



***Working collaboratively with vulnerable women to identify the best implementation gains by screening cervical cancer more effectively in European countries***

Grant Agreement No. 964049

Start date: 01. March 2021

Duration: 60 Months

**Deliverable No 4.2**  
*Qualitative study results*

Nature: Report

Planned delivery date: 31/08/2023

Actual delivery date: 31/01/2024

Lead Beneficiary: *RHR, Pia Kirkegaard, PSE, Lise Rochaix*

Partners involved: *INSERM, UBB, IOCN, HPRC*

Dissemination level		
<b>PU</b>	Public	<b>x</b>
<b>PP</b>	Restricted to other programme participants (including Commission Services)	
<b>RE</b>	Restricted to a group specified by the consortium (including the Commission Services)	
<b>CO</b>	Confidential, only for members of the consortium (including the Commission Services)	



*The CBIG-SCREEN project has received funding from the EU Horizon 2020 research and innovation programme under Grant Agreement No 964049.*

*Disclaimer: The content of this deliverable reflects only the authors' views. The European Commission bears no responsibility for any use of the information contained herein.*

**Executive summary**

CBIG-SCREEN is a project which aims to tackle inequalities in cervical cancer screening (CCS) by developing a Europe-wide knowledge framework around barriers to CCS.

In order for the aims of CBIG-SCREEN to be realised, it is crucial that the voices and perspectives of the target group – the vulnerable women – are heard and promoted.

The aim of Deliverable 4.2 is to identify the factors that hamper or facilitate that vulnerable women participate in CCS.

This report outlines the main objectives of CBIG-SCREEN, key findings from interview studies with vulnerable women in Romania, Bulgaria, France/Alsace and France/Reunion, and potential exploitation of the findings.

**Annexes**

- **Annex I** Summary of (i) Procedures and criteria used to identify/recruit participants and (ii) Informed consent procedures
- **Annex II** Copies of ethic documents

**Background and objectives**

The primary objective of the CBIG-SCREEN project is to address disparities within the cervical cancer screening (CCS) process. Although CCS initiatives contribute to lowering mortality rates, various subpopulations of vulnerable women are not adequately served by the current practices, exacerbating existing inequalities. The inadequate coverage of CCS among subpopulations with the highest risk of developing cancer adds to the challenges faced by underserved groups in maintaining their health.

The CBIG-SCREEN project aims to create a comprehensive knowledge framework across Europe regarding obstacles to CCS. It implements pilot interventions in Estonia, Portugal, and Romania, intending to provide decision-makers with evidence on effective strategies to expand the reach of CCS programmes. The project aims to produce a variety of outcomes tailored to the needs of high-risk, underserved women with limited access to CCS.

The overall objectives of CBIG-SCREEN are to:

- Increase structural knowledge and provide insights into performance and policies of screening vulnerable women;
- Increase early detection and appropriate management of CCS in vulnerable women;
- Create a flexible and responsive evaluation framework of co-constructed implementation models that predict the efficacy and effectiveness of tailored CCS programmes;

- Reduce the burden of cervical cancer in the European Union, improve life expectancy and well-being, and reduce health inequities;
- Decrease disease burden by more efficiently targeting vulnerable women, thus accelerating cervical cancer elimination.

It is a key priority of CBIG-SCREEN to collaborate with the target group to co-construct the new interventions. Through engaging the underserved women themselves, the projects seeks to identify varied and specific needs and preferences of the target groups. The aim is to develop tailored interventions instead of one-size-fits-all which have failed to reach vulnerable women in the past. The first step to engage is to understand, and in order to understand perceived and experiences barriers and preferences for CCS among subgroup of vulnerable women, interview studies were undertaken in different sites (Romania, Bulgaria, France/Alsace and France/Reunion) to explore how vulnerable women from different subgroups in different settings understand CC and CCS. Conducting interviews with vulnerable women about their understanding of CCS is a valuable and inclusive research method that can provide in-depth insights, enhance cultural sensitivity, and contribute to the development of more effective strategies to address health disparities. Understanding barriers and concerns regarding CCS is crucial for designing effective interventions that address needs and preferences.

The objective of task 4.2 in WP4 was to make a nuanced exploration of vulnerable women's barriers to CCS, promoting their perspectives, beliefs and experiences with CC and CCS, in four different sites.

### **Methodology**

Interviews with vulnerable women were conducted in Bulgaria, Romania, France/Alsace and France/ Reunion. Women were recruited through snow-ball sampling and interviews were conducted by experienced interviewers with a background in research and knowledge about vulnerability and CC and CCS. Approval from ethical boards and informed consent from the women to ensure confidentiality and privacy were obtained in all sites. The interviews were semi-structured, based on key questions in an interview guide (Table 1) while allowing for flexibility in the different sites. The interview guide was inspired by an interview guide developed for another project ('RESISTE'). In addition to the core questions, probing questions were added to encourage vulnerable women to elaborate on their responses and help CBIG-SCREEN gain a more comprehensive understanding of their perspectives. The interviews were recorded and transcribed verbatim. A framework analysis was applied through five steps: 1. Familiarisation (in the local languages), 2. identification of a thematic framework (a socioecological framework was chosen) through discussion between sites (in English), 3. indexing and 4. charting (in the local languages), and 5. mapping and interpretation (in English). The socioecological framework depicted patterns across sites, i.e. vulnerable women's barriers to CCS, to identify core features for international policy development.

Table 1: Interview guide

<p><u>Overview image of the participant</u></p> <p>1. For start, I would like to know you better. Can you tell me a bit about yourself?</p>	<p>Probing questions (make sure the following info is touched upon):</p> <p><i>Where do you live? Where do you come from? Your studies/qualifications? Work? Relationship/partnership? Children? What is your current life situation?</i></p>
<p><u>Experiences and perceptions of the healthcare system</u></p> <p>2. What are your views and opinions on your health and healthcare in general?</p> <p>3. How would you describe your experiences and encounters with healthcare?</p> <p>4. If you were seen by doctors/nurses how would you describe your experience? What made your experience like that?</p>	<p>Probes:</p> <p><i>What can you tell me about your health insurance status?</i></p> <p><i>What are the health issues that you've dealt with? How did you deal with them?</i></p> <p><i>If you dealt with these issues in another way, what were the reasons for this?</i></p>
<p><u>Knowledge about &amp; experience with CC</u></p> <p>5. As you were already informed, this project is about ways to improve cervical cancer screening. In your role as a potential beneficiary/patient, I'm curious to know what sort of information you have about cervical cancer.</p> <p>6. What are the things that make you {use participants' words in her answer to question 7} for CC in the future?</p> <p><i>TIP: use participants' own words in her answer to question 7. She might talk about "high/medium/low risk" or "vulnerability" or other term to describe her likelihood of developing CC in the future.</i></p> <p>7. How do you perceive your risk at getting CC? Why is that?</p>	<p>Probes:</p> <p><i>What is your experience with CC?</i></p> <p><i>Do you know anyone who suffered from CC?</i></p> <p><i>Where did you hear about it?</i></p> <p><i>What did you hear about it?</i></p> <p><i>How are your thoughts/emotions about CC and your own risk of getting it</i></p>
<p><u>Screening/Prevention of CC</u></p> <p>8. We discussed about CC which, naturally, makes us touch upon a related topic: What about cervical cancer prevention, what has been your experience with that?</p> <p>In case the woman doesn't mention Pap Smear or HPV and never heard of them, we briefly explain them</p> <p>9. What is your experience with CCS?</p> <p>10. Pap Smear/HPV {insert country situation here} is a free service for women over {insert country situation here}. However, the coverage is not 100%. For instance in {Country} it is around {insert</p>	<p>Probes:</p> <p><i>Did you have any information about CCS/HPV vaccination?</i></p> <p><i>From where did you get the information?</i></p> <p><i>What were you told?</i></p> <p><i>Is it something you've already done? When?</i></p> <p><i>How was it for you?</i></p> <p><i>Do you plan to keep on doing it whenever it is recommended?</i></p> <p><i>If not: Is it something you would do? Why/why not?</i></p>

<p><i>country statistics here</i>}. Why do you think we have this situation? What would be possible explanations?</p> <p>11. Can you think any barriers for you to participate in CCS? In terms of access, the procedure, follow up</p> <p>12. What would have to happen to make sure you have a CCS test?</p> <p>13. What about the women you know? How likely would it be for them to get screening? Why?</p> <p>14. Suppose you are heads-on convinced that CCS is something that you will have to do for your health. In what scenario/what would have to happen for you to change your mind and NOT perform CCS?</p>	<p><i>What are your fears/worries regarding CCS?</i></p> <p><i>What about other women’s concerns?</i></p>
<p><u>Self-sampling</u></p> <p>As part of this project we will investigate if self-sampling is a feasible way to make more women participate in CCS. Show a self- sampling kit and explain how it is done concretely (including the procedure of receiving, returning and getting test result).</p> <p>18. What do you think of such a screening system?</p> <p>19. Would you do it? (explore their concerns if any)</p> <p>20. Do you think other women would do it? (those who don't currently screen for example)</p> <p>21. How would you prefer to receive / return the kit? (post, pharmacy, doctor, do it yourself in a lab...)</p>	<p>Probes:</p> <p><i>Do you have any concerns about this method?</i></p> <p><i>Would you feel safe do to it on your own?</i></p> <p><i>Would you prefer to have support from someone (whom?)</i></p>
<p><u>Closure</u></p> <p>22. Thank you so much for openness to share your story and experiences with me. Women are experts in what is/what is not a sensible, feasible, right approach to CCS, since we are the beneficiaries of it. Although there is a lot of information I’ve heard from you and a lot of very useful input, I’m not sure whether you had the chance to tell your full story and opinion on CC and CCS. Are there any other things related to CC and CCS that we should explore?</p>	

## Achievements

A total of 71 women were interviewed in the four sites. The vulnerabilities were intersecting and covered low socio-economic status, ethnic minority status, unemployment etc. (Table 2). In Romania, 18 women (mean age 42 years, range 25-60) were interviewed and in Bulgaria, 27 women (mean age 39 years, range 20-60) were interviewed. In France/Reunion, 12 women (mean age 44, range 28-62) were interviewed and in Alsace, 14 (mean age 52, range 25-65) were interviewed.

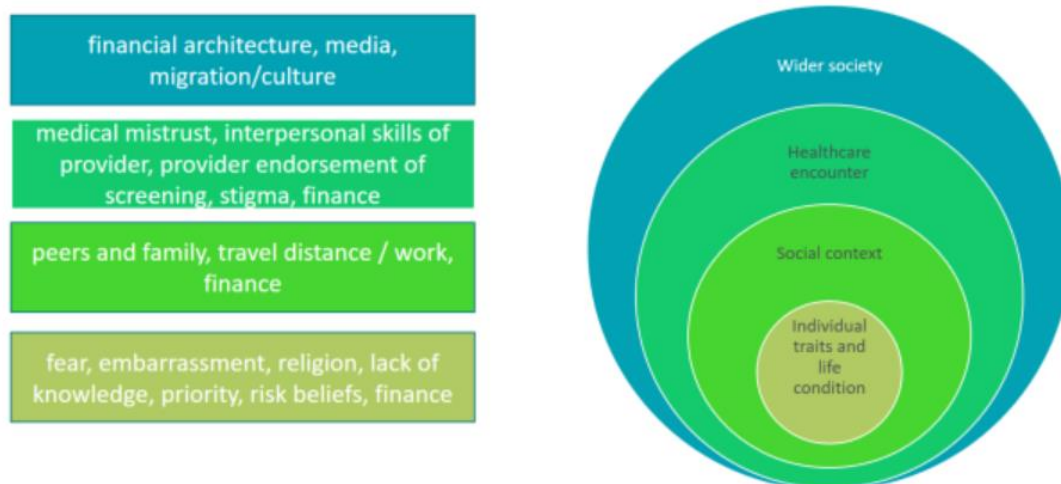
Table 2	Romania	Bulgaria	Alsace	Réunion	All sites
Interview participants	18	27	14	12	71
Age (years)					
Average	42	39	52	44	44
20-30	4	8	2	1	15
31-40	5	7	2	3	17
41-50	4	4	1	6	15
51-60	5	8	2	1	16
61-	0	0	7	1	8
Education					
No school	1	0	1	3	5
Elementary	1	3	2	0	6
Primary	0	8	6	1	15
Secondary	4	10	2	3	19
Higher	6	4	5	2	17
No info	6	2	0	3	11
Location					
Village	15	7	3	4	29
City	3	19	11	6	39
Prison	0	0	0	2	2
No info	0	1	0	0	1

Health insurance					
Insured	11	15	14	12	52
Not insured	6	12	0	0	18
Co-insured	1	-	-	-	1
Type of vulnerability					
Unemployed	12	10	2	12	36
Ethnic minority or migrant	2	13	3	6	24
Low socio economic status	15	12	8	12	47
Difficult access to healthcare	2	5	2	2	11
Disability, mental health problems, addiction	1	-	5	4	10

Four layers of influence on vulnerable women's participation in CCS are depicted in Figure 1: individual traits and life conditions; social contexts; healthcare encounters; and the influence of the wider society. The most prominent cross-cutting influences are described below.

Figure 1

### Socio-ecological model of influences



On the individual level, many feared discomfort and pain during the examination. In addition, they did not perceive themselves as being at risk of CC and called for better information about CC and the benefits of CCS from educational campaigns and from healthcare providers.

For some vulnerable women, religious beliefs played a role in influencing CCS, leading to hesitancy or refusal. However, this was less common and not cross-cutting. A very prominent cross-cutting finding was that the vulnerable women often adopted a reactive healthcare approach, seeking medical attention exclusively when they experienced symptoms. Many did not know about the asymptomatic nature of early-stage CC, and they did not know that CC is often curable if detected early. The prevailing focus on symptoms leads to the notion that visiting a healthcare professional only becomes pertinent when health issues arise. Only in case of childbirth, post-partum examination or birth control did the women seek medical attention without having symptoms.

On the social context level, the women explained that they faced numerous challenges and competing priorities in their daily lives. Familial expectations and financial responsibilities discouraged women from prioritizing their own health. Competing demands could lead to neglect of personal health, but for some women, having children could also encourage CCS participation, owing to a feeling of responsibility for their family. Social influences from family and peers helped reinforce the symptom-focused approach, shaping perceptions of when it is appropriate to contact a healthcare provider.

Having low socio-economic status means that marginal fluctuations in household income can have a large impact on daily life commitments. Therefore, work-related commitments and constraints often posed challenges for the vulnerable women, including inflexible work schedules, and lack of employer support.

On the healthcare encounter level, healthcare encounters in general defined (negative) experiences and expectations of CCS. Vulnerable women had negative experiences with the gynecological examination and felt stigmatized due to their vulnerabilities. They wanted healthcare providers to create a supportive and non-judgmental environment as the interpersonal skills of healthcare providers significantly influenced the CCS experience. The women called for ways to mitigate anxiety and fear associated with CCS and wanted the healthcare providers to display empathy and address individual concerns. They explained that the healthcare providers had failed to inform about CCS and that endorsement of CCS by healthcare providers could influence decisions to participate. Many women harbored a mistrust of the healthcare system due to opaque financial structures and incentives for healthcare providers. In addition, women who wanted CCS found it hard to navigate the healthcare system due to lack of CCS invitations, lack of reminders, lack of referrals and difficulties in getting an appointment.

On the society level – and pervading all levels - the financial barriers were the most prominent problem encountered by the vulnerable women. For many women, free-of-charge CCS and follow-up could increase CCS participation, but in places where CCS was free owing to universal health coverage for lower-income households or to insurance, many women were unaware of this. The women mentioned that the media could play a bigger role in provision of information about benefits and access to CCS. The vulnerable women also identified migration from countries without a

tradition for CCS as a challenge which required culturally sensitive educational campaigns to destigmatise CCS, promoting a positive narrative, and encouraging open dialogue about women's health.

In summary, barriers to CCS among vulnerable women included financial constraints in accessing CCS, previous negative healthcare experiences and lack of healthcare provider endorsement and information about CCS. Addressing these issues requires improved information dissemination, creating a supportive healthcare environment, and tackling systemic challenges. It is worth noting that literature about barriers to CCS among women *not* considered vulnerable from a socio-economic perspective shows that fear of the examination and embarrassment in the medical encounter is a common experience that hampers CCS. This experienced discomfort is 'universal' but stigma and medical distrust may be a more prominent experience in the healthcare encounter between vulnerable women and healthcare providers.

The interviews with the vulnerable women also introduced them to the notion of 'self-sampling' – see Table 1. Self-sampling in CCS requires that the woman receives a self-sampling kit, performs the self-sampling at home and returns the kit to a laboratory and waits for the result. This method is innovative and has the potential to increase participation among all women who wish to participate in CCS. The results from the interviews indicate that self-sampling has a great potential because it eliminates barriers at the individual level, the social level, and the healthcare encounter level. On the individual level, we saw that women only go to the healthcare provider when symptoms appear. With a self-sampling kit, women should only go to the healthcare provider for a gynecological examination if the self-sample is positive for Human Papillomavirus (HPV). In this way, the prompt to seek medical attention is a positive HPV result of the self-sampling. On the social context level, the self-sampling method bypasses the constraints regarding taking time off work, since it can be performed at any time of the day. In addition, self-sampling is performed in privacy without involvement of family or peers. On the healthcare encounter level, CCS with self-sampling only requires a gynecological examination in case of a positive HPV result which can reduce the number of required CCS related healthcare encounters.

### **Impact and potential exploitation of the results.**

The interview study has the potential to inform healthcare providers about the specific barriers vulnerable women face in accessing cancer screening services and may lead to the development of more accessible and inclusive healthcare services. Comparing findings across Bulgaria, Romania, and France/Alsace and France/Reunion reveals cross-cultural insights that can inform strategies for addressing health disparities and improving outcomes.

The interview study showed that self-sampling could make screening more accessible, although it requires building awareness about and HPV and CC. It also requires working closely with decision-makers to address any healthcare system-related barriers such as financial barriers.

The insights may foster collaboration to share best practices and address common challenges in cancer screening for vulnerable populations. Interventions may be based on self-sampling kits and include the following:

- a) Educating healthcare professionals on how to disseminate knowledge about CCS to vulnerable women and help destigmatize the screening process and design linguistically appropriate communication materials that resonate with the vulnerable population and are feasible for the healthcare providers to support and disseminate.
- b) Public media campaigns that provide information about the importance and potential of prevention of CC through screening and information about proper healthcare seeking behavior, including the fact that screening is for women without symptoms of CC.
- c) Targeted outreach programs to destigmatize the screening process and increase of awareness, and interventions that reduce transportation distances, for instance mobile screening units, or partnerships with local clinics for provision of self-sampling kits.
- d) Community engagement to build trust and address specific concerns. This could include health education workshops to provide education about the importance of cancer screening, the process involved, and the potential benefits. How to use self-sampling kits should be integrated in this.

### **Conclusions**

The study described in this Deliverable 4.2 showed that vulnerable women across countries shared similar experiences and barriers to CCS. This included financial barriers, limited awareness about CC and the benefits of screening, social influences reinforcing a symptom-focused approach, and difficulty navigating the healthcare system. The women wanted better information about CC and CCS from healthcare providers and public campaigns. Recommendations for interventions include educating healthcare providers to communicate effectively about CC and CCS, to provide self-sampling kits and to reduce financial and organisational constraints in access to CCS.

### **Partners involved in Deliverable 4.2**

PSE provided an interview guide already used in the French project RESISTE and translated it into English, and this interview guide inspired the development of an interview guide for all sites. All partners contributed to the adaptation of the RESISTE interview guide to CBIG-SCREEN objectives and to the development of the data and analysis framework.

PSE and INSERM made the final protocol for France/Alsace and France/Reunion and conducted all interviews in both sites.

UBB and IOCN made the final protocol for Romania and conducted all interviews in Romania.

HPRC made the final protocol for Bulgaria and conducted all interviews in Bulgaria.

RHR was in charge of coordinating the qualitative interviews in France/Alsace, France/Reunion, Bulgaria, and Romania, of conducting monthly meetings among all partners involved and of analysing the results.

The contributors on behalf of PSE and INSERM were:

Lise Rochaix  
Caroline Despres  
Camilla Fiorina  
Violette Delisle

Amber Cripps  
Margaux Guerrien  
Dolorès Pourette  
Alexandre Dumont  
Marc Bardou  
The contributors on behalf of HPRC and IOCN were:  
Irina Todorova  
Yulia Panayotova  
Tatyana Kotzeva  
Raya Mihaylova

The contributors on behalf of UBB were:  
Diana Taut  
Adriana Baban  
Nicoleta Jiboc

The contributors on behalf of RHR were:  
Pia Kirkegaard  
Rikke Buus Bøje

## References

- Crăciun IC, Todorova I, Băban A.** *"Taking responsibility for my health": Health system barriers and women's attitudes toward cervical cancer screening in Romania and Bulgaria.* J Health Psychol. 2020 Nov-Dec;25(13-14):2151-2163. doi: 10.1177/1359105318787616. Epub 2018 Jul 16. PMID: 30010430.
- Gale NK, Heath G, Cameron E, Rashid S, Redwood S.** *Using the framework method for the analysis of qualitative data in multi-disciplinary health research.* BMC Med Res Methodol. 2013 Sep 18;13:117. doi: 10.1186/1471-2288-13-117. PMID: 24047204; PMCID: PMC3848812.
- Hassine A, Antoni G, Fender M, Slama K, Léandri FX, Fanon JL, Auvray C, Jaffar Bandjee MC, Traversier N, Fagour L, Rochaix L, Fiorina C, Pourette D, Opigez E, Dumont A, Bardou M, Study Group R.** *Combined incentive actions, focusing on primary care professionals, to improve cervical cancer screening in women living in socioeconomically disadvantaged geographical areas: a study protocol of a hybrid cluster randomised effectiveness and implementation trial- RESISTE.* BMJ Open. 2022 Nov 23;12(11):e065952. doi: 10.1136/bmjopen-2022-065952. PMID: 36418118; PMCID: PMC9684961.
- McLeroy KR, Bibeau D, Steckler A, Glanz K.** *An ecological perspective on health promotion programs.* Health Educ Q. 1988 Winter;15(4):351-77. doi: 10.1177/109019818801500401. PMID: 3068205.
- Pourette D, Cripps A, Guerrien M, Desprès C, Opigez E, Bardou M, Dumont A.** *Assessing the Acceptability of Home-Based HPV Self-Sampling: A Qualitative Study on Cervical Cancer Screening Conducted in Reunion Island Prior to the RESISTE Trial.* Cancers (Basel). 2022 Mar 8;14(6):1380. doi: 10.3390/cancers14061380. PMID: 35326530; PMCID: PMC8946624.

**Stenzel** AE, Bustamante G, Sarkin CA, Harripersaud K, Jewett P, Teoh D, Vogel RI. *The intersection of sexual orientation with race and ethnicity in cervical cancer screening*. *Cancer*. 2022 Jul 15;128(14):2753-2759. doi: 10.1002/cncr.34213. Epub 2022 May 16. PMID: 35570647; PMCID: PMC9301613.

**Sun** L, Patel S, Fiorina C, Glass A, Rochaix L; CBIG-SCREEN Consortium; Foss AM, Legood R. *A systematic review of the cost-effectiveness of interventions to increase cervical cancer screening among underserved women in Europe*. *Eur J Health Econ*. 2023 Sep 20. doi: 10.1007/s10198-023-01627-1. Epub ahead of print. PMID: 37726429.

**Sundstrom** B, Smith E, Delay C, Luque JS, Davila C, Feder B, Paddock V, Poudrier J, Pierce JY, Brandt HM. *A reproductive justice approach to understanding women's experiences with HPV and cervical cancer prevention*. *Soc Sci Med*. 2019 Jul;232:289-297. doi: 10.1016/j.socscimed.2019.05.010. Epub 2019 May 10. PMID: 31121439.

**Tergas** AI. *Intersecting identities and cancer screening*. *Cancer*. 2022 Jul 15;128(14):2698-2700. doi: 10.1002/cncr.34212. Epub 2022 May 16. PMID: 35570646.

**Todorova** I, Baban A, Alexandrova-Karamanova A, Bradley J. *Inequalities in cervical cancer screening in Eastern Europe: perspectives from Bulgaria and Romania*. *Int J Public Health*. 2009;54(4):222-32. doi: 10.1007/s00038-009-8040-6. PMID: 19396397.

**Tranberg** M, Bech BH, Blaakær J, Jensen JS, Svanholm H, Andersen B. *HPV self-sampling in cervical cancer screening: the effect of different invitation strategies in various socioeconomic groups - a randomized controlled trial*. *Clin Epidemiol*. 2018 Aug 23;10:1027-1036. doi: 10.2147/CLEP.S164826. PMID: 30197540; PMCID: PMC6112594.

## Annex I - Summary of (i) Procedures and criteria used to identify/recruit participants and (ii) Informed consent procedures

### (i) Summary of procedures and criteria used to identify/recruit participants

- *Selection of participants (inclusion/exclusion criteria)*

**France and Romania:** For the qualitative interviews, vulnerable women were identified based on specific inclusion criteria reflecting increased risk of exclusion from health services. These included living in remote or rural areas, lacking health insurance, experiencing socio-economic precarity, or being the sole adult in a household (e.g., single mothers or women living alone).

**Romania:** Participants for the qualitative interviews were selected, based on several inclusion criteria, informed by the Research Questions. Our definition for vulnerability was based on these indicators: not living in remote (rural) areas, having low socioeconomic status, being unemployed and being from an ethnic minority. The sample for the interviews was purposeful. It was composed based on female gender, age (20-60), ethnicity, education, place of residence (remote or capital), low socioeconomic status, having previous PAP smears.

- *Recruitment process*

**France and Romania:** Women were recruited through snow-ball sampling and interviews were conducted by experienced interviewers with a background in research and knowledge about vulnerability and CC and CCS. Approval from ethical boards and informed consent from the women to ensure confidentiality and privacy were obtained in all sites.

**Bulgaria:** Recruitment was conducted through contacts with colleagues in Sofia and other cities in Bulgaria, who contacted potential participants through initial telephone calls and informational brochures. The interviews were conducted in-person.

- *Justification for the chosen criteria and procedures*

**France and Romania:** Age was chosen as a specific criteria because age specific approaches can improve education, awareness, and uptake. For example, younger women may require more information on HPV and the link to cervical cancer, while older women may need support around previous negative experiences or fears related to screening. Socioeconomic status (SES) was included as a criteria because lower SES is linked to lower screening rates and higher cervical cancer mortality.

**Bulgaria:** The criteria were related to increased vulnerability – i.e high risk of barriers to access to the healthcare system, and thus to cervical cancer screening.

### (ii) Summary of informed consent procedures

- *The process of obtaining consent including format*

**France:** Oral presentation of the study and verbal consent (including permission to record) were audio-recorded at the beginning of each interview. The original written information sheet was not used; instead, it was transformed into an oral presentation.

**Romania:** Participants were informed about the study purpose and procedures through an information sheet, which was read aloud to ensure understanding. Oral consent was obtained from all participants. For those interviewed face-to-face, written consent was also collected via a signed form. For phone interviews, verbal consent was audio-recorded in accordance with ethical guidelines.

**Bulgaria:** Participants were informed about the purpose of the study through an informational brochure and consent form. The purpose of the study, risks, benefits, audio recording procedure, data protection plan and the right to withdraw from the study were reviewed and read out

loud. Participants were given the opportunity to ask questions before the interview was initiated. Signed consent forms were collected from participants and a copy with contact information for the research team were handed out to each woman. Signed consent forms and interview transcripts are held at the HPRC office in a locked cabinet.

- *Information provided*
  - The legal basis for processing is the public interest mission of scientific research
  - Confidentiality and use of data
  - Institutions involved in collecting, processing, analyzing
  - Information on Data Access and data retention
  
- *Technical and organisational measures that were implemented to safeguard the rights and freedoms of the data subjects/research participants*

All data was handled following strict ethical guidelines, ensuring confidentiality and that participants' privacy was maintained. We kept all collected data secure by encryption and restricted access (GDPR-compliant measures such as BlueWhale to transfer data in a secure way), to protect it from unauthorised access. The data was used exclusively to analyse the relationship between vulnerability and cervical cancer screening, and we did not share or process any data for purposes unrelated to this study.
  
- *Explain how all the data they intend to process is relevant and limited to the purposes of the research project*

Only data that was necessary for this analysis was collected. The focus was solely on variables that contributed to the exploration of vulnerable women's barriers to cervical cancer screening, promoting their perspectives, beliefs and experiences with cervical cancer and screening. This ensured that data processing was limited and relevant to the research.

**Annex II** Copies of ethic documents**France:**

- Ethical approval
- Information sheet

**Romania:**

- Ethical approval
- Information sheet and consent sheet

**Bulgaria:**

- Ethics committee protocols 2022 and 2023
- Informed consent form
- CBIG-SCREEN WP4 information form

# COMITE DE PROTECTION DES PERSONNES SUD MEDITERRANEE III

Président: J-Y. LEFRANT Vice-Président: A-M. JOUBERT

Référence CPP à rappeler: **2018.10.04 / 18.07.11.52757** Nîmes, le: **31 Octobre 2018**

Lors de sa séance du: **03 octobre 2018** Présidée par Mme ou M: **J-Y. LEFRANT**

En présence des membres suivants: Mmes et MM:		Membres titulaires		Membres suppléants	
1 <sup>er</sup> Collège	Personnes qualifiées en recherche biomédicale	<input checked="" type="checkbox"/>	J-Y. LEFRANT S. DROUPY D. MOTTET	<input checked="" type="checkbox"/>	C. LECHICHE R. DE TAYRAC L. GONTHIER-MAURIN
	Compétents en biostatistique/épidémiologie	<input checked="" type="checkbox"/>	C. DEMATTEI	<input checked="" type="checkbox"/>	S. BASTIDE
	Médecins généralistes	<input checked="" type="checkbox"/>	M. GARCIA	<input checked="" type="checkbox"/>	P. SERAYET
	Pharmaciens hospitaliers	<input checked="" type="checkbox"/>	A. MOURGUES	<input checked="" type="checkbox"/>	G. LEGUELINEL
2 <sup>e</sup> Collège	Infirmiers	<input checked="" type="checkbox"/>	G. BAVILLE	<input checked="" type="checkbox"/>	A. GIRON
	Compétents en questions éthiques	<input checked="" type="checkbox"/>	C. BERHAULT		
	Psychologues	<input checked="" type="checkbox"/>	L. HERITIER		C. AYELA
	Travailleurs sociaux				
	Compétents en matière juridique	<input checked="" type="checkbox"/>	E. TOULOUSE-MULLER C. ROLLAND	<input checked="" type="checkbox"/>	M. GRIT
Personnes cooptées	Représentants d'associations agréées de malades et usagers du système de santé	<input checked="" type="checkbox"/>	A-M. JOUBERT		M. SANCHEZ
	Spécialiste pour défaut de consentement	<input checked="" type="checkbox"/>	Y. PRIOUX		

Les membres suivants s'étant retirés: Mmes et MM:

Le comité de protection des personnes Sud Méditerranée III a examiné les informations relatives à un projet référencé localement sous le numéro ci-dessus, et identifié par le numéro ci-dessous, relatif à:	<input type="checkbox"/>	Recherche interventionnelle de type 1
	<input checked="" type="checkbox"/>	Recherche interventionnelle de type 2
	<input type="checkbox"/>	Recherche non interventionnelle de type 3
	<input type="checkbox"/>	Utilisation d'éléments et produits du corps humain
	<input type="checkbox"/>	Collection d'échantillons biologiques

Numéro d'enregistrement: EudraCT ANSM 2018-A01841-54

Intitulé du projet: "Action incitative combinée, centrée sur les acteurs de soins primaires, pour améliorer le dépistage du cancer du col de l'utérus chez des femmes socialement défavorisées et non suivies : un essai hybride d'efficacité et de mise en œuvre"

Promoteur: CHU DE DIJON

Investigateur principal ou coordonnateur: PR. BARDOU

Lieu de recherche (si soumis à autorisation):

Au titre d'une demande d'avis concernant:	<input checked="" type="checkbox"/>	Projet initial	Dans le cadre de:	<input checked="" type="checkbox"/>	Première soumission
	<input type="checkbox"/>	Modification substantielle N°		<input type="checkbox"/>	Nouvelle soumission d'un projet modifié en réponse aux observations du comité

Date de réception du projet visé: 02 juillet 2018

<input checked="" type="checkbox"/>	Le comité, ayant examiné ou réexaminé le projet soumis, exprime en séance plénière l'avis ci-contre:	<input checked="" type="checkbox"/>	Favorable
<input type="checkbox"/>		<input type="checkbox"/>	Défavorable
<input type="checkbox"/>		<input type="checkbox"/>	Différé
<input type="checkbox"/>		<input type="checkbox"/>	P2P (sans 2 <sup>ème</sup> passage)
<input type="checkbox"/>		<input type="checkbox"/>	2P (2 <sup>ème</sup> passage)
<input type="checkbox"/>		<input type="checkbox"/>	Eclaircissements des réponses apportées

Date de prise d'effet du présent avis: 31 octobre 2018

Le président:  Le vice-président:  Le président de séance:

# COMITE DE PROTECTION DES PERSONNES SUD MEDITERRANEE III

Président: J-Y. LEFRANT Vice-Président: A-M. JOUBERT

Référence CPP à rappeler:	2018.10.04
---------------------------	------------

Le présent avis concerne spécifiquement les documents suivants:	Version n° :	En date du:
X Courrier de demande		22 juin 2018
X Formulaire de demande		22 juin 2018
X Bordereau d'enregistrement n° ID-RCB		22 juin 2018
X Attestation d'assurance		25 juin 2018
X Document Additionnel		22 juin 2018
X Protocole	01	21 juin 2018
X Résumé protocole	01	21 juin 2018
X lettre de pré-information envoi d'un kit de dépistage gratuit	1	22 juin 2018
X Note d'information groupe contrôle	1	22 juin 2018
X Note d'information groupe intervention 1	1	22 juin 2018
X Note d'information groupe intervention 2	1	22 juin 2018
X Note d'information groupe intervention 3	1	22 juin 2018
X Note d'information groupe intervention 4	1	22 juin 2018
X Courrier d'information patiente résultat test AHPV +	1	22 juin 2018
X Courrier d'information patiente résultat test AHPV -	1	22 juin 2018
X Notice de réalisation d'auto-prélèvement vaginal groupe contrôle	1	20 juin 2018
X Notice de réalisation d'auto-prélèvement vaginal groupe intervention 1	1	20 juin 2018
X Notice de réalisation d'auto-prélèvement vaginal groupe intervention 2	1	20 juin 2018
X Notice de réalisation d'auto-prélèvement vaginal groupe intervention 3	1	20 juin 2018
X Notice de réalisation d'auto-prélèvement vaginal groupe intervention 4	1	20 juin 2018
X Note d'information et formulaire de consentement destiné à la patiente – étude qualitative	1	22 juin 2018
X Courrier d'information professionnel de santé	1	22 juin 2018
X Courrier d'information professionnel de santé test AHPV +	1	22 juin 2018
X Courrier d'information professionnel de santé test AHPV -	1	22 juin 2018
X Note d'information et formulaire de consentement destiné au professionnel de santé – étude qualitative	1	22 juin 2018
X Liste investigateur	1	22 juin 2018
X CV du ou des investigateurs		
X Fiche de renseignement	1	20 juin 2018
X Auto-questionnaire à destination des patientes	1	20 juin 2018
X Grille d'entretien auprès des acteurs institutionnels	1	19 juin 2018
X Grille d'entretien avec les femmes incluses dans l'étude pour un auto-test	1	19 juin 2018
X Grille d'entretien avec les conjoints	1	19 juin 2018
X Grille d'entretien avec les professionnels de santé	1	19 juin 2018
X Justification de l'adéquation des moyens		

## REMARQUES

(1) Le comité prend en considération pour sa décision les conditions de validité de la recherche au regard de la protection des personnes, notamment l'information des participants avant et pendant la durée de la recherche y compris l'adéquation, l'exhaustivité et l'intelligibilité des informations écrites, les modalités de recueil de leur consentement, les indemnités éventuellement dues, la pertinence générale du projet et l'adéquation entre les objectifs poursuivis et les moyens mis en œuvre, ainsi que la qualification du ou des investigateurs.

(2) Quel que soit l'avis du Comité, il ne dégage pas le promoteur de sa responsabilité.

(3) Conformément à la réglementation, tout avis est transmis à l'autorité compétente et, en cas d'avis défavorable, aux autres comités.

(4) En cas d'avis différé, le promoteur est invité à transmettre au comité dans les meilleurs délais les informations complémentaires demandées et/ou le projet modifié répondant aux réserves exprimées. Il peut demander, ainsi que l'investigateur principal, à être entendu par le comité.

## MOTIVATION DE L'AVIS DU COMITE

Adresser la correspondance à : CPP SUD-MEDITERRANEE III, UFR MEDECINE 186, chemin du Carreau de Lanes CS 8021  
30908 NIMES Cedex 2  
Secrétariat : Mme CABRERA  
e-mail : [cpp.sudmediterranee3@gmail.com](mailto:cpp.sudmediterranee3@gmail.com)

Téléphone/Fax : 04 66 02 81 55

Page 2 sur 2

---

## **INTRODUCTION**

La fiche d'information sera remise aux femmes et le formulaire de consentement signé sera recueilli. Néanmoins, compte-tenu du profil des femmes et de notre population cible, des femmes précaires, dont certaines peuvent être illettrées et d'autres ne pas parler français, nous les informerons de manière privilégiée par oral et vérifierons le caractère éclairé de leur consentement de la même manière, lors de la prise de rendez-vous et à nouveau, lorsque nous les rencontrerons en face à face.

---

## FICHE D'INFORMATION DESTINEE AUX FEMMES

### Informations

Bonjour, je suis anthropologue, mon travail consiste à discuter avec des personnes sur des questions de santé.

Aujourd'hui, je viens vers vous car je réalise avec une équipe de chercheurs une étude sur le cancer du col de l'utérus. A l'heure actuelle, nous savons peu de choses sur les connaissances et les expériences qu'ont les femmes à propos de cette maladie. Par exemple, comment les femmes procèdent pour se protéger contre cette maladie ? Comment accèdent-elles à l'information et aux services liés au cancer du col de l'utérus ? Quelles difficultés rencontrent-elles ? Parlent-elles du dépistage, de la prévention ou de la maladie avec leur entourage ? Etc.

Si vous acceptez de participer à l'étude, vous serez invitée à discuter avec moi de tout ce dont je viens de vous parler. L'entretien aura lieu dans un endroit de votre convenance. Ce travail est complètement anonyme et confidentiel. Personne n'écouterà les entretiens à part les membres de l'équipe et votre nom n'apparaîtra sur aucun document.

Comme les entretiens, les résultats de l'étude seront totalement anonymisés. Ils feront l'objet de rédaction de rapports scientifiques. Ils seront également utilisés pour des publications scientifiques, des communications/conférences, des restitutions aux acteurs de terrain. Vous pourrez participer à une de ces restitutions ou obtenir les rapports si vous le souhaitez.

Cette étude est purement volontaire ; vous pouvez ne pas y participer. Si vous y participez et qu'ensuite vous changez d'avis, vous pourrez vous retirer à tout instant. Si vous refusez de participer ou si vous vous retirez de l'étude, vous ne serez pas pénalisée et vous continuerez à bénéficier de toutes les prestations auxquelles vous avez droit dans les structures de santé (lorsque nous nous serons rencontrées via ces structures).

En signant ce formulaire de consentement, vous attestez que vous avez compris les informations relatives à l'étude et que vous acceptez d'y participer.

Si vous avez des questions, vous pouvez nous contacter à n'importe quel moment de l'étude :

Dolorès Pourette : 0672001238 (coordinatrice de l'étude anthropologique)

Amber Cripps : 0693848634 (anthropologue)

## FORMULAIRE DE CONSENTEMENT ECLAIRE DESTINE AUX FEMMES

Mme....., m'a expliqué la nature et les objectifs de cette étude. J'ai également lu la fiche d'information relative à cette étude (ou j'ai compris l'explication orale) et je comprends de quoi il s'agit.

J'ai été informée des faits suivants :

- L'enquête consiste en un ou plusieurs entretiens,
- J'ai le droit de ne pas répondre aux questions qui me sont posées,
- J'ai la possibilité de faire appel à une personne de mon choix pour éclaircir les questions soulevées par ma participation à cette recherche,
- Mon nom n'est pas enregistré et aucun élément permettant de me reconnaître ne sera dévoilé,
- La personne qui réalise cette enquête est tenue au secret professionnel,
- Il m'est possible à tout moment de contacter la coordinatrice de l'étude, Dolorès Pourette (0672001238)
- J'ai le droit de quitter l'étude à n'importe quel moment sans que cela ait des répercussions pour moi,
- Je suis libre de revenir sur mon consentement à tout moment,
- J'aurai accès, si je le désire, aux résultats de la recherche

Mon consentement ne décharge en rien les personnes réalisant cette étude de leurs responsabilités. J'accepte librement de participer à cette recherche dans les conditions précisées dans la note d'information.

A....., le .....

Signature ou empreinte digitale

.....

## **FICHE D'INFORMATION ET DE DEMANDE DE CONSENTEMENT DESTINEE AUX ACTEURS INSTITUTIONNELS ET AUX PROFESSIONNELS DE SOINS**

### **But de la recherche**

Le but de cette recherche socio-anthropologique est de documenter l'ensemble des systèmes de contrainte qui entravent l'accès au dépistage organisé du Cancer du col de l'utérus (CCU) en France, tant du point de vue des acteurs et professionnels de santé travaillant sur la problématique que de celui des femmes confrontées ou susceptibles d'être confrontées au CCU dans le département. Les résultats de cette recherche permettront à l'équipe de recherche du projet RESISTE de développer une intervention de prévention du CCU pertinente, acceptable, de qualité, facilement reproductible (intégrée à des services de santé existants). Cette intervention serait évaluée dans le cadre d'une recherche interventionnelle, dans le but de produire des arguments en termes de faisabilité et des recommandations pratiques pour sa mise à l'échelle.

### **Procédures de la recherche**

Afin de documenter l'axe institutionnel nous réaliserons des entretiens semi-directifs avec des acteurs intervenants dans la lutte contre le CCU. L'entretien aura lieu dans un endroit de votre convenance. L'entretien sera enregistré si vous en êtes d'accord. Si vous acceptez que l'entretien soit enregistré, sachez que votre nom n'apparaîtra ni sur les fichiers audio, ni sur aucun document. Vous serez libre d'interrompre à tout moment l'enregistrement. Vous pourrez participer à cette étude sans que l'entretien ne soit enregistré. Le choix vous revient.

Au cours de l'entretien, nous parlerons de votre activité professionnelle, de vos conditions de travail, et de vos motivations personnelles. Nous recueillerons également des informations sur votre expérience dans la prise en charge et la prévention du CCU, vos perceptions du CCU, sa place au sein de votre structure, les formes de collaboration et les contraintes autour de la prise en charge du CCU, etc.

Nous pourrions être amenés à vous solliciter à plusieurs reprises, si vous l'acceptez, pour obtenir des informations complémentaires sur le sujet de l'étude.

Nous serons amenés également à solliciter votre accord afin de participer à des rencontres ou activités que votre structure pourrait organiser sur la prévention et la prise en charge du CCU.

### **Confidentialité et usages des données**

Toutes les informations de l'étude seront anonymes et confidentielles et feront l'objet de rédaction de rapports scientifiques. Les résultats seront utilisés pour des publications scientifiques, des communications/conférences, des restitutions aux acteurs de terrain auxquelles vous serez convié.

Si vous avez des questions, vous pouvez nous contacter à n'importe quel moment de l'étude :

Dolorès Pourette : 0672001238 (coordinatrice de l'étude anthropologique)

Amber Cripps : 0693848634 (anthropologue)



Nr. 17.091/12.12.2022

## AVIZ DE ETICA CERCETĂRII/ RESEARCH ETHICS APPROVAL

**Consiliul Științific al Universității Babeș-Bolyai din Cluj Napoca**

**The Scientific Council of the Babeș-Bolyai University of Cluj Napoca**

ACORDĂ/ HEREBY GRANTS

Proiectului de Cercetare/ On behalf of the Research Project: **CBIG-SCREEN – O abordare colaborativă a screening-ului cancerului de col uterin**

Cercetător principal/ Principal Researcher (UBB): **Prof. univ. dr. Adriana Băban**

în baza cererii înregistrate sub numărul/ on request submitted under the reference number:  
**557/ 29.11.2022**

AVIZUL FAVORABIL / THE ETHICS APPROVAL

Președinte al Consiliului Științific/ President of the Scientific Council  
Conf. univ. dr. Radu SILAGHI-DUMITRESCU



### **Consimțământ informat**

**Proiect: CBIG-SCREEN – O abordare colaborativă a screening-ului cancerului de col uterin.**

Investigatori (responsabili de date) și afilieri:

Contact: Băban Adriana Smaranda

e-mail: [adrianababan@psychology.ro](mailto:adrianababan@psychology.ro)

telefon: 0744581005

Despre proiect:

În CBIG-SCREEN cercetătorii vor colabora cu reprezentanți ai grupurilor de femei vulnerabile pentru a înțelege și a îmbunătăți modalitatea în care este oferit screening-ul cancerului de col uterin.

CBIG-SCREEN este un proiect EU care are ca scop reducerea consecințelor cancerului de col uterin în Uniunea Europeană, creșterea speranței de viață și stării de bine a femeilor, precum și reducerea discrepanțelor din sistemul de sănătate.

Participarea în cadrul proiectului:

Participarea dumneavoastră presupune o conversație cu cercetătorul CBOG-SCREEN (interviu), prin care să contribuiți cu cunoștințe și opinii în calitate de beneficiară a acestor servicii, în ceea ce privește: barierele privind modalitățile actuale în care este oferit screening-ul cancerului de col uterin, propriile experiențe referitoare la screening, soluții pentru îmbunătățirea serviciilor de screening a cancerului de col uterin, precum și în propunerea de noi soluții care vor fi testate pe perioada proiectului (de ex. disponibilitatea de a utiliza, potențial, un kit de autotestare HPV).

În cadrul acestei cercetări, vom intervieva diferite grupuri de femei sau experți implicați în screening-ul cancerului de col uterin. Întâlnirile individuale vor fi înregistrate audio sau video în urma oferirii acordului dvs. prealabil.

### **Riscuri și beneficii ale participării:**

Participarea în cadrul proiectului vă va oferi posibilitatea să vă exprimați opiniile referitor la accesul dvs. sau al persoanelor ca dvs. la screening-ul cancerului de col uterin. Nu există riscuri cunoscute privind participarea dumneavoastră în cadrul proiectului.

### **Confidențialitate:**

Toate informațiile obținute pe parcursul studiului vor fi codate pentru a proteja numele și identitatea fiecărui participant. Niciun nume sau alte date de identificare nu vor fi folosite în cadrul discuțiilor sau la raportarea datelor.

Înregistrările audio/video, alte materiale electronice sau transcrieri tipărite vor fi stocate în fișiere criptate sau într-un dulap, într-o locație sigură pentru o perioadă de cinci ani după publicarea acestor cercetări, urmând ca după această perioadă, toate materialele să fie distruse.

### **Participarea voluntară:**

Decizia dumneavoastră de a participa în cadrul acestui studiu este complet voluntară. Dacă decideți să nu participați, această decizie nu va afecta îngrijirea, serviciile sau beneficiile care vi se cuvin.

Dacă decideți să participați în cadrul acestui studiu, puteți să vă retrageți în orice moment, fără nici o consecință.

Dacă doriți să vă retrageți, vă rugăm să contactați:

Nume: Băban Adriana-Smaranda, responsabil proiect Universitatea Babeș-Bolyai

Detalii de contact: [adrianababan@psychology.ro](mailto:adrianababan@psychology.ro)

În cazul în care vă retrageți orice înregistrare cu dumneavoastră va fi ștersă.

Dacă aveți orice întrebare referitoare la protecția datelor dumneavoastră, vă rugăm să contactați biroul pentru protecția datelor.

Responsabil cu protecția datelor DPO Universitatea-Babeș-Bolyai

[Tel:0744423188/0264591906](tel:0744423188/0264591906)

E-mail: [dpo@ubbcluj.ro](mailto:dpo@ubbcluj.ro)

Prin semnarea acestui formular, autorizați folosirea și dezvăluirea următoarelor informații în scopul cercetării, educării sau publicării: folosirea înregistrărilor anonime, și a oricăror observații sau descoperiri deduse pe parcursul cercetării.

Informațiile vor fi împărtășite cu cercetători din cadrul Clinicii pentru screening și Cercetare a Cancerului, Regiunea Centrală a Danemarcăi, Danemarca. (responsabil de date: Pia Kirkegaard.

Email: [Piakik@rm.dk](mailto:Piakik@rm.dk) )

Accept în mod voluntar să particip în cadrul acestui program de cercetare:

**Da**

**Nu**

Înțeleg că mi se va da o copie a acestui Formular de consimțământ semnat.

Numele participantului:

Semnătură:      Data:

Numele martorului:

Semnătură:      Data:

Persoana care primește consimțământul:

Semnătură:

Data:

## СТАНОВИЩЕ

### На Комисията по етика на Българска социологическа асоциация

#### Относно проект „Ефективен скрининг за рак на маточната шийка (CBIG-SCREEN)“

На 13.04.2022 година в Комисията по етика на Българска социологическа асоциация (БСА) постъпи искане от проф. Татяна Коцева за одобрение на научно изследване по проект „Ефективен скрининг за рак на маточната шийка (CBIG-SCREEN)“.

На 19.04.2022 година Комисията по етика проведе заседание, на което участваха всички членове на Комисията:

- Доц. д-р Калоян Харалампиев – председател
- Проф. д-р Валентина Миленкова
- Проф. д-р Татяна Коцева
- Доц. д-р Светлана Събева
- Гл. ас. д-р Тодорка Кинева

Проф. Татяна Коцева в ролята си на вносител участва в заседанието без право на глас.

Комисията разгледа представените документи:

- Молба за одобрение на научно изследване;
- Информационна брошура на проект „Ефективен скрининг за рак на маточната шийка (CBIG-SCREEN)“;
- Покана за участие в проект;
- Сценарий за провеждане на консултативна група;
- Формуляр за информирано съгласие.

След проведеното обсъждане Комисията по етика дава положително становище за научното изследване по проект „Ефективен скрининг за рак на маточната шийка (CBIG-SCREEN)“ със следните аргументи:

- Целта на проекта е в обществена полза: разработване на програми за превенция на здравето, намаляване на неравенствата по отношение на това заболяване, намаляване на смъртността от рак на маточната шийка;
- Планирана е представителна извадка върху базата данни на Единната система за гражданска регистрация и административно обслужване на населението (ЕСГРАОН);
- На участващите в изследването жени ще бъдат предоставени информационни материали и ще бъдат помолени да подпишат формуляр за информирано съгласие;
- Участието в изследването ще бъде доброволно;
- Аудио записи ще се правят само след изрично съгласие на респондентите. В противен случай ще се правят само теренни записки;
- На респондентите е гарантирана анонимност;
- Респондентите няма да се задължават да споделят информация за здравословното си състояние;

В заключение Комисията по етика на БСА смята, че изследването по проект „Ефективен скрининг за рак на маточната шийка (CBIG-SCREEN)“ отговаря на етичните и на професионалните стандарти за провеждане на социологическо изследване.

19.04.2022 г.

София

.....

(Доц. д-р К. Харалампиев)

15.06.2023

## СТАНОВИЩЕ

### На Комисията по етика на Българска социологическа асоциация

#### Относно проект „Ефективен скрининг за рак на маточната шийка (CBIG-SCREEN) – втора част“

На 25.05.2023 година в Комисията по етика на Българска социологическа асоциация (БСА) постъпи искане от проф. Татяна Коцева за одобрение на научно изследване по проект „Ефективен скрининг за рак на маточната шийка (CBIG-SCREEN) – втора част“.

На 14.06.2023 година Комисията по етика проведе заседание, на което участваха всички членове на Комисията:

- Доц. д-р Калоян Харалампиев – председател
- Проф. д-р Валентина Миленкова
- Проф. д-р Татяна Коцева
- Доц. д-р Светлана Събева
- Доц. д-р Тодорка Кинева

Проф. Татяна Коцева в ролята си на вносител участва в заседанието без право на глас.

Комисията разгледа представените документи:

- Молба за одобрение на научно изследване;
- Покана за участие в проект;
- Формуляр за информирано съгласие за участие в групови срещи/семинари;
- Формуляр за информирано съгласие за участие в полу-структурирано интервю;
- Сценарий за провеждане на групови срещи/семинари;
- Протокол за провеждане на полу-структурирано интервю;

След проведеното обсъждане Комисията по етика дава положително становище за научното изследване по проект „Ефективен скрининг за рак на маточната шийка (CBIG-SCREEN) – втора част“ със следните аргументи:

- Целта на проекта е в обществена полза: разработване на програми за превенция на здравето, намаляване на неравенствата по отношение на това заболяване, намаляване на смъртността от рак на маточната шийка;
- На участващите в изследването жени ще бъдат предоставени информационни материали и ще бъдат помолени да подпишат формуляр за информирано съгласие;
- Участието в изследването ще бъде доброволно;
- Във формуляра за информирано съгласие респондентите ще бъдат уведомени, че могат да прекратят участието си в изследването по всяко време;
- Аудио записи ще се правят само след изрично съгласие на респондентите. В противен случай ще се правят само теренни записки;
- На респондентите е гарантирана анонимност;
- Респондентите няма да се задължават да споделят информация за здравословното си състояние;
- Въпросите във въпросниците не са сугестивни и не предизвикват опасения за дискриминация по пол, възраст, етнос и др.;

В заключение Комисията по етика на БСА смята, че изследването по проект „Ефективен скрининг за рак на маточната шийка (CBIG-SCREEN) – втора част“ отговаря на етичните и на професионалните стандарти за провеждане на социологическо изследване.

15.06.2023 г.

София

.....

(Доц. д-р К. Харалампиев)

## Формуляр за информирано съгласие

*“Съвместни действия за определяне на най-добри практики за ефективен скрининг за рак на маточната шийка в Европа.”*

### **За проекта:**

CBIG-SCREEN е европейски проект с обща цел да се намали тежестта на проблема с рака на маточната шийка (РМШ) в Европейския съюз, да се увеличи продължителността и качеството на живот на жените, както и да се намалят неравенствата по отношение на здравето. В проекта CBIG-SCREEN изследователите ще си сътрудничат с представители на необхванати от скрининг групи жени, с медицински специалисти, с представители на неправителствени организации, за да се подобри здравето във всяка от участващите страни и в ЕС.

За тази цел, ние от Научен център “Психология и здраве” организираме срещи с жени от различни населени места, за да поговорим по темата за рака на маточната шийка.

### **Участие в проекта:**

Съгласието Ви за участие означава, че бихте искали да споделите Вашия опит и мнение за трудности, които срещате, когато ходите на лекар или на гинеколог, както и да дадете предложения как да се подобри предлагането на скрининг за това заболяване.

Срещата ще е с продължителност около един час и ще се проведе на предварително определено и удобно за вас място.

Предвиждат се аудиозаписи на срещите.

### **Доброволно участие:**

Решението да участвате в това изследване е изцяло Ваше. Ако решите да се включите, можете да се откажете по всяко време.

### **Рискове и ползи:**

Няма рискове, свързани с Вашето участие в проекта.

### **Конфиденциалност:**

Цялата информация от проекта ще е анонимна с оглед защитата на личните Ви данни. При обсъждането и съобщаването на резултатите няма да се използват имена или друга разкриваща Ви информация.

Аудио записите и всички електронни или хартиени документи ще се съхраняват на безопасно място за пет години след публикуването на изследването, след което ще бъдат унищожени. Ако се откажете от участие, всеки запис с Вас ще бъде изтрит. За въпроси относно защитата на Вашите данни, моля, свържете с екипа на проекта.

Като подписвате този формуляр, Вие давате съгласие да се използва следната информация за целите на изследването: 1/Използване на анонимизираните записи с Ваше участие, 2/Всяко наблюдение и резултати вследствие на това изследване за образователни цели, научни публикации и/или презентации.

Обобщените анонимни данни ще бъдат споделени с изследователи от Клиника за изследване на скрининга на РМШ, Дания (Pia Kirkegaard. e-mail: [Piakik@rm.dk](mailto:Piakik@rm.dk))

За контакт с изследователите от българския екип:

Юлия Панайотова: тел. 0889320466; е-мейл: [yu.panayotova@gmail.com](mailto:yu.panayotova@gmail.com)

Рая Михайлова: тел. 0899564472; е-mail: [rayamichaylova@abv.bg](mailto:rayamichaylova@abv.bg)

Аз давам своето доброволно съгласие да участвам в интервю по проект CBIG-SCREEN.

Да             Не

Подпис:

Дата:



С помощта на всички заинтересовани групи - подлежащи на скрининг жени, лекари, изследователи и специалисти по обществено здраве, Ви предоставяме тази информация за рака на маточната шийка и как можете да се предпазите.

Можете да изпращате въпроси на:  
[bg.hpcenter@gmail.com](mailto:bg.hpcenter@gmail.com)

или да се обадите на телефон:  
0889320466 (Юлия Панайотова)



Международен проект по Рамковата програма на ЕС за научни изследвания и иновации „Хоризонт 2020“  
(Решение 964049)



- Ракът на маточната шийка е заболяване, което се развива „тайно“ в организма на жената, няма ранни симптоми, а когато болките се появят, не винаги лекарите могат да помогнат.
- Скринингът за рак на маточната шийка има за цел да открие ранни изменения в клетките, когато променените участъци могат да се отстранят, за да не се развие рак.
- Скринингът за рак на маточната шийка се прави чрез цитонамазка или тест за висрусна инфекция (HPV).
- Всички жени на възраст от 25 до 60 г. трябва да се преглеждат редовно за рак на маточната шийка, като се възползват от национални или местни кампании, или като помолят техния лекар да им осигури достъп до редовни прегледи.
- В началото скринингът следва да се прави веднъж годишно. След две нормални цитонамазки, изследването може да се провежда и веднъж на три години.
- За момичета, преди началото на полов живот, има и ваксина, която съществено намалява риска от поява на рак на маточната шийка. Скринингът и ваксинацията заедно осигуряват най-ефективната защита срещу рака на маточната шийка.



## ЕФЕКТИВЕН СКРИНИНГ ЗА РАК НА МАТОЧНАТА ШИЙКА (CBIG-SCREEN)

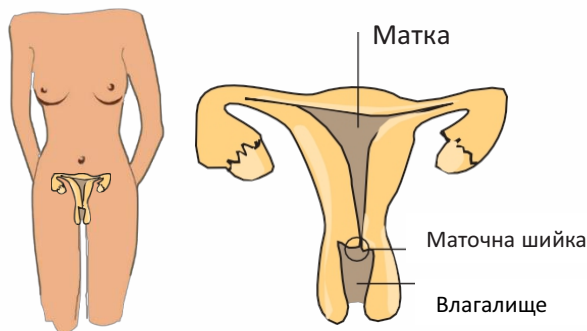
Проект **CBIG-SCREEN** е проект на Европейската комисия, който цели да намали здравните неравенства чрез подобряване на знанията и предлагането на скрининг за рак на маточната шийка на жените, в Европа, и в **България**. Със съвместни действия с необхванати от скрининг групи жени и експерти ще се търсят най-добри практики за ефективен скрининг за рак на маточната шийка в Европа.

<https://cbig-screen.eu>

В България проектът се води от  
Научен център „Психология и здраве“  
[www.healthpsychologycenter.org](http://www.healthpsychologycenter.org)

## Какво представлява ракът на маточната шийка?

Ракът на маточната шийка се развива в тази част от матката, която е отворена към влагалището. Ракът се развива, когато клетките на шийката покажат отклонения от нормата и растежът им излезе извън контрол. Превръщането на изменените клетки в рак на маточната шийка обикновено е дълъг процес, но това не бива да ни успокоява, защото при всяка жена процесите преминават различно. За щастие, ранните стадии се лекуват лесно, но не дават симптоми и могат да бъдат открити само чрез скрининг.



## Защо се прави скрининг?

Скринингът за рак на маточната шийка има за цел да открива изменени клетки в ранните стадии, когато те могат да бъдат отстранени, така че да не се развие рак на маточната шийка. След като ракът веднъж се е развил, лечението става много по-трудно и по-малко успешно.

## Кой подлежи на скрининг?

Всички жени на възраст от 25-30 до 60 години подлежат на скрининг.

В началото скрининг се прави веднъж годишно. След две нормални цитонамазки, изследването може да продължи веднъж на три години. Скринингът за рак на маточната шийка осигурява най-добрата защита, ако се провежда редовно.

## Какво трябва да направите?

За да си направите скринингов преглед е необходимо да посетите гинеколог или общопрактикуващ лекар. Това не трябва да е по време на месечния Ви цикъл. Помолете Вашият личен лекар за допълнителни указания.

## Как се прави скрининг?

Скринингът за рак на маточната шийка се прави чрез цитонамазка или HPV тест.

По време на кратък преглед, лекар (или акушерка) ще вземе проба от клетките на шийката на матката с малка шпатула или четка. Тези клетки се изпращат в лаборатория, където се изследват под микроскоп за изменения.

Има възможност и за тест в домашни условия, но за да го проведете, трябва да попитате Вашия лекар.



## Нормален резултат от цитонамазката?

Повечето жени имат нормален резултат. В този случай рискът за развитие на рак на маточната шийка е нисък и Ви трябва да продължите с редовните прегледи.

## Цитонамазка с изменения?

При някои жени резултатите от цитонамазката или HPV теста е с отклонения., но това не е причина за притеснение. Необходимо е навреме да се обърнете към акушер-гинеколог, който да Ви посъветва какво да направите в зависимост от резултата.

Възможните предложения са:

- нова цитонамазка след три до шест месеца
- допълнителни изследвания
- колпоскопия – процедура, при която лекарят има възможност да огледа маточната шийка по-отблизо.

Ако се налагат допълнителни процедури, лекарят ще Ви информира. Лечението обикновено не засяга сексуалния живот или способността Ви да имате деца.