CBIG-SCREEN

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 6.4
Midterm recruitment report

Nature:
Planned delivery date: March 2024
Actual delivery date: 29 April 2024
Lead Beneficiary: IARC, *Partha Basu*

Dissemination level		
PU	Public	**X**
PP	Restricted to other programme participants (including Commission Services)	
RE	Restricted to a group specified by the consortium (including the Commission Services)	
CO	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.

I. Introduction – Scope of the deliverable

The scope of this deliverable pertains to the CBIG-SCREEN project, specifically within Work Package 6 (WP6), overseen by IARC. The primary goal of WP6 is to pilot and assess co-created strategies for cervical cancer screening (CCS) among vulnerable women in Estonia, Portugal, and Romania. The aim is to enhance their adherence to CCS and improve screening participation rates. The study will be conducted in two phases in the three intervention countries.

The study to evaluate the co-constructed strategies to improve screening participation of the vulnerable women is being implemented in two phases. In phase I women are receiving the usual standard of care in the respective setting for screening, diagnosis, and treatment. No study-specific interventions other than collecting routine data were planned for phase I. The phase I study aims to evaluate the impact of the current standard-of-care practices in CCS on participation of the vulnerable women to HPV detection-based CCS care cascade. In phase II specific strategies are planned to be implemented. They are expected to cover the entire screening continuum starting from invitation to treatment of screen detected cases. The primary objective of phase II is to assess the difference in rates of participation to screening and further management between baseline (phase I; pre-intervention) and phase II (post-intervention), in the CCS programme. The assessment will be performed for each of the three participating countries (Estonia, Portugal, and Romania) independently.

In each participating country, the target of recruiting for phase II was 700 women per country, the sample size for the phase I pilot was not estimated separately. The number was kept same as that required for the phase II intervention study. Sample size estimation for phase II was carried out for the assessment of the outcome on compliance to CCS continuum. The CCS continuum involves participation to screening and compliance to further investigations and/or to treatment, as required.

II. Objectives

The deliverable's objective is to report the status of recruitment for the phase I pilot in Estonia, Portugal, and Romania.

III. Partner(s) Involved

- International Agency for Research on Cancer (IARC), 25 avenue Tony Garnier, 63007 Lyon, France
- University of Tartu (TU), Ülikooli 18, 50090, Tartu, Estonia
- Instituto de Saúde Pública da Universidade do Porto (ISPUP), Rua das Taipas, 135-139 Porto, 4050-600 Portugal
- Institute of Oncology Cluj-Napoca (IOCN), Republicii 34-36, 400015 Cluj Napoca, Romania
- Universitatea Babes-Bolyai (UBB), Republicii 37, 400015 Cluj Napoca, Romania

IV. Results/Achievements

The phase I study is nested within the country's CCS programme and aims to collect data for approximately 700 women per country across all stages of the cascade, including screening, compliance with further investigation such as colposcopy, and/or necessary treatment. A data collection tool was developed in Excel to gather information from the entire cascade for aggregated data, including variables, such as the age distribution of enrolled women, participation refusals, screening history of participants who accepted and for those who refused to participate, information regarding HPV testing, the method of sample collection (self-collection or provider-collected), triage test results for HPV-positive cases, colposcopy findings, and details of treatment in case it was needed. All data are being collected stratified by vulnerability.

The recruitment for phase I so far is as follows:

Estonia:

Estonia has identified a cohort of 2,408 women living with HIV (WLHIV) in Ida-Viru County, corresponding to diagnosis made from 2004 to 2021. Within this cohort, 1,456 women (60.5%) were diagnosed between 2004 and 2009, 650 (26.9%) between 2010 and 2015, and 302 (12.5%) between 2016 and 2021. From this group, a total of 328 WLHIV aged 30 to 65 years old were identified as have been invited for CCS. For these 328 women, aggregated data about their screening history was retrieved from their electronic health records (e-health data), showing that 176 women (54%) had undergone CCS in the last five years.

Portugal:

The phase I of the study is ongoing in the North region, which includes approximately ten primary health care centres in Vila Real, three in Porto, and the agreement for participation of primary health centres in Vila Nova de Gaia is ongoing. Ethical approvals were obtained Porto and Vila Real in December 2023 and in Vila Nova de Gaia in March 2024.
The research team have identified 517 eligible women living in low socioeconomic areas in Porto, for whom data collection is currently in progress. Additionally, the team is working with several support institutions (Médicos do Mundo, Cáritas Vila Real, Porto G, and DICAD, among others) to assist in locating other vulnerable populations including drug users, sex workers, migrants, homeless and Roma populations. Simultaneously, the team is extracting the lists of eligible women for the CCS programme this year in each of the collaborating primary healthcare units. Until now, additionally 289 women from Vila Real have been identified, and a similar process will start soon for Vila Nova de Gaia. So far 53 women have been invited to the study in Porto.

Romania:

In Romania, a total of 733 women have been recruited for phase I. The primary target were vulnerable women living in rural and isolated areas, including women not declared to be part of the Roma community. Recruitment was conducted mainly in campaigns in Bistrita Nasaud, Maramures and Salaj, and 100 women attended mobile units in Cluj.

V. Impact

The phase I data will be the main resource for analysing and preparing a preliminary report on the existing standard of care for CCS in the three intervention countries, and evaluating the results in phase II through comparison.

VI. Publication(s) planned

Tisler et al. Report of data of women living with HIV in Estonia (cohort, 2004 - 2021). Submitted to EJPH.

VII. Conclusions

The recruitment for the phase I protocol across Estonia, Portugal, and Romania has advanced on the identification of eligible women for CCS within their respective regions. In Estonia, a cohort of 2,408 WLHIV in Ida-Viru County has been identified, with 328 of them already been invited to CCS, for which data regarding cervical cancer screening history has been collected and information regarding the results of screening, triaging, and other clinical management is being depurated. In Portugal, collaborators are working to engage vulnerable populations in Porto, Vila Real, and Vila Nova de Gaia; while in Romania, 733 women have been already recruited in Cluj, Bistrita Nasaud, Maramures and Salaj. As data collection progresses, there will be a better understanding of the status of CCS in vulnerable women in these three countries.