. Facebook) and through advertisement in local organisations, such as universities. For the survey, the link was distributed via social networks, universities and support groups.

**WP4 and WP6 – Interviews and survey with health professionals –** The interviews and the online survey within these work packages involved the recruitment of health professionals, namely, general practitioners, gynaecologists and specialist nurses who are prescribers of CHC. We included both male and female health professionals and no age limits were adopted. Health professionals were recruited via local professional networks and sexual health workshops. The link to the online survey was also distributed via professional networks and social networks.

**WP7** – **Project outputs** – Not applicable, since this work package aimed to aggregate all the findings of the project.

#### 9.4. Variables

Not applicable. The empirical research comprised a qualitative study and a cross-sectional survey

which derived from the qualitative data collected during those interviews. We did not seek to prove, disprove or investigate any particular outcomes, exposures, potential confounders or effect modifiers.

### 9.5. Data sources and measurement

This project collected data from various sources, namely:

**WP1** – **Literature Review** – For the literature review, we searched for papers in major international databases, namely, PubMed, EMBASE, Global Health Archive, MEDLINE, PSYCHINFO, Web of Science Core Collection, CINAHL and SCOPUS. Our search strategy was based on relevant MeSH words retrieved from PubMed which were combined using Boolean operators (see strategy below). Papers were screened and selected based on the following eligibility criteria: (i) focus on information sources used by women to make decisions about CHC OR information sources used by prescribers to advice women and awareness of VTE risks among women and prescribers; (ii) published between 2013 and 2017; (iii) studies conducted in European countries. The full search strategy is presented below.

#### SEARCH STRATEGY:

- 1. female\*.mp.
- 2. adult\*.mp.
- 3. exp adolescence/ or adolescen\*.mp.
- 4. teen\*.mp.
- 5. youth\*.mp.
- 6. female/
- 7. woman.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading]
- 8. women.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading]
- 9. exp patient/
- 10. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9
- 11. exp health care personnel/
- 12. exp medical staff/
- 13. exp nurse/
- 14. exp physician/
- 15. health care provider\*.mp.
- 16. exp general practitioner/
- 17. health care professional\*.mp.
- 18. prescriber\*.mp.
- 19. doctor\*.mp.
- 20. exp health practitioner/
- 21. health professional\*.mp.
- 22. family physician\*.mp.
- 23. 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22
- 24. exp oral contraceptive agent/ or exp oral contraception/
- 25. exp contraceptive agent/
- 26. reproductive control agents.mp.
- 27. hormonal oral contraceptive\*.mp.
- 28. female contraceptive agent\*.mp.
- 29. exp contraceptive agent/
- 30. exp hormonal contraception/ or exp contraception/ or exp oral contraception/
- 31. combined hormonal contracept\*.mp.

- 32. exp birth control/
- 33. exp female contraceptive device/ or female contracept\*.mp.
- 34. combined oral contracept\*.mp.
- 35. 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34
- 36. exp attitude to health/ or exp health education/
- 37. exp counseling/
- 38. exp consumer health information/ or exp medical information/
- 39. exp patient education/ or exp health literacy/
- 40. patient medication knowledge.mp.
- 41. health communicat\*.mp.
- 42. health knowledge.mp.
- 43. patient perception\*.mp.
- 44. health awareness.mp. or exp awareness/
- 45. health advice.mp.
- 46. inform\* source\*.mp.
- 47. contracept\* choice.mp.
- 48. patient drug knowledge.mp.
- 49. 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48
- 50. exp venous thromboembolism/
- 51. exp embolism/
- 52. exp thrombosis/
- 53. exp thromboembolism/
- 54. exp cardiovascular disease/
- 55. exp cardiovascular disease/
- 56. exp cardiovascular disease/
- 57. exp risk/ or exp risk factor/
- 58. exp side effect/ or adverse effect\*.mp.
- 59. undesirable effect\*.mp.
- 60. 50 or 51 or 52 or 53 or 54 or 55 or 56 or 57 or 58 or 59
- 61. 10 and 23 and 35 and 49 and 60 (i.e. combination of all terms above)

**WP2 – Internet search –** The internet searches were conducted using the Google Search Engine. The key words for this search were identified in collaboration with three lay females aged between 20 and 30 years old, who were asked the following question: "Which words would you use on google to search for information about the risks of blood clots when taking the pill?" The preliminary version of the search guide was then revised and piloted by one of the women, who commented on the clarity and the appropriateness of the language used in the guide. The final version of the guide was delivered on the 6th of March. The searches were conducted in the UK but a VPN service was used for remote access to local internet servers of each country. This ensured that the results were obtained as if they were searched locally in each country. Due to the large number of results available on Google, we limited our search to the first 10 pages of results. This limit was agreed between the research team because it is believed that in real-life searches it is unlikely that those searching for information will search further than this. For the internet search, initially the key words were translated to each target language and combined as shown below:

|                          | word |                                  |
|--------------------------|------|----------------------------------|
| 1.1 - The pill *OR*      |      | 2.1 - Blood clot *OR*            |
|                          |      |                                  |
| 1.2 - Combined pill      | AND  | 2.2 - Clot in vein *OR*          |
| *OR*                     | AND  |                                  |
| 1.3 - Contraceptive pill |      | 2.3 - Thrombosis *OR*            |
| *OR*                     |      |                                  |
| 1.4 - Contraceptive      |      | 2.4 - DVT (Deep vein thrombosis) |
| *OR*                     |      | *OR*                             |
| 1.5 - Birth control pill |      | 2.5 - Risk *OR*                  |
|                          |      | 2.6 - Side-effect                |

Before the search was conducted the fields "Language" (e.g. "Danish"), "Region" (e.g. "Denmark") and "Site or Domain" (e.g. ".dk") were filled in the "Advanced Search" menu of Google to narrow down the results and ensure that only results relevant for each country were selected. The websites to be reviewed were selected according to the following inclusion criteria: (i) to be a website targeting women and/or health professionals; (ii) to provide information about oral contraceptives, in particular CHC; and (iii) to discuss the risks of CHC, including blood clots. We excluded websites that were: (i) scientific electronic databases with links to publications about this topic; (ii) did not refer to CHC and/or its risks; (iii) had not been updated since 2013; and (iv) did not have a European scope (e.g. website written in English by an Australian association).

WP3 and WP5 - Interviews and survey with women - Qualitative and basic quantitative data were collected among women who are users of CHC. For qualitative data, individual semi-structured interviews were conducted. The interview protocol was designed by the UK research team in English and discussed with the study partners from Denmark and Slovakia in a joint Skype meeting. After the final version of the interview protocol was produced, translated and adapted into each country/language, a local PPI advisor (lay person) was asked to provide feedback about the clarity and appropriateness of the language used, and minor adjustments were made accordingly. All interviews were audio-recorded, transcribed verbatim and, whenever needed, translated into English. The UK version of the interview protocol is provided in the appendices (Appendix 1). Basic quantitative data were collected in the online survey. The survey was developed by the UK research team in English and discussed with the study partners from Denmark in a joint Skype meeting. After the final version of the survey was produced, it was sent out to our local study partners for translation and adaptation to each country, including the local language. All language versions of the survey were piloted by the local research teams before the final link to the survey was distributed. Survey responses from all the countries were electronically transferred into RedCap, a secure electronic database situated at UCL, in the UK. The UK version of the survey is provided in Appendix 2.

**WP4 and WP6 – Interviews and survey with health professionals –** Qualitative and basic quantitative data were also collected among health prescribers who are prescribers of CHC. For qualitative data, individual semi-structured interviews were conducted. The interview protocol was drafted by the UK research team in English and discussed with the study partners from Denmark and

Slovakia in a joint Skype meeting. Here we discussed the clarity and appropriateness of the language. After that, as in WP3, the final version of the interview protocol was translated and adapted for each country. All interviews were audio-recorded, transcribed verbatim and, as necessary, translated into English. The UK version of the interview protocol is provided in Appendix 3. Basic quantitative data were collected in the online survey. The survey was developed by the UK research team in English and discussed with the study partners from Denmark in a joint Skype meeting. After the final version of the survey was produced, it was sent out to our local study partners for translation and adaptation to each country. All language versions of the survey were piloted by the local research teams before the final link to the survey was distributed. Survey responses from all the countries were electronically transferred into RedCap, a secure electronic database situated at UCL, in the UK. The UK version of the survey is provided in Appendix 4.

## 9.6. Bias

Not applicable. Since our study did not follow an experimental design, i.e., did not aim to provide quantitative estimations of the effect of an intervention, or estimate whether there had been any potential factor (e.g. selection bias) resulting in deviation of our results from the "true values".

# 9.7. Study size

The expected study size for each work package was as follows:

**WP1 – Literature review –** This study comprised of a literature review and hence no sample size was expected.

**WP2 – Internet search –** This study comprised of an internet search and hence no sample size was expected.

**WP3 and WP5** – **Interviews and survey with women** – We aimed to recruit 24 women across three countries (Denmark, Slovakia and UK), which was the number estimated at which data saturation would be reached. For the survey, we expected to recruit a sample size of 600 women over the six participating countries (Denmark, Germany, Spain, Slovakia, The Netherlands and the UK).

**WP4 and WP6 – Interviews and survey with health professionals –** We aimed to recruit 24 health professionals across three countries (Denmark, Slovakia and UK), which was the number estimated at which data saturation would be reached. For the survey, we expected to recruit a sample size of 600 health professionals over the six participating countries (Denmark, Germany, Spain, Slovakia, The Netherlands and the UK).

# 9.8. Data transformation

Not applicable, since the project included basic quantitative descriptive information only (e.g. counts, percentages) which did not require any manipulation for subsequent analyses.

#### 9.9. Statistical methods

#### 9.9.1. Main summary measures

Qualitative data collected for this project were summarised and interpreted using thematic analysis. For quantitative data collected in the survey, basic descriptive measures such as mean and percentages were computed.

### 9.9.2. Main statistical methods

This project used only basic descriptive statistics to summarise the quantitative data from the survey conducted with women and health professionals.

### 9.9.3. Missing values

Not applicable, since no statistical tests were performed.

### 9.9.4. Sensitivity analyses

Not applicable, since no statistical tests were performed.

#### 9.9.5. Amendments to the statistical analysis plan

None.

#### 9.10. Quality control

Data collection and analysis were led by the UK team in order to ensure consistency across the countries. The UK team worked closely with other European partners with regular contact to ensure high quality data collection. The analysis was conducted by the local UK research team to ensure comparability and quality of analysis. The Principal Investigator (FS) and Research Associate (PA) met regularly and both the Principal Investigator and Research Associate took part in communications with other European partners.

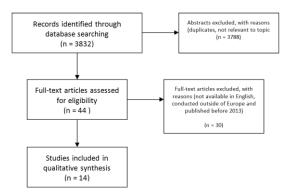
# 10. Results

The results obtained in each work package were as follows:

### 10.1. Participants

**WP1 – Literature search –** A total of 14 papers were selected for review in the electronic databases (see the flowchart below with details about the search strategy).

#### Figure 1: Flowchart with search strategy for literature review (WP1)



**WP2 – Internet search –** A total of 357 websites (see Appendix 5 for a full list) were identified and retrieved from Google across the six countries. The number of websites retrieved in each country was:

Table 1: Distribution of websites selected for review per country

| Country         | N websites selected | %  |
|-----------------|---------------------|----|
| UK              | 80                  | 22 |
| Denmark         | 82                  | 23 |
| Germany         | 113                 | 32 |
| Spain           | 22                  | 6  |
| The Netherlands | 38                  | 11 |
| Slovakia        | 22                  | 6  |
| Total           | 357                 |    |

**WP3 and WP5 – Interviews and survey with women –** A total of 16 women were interviewed across Denmark and the UK. The sample was judged to be sufficient in terms of data saturation as ongoing analysis found no new codes were identifiable at this point. A total of 1092 women from Denmark, Slovakia, Spain and the UK responded to the online survey.

**WP4 and WP6** – **Interviews and survey with health professionals** – A total of 16 health professionals were interviewed across Denmark and the UK. The sample was judged to be sufficient in terms of data saturation as ongoing analysis found no new codes were identifiable at this point. A total of 51 health professionals from Denmark, Slovakia, Spain and the UK responded to the online survey.

# 10.2. Descriptive data

**WP1 – Literature search –** Table 2 below presents the general characteristics of the studies that were included in the literature review. The majority were cross-sectional surveys which were conducted with women.

**Table 2:** General characteristics of the studies selected for the literature review (WP1)

| Study ID 🔻 Reference (first author, year) 🔻     | ▼                   | 🔻 Location (in Europe) 🔫                     | ▼ Target population ▼ Sample size |                            | <ul> <li>Study design</li> </ul> |
|---|---------------------|--|-----------------------------------|----------------------------|----------------------------------|
| 1 Reilhac et al. (2016)                         | health centres      | France                                       | doctors, women                    | 161 doctors, 631 women RCT | RCT                              |
| 2 Nappi, Kaunitz & Bitzer (2016)                | n/a                 | n/a  | n/a                               | 96 studies                 | literature review                |
| 3 Blidaru, Furau & Socolov (2016)               | university          | Romania                                      | women                             | 110                        | 1105 cross-sectional survey      |
| 4 Melki-Fed & Gruber (2014)                     | health centres      | Switzerland                                  | women                             | 103                        | 1032 pre/post study              |
| 5 Kucuk, Aksu & Sezer (2014)                    | health centres      | Turkey                                       | women                             | 41                         | 418 cross-sectional survey       |
| 6 Buhling et al. (2014)                         | online survey       | Germany                                      | doctors                           | 201                        | 2016 cross-sectional survey      |
| 7 Mansour (2014)                                | online survey       | France, Germany, Italy                       | women                             | 1205                       | 12094 cross-sectional survey     |
| 8 Gambera et al. (2015)                         | gyneacology centres | Italy  | women                             | 191                        | 1919 pre/post study              |
| 9 Dehlendorf, Krajewski & Borrero (2014) n/a    | n/a                 | n/a  | n/a                               | n/a                        | literature review                |
| 10 Jost et al. (2014)                           | postal survey       | France                                       | women                             | 596                        | 5963 cross-sectional survey      |
| 11 Egarter et al. (2013)                        | health centre       | Austria, Belgium, Czech Republic and S women | women                             | 1878                       | 18787 cross-sectional survey     |
| 12 Johnson, Pion & Jennings (2013)              | online survey       | UK, Germany, Italy, Spain                    | women                             | 254                        | 2544 cross-sectional survey      |
| 13 Denis, Storms, Peremans, Roven & Verho onlin | online survey       | Belgium                                      | men and women                     | 118                        | 1185 cross-sectional survey      |
| 14 Brynhildsen (2014)                           | n/a                 | n/a  | n/a                               | n/a                        | literature review                |

**WP2 – Internet search –** Tables 3 and 4 represent the general characteristics of the websites which were selected for this study. The majority of the websites targeting women were either media-

related (e.g. news agencies) or websites of medical organisations or services. Interactive websites, where readers could post questions and discuss topics with other individuals, were only found in Spain (n = 12, 55%) and the UK (n = 34, 43%), where approximately half of the websites were interactive. Reference was made to the EMA guidelines in Germany (n = 3, 3%), Spain (n = 1, 5%) and UK (n = 7, 9%).

| Target population          | Total    | Denmark | Germany  | Netherlands | Slovakia | Spain   | UK      |
|----------------------------|----------|---------|----------|-------------|----------|---------|---------|
| General population         | 81 (23)  | 1 (1)   | 5 (4)    | 19 (50)     | 1 (5)    | 10 (45) | 45 (56) |
| Health professionals       | 14 (4)   | 3 (4)   | 5 (4)    | 4 (11)      | 0 (0)    | 0 (0)   | 2 (3)   |
| Under 25s/youth/students   | 4 (1)    | 0 (0)   | 0 (0)    | 0 (0)       | 1 (5)    | 0 (0)   | 3 (4)   |
| Women                      | 237 (66) | 77 (94) | 102 (90) | 15 (39)     | 2 (9)    | 11 (50) | 30 (38) |
| Women/health professionals | 21 (6)   | 1 (1)   | 1 (1)    | 0 (0)       | 18 (52)  | 1 (5)   | 0 (0)   |

Table 3 – Number of websites by target population (%)

| <b>Table 4</b> – Number of websites by type (%) | Table 4 – | Number of websites b | by type (%) |
|---|-----------|----------------------|-------------|
|---|-----------|----------------------|-------------|

| Type of website                  | Total    | Denmark | Germany | Netherlands | Slovakia | Spain  | UK      |
|----------------------------------|----------|---------|---------|-------------|----------|--------|---------|
| Beauty/fitness/lifestyle website | 25 (7)   | 6(7)    | 15 (13) | 0 (0)       | 1 (5)    | 2 (9)  | 1 (1)   |
| Charity                          | 6 (2)    | 0(0)    | 1 (1)   | 3 (8)       | 0 (0)    | 0 (0)  | 2 (3)   |
| Health blog/network              | 26 (7)   | 4 (5)   | 5 (4)   | 2 (5)       | 3 (14)   | 4 (18) | 8 (10)  |
| Insurance services               | 1 (0)    | 0(0)    | 0 (0)   | 1 (3)       | 0 (0)    | 0 (0)  | 0 (0)   |
| Legal services                   | 2 (1)    | 0(0)    | 1 (1)   | 0 (0)       | 0 (0)    | 0 (0)  | 1 (1)   |
| Media                            | 110 (31) | 16 (22) | 42 (37) | 1 (3)       | 0 (0)    | 9(41)  | 42 (53) |
| Medical organisation/services    | 140 (39) | 54 (66) | 46 (41) | 7 (18)      | 18 (82)  | 2 (9)  | 13 (16) |
| National health service          | 5 (1)    | 0(0)    | 0 (0)   | 1 (3)       | 0 (0)    | 1 (5)  | 3 (4)   |
| Personal blog                    | 4 (1)    | 2 (2)   | 0 (0)   | 0 (0)       | 0 (0)    | 1 (5)  | 1 (1)   |
| Petition website                 | 1 (0)    | 0(0)    | 1 (1)   | 0 (0)       | 0 (0)    | 0 (0)  | 0 (0)   |
| Religious blog                   | 1 (0)    | 0(0)    | 0 (0)   | 0 (0)       | 0 (0)    | 0 (0)  | 1 (1)   |
| Science blog                     | 2 (1)    | 0(0)    | 1 (1)   | 0 (0)       | 0 (0)    | 0 (0)  | 1 (1)   |
| Support group                    | 33 (9)   | 0(0)    | 1 (1)   | 23 (61)     | 0 (0)    | 3 (14) | 6 (8)   |
| Travel blog                      | 1 (0)    | 0(0)    | 0 (0)   | 0 (0)       | 0 (0)    | 0 (0)  | 1 (1)   |

**WP3 – Interviews with women –** For the interview study with women, we interviewed 8 women in the UK and 8 in Denmark. Tables 5, 6, 7 and 8 below present the general socio-demographic characteristics of the respondents.

**Table 5** – Women by age group (N=16)

| Age group | N all (%) | n Denmark<br>(%) | n UK<br>(%) |
|-----------|-----------|------------------|-------------|
| < 18      | 1 (6)     | 1 (13)           | 0 (0)       |
| 18-24     | 7 (44)    | 3 (37)           | 4 (50)      |
| 25-34     | 5 (31)    | 2 (24)           | 3 (37)      |
| 35-44     | 1 (6)     | 1 (13)           | 0 (0)       |
| 45-54     | 2 (13)    | 1 (13)           | 1 (13)      |
|           | 16 (100)  |                  |             |

Table 6 – Women by ethnicity group (N=16)

| Ethnicity     | N all (%) | n Denmark<br>(%) | n UK (%) |
|---------------|-----------|------------------|----------|
| White British | 6 (38)    | 0 (0)            | 6 (74)   |
| Other White   | 1 (6)     | 0 (0)            | 1 (13)   |
| Asian Indian  | 1 (6)     | 0 (0)            | 1 (13)   |
| Danish        | 8 (50)    | 8 (100)          | 0 (0)    |
|               | 16 (100)  |                  |          |

## Table 7 – Women by educational level (N=16)

| Educational level                    | N all (%) | n Denmark<br>(%) | n UK<br>(%) |
|--------------------------------------|-----------|------------------|-------------|
| No qualification(s)                  | 4 (24)    | 4 (50)           | 0 (0)       |
| GCSEs / A levels                     | 2 (13)    | 2 (25)           | 0 (0)       |
| Higher education diploma<br>/ degree | 8 (50)    | 2 (25)           | 6 (75)      |
| Post-graduate education              | 2 (13)    | 0 (0)            | 2 (25)      |
|                                      | 16 (100)  |                  |             |

Table 8 – Women by employment status (N=16)

| Employment<br>status | N all (%) | n<br>Denmark<br>(%) | n UK<br>(%) |
|----------------------|-----------|---------------------|-------------|
| Full-time            | 6 (38)    | 2 (24)              | 4 (50)      |
| Part-                |           |                     | 0 (0)       |
| time/casual          | 3 (19)    | 3 (38)              |             |
| Student              | 7 (44)    | 3 (38)              | 4 (50)      |
|                      | 16 (100)  |                     |             |

**WP4 – Interviews with health professionals –** For the interview study with health professionals, we interviewed 8 professionals in the UK and 8 in Denmark. The majority of these professionals were women with a mean of 17 years (SD = 13) of clinical practice. Tables 9, 10 and 11 below present the socio-demographics of the respondents, and tables 12, 13 and 14 the general characteristics of their professional background.

Table 9 – Health professionals by gender (N=16)

| Gender | N all<br>(%) | n<br>Denmark<br>(%) | n UK<br>(%) |
|--------|--------------|---------------------|-------------|
| Female | 10 (63)      | 3 (37)              | 7 (87)      |
| Male   | 6 (37)       | 5 (63)              | 1 (13)      |
|        | 16 (100)     |                     |             |

| Age<br>group | N all (%) | n<br>Denmark<br>(%) | n UK<br>(%) |
|--------------|-----------|---------------------|-------------|
| 25-34        | 4 (25)    | 1 (13)              | 3 (37)      |
| 35-44        | 2 (13)    | 1 (13)              | 1 (13)      |
| 45-54        | 5 (31)    | 3 (37)              | 2 (24)      |
| 55-64        | 3 (19)    | 2 (24)              | 1 (13)      |
| 65-74        | 2 (12)    | 1 (13)              | 1 (13)      |
|              | 16 (100)  |                     |             |

Table 10 – Health professionals by age group (N=16)

Table 11 – Health professionals by ethnicity (N=16)

| Ethnicity     | N all (%) | n<br>Denmark<br>(%) | n UK<br>(%) |
|---------------|-----------|---------------------|-------------|
| White British | 5 (31)    | 0 (0)               | 5 (63)      |
| Other White   | 2 (13)    | 0 (0)               | 2 (24)      |
| Asian Indian  | 1 (6)     | 0 (0)               | 1 (13)      |
| Danish        | 8 (50)    | 8 (100)             | 0 (0)       |
|               | 16 (100)  |                     |             |

Tables 12 - Health professionals by type of practitioner (N=16)

| Type of<br>practitioner | N all (%) | n<br>Denmark<br>(%) | n UK<br>(%) |
|-------------------------|-----------|---------------------|-------------|
| Nurse                   | 4 (25)    | 0 (0)               | 4 (50)      |
| Doctor                  | 12 (75)   | 8 (100)             | 4 (50)      |
|                         | 16 (100)  |                     |             |

Table 13 – Health professionals by type of practice (N=16)

| Type of service           | N all (%) | n<br>Denmark<br>(%) | n UK<br>(%) |
|---------------------------|-----------|---------------------|-------------|
| General Practice          | 2 (13)    | 1 (13)              | 1 (13)      |
| Family Planning<br>Clinic | 2 (13)    | 0 (0)               | 2 (24)      |
| Sexual Health<br>Clinic   | 5 (31)    | 1 (13)              | 4 (50)      |
| Private Practice          | 6 (37)    | 6 (75)              | 0 (0)       |
| Other                     | 1 (6)     | 0 (0)               | 1 (13)      |
|                           | 16 (100)  |                     |             |

Table 14 – Health professionals by location of practice (N=16)

| Location of current practice | N all (%) | n<br>Denmark<br>(%) | n UK<br>(%) |
|------------------------------|-----------|---------------------|-------------|
| Urban                        | 10 (62)   | 4 (50)              | 6 (75)      |
| Suburban                     | 3 (19)    | 1 (13)              | 2 (25)      |
| Rural                        | 3 (19)    | 3 (37)              |             |

| 16 (100) |
|----------|
|----------|

**WP5 – Survey with women –** For the online survey, among the 1092 women that responded, 948 were from Denmark (response rate<sup>1</sup> 46%), 48 from Slovakia (response rate 18%), 18 from Spain (response rate 46%) and 78 from the UK (response rate 53%). Among these, the majority were taking CHCs, and approximately 20% were using other contraceptive methods (see Table 15). Tables 16, 17 and 18 below present the general characteristics of the respondents.

| Table 15 - Contraceptiv | e methods used by women | (N=1092) |
|-------------------------|-------------------------|----------|
|-------------------------|-------------------------|----------|

| Current contraceptive method         | N all (%)  | n<br>Denmark<br>(%) | n<br>Slovakia<br>(%) | n Spain<br>(%) | n UK<br>(%) |
|--------------------------------------|------------|---------------------|----------------------|----------------|-------------|
| Oral combined hormonal<br>"pill"     | 832 (76)   | 753 (79)            | 22 (46)              | 3 (17)         | 54 (69)     |
| Oral progestogen-only<br>"mini-pill" | 60 (6)     | 53 (6)              | 0 (0)                | 0 (0)          | 7 (9)       |
| Contraceptive implant                | 13 (1)     | 11 (1)              | 0 (0)                | 0 (0)          | 2 (3)       |
| Contraceptive patch                  | 3 (0)      | 1 (0)               | 0 (0)                | 0 (0)          | 2 (3)       |
| Contraceptive injections             | 5 (1)      | 2 (0)               | 2 (4)                | 0 (0)          | 1 (1)       |
| Intra-uterine devices                | 79 (7)     | 66 (7)              | 3 (6)                | 6 (33)         | 4 (5)       |
| Vaginal ring                         | 14 (1)     | 11 (1)              | 2 (4)                | 1 (6)          | 0 (0)       |
| Other                                | 86 (8)     | 51 (6)              | 19 (40)              | 8 (44)         | 8 (10)      |
|                                      | 1092 (100) |                     |                      |                |             |

 Table 16 - Women by age group (N=1092)

| Age                | N all (%)  | n<br>Denmark<br>(%) | n Slovakia<br>(%) | n Spain<br>(%) | n UK (%) |
|--------------------|------------|---------------------|-------------------|----------------|----------|
| Under 16 years old | 6 (1)      | 6 (1)               | 0 (0)             | 0 (0)          | 0 (0)    |
| 16-24 years old    | 803 (74)   | 754 (80)            | 15 (31)           | 2 (10)         | 32 (40)  |
| 25-34 years old    | 223 (20)   | 167 (17)            | 10 (21)           | 5 (28)         | 41 (53)  |
| 35-44 years old    | 38 (4)     | 20 (2)              | 11 (23)           | 5 (28)         | 2 (3)    |
| 45-49 years old    | 13 (1)     | 1 (0)               | 5 (10)            | 5 (28)         | 2 (3)    |
| No answer          | 9 (1)      | 0 (0)               | 7 (15)            | 1 (6)          | 1 (1)    |
|                    | 1092 (100) |                     |                   |                |          |

17 – Women by educational level (N=1092)

<sup>&</sup>lt;sup>1</sup> In this case, response rate refers to the proportion of people that opened the survey, in relation to those who opened it and completed it. Estimates of how many people found the advert but did not open the survey link cannot be ascertained.

| Education                       | N (all)    | n<br>Denmark<br>(%) | n<br>Slovakia<br>(%) | n Spain<br>(%) | n UK<br>(%) |
|---------------------------------|------------|---------------------|----------------------|----------------|-------------|
| No qualification                | 3 (0)      | 0 (0)               | 2 (4)                | 0 (0)          | 1 (1)       |
| Elementary/basic Education      | 156 (14)   | 154 (16)            | 2 (4)                | 0 (0)          | 0 (0)       |
| Secondary school/GCSE/A levels  | 396 (36)   | 365 (39)            | 18 (38)              | 3 (16)         | 10 (13)     |
| Higher education diploma/degree | 479 (44)   | 429 (45)            | 14 (29)              | 7 (39)         | 29 (37)     |
| Post-graduate Education         | 49 (5)     | 0 (0)               | 5 (10)               | 7 (39)         | 37 (48)     |
| No answer                       | 9 (1)      | 0 (0)               | 7 (15)               | 1 (6)          | 1 (1)       |
|                                 | 1092 (100) |                     |                      |                |             |

Table 18 – Women by employment status (N=1092)

| Employment<br>status | N all (%)  | n<br>Denmark<br>(%) | n<br>Slovakia<br>(%) | n Spain<br>(%) | n UK<br>(%) |
|----------------------|------------|---------------------|----------------------|----------------|-------------|
| Full-time            | 282 (26)   | 224 (24)            | 28 (58)              | 8 (44)         | 22 (28)     |
| Part-time            | 114 (10)   | 102 (11)            | 4 (8)                | 4 (22)         | 4 (5)       |
| Student              | 611 (56)   | 551 (57)            | 9 (19)               | 3 (17)         | 48 (62)     |
| Other                | 76 (7)     | 71 (8)              | 0 (0)                | 2 (11)         | 3 (4)       |
| No answer            | 9 (1)      | 0 (0)               | 7 (15)               | 1 (6)          | 1 (1)       |
|                      | 1092 (100) |                     |                      |                |             |

**WP6 – Survey with health professionals –** For the online survey, among the 51 health professionals that responded, 5 were from Denmark (response rate<sup>2</sup> 21%), 4 from Slovakia (response rate 67%), 31 from Spain (response rate 89%) and 11 from the UK (response rate 58%). Among these, the majority were either doctors or midwives practicing in Primary Care services in urban settings (see Tables 19, 20 and 21). Tables 22, 23 and 24 present the general socio-demographic characteristics of the respondents.

Table 19 – Health professionals by type of practitioner (N=51)

| Type of<br>practitioner | N all (%) | n<br>Denmark<br>(%) | n<br>Slovakia<br>(%) | n Spain<br>(%) | n UK<br>(%) |
|-------------------------|-----------|---------------------|----------------------|----------------|-------------|
| Nurse                   | 13 (26)   | 1 (20)              | 0 (0)                | 8 (26)         | 4 (36)      |
| Doctor                  | 19 (37)   | 4 (80)              | 4 (100)              | 4 (13)         | 7 (64)      |
| Midwive                 | 19 (37)   | 0 (0)               | 0 (0)                | 19 (61)        | 0 (0)       |
|                         | 51 (100)  |                     |                      |                |             |

Table 20 - Health professionals by type of current practice (N=51)

| Type of current<br>practice | N all (%) | n<br>Denmark<br>(%) | n<br>Slovakia<br>(%) |         | n UK (%) |
|-----------------------------|-----------|---------------------|----------------------|---------|----------|
| Primary Care                | 22 (43)   | 2 (40)              | 2 (50)               | 12 (39) | 6 (55)   |

 $<sup>^2</sup>$  In this case, response rate refers to the proportion of people that opened the survey, in relation to those who opened it and completed it. Estimates of how many people found the advert but did not open the survey link cannot be ascertained.

| Family planning clinic | 6 (12)   | 0 (0)  | 0 (0)  | 4 (13) | 2 (18) |
|------------------------|----------|--------|--------|--------|--------|
| Sexual health clinic   | 6 (12)   | 0 (0)  | 0 (0)  | 6 (19) | 0 (0)  |
| Private practice       | 12 (24)  | 0 (0)  | 1 (25) | 8 (26) | 3 (27) |
| Other                  | 1 (2)    | 1 (20) | 0 (0)  | 0 (0)  | 0 (0)  |
| University             | 3 (6)    | 2 (40) | 1 (25) | 0 (0)  | 0 (0)  |
| No answer              | 1 (2)    | 0 (0)  | 0 (0)  | 1 (3)  | 0 (0)  |
|                        | 51 (100) |        |        |        |        |

Table 21 – Health professionals by location of current practice (N=51)

| Location of<br>current<br>practice | N all (%) | n<br>Denmark<br>(%) | n<br>Slovakia<br>(%) | n Spain<br>(%) | n UK<br>(%) |
|------------------------------------|-----------|---------------------|----------------------|----------------|-------------|
| Urban                              | 42 (82)   | 5 (100)             | 3 (75)               | 28 (90)        | 6 (55)      |
| Suburban                           | 6 (12)    | 0 (0)               | 1 (25)               | 1 (3)          | 4 (36)      |
| Rural                              | 3 (6)     | 0 (0)               | 0 (0)                | 2 (7)          | 1 (9)       |
|                                    | 51 (100)  |                     |                      |                |             |

Table 22 – Health professionals by gender (N=51)

| Gender | N all (%) | n<br>Denmark<br>(%) | n Slovakia<br>(%) | n Spain<br>(%) | n UK (%) |
|--------|-----------|---------------------|-------------------|----------------|----------|
| Male   | 4 (8)     | 3 (60)              | 0 (0)             | 1 (3)          | 0 (0)    |
| Female | 47 (92)   | 2 (40)              | 4 (100)           | 30 (97)        | 11 (100) |
|        | 51 (100)  |                     |                   |                |          |

Table 23 – Health professionals by age group (N=51)

| Age             | N all (%) | n<br>Denmark<br>(%) | n<br>Slovakia<br>(%) | n Spain<br>(%) | n UK<br>(%) |
|-----------------|-----------|---------------------|----------------------|----------------|-------------|
| 25-34 years old | 1 (2)     | 0 (0)               | 0 (0)                | 0 (0)          | 1 (9)       |
| 34-44 years old | 17 (33)   | 3 (60)              | 4 (100)              | 10 (32)        | 0 (0)       |
| 45-54 years old | 19 (37)   | 2 (40)              | 0 (0)                | 9 (29)         | 8 (72)      |
| 55-64 years old | 14 (28)   | 0 (0)               | 0 (0)                | 12 (39)        | 2 (18)      |
|                 | 51 (100)  |                     |                      |                |             |

 Table 24 - Health professionals by employment status (N=51)

| Employment status | N all<br>(%) | n<br>Denmark<br>(%) | n<br>Slovakia<br>(%) | n Spain<br>(%) | n UK<br>(%) |
|-------------------|--------------|---------------------|----------------------|----------------|-------------|
| Full-time         | 47 (92)      | 5 (100)             | 4 (100)              | 31 (100)       | 7 (64)      |
| Part-time         | 3 (6)        | 0 (0)               | 0 (0)                | 0 (0)          | 3 (27)      |
| Student           | 1 (2)        | 0 (0)               | 0 (0)                | 0 (0)          | 1 (9)       |

| 51 (100) |  |  |  |
|----------|--|--|--|
|----------|--|--|--|

### 10.3. Outcome data

Not applicable, since we did not follow an experimental study design.

# 10.4. Main results

**WP1 – Literature review –** The literature review aimed to provide an account of what is known about the experiences of women when searching for information about CHC and its risks, as well as the decision-making process involved in choosing a contraceptive method. We were particularly interested in how women communication with health professionals during this process. The search was conducted to focus on studies published after 2013 as this was when the EMA published the most recent guidance on the risks of VTE associated with CHC. Overall, our review revealed that:

1. Despite guidance from the EMA women still tend to have limited knowledge about CHC and its risks

Several studies reported knowledge gaps among women that use CHC. For instance, in Belgium, a recent study has shown that four out of ten adolescent women (43%) did not know how to use CHC, for instance, that after using emergency contraception, they must return to their regular CHC on the same day (8). Similarly, in a French study by Jost et al. (9), only 63% of women considered themselves to have a good level of information about contraceptives on their first use. This is particularly relevant when it comes to the risks of CHC, as women have reported misconceptions in this regard (10).

2. Poor knowledge about contraceptives, in general, and CHC in particular, may result in dissatisfaction, incorrect use and non-compliance

Some studies have reported that women find CHC burdensome and would prefer to use a non-daily contraceptive, but still continue using CHC due to lack of knowledge about other options (11). Other studies (12) have reported that before receiving counselling about CHC, women tended to misunderstand aspects such as "How does the pill work", which may have an impact on how they use CHC.

3. Providing counselling about CHC is likely to increase knowledge and support the decisionmaking process about contraceptive methods

As a response to women having potentially poor knowledge about CHC, several studies emerged to explore the impact that counselling provision could have in improving this situation. The results were optimistic, with reports that providing structured and specific information about CHC was likely to improve women's knowledge about this contraceptive method (11, 12). Besides improving knowledge about CHC, providing counselling and information about CHC was also reported to improve women's decision-making process, by reinforcing their initial choice or, in some cases, encouraging them to opt for another method that is better suited to their needs and preferences.

For instance, in countries like Italy and Switzerland, it was shown that over 30% of women selected a different method from their original intention after counselling (13, 14). Moreover, in the European CHOICE study (15), a survey has shown that after receiving contraceptive counselling, women tended not to choose CHC due to its "daily use" and fear of "forgetting to take it".

### 1. The perceptions of health professionals about CHC tend to influence women's choices

As prescribers of CHC, health professionals communicate with women about their contraceptive choice. The extent and format of communication will vary at a national, local or even individual level. We found a limited number of studies about this topic. However, the literature suggests that the range of contraceptive choices used by health professionals in their personal life is likely to differ from those which they prescribe patients (16).

Overall, this initial literature review has revealed that women may have gaps in their knowledge regarding CHCs; but providing information and counselling about contraceptives is likely to improve their knowledge and support their decision-making. Communication with health professionals plays an important role in this process, since their perceptions about contraceptives are likely to influence women's choices.

**WP2 – Internet search –** For each website selected for review, researchers extracted qualitative information about their contents. A content analysis was conducted on the descriptive information provided on each website, from which 20 themes, or categories of information emerged (see table 25 below).

| Theme codes | Definition / explanation  |
|-------------|---|
| ADP         | Advantages/benefits about the pill  |
| AP          | Alternative contraceptive methods to using the pill   |
| BC          | Blood clots as risk   |
| BWER        | Bad/negative women experiences or reports about using the pill  |
| DC          | <b>D</b> octor <b>c</b> ommunication (i.e. the importance of talking with doctor about the pill)      |
| DP          | Disadvantages about the pill  |
| EA          | Emergency advice (e.g. warning symptoms, life-saving actions)   |
| EB          | Emphasis on beauty/lifestyle motives for using the pill (e.g. improving skin, hair)                   |
| FC          | <b>F</b> amily <b>c</b> ommunication (i.e. the importance of talking to family members, in particular |
|             | mothers, about the pill)  |
| GIP         | General information about the pill (e.g. history, how it works, how to take it)                       |
| IC          | Information about contraceptive methods in general  |
| MP          | Myths about the pill  |
| NBC         | No blood clots mentioned as a risk  |
| RD          | Resources for doctors (e.g. symptom checklists, procedures to adopt)                                  |
| RV          | <b>R</b> isk <b>v</b> ariations when using the pill (e.g. groups with higher risk, risk factors)      |
| SPD         | Suggests/advices pill is dangerous to use   |
| SPS         | Suggests/advices pill is safe to use  |
| VSE         | Various side-effects of the pill (besides blood clots)  |

 Table 25 – Themes (categories) covered by websites

| WP | Which is the most dangerous/safe type of pill |
|----|---|
| WW | Women worries about the pill                  |

Nearly all selected websites mentioned blood clots as a risk of taking CHC (n = 343, 96%) and just under half (n = 164, 46%) mentioned side-effects of CHC, other than blood clots, and general information about CHC (n = 151, 42%). Only a minority of websites referred to the importance of talking to health professionals about CHC (n = 23, 6%) (see Table 26)

 Table 26 - Themes covered by the selected websites across the six countries

| Themen $%$ n $%$ nn $%$ n $%$ nn $%$ nn $%$ n $%$ nn $%$ nn $%$ nn $%$ nn <th></th> <th>√î Total 👻</th> <th></th> <th>🔻 Denmark 👻</th> <th>P</th> <th><ul> <li>✓ Germany</li> </ul></th> <th></th> <th><ul> <li>Netherlands</li> </ul></th> <th>+</th> <th><ul> <li>✓ Slovakia </li> </ul></th> <th>S<br/>►</th> <th><ul> <li>✓ Spain </li> </ul></th> <th>→ UK</th> <th>►<br/>×</th> <th>•</th>   |          | √î Total 👻 |        | 🔻 Denmark 👻 | P   | <ul> <li>✓ Germany</li> </ul> |   | <ul> <li>Netherlands</li> </ul> | +       | <ul> <li>✓ Slovakia </li> </ul> | S<br>► | <ul> <li>✓ Spain </li> </ul> | → UK | ►<br>× | •   |
|--|----------|------------|--------|-------------|-----|-------------------------------|---|---------------------------------|---------|---------------------------------|--------|------------------------------|------|--------|-----|
| 80         22         26         32         24         21         61         42         0         2         9         1           8         41         11         13         16         22         13         16         22         13         06         2         0         0         2         0         0         1         55         0         0         0         2         0         0         0         0         2         0         0         0         2         0   | Theme    |            | %      |             | %   | u                             |   |                                 | %       |                                 |        |                              |      | %      |     |
| 41         11         13         16         22         19         10         1         5         0<  | ADP      | 80         | 22     |             | 32  |                               |   | 16                              | 42      |                                 | 0      | 2                            | 6    | 12     | 15  |
| R         343         96         78         95         113         100         37         97         19         86         22         100           6         5         1         5         1         1         17         15         10         26         0  | AP       | 41         | 11     |             | 16  |                               |   |                                 | 0       | -                               | 5      | 0                            | 0    | 5      | 9   |
| R         62         17         9         11         17         15         10         26         0<  | BC       | 343        | 96     |             | 96  |                               |   |                                 | 97      |                                 | 86     | 22                           | 100  | 80     | 100 |
| 23         6         5         6         13         12         0   | BWER     | 62         | 17     |             | 1   |                               |   |                                 | 26      |                                 | 0      | 0                            | 0    | 70     | 88  |
| 54         15         11         13         23         20         12         32         1         5         1  | DC       | 23         | 9      |             | e e |                               |   |                                 | 0       |                                 | 0      | 0                            | 0    | 5      | 9   |
| 65         18         26         32         23         20         5         13         2         9         0         0         0           1         1         0         1         1         15         1         15         1   | DP       | 54         | 15     |             | 10  |                               |   |                                 | 32      | -                               | 5      | 1                            | 5    | 9      | 8   |
| 18         5         0         17         15         10         0 <th>EA</th> <th>65</th> <th>18</th> <th></th> <th>32</th> <th></th> <th></th> <th></th> <th>13</th> <th></th> <th>6</th> <th>0</th> <th>0</th> <th>6</th> <th>11</th>              | EA       | 65         | 18     |             | 32  |                               |   |                                 | 13      |                                 | 6      | 0                            | 0    | 6      | 11  |
|  | EB       | 18         | 5      |             |     |                               |   |                                 | 0       |                                 | 0      | 0                            | 0    | -      | -   |
|  | Ъ<br>С   | -          | 0      | -           |     | 1                             |   |                                 | 0       |                                 | 0      | 0                            | 0    | 0      | 0   |
|  | GIP      | 151        | 42     |             | 65  |                               |   |                                 | 53      |                                 | 55     | 80                           | 36   | 27     | 34  |
|  | <u>ບ</u> | 26         | 7      |             | 1   |                               |   |                                 | ę       |                                 | 0      | 6                            | 41   | с      | 4   |
|  | MP       | 6          | ŝ      | -           | -   | 1                             | 1 | 2                               | 5       |                                 | 0      | ١                            | 5    | 4      | 5   |
| $ \begin{array}{ c c c c c c c c c c c c c c c c c c c$  | NBC      | 10         | r<br>r |             | 4   |                               |   | -                               | en<br>N |                                 | 14     | 0                            | 0    | 0      | 0   |
|  | RD       | e          | -      | 0           |     |                               |   |                                 | 0       |                                 | 0      | 0                            | 0    | 0      | 0   |
| 21         6         8         10         9         8         0         0         1         5         7         1         5         7         1         5         7         1         5         7         1         5         7         1         5         7         1         5         7         1         5         7         1         5         7         1         5         7         1         5         7         1         5         7         1         5         7         1         5         7         1         5         7         1         5         1         5         1         5         1         5         1         5         1         5  | RV       | 121        | 34     |             | 50  |                               |   |                                 | 11      | 5                               | 23     | 2                            | 6    | 16     | 20  |
| 35         10         18         22         14         12         1         3         0 </th <th>SPD</th> <th>21</th> <th>9</th> <th></th> <th>10</th> <th></th> <th></th> <th></th> <th>0</th> <th>1</th> <th>5</th> <th>1</th> <th>5</th> <th>2</th> <th>З</th>        | SPD      | 21         | 9      |             | 10  |                               |   |                                 | 0       | 1                               | 5      | 1                            | 5    | 2      | З   |
| 164         46         37         45         112         99         20         53         6         27         13         59         7           92         26         41         50         40         35         2         5         1         5         0   | SPS      | 35         |        |             | 22  |                               |   | 1                               | 3       |                                 | 0      | 0                            | 0    | 2      | 3   |
| 92         26         41         50         40         35         2         5         1         5         0 </th <th>VSE</th> <th>164</th> <th>46</th> <th></th> <th>46</th> <th></th> <th></th> <th></th> <th>53</th> <th></th> <th>27</th> <th>13</th> <th>59</th> <th>77</th> <th>96</th> | VSE      | 164        | 46     |             | 46  |                               |   |                                 | 53      |                                 | 27     | 13                           | 59   | 77     | 96  |
|  | WP       | 92         | 26     |             | 50  |                               |   |                                 | 5       | -                               | 5      | 0                            | 0    | 8      | 10  |
|  | WM       | 2          | -      | 0           | 0   |                               |   |                                 | 0       |                                 | 0      | 0                            | 0    | 2      | ς.  |

**WP3 – Interviews with women –** A thematic analysis conducted with the qualitative data generated from the interviews with women revealed several themes and sub-themes that represent the experience of women when searching for information about CHC and choosing to use this contraceptive method. Table 27 shows general socio-demographic characteristics of these women.

#### Table 27 – General characteristics of women interviewed (N=16)

|       |         | Age     |               |                                   | Employment       |                      |
|-------|---------|---------|---------------|-----------------------------------|------------------|----------------------|
| ID    | Country | (years) | Ethnicity     | Education                         | status           | Occupation           |
|       |         |         |               |                                   |                  | External Affairs     |
| W1-UK | UK      | 25-34   | Other White   | Post-graduate education           | Full-time        | Assistant            |
| W2-UK | UK      | 18-24   | White English | Higher education diploma / degree | Student          | Student              |
| W3-UK | UK      | 18-24   | White English | Higher education diploma / degree | Student          | Student              |
| W4-UK | UK      | 18-24   | White English | Higher education diploma / degree | Student          | Student              |
| W5-UK | UK      | 25-34   | Asian Indian  | Post-graduate education           | Full-time        | Researcher           |
| W6-UK | UK      | 25-34   | White English | Higher education diploma / degree | Full-time        | Volunteering Manager |
| W7-UK | UK      | 18-24   | White English | Higher education diploma / degree | Student          | Student              |
| W8-UK | UK      | 45-54   | White English | Higher education diploma / degree | Full-time        | Business Director    |
| W1-DK | Denmark | 18-24   | Danish        | No qualification(s)               | Student          | Student              |
| W2-DK | Denmark | 35-44   | Danish        | No qualification(s)               | Part-time/casual | Chef assistant       |
| W3-DK | Denmark | 25-34   | Danish        | Higher education diploma / degree | Full-time        | Chef                 |
| W4-DK | Denmark | 45-54   | Danish        | No qualification(s)               | Part-time/casual | Chef assistant       |
| W5-DK | Denmark | 18-24   | Danish        | GCSEs / A levels                  | Part-time/casual | Teaching assistant   |
| W6-DK | Denmark | 25-34   | Danish        | Higher education diploma / degree | Full-time        | Statistical analyst  |
| W7-DK | Denmark | < 18    | Danish        | No qualification(s)               | Student          | Student              |
| W8-DK | Denmark | 18-24   | Danish        | GCSEs / A levels                  | Student          | Student              |

The first theme referred to **knowledge and information sought by women prior to making their decision**. We found that some women 1) did not have information available to them (*There was a lot less availability of information from back then I just continued because it suited me*, W5, UK); 2) gained knowledge through their family/friends/peers (*I talked to my mother and she took the pill when she was young. I have received knowledge from my mother, I have not made a specific choice, but listened to my mother and her suggestions,* W8, Denmark); and 3) gained knowledge through websites (*I took a quick look online just before I went to the clinic to see what they had and stuff. So that was about it, yeah,* W4, UK). Specifically, in Denmark, some women reported gaining knowledge through schools (*Sex lessons in primary school (...) I remember that was a recurring event in primary school in week 6 each year,* W1, Denmark), whilst some women in the UK reported either not seeking information, or seeking minimal information about CHC (*I know it sounds weird but I didn't read up much about contraception at the time,* W1, UK).

The second theme encompassed **women's awareness of regulatory bodies**, in which we found information about women's level of interest, awareness and where they heard about these sources.

Due to our interest in this topic, women were prompted to discuss regulatory bodies if they did not raise them themselves during the interview (see Annex 1). Regarding **interest**, there were women having 1) no interest (I never thought about it. Maybe that will happen when I get older, I don't know, W7, UK); 2) interest for family reasons (Obviously when you have children with illnesses, you tend to google stuff (...) it is normally the NHS site that comes first and again probably the one I would trust, W8, UK); and 3) interest for double-checking purposes (I had mislaid the patient information leaflet and got onto the Danish Health and Medicine Authority's homepage to find it, W5, Denmark). In terms of **awareness**, there were women with 1) no awareness about any regulatory bodies (I probably read about it but I have not retained anything, W6, UK); and 2) awareness of national and/or international bodies (I know that the patient information leaflet must be approved by the public authorities and I think in Denmark that would be the Danish Health and Medicine Authority, W5, Denmark). When it comes to **where/how** women heard about these regulatory bodies, women referred to 1) their professional experience (Only on a professional basis because now I work as the external affairs assistant [of a sexual health organisation] so I had to learn all the different players, W1, UK); and 2) the media (I suppose in the news, if you listen to the news when they are talking about new drug developments and I have got a slightly scientific background myself, so, I am probably more aware of the news that are reported, regarding care and medicines, so I would probably have heard about them listening to Radio 4, W8, UK). In the UK, but not in Denmark, some women also reported having heard about health regulators through their family (In my family it is important to keep oneself informed and medication is important to stay updated, W5, UK).

The third theme related to the **process of choosing to take CHC**. We found information about the motivations and reasons behind their choice, the influences that they had and who suggested they should use CHC. When it comes to **women's motivations to use CHC**, women referred 1) to being in a relationship; 2) that it was the only method known; 3) to the "pill" as a modern thing to do; 4) to taking it to improve a condition; 5) to taking it to avoid pregnancy; 6) to taking it for a medical condition such as migraines; 7) to it as being the most convenient contraceptive method to take; 8) to it as being effective form of contraception; 9) to it in relation to friends were using it; 10) to the visibility of the "pill"; 11) to the "pill" as widely accepted; 12) to it as reversible; 13) to it as easy to access; and 14) to not wanting anything "inside" the body as in comparison with an implant. Regarding **influences**, women referred to 1) previous experiences of family/friends (*I feel like my* friends influenced me a lot more just because like, than the websites, because if you know someone who is on something you are more likely to do it yourself rather than something you haven't heard much about, W2, UK); 2) information provided by health professionals (I know that a lot is discussed and written on the internet about side effects, but as long as my GP thinks the pill is the best choice for me, I think I will continue using that, W3, Denmark); and 3) the internet (Before I started to take it, back at home, I double-checked online to see if anyone had had any like really bad experience, W7, UK). When it comes to the suggestion to use CHC, women reported choosing CHC 1) on their own (I decided which one I wanted to use (...) I went to the GP to get it, W2, UK); 2) co-jointly with the doctor (She obviously told me more what about the pill does, and I thought that was the best option, really, W3, UK); and 3) with friends (I did that together with my friends, W3, Denmark).

The fourth theme referred to awareness about the side-effects of CHC, about which women referred to the information that they searched about side-effects, their worries and changes in perception over time. When it comes to searching for information about CHC side-effects, women reported 1) not searching any further after speaking to the doctor (I spoke with my GP. I know there are side effects of all medicine but I trust my GP helps me make the right choice for me, W4, Denmark); 2) searching on the internet (I went to NHS choices and found that happens and what we experience, W2, UK); 3) talking to their friends/peers/family (My ex, the partner back then, he was a medical student, so he was pretty aware of these kinds of things and I remember that we talked a lot about vein thrombosis, W1, UK); and 4) reading the CHC leaflet (Yes, I read the patient information leaflet every year so I believe I know about the side effects and other things, W1, Denmark). Some women in Denmark, but not in the UK, reported having no interest in searching for it (No I haven't. Don't think it is something I have to relate to, W7, Denmark). Regarding women's worries about the side-effects of CHC, women reported 1) believing that CHC were safe (The pill works for me so why worry, W7, Denmark); 2) worrying about its effects on mood swings (I quit taking the pill five months ago, because I wanted to understand by myself if it had any effect, if it was making me feel down, and I think I noticed that I felt a little better without taking the pill, W1, UK); and 3) worrying about the interference of CHC with other clinical conditions (I had seizures and headaches so especially when they put me on the pill and some of them can give you really bad headaches and obviously I did not want to make something that I have already worse. So I definitely looked at them a lot, W4, UK). When it comes to changes in risk perception, women in the UK reported that their awareness increased with time and experience in using CHC (When I decided to take the pill, I wasn't really aware of all side-effects, I just knew about the one that happens very rarely which is deep vein thrombosis ( ... ) now I am much more aware of the effects that the pill might have on mood, W1, UK).

The fifth theme related to the **continued use of CHC**. Women referred to their experience with consultations, sources of information about CHC and changes in decisions to take CHC. When relating experience with consultations, women in the UK, (but not in Denmark), considered that 1) they tended to be brief and not enough (I remember that those consultations were very quick, they would ask some questions..., W1, UK); 2) limited in number over time (I could enter information and get the prescription renewed and I would only see another healthcare professional again after three years, W1, UK); and 3) did not discuss other methods (Literally in the last 10 years I was only given one leaflet by the GP about long-acting methods and that was the only time I looked at it, W5, UK). When it comes to sources of information about CHC, women either tended to search for information 1) by themselves (Generally I have looked at effectiveness and I have been fine with it so I just continued, W5, UK); or 2) jointly with a health professional (I talk to my GP about it each year or every two years and think he will keep me informed about what I need to know about the *pill*, W4, Denmark). Finally, when it comes to the **reasons why women might consider stopping** to take CHC, they referred to 1) taking less medication (I have gone through phases in which I considered taking less medication and I spoke to my GP about it, W5, UK); 2) stopping daily intake of contraceptives (Maybe I should change my contraception method to not have to take the pill every day, W6, UK); and 3) exploring other methods (The implant... I considered it because I work at X I know more about contraception, and I also considered the coil, W6, UK).

The sixth theme referred to communication with health professionals about CHC. Women talked about their interactions with professionals in their first consultation, the therapeutic alliance, level of satisfaction with information provided and information gaps. In relation to the first consultation about CHC, both British and Danish women felt that the interaction with the health professional was either 1) limited (I kind of just asked for the pill. I don't really think we had much of a conversation, W2, UK); or 2) satisfactory (I talked about it with my doctor and she obviously said that there's an injection option and other things, but I just chose the pill, W3, UK). Regarding therapeutic alliance, women either 1) had a trusting relationship with their CHC prescriber (*I have* not looked-for information elsewhere other than from my GP. I trust that he keeps me informed and would inform me if he thinks there is knowledge that I need to know of, W2, Denmark); or 2) were critical of the assumption that all women are happy to take CHC (Gynaecologists should discuss different options, instead of having assumptions that every woman wants the new generation pills, for example, W1, UK). When it comes to the satisfaction with information provided about CHC, women in Denmark reported dissatisfaction with the language used (The doctor talks as if I ought to know and that is not a nice feeling to have. It makes me feel stupid and ignorant, which I don't think I am, W3, Denmark); whilst women in the UK reported 1) receiving general information about CHC (The doctor told me a lot about it. I remember I went there wanting just the pill and not any other form of contraceptives, W2, UK); 2) receiving information about other contraceptive methods (The doctor gave me a lot of information on each type of contraceptive so that I could make an informed decision, W3, UK); 3) receiving leaflets (I think they did give me a leaflet to explain more but I really can't remember going into more detail, W6, UK). Women in Denmark, but not in the UK, reported receiving specific information about side-effects (My doctor informed me about the primary side effect which increased blood pressure and the risk of blood clots, W5, Denmark). Women in the UK also identified topics which they felt were not discussed, namely: 1) explanation of how CHC work; 2) information on side-effects; 3) personalised information; 4) alternatives to CHC; 5) emergency advice; 6) perception of CHC risk; 7) interaction of CHC with other medications/health conditions; 8) changes in CHC brand names. The women interviewed who were from Demark only reported missing information about the effects of CHC for general health care.

The seventh theme encompassed the preferences of women in terms of **formats for information provision about CHC**. For this purpose, women in the UK and Denmark mentioned 1) **leaflets** (*I guess it can complement what the doctor is saying because sometimes when you are in a consultation and they can talk and talk and you don't remember everything.*); 2) **websites** (*When things change, or need to be amended, it is just easier to do that online,* W5, UK); 3) **verbal discussions with health professionals** (*I depend on my GP informing me about what I need to know,* W4, Denmark); 4) **school education** (*Sex lessons and biology lessons in school also contribute with knowledge about the topic,* W1, Denmark); 5) **standardised letters sent by General Practitioners** to women (*You could inform every female who is listed with a doctor,* W6, *UK*); 6) **media** (*I would also like to be informed through the media if there is something I ought to know NOW,* W5, Denmark); and 7) other **women/peers** (*It would also be good to talk to people who use other methods as well... I don't know many people who use other methods, with my age, that actually... for instance, have an implant, and if they are happy or not happy about it. That is good, this kind of exchange in information,* W1, UK). The eighth and final theme discussed by British and Danish women was the reliability of information sources about CHC. For women, information is considered reliable when 1) it comes from a source that is well-known to general public (If I know the organisation than I would assume it is reliable, like national organisations, W6, UK); 2) it comes from individuals/institutions with reputation in the field (It would have to be material written by someone trustworthy, someone with a title that makes them worthy of my trust, W8, Denmark); 3) it comes from a health professional (If it's my doctor I trust them, W3, UK); 4) it comes from friends (To know your friends experience... I trusted them and I wanted to know what they thought, W2, UK); 5) it **does not use lay terms** (Language, it means a lot to me, it's a big one, so if I think it is written by a lay person or another non-professional I would not really..., W5, UK); 6) it uses scientific citations (If it has sources, studies referenced to and things that show where the information has come from, W5, UK); 7) it is written by clinicians (For example FPA, they don't have clinics linked to them but I presume they have some clinical person that they consult with to make sure that the information they are providing is accurate. So I suppose for me is having that clinical background, W6, UK); 8) it is the official medication leaflet (The patient information leaflet is always correct. I know that the company has to provide correct information and that authorities make sure they obey the rules, W5, Denmark); and 9) repeated across different sources (If I can find the same information on several sites then I have faith in it., W7, Denmark). On the other hand, unreliable sources are 1) those provided by newspapers / tabloid websites (Tabloids and how it affects your personal life, you know what I mean? Sometimes I feel like they are not completely accurate, W2, UK); 2) the subjective opinions of health professionals (I am aware that GPs say different things particularly like about contraception, W5, UK); and 3) other's experiences with CHC (I read a quite a lot of reviews online about things and I tried not to look at them too much because everyone is different and you don't know how you are going to be affected by them, W4, UK).

**WP4 – Interviews with health professionals –** A thematic analysis conducted with the qualitative data generated from the interviews with health professionals also revealed several themes and sub-themes that represent the experience of health professionals when providing information about CHC to women requesting contraceptive advice or prescriptions. Table 28 shows general socio-demographic characteristics of these health professionals.

| ID     | Country | Gender | Age   | Ethnicity     | Type of<br>practitioner | Experience<br>(years) | Type of practice       | Location<br>of practice |
|--------|---------|--------|-------|---------------|-------------------------|-----------------------|------------------------|-------------------------|
| HP1-UK | UK      | Female | 45-54 | Other White   | Doctor                  | 15                    | Sexual Health Clinic   | Urban                   |
| HP2-UK | UK      | Female | 25-34 | White English | Doctor                  | 9                     | Other                  | Urban                   |
| HP3-UK | UK      | Female | 25-34 | White English | Nurse                   | 3                     | Family Planning Clinic | Urban                   |
| HP4-UK | UK      | Male   | 65-74 | White English | Doctor                  | 41                    | Sexual Health Clinic   | Urban                   |
| HP5-UK | UK      | Female | 35-44 | White English | Doctor                  | 1                     | General Practice       | Urban                   |
| HP6-UK | UK      | Female | 45-54 | White English | Nurse                   | 20                    | Sexual Health Clinic   | Urban                   |
| HP7-UK | UK      | Female | 55-64 | Asian Indian  | Nurse                   | 30                    | Sexual Health Clinic   | Suburban                |
| HP8-UK | UK      | Female | 25-34 | Other White   | Nurse                   | 5                     | Family Planning Clinic | Suburban                |
| HP1-DK | Denmark | Male   | 45-54 | Danish        | Doctor                  | 18                    | Private Practice       | Rural                   |

Table 28 - General characteristics of health professionals interviewed (N=16)

| HP2-DK | Denmark | Female | 25-34 | Danish | Doctor | 2  | General Practice     | Rural    |
|--------|---------|--------|-------|--------|--------|----|----------------------|----------|
| HP3-DK | Denmark | Male   | 65-74 | Danish | Doctor | 32 | Private Practice     | Suburban |
| HP4-DK | Denmark | Female | 35-44 | Danish | Doctor | 9  | Private Practice     | Urban    |
| HP5-DK | Denmark | Male   | 55-64 | Danish | Doctor | 36 | Private Practice     | Rural    |
| HP6-DK | Denmark | Male   | 45-54 | Danish | Doctor | 13 | Sexual Health Clinic | Urban    |
| HP7-DK | Denmark | Male   | 55-64 | Danish | Doctor | 27 | Private Practice     | Urban    |
| HP8-DK | Denmark | Female | 45-54 | Danish | Doctor | 10 | Private Practice     | Urban    |

The first theme referred to the **information sources used to advise women about CHC**, in which health professionals discussed the sources that they use and those that they do not use but are aware of. Regarding the **sources used**, health professionals from both countries reported using 1) **national sexual health charities** and organisations (e.g. Family Planning Association); 2) **national health bodies** (e.g. Danish Health and Medicines Institute); 3) **peers**; 4) **conferences**; 5) **scientific publications**; 6) **drug companies** and 7) **patient groups**. In the UK, professionals also use **local resources** (e.g. guidelines produced by local clinical practice groups) and in Denmark some professionals reported relying only on their **own experience / knowledge**. When it comes to **awareness of other sources** not used in their practice, health professionals reported 1) not being aware of any; 2) knowing about the existence of electronic applications (*I think there are a lot of apps [applications] out there and other websites where you can get information from. I don't know specifically which ones they are using but I know some are using apps and internet to get information*, HP1, UK) and 3) knowing about other websites. In Denmark, some professionals also reported not having an interest or need to know about other sources (*I have a single practice and I stick with that*, HP5, Denmark).

The second theme referred to the **format used to communicate with women about CHC**. Health professionals reported using leaflets in the UK to 1) provide general information about the pill and 2) to help women retaining information (People can go home, and read it again, and it also can have links. Where I work, we have a link [on the leaflet] to information on the website, so everybody can go there and read through the different ways of taking the combined pill, HP1, UK); whereas in Denmark leaflets are used to complement verbal discussions (If they are in doubt about what they want or just want to think it over once more before making a decision, I give them some written information, HP4, Denmark); demonstrations and models of the pelvic area were reported by one health professional in the UK to explain the female anatomy; videos; websites are used in Denmark and the UK to 1) complement or substitute for the leaflet, 2) overcome language barriers, 3) explore specific clinical conditions, 4) provide general information about CHC, 5) help contextualising CHC risks (I think it gives you a good explanation of the risks of the pill because it's a difficult thing to communicate, the risks, and then at a follow-up consultation once they have some information and can put things in context then I go into risks in more detail, HP5, UK), 6) make information attractive, and 7) expand information about specific methods; verbal discussions are used in the UK to 1) listen to the woman and 2) to discuss contraception options; whereas in Denmark they are used to 1) evaluate the woman's level of knowledge about CHC, 2) understand the woman's motivations (Everyone comes in for an appointment and a talk about why they want to use contraceptives and all risk factors are reviewed and the women are screened to see if they *can have the pill. All this happens through oral communication, in the conversation at the appointment*, HP1, Denmark) and 3) discuss the pros and cons of CHC. In the UK, one professional has also mentioned recommending **mobile applications for telephones or tablets to manage CHC** daily intake.

The third theme encompassed the training received by health professionals to provide information and prescribe CHC, in which professionals discussed their training for qualifications, additional training received, type of training received and reasons to seek training. In terms of training towards qualifications, health professionals in our sample had 1) medical or nursing degrees; 2) medical degrees with a specialisation in gynaecology; or 3) nursing degree with a specialisation in sexual health. Regarding **additional training**, there were professionals 1) who had not engaged in any courses after their initial training (I remember some education from when I was in specialist training, but not other than that, HP7, Denmark); 2) who received updates in their practice (In the practice where I work, we regularly try to go through all our guidelines and when doing so we search for new knowledge and update, HP4, Denmark) and 3) who received additional training. Among these, the training had been 1) sought by the professional; 2) sought by the employer; 3) a joint decision of the professional and the employer; and 4) promoted by drug companies. In relation to the **type of training** received, professionals were either provided with 1) face-to-face/online modules about CHC; or 2) practice/learning by observation (e.g. internships) (So initially I would watch other practitioners and then they would watch me. So I suppose in that aspect *I* was learning how to do a consultation, HP3, UK).

The fourth theme referred to the contact with regulatory bodies about CHC, in which professionals discussed the regulators known to them, their interaction with these regulators, satisfaction with information provided and preferred formats of communication. When it comes to awareness, professionals identified local, national and also international regulators, namely, the EMA and WHO. In terms of **interaction** with regulators, some professionals reported not having had any experience of communicating or receiving information from them; whilst others referred to 1) electronic messages (We receive regular emails and we can access their page to check updates if we are not sure, HP7, UK), 2) conferences; 3) webinars (They also have webinars which actually I haven't quite managed to log in to but you know it's really good that you can get access to that information, HP6, UK), 4) magazines or 5) scientific publications as forms of communication. Regarding satisfaction with the amount of information received, professionals were satisfied with the frequency of messages received (I wouldn't like any more emails but I think it's quite a good way to be updated, but as I said, I wouldn't like to receive more than I do, HP1, UK) and reported wanting to be contacted mostly to provide information updates (Whenever something changes but otherwise I guess probably two or three times a year, probably. Because I wouldn't go and read all of their monthly updates, HP2, UK). Regarding their communication preferences, professionals were in favour of 1) presentations (I would prefer somebody presenting it to me because I find it easier to learn, HP1, UK); 2) electronic messages (I think emails are faster, so you definitely have the information straight away, HP7, UK); 3) magazines or paper copies of documents (To have it in your hand, rather than looking back through many millions of emails or you may have deleted it by accident. So it's good to have the paper copy to refer back to as when needed and also

is good for new students coming in that we can train them and give them this information as well, HP7, UK); 4) websites (I prefer it to be online and possibly as an app that is patient-friendly which I can refer to. I move around a lot, HP6, Denmark); 5) scientific journals, and 6) common platforms for professionals (I think it is important to get things incorporated in lægehåndbogen (The reference book doctors use). The layout is identical for all topics, we know that professionals wrote the texts and therefore it is possible to update oneself on all topics spending 2-3 minutes per topic. We know that doctors with specialty in each particular topic wrote the material, so if it is a question of updating all GPs in one area, I believe lægehåndbogen is the right place to start, HP1, Denmark).

The fifth and final theme was **challenges faced by health professionals when prescribing CHC**. In the UK, these were 1) lack of standardised guidelines/materials; 2) lack of information about continuous use of CHC; 3) the difficulties faced helping patients retain information; 4) difficultly in knowing if women use the resources offered; 5) short appointments; 6) not enough time for women to make informed decisions; 7) no training on how to inform women; 8) lack of economic resources to buy information materials; 9) a feeling that services may not match patient needs; 10) certain policies being hard to implement in practice; 11) lack of information about real effectiveness of CHC; 12) patients misperceptions about risk; 13) difficulties communicating about risks; 14) the feeling that patients underestimate risks; 15) lack of time to read guidelines; 16) respecting patient choice; 17) unreliable information provided online/media. In Denmark, professionals referred to 1) the need to personalise information provided to patients; and 2) the need for trusted sources.

**WP5** – **Survey with women** – The 1092 women in this survey had been using contraceptives, on average for 5 years (min=0, max=30 years, SD=4 years). The majority sought information about CHC before taking it, and most of these women consulted either health professionals or websites to search for this information. Most women reported having no knowledge about health regulators or health agencies. Only a small proportion were aware of the European Medicines Agency, mostly via the media or websites. Tables 29, 30, 31, 32 and 33 provide full data on this.

| Did you seek information<br>about CHC before you<br>decided to take it? | N all (%)  | n Denmark<br>(%) | n Slovakia<br>(%) | n Spain<br>(%) | n UK<br>(%) |
|---|------------|------------------|-------------------|----------------|-------------|
| Yes   | 725 (66)   | 614 (65)         | 31 (65)           | 12 (67)        | 68 (87)     |
| No  | 367 (34)   | 334 (35)         | 17 (35)           | 6 (33)         | 10 (13)     |
| Total   | 1092 (100) |                  |                   |                |             |

Table 29 - Women's interesting in seeking information on CHC prior to prescription (N=1092)

Table 30 – Sources used to seek information about CHC (n =739)

| Sources of<br>information – CHC | N all (%) | n Denmark (%) | n Slovakia (%) | n Spain (%) | n UK (%) |
|---------------------------------|-----------|---------------|----------------|-------------|----------|
|                                 |           |               | 18 (38)        | 2 (11)      | 15 (19)  |
| Websites                        | 242 (22)  | 207 (22)      | 4 (8)          | 5 (28)      | 15 (19)  |
| Friends/family/peers            | 134 (12)  | 110 (12)      | 4 (0)          | 5 (20)      | . ,      |
| Doctors/nurses/midwives         | 338 (31)  | 287 (30)      | 6 (13)         | 6 (33)      | 39 (50)  |

| Schools   | 11 (1)     | 9 (1)    | 1 (2)   | 0 (0)  | 1 (1)  |
|-----------|------------|----------|---------|--------|--------|
| Other     | 14 (1)     | 9 (1)    | 4 (8)   | 1 (6)  | 0 (0)  |
| No answer | 353 (33)   | 326 (34) | 15 (31) | 4 (22) | 8 (10) |
| Total     | 1092 (100) |          |         |        |        |

Table 31 – Awareness of the European Medicines Agency among women (N=1902)

| Have you heard of<br>the European<br>Medicines Agency? | N all (%)     | n Denmark (%) | n Slovakia (%) | n Spain (%) | n UK (%) |
|--|---------------|---------------|----------------|-------------|----------|
| Yes  | 187 (17)      | 114 (15)      | 17 (35)        | 13 (72)     | 13 (17)  |
| No   | 851 (78)      | 759 (80)      | 24 (50)        | 5 (28)      | 63 (80)  |
| Unsure   | 54 (5)        | 45 (5)        | 7 (15)         | 0 (0)       | 2 (3)    |
| Total  | 1092<br>(100) |               |                |             |          |

| Table 32 – Sources used to see | k information about the Europear | Medicines Agency (N=1902) |
|--------------------------------|----------------------------------|---------------------------|
|                                |                                  |                           |

| Sources of<br>information - EMA | N all (%)     | n Denmark (%) | n Slovakia (%) | n Spain (%) | n UK (%) |
|---------------------------------|---------------|---------------|----------------|-------------|----------|
| Websites                        | 38 (4)        | 21 (2)        | 10 (21)        | 3 (17)      | 4 (5)    |
| Friends/family/peers            | 17 (3)        | 13 1)         | 0 (0)          | 1 (6)       | 3 (4)    |
| Health professionals            | 25 (2)        | 17 (1)        | 1 (2)          | 6 (33)      | 1 (1)    |
| Schools                         | 59 (5)        | 54 (6)        | 3 (6)          | 1 (6)       | 1 (1)    |
| Media                           | 69 (6)        | 54 (6)        | 5 (10)         | 3 (17)      | 7 (9)    |
| No answer                       | 884 (80)      | 789 (83)      | 29 (60)        | 4 (22)      | 62 (80)  |
| Total                           | 1092<br>(100) |               |                |             |          |

Table 33 - Awareness of updates on CHC from health regulators among women (N=1092)

| Have you ever got<br>any information<br>from health<br>organisations or<br>medicines<br>regulators? | N all (%)  | n Denmark (%) | n Slovakia (%) | n Spain (%) | n UK (%) |
|---|------------|---------------|----------------|-------------|----------|
| Yes   | 340 (31)   | 312 (33)      | 2 (4)          | 2 (11)      | 24 (31)  |
| No  | 436 (40)   | 342 (36)      | 40 (80)        | 14 (78)     | 40 (51)  |
| Unsure  | 316 (29)   | 294 (31)      | 6 (13)         | 2 (11)      | 14 (18)  |
| Total   | 1092 (100) |               |                |             |          |

On a scale where 1 was "totally disagree" and 5 "totally agree, women were likely to report considering the risks of CHC; were more likely than not to report concerns about the risks of CHC; mostly agreed that CHC were safe to use; were more likely than not to report that the prescriber had informed them about what they needed to know; mostly reported they had not searched for information **before** taking CHC and were more likely to seek information **after** taking CHC; finally

women more frequently reported talking to their friends and family about CHC and reading the leaflets provided with CHC (see Table 34; appendix 6 provides more detailed information).

|                                | 1 = Totally<br>disagree | 2 = Slighlty<br>disagree | 3 = Not<br>agree or<br>disagree | 4 = Slighly<br>agree (%) | 5 = Totally<br>agree (%) |             |
|--------------------------------|-------------------------|--------------------------|---------------------------------|--------------------------|--------------------------|-------------|
|                                | (%)                     | (%)                      | (%)                             |                          |                          | M (SD)      |
| I have never considered the    |                         |                          |                                 |                          |                          |             |
| risks of the pill              | 387 (35)                | 332 (30)                 | 100 (9)                         | 179 (16)                 | 94 (10)                  | 2.32 (1.33) |
| I am concerned about the       |                         |                          |                                 |                          |                          |             |
| side-effects from the pill     | 156 (14)                | 230 (21)                 | 197 (18)                        | 326 (30)                 | 183 (17)                 | 3.14 (1.31) |
|                                |                         |                          |                                 |                          |                          |             |
| The pill is safe to use        | 57 (5)                  | 156 (14)                 | 212 (19)                        | 496 (46)                 | 171 (16)                 | 3.52 (1.07) |
| The person who prescribed      |                         |                          |                                 |                          |                          |             |
| me the pill told me all I      |                         |                          |                                 |                          |                          |             |
| needed to know                 | 82 (8)                  | 137 (12)                 | 147 (14)                        | 300 (28)                 | 426 (38)                 | 3.78 (1.28) |
| I searched the web to find     |                         |                          |                                 |                          |                          |             |
| information about the risks of |                         |                          |                                 |                          |                          |             |
| the pill BEFORE taking it      | 389 (36)                | 139 (13)                 | 102 (9)                         | 163 (14)                 | 299 (28)                 | 2.86 (1.66) |
| I searched the web to find     |                         |                          |                                 |                          |                          |             |
| information about the risks of |                         |                          |                                 |                          |                          |             |
| the pill AFTER taking it       | 255 (24)                | 124 (11)                 | 163 (15)                        | 285 (26)                 | 263 (24)                 | 3.16 (1.51) |
| I talked to my                 |                         |                          |                                 |                          |                          |             |
| friends/family/peers about the |                         |                          |                                 |                          |                          |             |
| pill                           | 91 (8)                  | 57 (5)                   | 93 (8)                          | 311 (29)                 | 540 (50)                 | 4.05 (1.24) |
|                                |                         |                          |                                 |                          |                          |             |
| I read the leaflet in the box  | 113 (10)                | 68 (7)                   | 54 (5)                          | 197 (18)                 | 659 (60)                 | 4.12 (1.35) |

Table 34 – Beliefs, behaviours and attitudes when searching for information about CHC

When it comes to receiving information about CHC and its risks, women tended to prefer verbal discussions with their health professionals, followed by websites. Education about sexual health education at schools and information from regulatory authorities about health were considered as the least important formats to gain information about CHC (see Table 35).

Table 35 – Preference about formats of information provision about CHC

| Format of information provision             | More important |      | Least important |      |  |
|---|----------------|------|-----------------|------|--|
|   | N (all)        | %    | N (all)         | %    |  |
| Leaflets                                    | 73             | 6.7  | 200             | 18.3 |  |
| Websites                                    | 179            | 16.4 | 124             | 11.4 |  |
| Regulatory authorities                      | 42             | 3.8  | 244             | 22.3 |  |
| Verbal discussions with health professional | 665            | 60.9 | 207             | 19.0 |  |
| Education about relationships in school     | 105            | 9.6  | 268             | 24.5 |  |

Finally, when asked about their risk perception about experiencing a CHC-related VTE, on a scale from 1 ("extremely unlikely") to 10 ("extremely likely"), more women judged the risk to be unlikely than judged it to be likely (see Table 36).

| Risk perception - women<br>(1-10) | n Denmark<br>(%) | n Slovakia<br>(%) | n Spain (%) | n UK (%) |
|-----------------------------------|------------------|-------------------|-------------|----------|
|                                   |                  |                   |             |          |
| 1 = Extremely unlikely            | 97 (10)          | 2 (4)             | 2 (11)      | 8 (10)   |
| 2                                 | 183 (19)         | 4 (8)             | 3 (17)      | 22 (28)  |
| 3                                 | 219 (23)         | 3 (6)             | 4 (22)      | 26 (34)  |
| 4                                 | 125 (13)         | 2 (4)             | 2 (11)      | 7 (9)    |
| 5                                 | 140 (15)         | 11 (23)           | 1 (6)       | 5 (6)    |
| 6                                 | 74 (8)           | 5 (10)            | 2 (11)      | 5 (6)    |
| 7                                 | 49 (5)           | 3 (6)             | 2 (11)      | 4 (5)    |
| 8                                 | 40 (4)           | 7 (15)            | 1 (6)       | 1 (1)    |
| 9                                 | 6 (1)            | 1 (2)             | 1 (6)       | 0 (0)    |
| 10 = Extremely likely             | 15 (2)           | 10 (21)           | 0 (0)       | 0 (0)    |
| No answer                         | 5 (1)            | 0 (0)             | 0 (0)       | 53 (68)  |
| Total N of respondents            | 948 (100)        | 48 (100)          | 18 (100)    | 78 (100) |

Table 36 – Women's perception of the risk of developing a CHC-related VTE

**WP6 Survey with health professionals** – The 51 health professionals in this survey had been prescribing CHC on average for 20 years (min=0, max=44 years, SD=11 years). When providing information about CHC to women professionals reported relying on national guidelines. Scientific publications, on the other hand, were the least used format. Regarding the formats in which this information is shared with women, professionals tend to prefer leaflets and were less in favour of verbal conversations (see Tables 37 and 38).

Table 37 – Sources used by health professionals to provide information about CHC (N=51)

| Sources of information |      |       |
|------------------------|------|-------|
| about CHC              | Most | Least |
| used                   | used | used  |

|                 |         | n       | n        | n Spain | n UK   |        | n       | n        | n      | n UK   |
|-----------------|---------|---------|----------|---------|--------|--------|---------|----------|--------|--------|
|                 | N all   | Denmark | Slovakia | (%)     | (%)    | N all  | Denmark | Slovakia | Spain  | (%)    |
|                 | (%)     | (%)     | (%)      |         |        | (%)    | (%)     | (%)      | (%)    | a (a)  |
| Own             |         |         |          |         |        |        | 0 (0)   | 0 (0)    | 5 (16) | 0 (0)  |
| knowledge       | 9 (18)  | 1 (20)  | 3 (75)   | 2 (7)   | 3 (27) | 5 (10) |         |          |        |        |
| latomeage       | J (10)  | 1 (20)  | 5 (75)   |         | 5 (27) | 5 (10) | 0 (0)   | 0 (0)    | 2 (6)  | 0 (0)  |
| National        |         |         |          |         |        |        | - (-)   | - (-)    | - (-)  | - (-)  |
| guidelines      | 21 (41) | 3 (80)  | 0 (0)    | 13 (42) | 5 (46) | 2 (4)  |         |          |        |        |
| International   |         |         |          |         |        |        |         |          | 2 (6)  | 1 (9)  |
| guidelines      | 5 (10)  | 0 (0)   | 1 (25)   | 4 (13)  | - (-)  | 5 (10) | 2 (40)  | - (-)    | - (-)  |        |
| Sexual health   |         | 0 (0)   | 0 (0)    | 0 (0)   | 0 (0)  |        | 0 (0)   | 0 (0)    | 0 (0)  | 1 (9)  |
| charities       | 0 (0)   | 0 (0)   | 0 (0)    |         |        | 1 (2)  | 0 (0)   | 0 (0)    | 1 (2)  | 1 (0)  |
| Professional    | 7 (1 4) | 0 (0)   | 0 (0)    | 5 (16)  | 3 (18) | 2 (1)  | 0 (0)   | 0 (0)    | 1 (3)  | 1 (9)  |
| bodies          | 7 (14)  | 0 (0)   | 0 (0)    | 5 (10)  | 5 (10) | 2 (4)  |         | 0 (0)    | 0 (0)  | 1 (0)  |
|                 | C (11)  | 0 (0)   | 0 (0)    | 5 (16)  | 1 (9)  | 2 (4)  | 1 (20)  | 0(0)     | 0 (0)  | 1 (9)  |
| Local resources | 6 (11)  | 0 (0)   | 0 (0)    | 0 (0)   | 0 (0)  | 2 (4)  | 1 (20)  | 0 (0)    | 0 (0)  | 3 (27) |
| Peers           | 1 (2)   | 0(0)    | 0(0)     | 0(0)    | 0(0)   | 4 (8)  | 1 (20)  | 0(0)     | 0(0)   | 5 (27) |
| reels           | 1 (2)   | 0 (0)   | 0 (0)    |         |        | 4 (0)  | 0 (0)   | 0 (0)    | 1 (3)  | 0 (0)  |
| Conferences     | 1 (2)   | 0(0)    | 0(0)     | 1 (3)   | 0 (0)  | 1 (2)  | 0(0)    | 0 (0)    | 1 (3)  | 0(0)   |
| Scientific      | 1 (2)   | 0 (0)   | 0 (0)    | - (-)   | - (-)  | 10     |         | 0 (0)    | 6 (19) | 3 (27) |
| publications    | 1 (2)   | 0 (0)   | 0 (0)    | 1 (3)   | 0 (0)  | (20)   | 1 (20)  | 0 (0)    | 0 (10) | 0 (_/) |
| Drug            | - (-)   | 0 (0)   | 0 (0)    | 0 (0)   | 0 (0)  | (==)   | 0 (0)   | 1 (25)   | 2 (6)  | 0 (0)  |
| companies       | 0(0)    | ,       | ( )      | ( )     |        | 3 (6)  | ( )     | . ,      |        | . ,    |
|                 | 0 (0)   | 0 (0)   | 0 (0)    | 0 (0)   | 0 (0)  |        | 0 (0)   | 0 (0)    | 2 (6)  | 0 (0)  |
| Patient groups  | . ,     |         | . ,      |         | . ,    | 4 (8)  |         |          | . ,    | . ,    |
|                 | 0 (0)   | 0 (0)   | 0 (0)    | 0 (0)   | 0 (0)  |        | 0 (0)   |          | 2 (6)  | 1 (9)  |
| Other           |         |         |          |         |        | 5 (10) |         | 3 (75)   |        |        |
|                 | 0 (0)   | 0 (0)   | 0 (0)    | 0 (0)   | 0 (0)  |        |         |          |        |        |
| No answer       |         |         |          |         |        | 7 (14) | 0 (0)   | 0 (0)    | 7 (23) | 0 (0)  |
|                 | 51      |         |          |         |        | 51     |         |          |        |        |
|                 | (100)   |         |          |         |        | (100)  |         |          |        |        |

Table 38 - Formats preferred by health professionals to provide information about CHC (N=51)

|                       | Most<br>important |                     |                      |                |             | Least<br>important |                     |                      |                |          |
|-----------------------|-------------------|---------------------|----------------------|----------------|-------------|--------------------|---------------------|----------------------|----------------|----------|
|                       | N all (%)         | n<br>Denmark<br>(%) | n<br>Slovakia<br>(%) | n Spain<br>(%) | n UK<br>(%) | N all (%)          | n<br>Denmark<br>(%) | n<br>Slovakia<br>(%) | n Spain<br>(%) | n UK (%) |
| Leaflets              | 31 (61)           | 5 (100)             | 1 (25)               | 19 (61)        | 6 (55)      | 10 (20)            | 0 (0)               | 2 (50)               | 5 (16)         | 3 (27)   |
| Websites              | 2 (4)             | 0 (0)               | 0 (0)                | 1 (3)          | 1 (9)       | 6 (12)             | 0 (0)               | 1 (25)               | 4 (13)         | 1 (9)    |
| Verbal<br>discussions | 13 (26)           | 0 (0)               | 3 (75)               | 8 (23)         | 2 (18)      | 29 (57)            | 4 (75)              | 0 (0)                | 19 (61)        | 6 (55)   |
| No answer             | 5 (10)            | 0 (0)               | 0 (0)                | 3 (10)         | 2 (18)      | 6 (12)             | 1 (25)              | 1 (25)               | 3 (10)         | 1 (9)    |
|                       | 51 (100)          |                     |                      |                |             | 51 (100)           |                     |                      |                |          |

When asked about the kind of health regulators accessed for information about CHC, professionals tended to be more aware of national bodies, rather than international bodies. Also, 12 out of 51 respondents reported not having heard about any international health regulators or health agencies (see Tables 39 and 40).

| Table 39 – National health regulators used by health professionals to seek information about CHC |  |
|--|--|
| (N=51)   |  |

| National health regulators used by prescribers                | N (all) | Denmark | Slovakia | Spain | UK |
|---|---------|---------|----------|-------|----|
| Asociacion de Anticoncepcion                                  | 1       |         |          | ~     |    |
| Associació Catalana de Contracepció                           | 1       |         |          | ~     |    |
| Danish College of General Practitioners                       | 1       | ✓       |          |       |    |
| Danish Health Authority                                       | 1       | ✓       |          |       |    |
| Danish Medicines Agency                                       | 1       | ✓       |          |       |    |
| Danish Society of Obstetrics and Gynaecology                  | 1       | ~       |          |       |    |
| Ministerio de Salud   | 5       |         |          | ~     |    |
| Faculty of Sexual and Reproductive Health                     | 5       |         |          |       | ~  |
| Family Planning Association                                   | 1       |         |          |       | ~  |
| FSRH UK Medical Eligibility Criteria for<br>Contraceptive Use | 1       |         |          |       | ~  |
| Institut for Rationel Farmakoterapi                           | 4       | ~       |          |       |    |
| Institut Nacional del Medicament                              | 1       |         |          | ~     |    |
| Instituto Catalan de la Salud                                 | 1       |         |          | ~     |    |
| Public Health Authority of the Slovak Republic                | 1       |         | ~        |       |    |
| Royal College of Obstectrics and Gynaecology                  | 2       |         |          |       | ~  |
| Sociedad Española de Contracepcion                            | 7       |         |          | ~     |    |
| Sociedad Española de Obstetricia y Ginecología                | 6       |         |          | ~     |    |
| Societat Catalana Contracepció                                | 1       |         |          | ~     |    |
| State Institute for Drug Control                              | 1       |         | ~        |       |    |
| Total No. Organisations                                       | 20      |         |          |       |    |

**Table 40** – International health regulators used by health professionals to seek information aboutCHC (N=51)

| International Health Regulators                | N of<br>professionals<br>(%) | n Denmark<br>(%) | n Slovakia<br>(%) | n Spain<br>(%) | n UK<br>(%) |
|--|------------------------------|------------------|-------------------|----------------|-------------|
| European Medicines Agency                      | 5 10)                        | 2 (40)           | 1 (25)            | 2 (6)          | 0 (0)       |
| European Society of Contraception              | 3 (6)                        | 0 (0)            | 0 (0)             | 2 (6)          | 1 (9)       |
| International Planned Parenthood<br>Federation | 1 (2)                        | 0 (0)            | 0 (0)             | 1 (3)          | 0 (0)       |
| World Health Organisation                      | 23 (45)                      | 0 (0)            | 1 (25)            | 18 (58)        | 4 (36)      |
| No answer                                      | 19 (37)                      | 3 (60)           | 2 (50)            | 8 (26)         | 6 (55)      |
| Total  | 51 (100)                     |                  |                   |                |             |

Respondents tended to report receiving information updates about CHC from any of the sources mentioned above, although the frequency was variable. Health professionals tend to prefer to receive information by e-mail, and were less keen on online webinars (see Tables 41, 42 and 43).

Table 41 – Experience of receiving information updates on CHC from health regulators (N=51)

| Do you receive information<br>updates from any health<br>regulators / bodies about<br>CHC? | N all<br>(%) | n<br>Denmark<br>(%) | n<br>Slovakia<br>(%) | n Spain<br>(%) | n UK<br>(%) |
|--|--------------|---------------------|----------------------|----------------|-------------|
| Yes  | 34 (67)      | 4 (80)              | 1 (25)               | 21 (68)        | 8 (73)      |
| No   | 13 (26)      | 0 (0)               | 3 (75)               | 8 (26)         | 2 (8)       |
| Unsure   | 4 (8)        | 1 (20)              | 0 (0)                | 2 (7)          | 1 (9)       |
| Total  | 51<br>(100)  | _ (10)              |                      | _ (')          |             |

Table 42 – Frequency of updates received from regulators about CHC (N=51)

| Frequency        | N all (%) | n<br>Denmark<br>(%) | n<br>Slovakia<br>(%) | n<br>Spain<br>(%) | n UK<br>(%) |
|------------------|-----------|---------------------|----------------------|-------------------|-------------|
| Variable         | 21 (41)   | 1 (20)              | 1 (25)               | 17 (55)           | 2 (18)      |
| Weekly           | 1 (2)     | 0 (0)               | 1 (25)               | 0 (0)             | 0 (0)       |
| Monthly          | 4 (8)     | 0 (0)               | 0 (0)                | 2 (6)             | 2 (18)      |
| Every 3-6 months | 6 (12)    | 0 (0)               | 0 (0)                | 1 (3)             | 5 (46)      |
| Yearly           | 5 (10)    | 3 (60)              | 0 (0)                | 2 (6)             | 0 (0)       |
| Other            | 9 (18)    | 1 (20)              | 1 (25)               | 5 (16)            | 2 (18)      |
| No answer        | 5 (9)     | 0 (0)               | 1 (25)               | 4 (31)            | 0 (0)       |
| Total            | 51 (100)  |                     |                      |                   |             |

| Table 43 – Formats | preferred to receiv | e updates on CHC | C from regulators (N=51) |
|--------------------|---------------------|------------------|--------------------------|
|                    | preferred to receiv | e apaacee on ene |                          |

| Formats to<br>receive updates<br>about CHC | Most<br>Preferred |                |                 |              |        | Least<br>Preferred |                |                 |         |        |
|--|-------------------|----------------|-----------------|--------------|--------|--------------------|----------------|-----------------|---------|--------|
|  |                   | n              | n               | n            | n UK   |                    | n              | n               | n Spain | n UK   |
|  | N all (%)         | Denmark<br>(%) | Slovakia<br>(%) | Spain<br>(%) | (%)    | N (all)            | Denmark<br>(%) | Slovakia<br>(%) | (%)     | (%)    |
|  | 11 un (70)        | ( ) 0 )        | 0 (0)           | 18           | 4 (36) |                    | (70)           | 1 (25)          | 2 (6)   | 2 (18) |
| E-mails                                    | 23 (45)           | 1 (20)         | .,              | (58)         | . ,    | 5 (10)             | 0 (0)          | . ,             |         | . ,    |
| Conferences and                            |                   | ( (2.2)        | 0 (0)           | 7            | 4 (36) |                    | a (a)          | 0 (0)           | 3 (10)  | 1 (9)  |
| meetings                                   | 12 (24)           | 1 (20)         |                 | (23)         |        | 4 (8)              | 0 (0)          |                 |         |        |
|  |                   |                | 0 (0)           | 0 (0)        | 0(0)   |                    |                | 0 (0)           | 1 (3)   | 1 (9)  |
| Online seminars                            | 0 (0)             | 0 (0)          |                 |              |        | 2 (4)              | 0 (0)          |                 |         |        |
| Presentations                              | 3 (6)             | 1 (20)         | 0 (0)           | 2 (6)        | 0 (0)  | 3 (6)              | 1 (20)         | 0 (0)           | 2 (6)   | 0 (0)  |
| Magazines                                  | 0 (0)             | 0 (0)          | 0 (0)           | 0 (0)        | 0 (0)  | 6 (12)             | 2 (40)         | 1 (25)          | 1 (3)   | 2 (18) |
|  |                   |                | 0 (0)           | 1 (3)        | 1 (9)  |                    | 0 (0)          | 0 (0)           | 1 (3)   | 2 (18) |
| Website                                    | 3 (6)             | 1 (20)         |                 |              |        | 3 (6)              |                |                 |         |        |
| Scientific journals                        | 4 (8)             | 0 (0)          | 1 (25)          | 2 (6)        | 1 (9)  | 7 (14)             | 1 (20)         | 0 (0)           | 5 (16)  | 1 (9)  |
| Exchange                                   |                   |                | 1 (25)          | 0 (0)        | 0 (0)  |                    | 0 (0)          | 0 (0)           | 8 (26)  | 0 (0)  |
| platforms                                  | 1 (2)             | 0 (0)          |                 |              |        | 8 (16)             |                |                 |         |        |
| No answer                                  | 5 (9)             | 1 (20)         | 2 (50)          | 1 (3)        | 1 (9)  | 13 (25)            | 1 (20)         | 2 (50)          | 8 (26)  | 2 (18) |
| Total                                      | 51 (100)          |                |                 |              |        | 51 (100)           |                |                 |         |        |

Little over half of the sample was aware about the guidelines about CHC produced by the European Medicines Agency. However, most of the respondents reported not using these guidelines in their daily practice (see Tables 44 and 45).

| The European Medicines<br>Agency produces<br>guidance about<br>combined hormonal<br>contraceptives. Are you<br>aware of this guidance? | N all (%) | n<br>Denmark<br>(%) | n Slovakia<br>(%) | n Spain<br>(%) | n UK (%) |
|--|-----------|---------------------|-------------------|----------------|----------|
| Yes  | 27 (53)   | 2 (40)              | 1 (25)            | 20 (65)        | 4 (36)   |
| No   | 24 (47)   | 3 (60)              | 3 (75)            | 11 (35)        | 7 (64)   |
| Total  | 51        |                     |                   |                |          |

Tables 44 – Awareness of the EMA guidelines about CHC (N=51)

**Table 45** – Use of the EMA guidelines about CHC on daily practice (N=51)

| Do you use EMA<br>guidance in your<br>everyday practice? | N all<br>(%) | n Denmark<br>(%) | n Slovakia<br>(%) | n Spain<br>(%) | n UK (%) |
|--|--------------|------------------|-------------------|----------------|----------|
| Yes  | 15 (30)      | 1 (20)           | 0 (0)             | 13 (42)        | 1 (9)    |
| No   | 32 (63)      | 4 (80)           | 4 (100)           | 14 (45)        | 10 (90)  |
| No answer  | 4 (8)        | 0 (0)            | 0 (0)             | 4 (13)         | 0 (0)    |
| Total  | 51<br>(100)  |                  |                   |                |          |

Finally, when asked about their risk perception concerning a CHC-related VTE, on a scale from 1 ("extremely unlikely") to 5 ("extremely likely"), health professionals from Slovakia judged this as likely while health professionals in Denmark, Spain and the UK erred towards judging this event as unlikely (see Table 46).

Table 46 Health Professionals perception of the risk of developing a CHC-related VTE

| Risk perception – health<br>professionals (1-5) | n Denmark<br>(%) | n Slovakia<br>(%) | n Spain (%) | n UK (%) |
|---|------------------|-------------------|-------------|----------|
| 1 = Extremely unlikely                          | 1 (20)           | 0 (0)             | 4 (13)      | 4 (36)   |
| 2   | 3 (60)           | 0 (0)             | 19 (61)     | 5 (45)   |
| 3   | 1 (20)           | 0 (0)             | 7 (23)      | 2 (18)   |
| 4   | 0 (0)            | 1 (25)            | 1 (3)       | 0 (0)    |
| 5 = Extremely likely                            | 0 (0)            | 3 (75)            | 0 (0)       | 0 (0)    |

| No answers          | 0 (0)   | 0 (0)   | 0 (0)   | 0 (0)    |
|---------------------|---------|---------|---------|----------|
| Total N respondents | 5 (100) | 4 (100) | 3 (100) | 11 (100) |

# 10.5. Other analyses

None.

# 10.6. Adverse events/adverse reactions

Not applicable, as this study did not follow an experimental design with medicines.

# 11. Discussion

# 11.1. Key results

Our main goal was to understand if women and health professionals consider and are aware of the risks of VTE when making decisions about use of CHC. According to the women interviewed, women tend to consider CHC to be safe. Only a few reported being concerned about the effects of CHC on mood swings and other general health conditions. Many women did not search for further information apart from that provided by the health professional. However, women identified areas in which they would like to have been informed in their consultations, namely, information about other contraceptives, how CHC work and side-effects. Similar findings were obtained in the survey, where more than one third of women reported not seeking any information prior to making their decision about taking CHC. When asked about the likelihood of having a VTE following the use of CHC, women did not generally considered this to be likely. Health professionals reported difficulties in communicating the risks of CHC to women and challenges in addressing the perceived misconceptions about those risks. Mostly importantly, the health professionals reported that addressing both general information about CHC, its risks and supporting women making an informed decision is difficult within the time assigned for their consultations. Health professionals form countries other than Slovakia did not consider VTE to be a likely event following the use of CHC.

We also aimed **to understand what sources of information inform women and health professionals' assessments of CHC**. In the internet search, we found nearly 400 websites, over six EU countries, with information about CHC and its risks, in particular, VTE. Most of these websites also reported other side-effects, risk variations (e.g. age) and general information about CHC. These websites were retrieved from Google, which means they are easily and publicly accessible to the whole population. When asked about which sources of information they use, women reported seeking information mostly when in consultations with health professionals, followed by websites and family/friends. These results were obtained from interviews and the survey. Women tended to prefer receiving information via health professionals, who they consider to be trustworthy and reliable. Health professionals tended to seek information from national guidelines, rather than international bodies, to inform women about CHC and their risks. Interestingly, almost one quarter of the professionals surveyed reported using only their own knowledge and experience to communicate about CHC with women. In terms of the format used to communicate with women, most health professionals rely on leaflets. Reasons for using leaflets included helping women retaining information and complementing verbal discussions about CHC. It is also worth highlighting the variation that seems to exist in the type of training that professionals receive to prescribe and discuss CHC with women. Some professionals reported not having received additional training apart from their general medical/nursing degrees. In light of this, we believe that there is a need for both national (e.g. Royal Colleges) and international (e.g. EMA) organisations to promote further training opportunities for individuals who work in this field, including initiatives such as free webinars or online courses.

Our final goals were to document awareness, knowledge, attitudes and practices related to recommendations from regulatory authorities; the level of communication with regulatory authorities and how communication could be improved. When prompted to discuss their knowledge about regulatory health authorities, most women tended to identify only national health organisations. For instance, in the survey, over 70% of women said that they had never heard about the EMA. When they hear about regulators such as the EMA, this tends to occur via media sources. When it comes to receiving information about regulatory authorities, women reported this to be one of the least important sources to gain information, and in the interviews some mentioned having no interest at all in learning from these organisations. Although our sample was limited in its extent, the results of this study suggest that organisations such as the EMA may need to increase their profile and visibility among the general population when it comes to disseminating information about drug safety. Since, according to our study, women seem to prefer receiving information about CHC in verbal consultations with their doctors, one suggestion could be that professionals are encouraged to discuss information about drug safety with their patients, e.g. by directing or showing the EMA website during consultations. Some health professionals, on the other hand, did report guiding their clinical practice using national regulatory authorities, including local guidelines or national professional organisations (e.g. Royal College of Obstetrics and Gynaecology). Among the international regulatory authorities, most people referred to the World Health Organisation and EMA. Little over half of the sample (53%) was aware of EMA guidance on CHC, even though most health professionals did not report using the guidance in practice. This aspect should be considered by the EMA when disseminating its information to the public. Most health professionals reported receiving updates from regulatory bodies, but the frequency of these updates is variable. Most people preferred receiving updates by e-mail, mainly because this made it easier to access and allows for rapid communication of updated information. Professionals reported being satisfied with the amount of information that they receive from regulatory bodies. However, in the interviews, professionals highlighted the lack of time in their daily practice to read the guidelines and the updates sent out by regulatory bodies.

# 11.2. Limitations

The number of countries recruited was below expected, particularly for the survey study. We aimed to recruit six EU countries, namely, Denmark, Germany, the Netherlands, Slovakia, Spain and the UK. Unfortunately, no organisation contacted in Germany responded to our invitations for collaboration; and in the Netherlands, although a positive answer was received from our local contact point, the timeframes required for ethics approval did not aligned with our timeline. For the interviews, we aimed to recruit three countries (Denmark, Slovakia and the UK), but we could only obtain the Danish and British data in time for this report. As explained elsewhere, ethics approval for Slovakia was due in May 2017 but was only obtained in October 2017. Slovakian data for women has recently been completed and will be included in future outputs of this project. However, interview data from Slovakian health professionals remains unavailable. Because of this, comparisons between countries were not possible.

The second limitation is the overall sample size. In the interview study, although we reached the expected sample size for Denmark and the UK, data from Slovakia could not be included, resulting in a total sample size below expected. With only two countries being contrasted it is difficult to examine cultural differences between the countries. In the survey, although the total sample for women exceeded our expectations (expected N=600 vs. final N=1092), the expected sample size per country was not achieved (N=100), with very low numbers in Spain and Slovakia. With this disparity in sample sizes per country (e.g. 948 women in Denmark vs. 18 women in Spain), it was not possible to conduct the statistical analysis originally planned. Regarding the survey, we do not know the number of individuals who had access to the survey but chose not to open the survey link. For this reason, it is possible that our sample is biased towards those with an interest in CHCs. Future studies should revise their methodological options to enhance details of response rate, for example by placing the invitation in a designated website, whose number of "visitors" could be compared with the number of those opening the survey link.

The third limitation relates to the language differences between countries. All the research materials (e.g. internet search protocol, interview protocol and survey) were developed in English, by the local UK research team, and discussed with at least two international partners for feedback. However, in order to be administered in each country, these documents had to be locally translated. Because the UK research team was not fluent in the languages of the other participating countries, it is possible that certain terms or words have been adapted in order to be meaningful to each language, and in doing so the nuanced meaning may have changed.

The fourth and final limitation refers to the methods used for data collection. The interviews were collected by different researchers, which may have resulted in variability in data collection. A semistructured interview protocol was developed to minimise any variability; however, it is possible that different interview styles may have impacted on the amount and quality of information collected across researchers and/or countries. In relation to the survey, the internet is an excellent way to quickly access a large number of people. However, when data is collected in social networks such as Facebook, this limits the reach of the survey to social media users.

# 11.3. Interpretation

In the last ten years, the literature has reported that women are likely to have negative views about CHCs (1, 2, 3). In our internet search, we found that the media plays a very important role in disseminating information about the CHC, which often tends to be case reports of VTE episodes. However, data from interviews and the survey found that women in our sample appear to be quite positive about CHC and consider it relatively safe to use.

Previous studies have also suggested that women tend to have knowledge gaps about CHC and its risks. These findings have been reported prior to 2013 (4) and our literature review of recent studies indicated that has not changed (8, 9). Although our empirical studies did not assess women's knowledge about CHC, we did find that over one third of women did not seek any information about these medicines before deciding to take it, which raises the question about whether they were well-informed to make their decision. If we take in to consideration that apart from consulting health professionals, websites are the second most used source of information about CHC, it is likely that women are making decisions based on information whose reliability is difficult to assess.

The literature has shown that providing women with counselling and structured information about CHC is likely to improve their knowledge about CHC, and in turn, improve compliance (11, 12). In other words, it is important to understand the best format to provide such counselling in such a way that meets the needs and preferences of women. In our sample, women reported that they preferred receiving information about CHC through verbal consultations with their health professionals, followed by websites. This finding is very important, as it is in line with previous research indicating that health professionals' opinion about CHC is likely to influence women's choices (16). This suggests that verbal communication between women and health professionals must be attended to and methods of improving this process should be explored. For instance, our study has revealed topics about CHC which women would have liked to further discuss with their professionals (e.g. emergency advice, side-effects). On the other hand, some health professionals have also reported in the interviews that, during clinical training, they received no specific training on how to inform women about CHC. Health professionals also reported that they preferred using leaflets, as a complement to verbal discussions, when talking about CHC. Hence, future research could focus on the development of a training package for health professionals, possibly delivered via the internet, to guide them on how to discuss contraceptive choices in general with women, and the topics that should be covered when discussing CHC, keeping in mind the needs and worries reported by women about CHCs. When developing these packages, though, it is important to bear in mind the time constraints that health professionals have in their clinical practices, and any proposal for information provision should be adjusted to the time that is typically assigned for consultations in each country; which, according to the health professionals in our sample, is very limited and unrealistic considering the amount of information that should be discussed and tasks performed (e.g. physical examination). This is why an internet intervention that could be shared and accessed by women outside of the consultation prior and following a medical consultation could provide a resource of value to both women and health professionals.

To our knowledge, no previous studies have reported awareness, perceptions and usage of information about CHC provided by regulatory bodies during professional-women communication. However, our project suggests that women have limited knowledge about the existence of regulatory bodies. Although health professionals have a greater awareness about regulatory bodies, most professionals suggested they did not use their guidelines, such as those produced by the EMA, in their practice. The fact that professionals opt to rely on local or national documents, and less on international guidance, is likely to result in a great diversity of practices and the dissemination of divergent information across countries. Hence, future research is needed to evaluate the impact of this divergence, and the extent to which different countries tend to differ or not when it comes to the prescription of CHC.

# 11.4. Generalisability

The results of this study must be interpreted with caution in relation to generalisability. Of particular concern is the survey conducted with women as the vast majority of the respondents were from Denmark, with only a minority from the other three countries (Slovakia, Spain and UK). Future studies should collect a larger number of respondents across countries to allow for comparisons at the country level. Among health professionals, even though the sample size was more evenly distributed between countries, the overall number of respondents was extremely small and below our expected sample size, limiting the scope of the conclusions.

# 12. Other information

None.

# 13. Conclusion

This project has demonstrated that women prefer information informing the decision to take a CHC to be delivered by health professionals. They also generally consider CHC to be safe but feel the need to receive more information about possible side-effects and risks during consultations with their health professionals. Health professionals, other than those from Slovakia, do not believe the risk of VTE associated with CHC to be a problem and tend to rely on national and local regulatory bodies to provide information about CHC to women, rather than international guidelines (e.g. EMA). Professionals find it difficult to communicate all aspects involved in the use of CHC in short consultations and would prefer longer appointments to address all the information relevant for women's decision-making about contraception. Overall, our findings show that health professionals can play a key role in improving women's knowledge and perception about CHC and its risks, and future research should be conducted to support professionals in this task.

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# Appendices

# Annex 1. List of stand-alone documents

None.

# **Annex 2. Additional information**

## Appendix 1

#### 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

#### <u>version</u>)

- Audio recording equipment
- Patient information sheet and consent form

<u>Label notes & recorded file</u>: 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.

<u>Interview Strategy</u>: 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?".

<u>Introduction for the participant:</u> 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. 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."

#### Interview Schedule

"There are currently thousands of women in the UK and abroad who are taking the pill but we do not 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."

## Socio-demographics form (To be completed by the researcher)

## Age

Under 18 years old 18-24 years old 25-34 years old 35-44 years old 45-54 years old 65-74 years old 75 years or older

#### Ethnicity

\*adapted from the Office for National Statistics (v3.3, May 2015) White English/ Welsh/ Scottish/ Northern Irish/ British Irish Gypsy, Traveller or Irish Traveller Any other White background Mixed/ Multiple ethnic groups White and Black Caribbean White and Black African White and Asian Any other Mixed/ Multiple ethnic background Asian/ Asian British Indian Pakistani Bangladeshi Chinese Any other Asian background Black/ African/ Caribbean/ Black British African Caribbean Any other Black/ African/ Caribbean background Other ethnic group Arab Any other ethnic group **Employment status** Full time Occupation \_\_\_\_\_ Part-time/casual Occupation \_\_\_\_\_ Student Unemployed Other Please specify \_\_\_\_\_ Education

> No qualification GCSE's / A levels Higher education diploma / degree Post-graduate education

## Appendix 2

## Survey – Women Version (V1.1, UK/2017)

## PART 1: General information about your pill

Are you currently taking oral combined hormonal contraceptives ("the pill")?
Yes
No
If YES, which one?
Oral progestogen-only contraceptive ("mini-pill")
Contraceptive implant
Contraceptive patch
Contraceptive injections
Intra-uterine devices
Vaginal ring
Other
Please specify \_\_\_\_

How long have you been using this contraceptive? \_\_\_\_ (Years)

## PART 2: Searching for information about the pill

Did you seek information about the pill before you decided to take it? Yes No

#### If YES, where?

Website Friends/family/peers Health professionals Schools Other Please specify \_\_\_\_

Have you ever got any information from national health organisations or medicines regulators?

Yes No Unsure

# If YES, please specify \_\_\_\_

#### Have you heard of the European Medicines Agency?

| Yes    |
|--------|
| No     |
| Unsure |

If YES, where? At work Media Family/friends/peers Other Please specify \_\_\_\_

#### Please rank the following on a scale from 1 (totally disagree) to 5 (totally agree)

1 - totally disagree, 2- slightly disagree, 3 - not agree or disagree, 4 - slightly agree, 5 - totally agree

I have never considered the risks of the pill I am concerned about the side-effects from the pill The pill is safe to use The person who prescribed me the pill told me all I needed to know I searched the web to find information about the risks of the pill before taking it I searched the web to find information about the risks of the pill after taking it I talked to my friends/family/peers about the pill I read the leaflet in the box

# Please rank the following sources of information about the pill from the most important to the least important source of information about taking the pill

Leaflets Websites Regulatory authorities Verbal discussions with health professional Education about relationships taught in school

# On a scale from 1 to 10, how likely do you think it is that you might get a blood clot from using the pill?

1 – Extremely unlikely (...) 10 – Extremely likely

#### PART 3: A bit about yourself

#### Age

Under 18 years old 18-24 years old 25-34 years old 35-44 years old 45-54 years old 65-74 years old 75 years or older

#### Ethnicity

\*adapted from the Office for National Statistics (v3.3, May 2015) White English/ Welsh/ Scottish/ Northern Irish/ British Irish Gypsy, Traveller or Irish Traveller Any other White background Mixed/ Multiple ethnic groups White and Black Caribbean White and Black African White and Asian Any other Mixed/ Multiple ethnic background Asian/ Asian British Indian Pakistani Bangladeshi Chinese Any other Asian background Black/ African/ Caribbean/ Black British African Caribbean Any other Black/ African/ Caribbean background Other ethnic group Arab Any other ethnic group

#### **Employment status**

Full time Occupation \_\_\_\_ Part-time/casual Occupation \_\_\_\_ Student Unemployed Other Please specify \_\_\_\_

#### Education

No qualification GCSE / A levels Higher education diploma / degree Post-graduate education

This will be saved and administered separately to your responses

# IF YOU WISH TO ENTER THE DRAW TO WIN A £50 VOUCHER, PLEASE PROVIDE US WITH YOUR E-MAIL ADDRESS HERE \_\_\_\_

## Appendix 3

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

#### **Instructions**

<u>Preparation</u>: 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
- Audio recording equipment
- Patient information sheet and consent form

<u>Label notes & recorded file</u>: 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.

<u>Interview Strategy</u>: 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?".

<u>Introduction for the participant:</u> 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. 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."

#### **Interview Schedule**

"There are currently thousands of women in the UK and abroad who have been prescribed with the pill but we do not how and why people make that choice. During this conversation, we will talk about what you think about this and your experience as a prescriber of this medicine."

- 1. Which information sources do you use to advise women regarding contraceptive choice?
- 2. How do you provide this information to women?
  - E.g. Verbal conversation
  - Leaflets
  - Internet
- 3. Awareness about other information sources used by colleagues and which ones do colleagues use?
- 4. Have you received specific training on how to advise women about contraceptive choices?
  - Who was the training provider
  - Last training received
- 5. Have you participated in any continuing professional development initiatives/training courses regarding contraceptives and, if yes, if these were sought by you or promoted by others (who)?
- 6. How do continuing professional development initiatives and updates to information influence your practice?
- 7. Which regulators documents do you tend to rely on to advise women about contraceptives?
- 8. Have you ever received advice from regulators about contraceptives, how frequently and in which format?
- 9. How would you like to receive information from regulators about updates to 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."

## Socio-demographics form (To be completed by the researcher)

#### Age

Under 18 years old 18-24 years old 25-34 years old 35-44 years old 45-54 years old 65-74 years old 75 years or older

# Gender

- 1. Male
- 2. Female

#### Ethnicity

\*adapted from the Office for National Statistics (v3.3, May 2015) White English/ Welsh/ Scottish/ Northern Irish/ British Irish Gypsy, Traveller or Irish Traveller Any other White background Mixed/ Multiple ethnic groups White and Black Caribbean White and Black African White and Asian Any other Mixed/ Multiple ethnic background Asian/ Asian British Indian Pakistani Bangladeshi Chinese Any other Asian background Black/ African/ Caribbean/ Black British African Caribbean Any other Black/ African/ Caribbean background

Other ethnic group Arab Any other ethnic group

## Type of practitioner

Nurse Doctor Other Please specify

#### Years of clinical practice

Number of years prescribing contraceptives \_\_\_\_\_

### Type of current service

General practice Family planning clinic Sexual health clinic Private practice Other Please specify \_\_\_\_\_

#### Location of current practice

Urban Suburban Rural

## **Appendix 4**

Survey – Health Professionals Version (V1.1, UK/2017)

PART 1: General information about your professional background

Type of practitioner Nurse Doctor Other Please specify \_\_\_\_

#### Years of clinical practice

Number of years prescribing contraceptives \_\_\_\_\_

## Type of current practice

General practice Family planning clinic Sexual health clinic Private practice Other Please specify \_\_\_\_

#### Location of current practice

Urban Suburban Rural

PART 2: Resources about combined hormonal contraceptives used

# Please rank the sources of advice you use for your patients when prescribing combined hormonal contraceptives (where 1 is the most frequently used?)

I generally rely solely on my own experience and knowledge National health organisations International health organisations Sexual health charities Professional bodies Local resources (e.g. documents prepared by local clinical practice) Peers Conferences Scientific publications Drug companies Patient groups Other. Please specify \_\_\_\_\_

Please rank the following sources of information that can be shared with patients about combined hormonal contraception. Mark 1 as the most important and 3 as the least.

Leaflets Websites / electronic applications ("apps") Verbal discussions between yourself and the patient

Which health regulators / bodies to you tend to rely on to prescribe combined hormonal contraceptives? National

Please specify \_\_\_\_

#### International

Please specify \_\_\_\_

# Did you receive information updates from any health regulators / bodies about the combined hormonal contraceptives?

Yes No Unsure / cannot remember

If YES, with which frequency

Variable Weekly Monthly Every 3-6 months Yearly Other Please specify \_\_\_\_\_

The European Medicines Agency produces guidance about combined hormonal contraception. Are you aware of this guidance?

Yes No

Do you use it in your everyday practice? Yes No

What is your preferred format for receiving updates from health regulators / bodies? Please rank the following from 1 to 8, where 1 is your preferred format.

E-mails updates Conferences and meetings Online seminars Presentations Magazines Website Scientific Journals Exchange platforms Are there any other formats in which you receive information? Please specify

In a scale from 1 to 5, how likely do you think that venous thromboembolism can occur following the use of combined hormonal contraceptives?

1– Extremely unlikely (...) 5 – Extremely likely

PART 3: A bit about yourself

#### Gender

Male Female **Age** Under 25 years old 25-34 years old 35-44 years old 45-54 years old 55-64 years old 65-74 years old 75 years or older

Ethnicity (adapted from the Office for National Statistics, v3.3, May 2015) White English/ Welsh/ Scottish/ Northern Irish/ British Irish Gypsy, Traveller or Irish Traveller Any other White background Mixed/ Multiple ethnic groups White and Black Caribbean White and Black African White and Asian Any other Mixed/ Multiple ethnic background Asian/ Asian British Indian Pakistani Bangladeshi Chinese Any other Asian background Black/ African/ Caribbean/ Black British African Caribbean Any other Black/ African/ Caribbean background Other ethnic group Arab Any other ethnic group

This will be saved and administered separately to your responses

# IF YOU WISH TO ENTER THE DRAW TO WIN A £50 VOUCHER, PLEASE PROVIDE US WITH YOUR E-MAIL ADDRESS HERE \_\_\_\_

#### Appendix 5

Full list of websites identified in the internet search (WP2)

| Cou  | Name of      | Website address  |
|------|--------------|--|
| ntry | host website |  |
| Den  | Kvinde       | http://www.kvindeguiden.dk/temaer/sundhed/artikel/guide-saadan-tager-i-p-pille-    |
| mar  | Guiden       | snakken/   |
| k    |              |  |
| Den  | frekvensen   | http://f-frekvensen.dk/vi-bliver-nodt-til-at-tale-om-p-pillen/                     |
| mar  |              |  |
| k    |              |  |
| Den  | ninkas       | http://www.ninkasdetox.dk/bloggen/article/kernesund-praevention/                   |
| mar  | detox        |  |
| k    |              |  |
| Den  | style trends | http://styletrends.dk/vidste-du-ikke-p-piller/                                     |
| mar  |              |  |
| k    |              |  |
| Den  | findhvordan  | http://www.findhvordan.dk/hvordan-virker-p-piller/                                 |
| mar  |              |  |
| k    |              |  |
| Den  | vi unge      | http://www.viunge.dk/kaerlighed/krop/den-her-bivirkning-ved-p-piller-skal-du-kende |
| mar  |              |  |
| k    |              |  |
| Den  | World Care   | http://worldcare.dk/har-du-taenkt-hvad-hormon-baseret-praevention-gor-ved-dig-     |
| mar  |              | vores-born-og-vores-miljo/   |
| k    |              |  |
| Den  | doktorABC.   | http://www.doktorabc.dk/108/p-piller   |

| mar      | dk          |   |
|----------|-------------|---|
| k        | UK          |   |
|          | hadia hav   | http://hosishay.dl/fog.am.m.millar/   |
| Den      | basic box   | http://basicbox.dk/faq-om-p-piller/   |
| mar      |             |   |
| k        |             |   |
| Den      | LetsTalkAbo | http://www.letstalkaboutit.dk/guide-til-valg-af-praevention/                        |
| mar      | utIt        |   |
| k        |             |   |
| Den      | edith       | http://navisen.dk/blog/den-omstridte-p-pille-mellem-frygt-og-fakta/                 |
| mar      | Ingerslev   |   |
| k        | Svare       |   |
| Den      | Dagens DK   | http://www.dagens.dk/indland/sophie-fik-en-blodprop-og-d%C3%B8de-af-disse-p-        |
| mar      | -           | piller-alligevel-kan-du-fortsat-k%C3%B8be-dem-p%C3%A5                               |
| k        |             |   |
| Den      | samvirke    | http://samvirke.dk/artikler/drop-menstruationen-hvis-du-er-traet-af-at-blode        |
| mar      | Summite     |   |
| k        |             |   |
|          | ach dl      | http://www.zoh.dk/artikal/on.ppilla.kap.ia.alammaa                                  |
| Den      | aoh.dk      | http://www.aoh.dk/artikel/en-ppille-kan-jo-glemmes                                  |
| mar      |             |   |
| k        |             |   |
| Den      | sundhed     | http://www.magasinet-sundhed.dk/sundhed/artikler/kvinder-risikerer-blodprop-med-    |
| mar      |             | ny-praevention/   |
| k        |             |   |
| Den      | ALT         | http://www.alt.dk/artikler/ikke-godkendt-sandie-jeg-droppede-p-piller-og-nu-        |
| mar      |             | anbefaler-jeg-hormonspiral-til-alle-mine-veninder                                   |
| k        |             |   |
| Den      | TV2         | http://nyheder.tv2.dk/samfund/2016-06-09-faa-overlaegens-raad-saadan-undgaar-du-    |
| mar      |             | at-bruge-risikable-p-piller   |
| k        |             |   |
| Den      | Kristeligt  | https://www.kristeligt-dagblad.dk/liv-sjael/p-piller-er-bedre-end-deres-rygte       |
| mar      | Dagblad     |   |
| k        | Dugbluu     |   |
|          | motrogypro  | https://www.mx.dk/nyheder/danmark/story/26109883                                    |
| Den      | metroexpre  | https://www.inx.uk/hyneuer/uaninark/story/20109885                                  |
| mar      | SS          |   |
| k        |             |   |
| Den      | voksne      | http://voksnekvinder.dk/blogs/entry/p-piller-og-risikoen-for-blodpropper.html       |
| mar      | kvinder     |   |
| k        |             |   |
| Den      | Politiken   | http://politiken.dk/forbrugogliv/sundhedogmotion/art5637629/P-piller-og-anden-      |
| mar      |             | hormonel-pr%C3%A6vention-kan-give-depression  |
| k        |             |   |
| Den      | Politiken   | http://politiken.dk/forbrugogliv/sundhedogmotion/art5587329/17-%C3%A5rig-fik-       |
| mar      |             | blodprop-Jeg-t%C3%A6nkte-slet-ikke-at-p-piller-var-farlige                          |
| k        |             |   |
| Den      | Avisen      | https://www.avisen.dk/p-piller-beskytter-mod-mere-end-graviditet_378449.aspx        |
| mar      |             |   |
| k        |             |   |
| K<br>Den | newsdesk    | http://newsdesk.aller.dk/node/3399  |
|          | NEWSUESK    |   |
| mar      |             |   |
| k        |             |   |
| Den      | BT.dk       | http://www.bt.dk/forbrug/laeger-er-enige-p-piller-kan-beskytte-dig-mod-livstruende- |
| mar      |             | sygdomme  |
| k        |             |   |
| Den      | Ekstra      | http://ekstrabladet.dk/nyheder/samfund/mange-yngre-kvinder-tager-stadig-de-         |
|          |             | I   |

| mar<br>k | Bladet        | farligste-p-piller/5592246   |
|----------|---------------|--|
| Den      | den store     | http://denstoredanske.dk/Krop,_psyke_og_sundhed/Sundhedsvidenskab/Pr%C3%A6ve         |
|          |               |  |
| mar      | danske        | ntion/pr%C3%A6vention  |
| k        |               |  |
| Den      | laegemiddel   | https://laegemiddelstyrelsen.dk/da/nyheder/2015/2-generations-p-piller-giver-lavest- |
| mar      | styrelsen     | risiko-for-blodpropper/  |
| k        |               |  |
|          | IRF           | http://www.irf.dk/dk/redskaber/faq/spoergsmaal_og_svar_om_hormonel_kontraceptio      |
| Den      | IKF           |  |
| mar      |               | n_og_trombose.htm  |
| k        |               |  |
| Den      | medicinsk     | medicinsktidsskrift.dk/reguleringer/vejledninger/79-opdateret-vejledende-materiale-  |
| mar      | tidsskrift    | om-p-piller.html   |
| k        |               |  |
|          |               |  |
| Den      | net doktor    | http://www.netdoktor.dk/sunderaad/fakta/p-piller.htm                                 |
| mar      |               |  |
| k        |               |  |
| Den      | P-pille.dk    | http://p-pille.dk/p-piller/  |
| mar      |               |  |
|          |               |  |
| k        |               |  |
| Den      | sundhed.dk    | https://www.sundhed.dk/borger/patienthaandbogen/kvindesygdomme/sygdomme/prae         |
| mar      |               | vention/praevention-forskellige-praeventionsmetoder/                                 |
| k        |               |  |
| Den      | Sexlinien     | http://www.sexlinien.dk/emneside-praevention/praevention-mellem-kvinder-og-          |
|          | Seximen       |  |
| mar      |               | maend/laegen-om-p-piller.aspx  |
| k        |               |  |
| Den      | Apotek        | http://www.apoteket.dk/Laegemidler/Medicinbrug/L%C3%A6gemiddelgrupper/P-             |
| mar      |               | piller_minipiller.aspx   |
| k        |               |  |
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