Health Research Policy and Systems

RESEARCH

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Development and pilot implementation of a novel protocol to assess capacity and readiness of health systems to adopt HPV detection-based cervical cancer screening in Europe

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Abstract

Background Cervical cancer remains a significant public health concern in Europe. Effective introduction and scaling up of human papillomavirus (HPV) detection-based cervical cancer screening (CCS) requires a systematic assessment of health systems capacity. However, there is no validated capacity assessment methodology for CCS programmes, especially in European contexts. Addressing this gap, our study introduces an innovative and adaptable protocol for evaluating the capacity of CCS programmes across varying European health system settings.

Methods Our research team developed a three-step capacity assessment framework, incorporating a health policy review checklist, a facility visit survey, and key informants' interview guide followed by a strengths, weaknesses, opportunities and threats (SWOT) analysis. Piloting this comprehensive approach, we explored the CCS capacity in three countries: Estonia, Portugal and Romania. These countries were selected due to their contrasting healthcare structures and resources, providing a diverse overview of the European context.

Results Conducted over a period of 9 months, the capacity assessment covered multiple resources, 27 screening centres, 16 colposcopy and treatment centres and 15 key informant interviews. Our analysis highlighted both shared and country-specific challenges. A key common issue was ensuring high compliance to follow-up and management of screen-positive women. We identified considerable heterogeneity in resources and organization across the three countries, underscoring the need for tailored, rather than one-size-fits-all, solutions.

Conclusions Our study's novelty lies in the successful development of this capacity assessment methodology implementable within a relatively short time frame, proving its feasibility for use in various contexts and countries. The resulting set of materials, adaptable to different cancer types, is a ready-to-use toolkit to improve cancer screening processes and outcomes. This research marks a significant stride towards comprehensive capacity assessment for CCS programmes in Europe. Future directions include deploying these tools in other countries and cancer types, thereby contributing to the global fight against cancer.

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Keywords Cervical cancer, Screening, Capacity assessment, Implementation, Contextual analysis, Europe, Romania, Estonia, Portugal, Vulnerable women, Facility visit, Interview, HPV-based screening

Introduction

Cervical cancer remains a significant global public health issue, with high disparity in incidence being reported even within Europe [1, 2]. Despite advancements in medical technology, the disease continues to pose a substantial public health challenge, largely accounting for cancer-related morbidity and mortality among women [3, 4]. Quality assured cervical cancer screening (CCS) programmes play a pivotal role in reducing burden of the disease by identifying precancerous changes for timely intervention [5].

Most successful cancer screening programmes are built and integrated within health systems and healthcare services that are effective and efficient [5]. Health system capacity assessment, also often referred to as baseline assessment, is a systematic approach to evaluate the adequacy and effectiveness of existing resources, systems and processes for the delivery of healthcare services [6]. In the context of CCS, it provides valuable insights into whether the infrastructure and resources are in place to effectively screen eligible women and appropriately manage the women who are tested positive [7].

As European countries transition towards human papillomavirus (HPV) detection-based screening, as recommended in the new approach to cancer screening adopted by the Council of European Union (EU) in 2022, the importance of capacity assessment takes on a new dimension [8]. HPV-based screening offers enhanced and objective technology, potentially improving secondary prevention of cervical cancer [9]. Nevertheless, the policy change necessitates robust healthcare systems that can manage the transition effectively, ensuring high-quality services with access to all [10]. The shift calls for a comprehensive and standardized approach to capacity assessment that considers these new demands on health systems.

In recognition of this need, the multi-centric CBIG-SCREEN project was launched in the year 2021, supported by the EU Horizon 2020 Research and Innovation Programme [11]. This ambitious initiative aims to provide guidance to the European countries on how to improve participation in CCS among vulnerable and underserved groups using HPV testing. Definition of women in vulnerable situation in the CBIG-SCREEN implementation research project was guided by a stakeholder survey among European countries, including the three intervention countries (Estonia, Portugal and Romania), resulting in a country-specific definition of vulnerable groups [12]. Through various work packages, the CBIG-SCREEN implementation research project co-creates tailored interventions to overcome barriers to CCS participation for vulnerable women, examines preferences for strategies to increase screening uptake and importantly, evaluates the capacity and preparedness of health systems to deliver these services [11].

One of the key components of the CBIG-SCREEN project is to develop and pilot a new capacity assessment tool. This tool is expected to facilitate the successful transition to HPV detection-based screening while simultaneously supporting coverage enhancement in countries/regions where HPV screening has already been implemented. It does this by enabling a comprehensive evaluation of the health systems in the selected intervention countries. These assessments will help the project team to refine the delivery of CCS services and design locally contextualized delivery models in collaboration with national and local stakeholders, addressing the unique challenges presented by the diverse health care systems, HPV-based screening policies and socio-economic contexts in these countries.

This paper describes the development, within the framework of the CBIG-SCREEN project, of a new capacity assessment tool and its pilot implementation in the context of rolling out HPV detection-based screening in selected EU member states. The overarching goal of the capacity assessment exercise is to enhance our understanding of current capacities of the health system to roll out HPV detection-based screening ensuring high coverage, especially among vulnerable women. These are mainly women who have limited access to healthcare due to social determinants and/or structural barriers, though the country-specific profiles of vulnerable women have been defined by stakeholder groups from respective countries. Focus of the current manuscript is description of the new capacity assessment protocol and tools and how these were piloted in the three countries. Detailed outcomes of the capacity assessment by countries will be described in future publications.

Methods

The methodology involved (1) developing the protocol and capacity assessment tool and (2) pilot-testing this new tool to assess health systems' readiness and capacity in selected regions of Estonia, Portugal and Romania.

Developing the protocol and tools for capacity assessment

We conducted a review of existing literature to explore the availability of tools suitable for conducting comprehensive healthcare capacity assessment. We carefully examined their applicability for assessing the health systems in the context of implementing HPV detection-based tests. Our methodology, commonly employed in rapid literature reviews, revealed that while some of the available tools targeted health services delivery or cancer control services in general; there was only one that addressed integrating CCS into reproductive health services [13–15]. Even the last mentioned tool, published in 2001, did not deal with HPV detection tests. This finding highlighted the requirement for a validated tool that will help comprehensive understanding of the capacities to deliver effective CCS and further management services as the European countries switch from cytology to HPV detection-based programmes.

To overcome these gaps, we decided to develop a capacity assessment protocol and supporting tools of our own. We primarily leveraged the Service Availability and Readiness Assessment (SARA) tool, designed to assess and monitor the service delivery of the health sector in general, developed through a collaborative effort between the WHO and the United States Agency for International Development (USAID) [14]. We also adapted tools used by the Cancer Screening in Five Continents (CanScreen5) project of the International Agency for Research on Cancer (IARC/WHO) to collect information on policies and organization of CCS programmes globally [16]. We tailored these tools to assess the specific capacities required for delivering HPV-based cervical screening, triaging and diagnostic services and pre-cancer treatment within a country's health system. Our scope encompassed both public and private sectors, including for-profit and not-for-profit entities, as well as faith-based and non-governmental organizations. It is important to note that the management of invasive cervical cancer was beyond the scope of this assessment. Though our approach and tools were most suited to the CCS protocol commonly followed within the EU, these can be tailored to be used in other countries as well. The assessment may encompass an entire country or a region within.

Our capacity assessment protocol (*Cervical cancer screening related service availability and readiness assessment or CervScreen-SARA protocol*) involved the following three-step process, each step contributing to comprehensive assessment of the health system (Table 1).

Desk review

The first step of *CervScreen-SARA* was a desk review consulting relevant policies, protocols and other pertinent documents available on health infrastructure and service delivery in general, and cervical screening in particular in the target region/country. We developed a checklist (see Additional file: Appendix S1) to systematically extract key information on four dimensions of CCS programme: (1) policies and governance; (2) screening protocols and management guidelines; (3) information systems utilized for screening implementation (call-recall) and monitoring; and (4) quality assurance process. The checklist aimed to provide a holistic understanding of the policies, organizational structures and practices surrounding CCS within a country, and facilitates comparability between countries. Particular attention was given to identify any policy or activity related to improving CCS among vulnerable women.

Facility visits

The second step of the capacity assessment process was a facility visit in the target region/country to verify information gathered through the desk review with existing practices and collect further information related to functioning of the facilities in the context of CCS service delivery. To save time, effort and resources, only a selected sample of the facilities were to be incorporated in the facility visits. To start with, all facilities providing various types of services related to CCS care continuum (invitation, sample collection, laboratories analysing samples, colposcopy and pre-cancer management) needed to be enlisted. This list became the sampling framework to select facilities for the country/region. We followed a stratified sampling design on the basis of categories of services provided to randomly select the facilities. For example, these services may be broadly categorized into following groups in most European countries: screening services, colposcopy coupled with pre-cancer treatment services and laboratories involved in HPV tests, cytology and histopathology. Details of the sample size estimates are described later in the description of the piloting process.

Using a structured questionnaire, a trained team of investigators followed the process of service delivery at a particular health facility and tried to assess the facilitators and barriers to either deliver or switch to HPV detection-based screening at the facility level. The structure of the questionnaire was conceptualized from the SARA tool. The final structure and contents were enhanced by researchers' field experience, and further refined in collaboration with local research teams after preliminary visits to screening and colposcopy and treatment facilities. To cover particularities of CCS we added specific sections to the facility visit survey covering (1) health facility identification; (2) facility governance and coordination; (3) user charges; (4) infrastructure; (5) human

Table 1 Detailed process of piloting the CervScreen-SARA tool for capacity assessment in three European countries

Capacity assessment activity	What was covered in the activity?	Who conducted the activity?	What were the data sources?
Desk review	• CCS policies and governance • CCS protocol and guidelines • Information system to monitor cancer screening • Quality assurance	Data gathering and revision by IARC team Discussion with and provision of additional sources by local partners	• Documents related to CCS policies, laws, protocols, practice guidelines, evaluation reports, etc. issued/published by the MoH/screening programme • Other relevant documents (including peer-reviewed journal publications) identified by screening programme coordinators and other health officials associated with planning, implementation and monitoring of CCS and other experts • Civil society organizations involved in CCS may publish relevant documents and enquiries should be sent to them as well
Facility assessment	*Type of facilities visited* • Screening facilities • Colposcopy and treatment facilities *10 Dimensions explored* • General information • Governance and coordination • User charges • Infrastructure • Human resources • Essential support services • Monitoring and evaluation • Supply chain management • Infection control and waste management • Suggestions from health providers for improvement of screening and colposcopy services	Team of IARC and local experts. Local team in charge of translating when needed	Facility-in-charge and other relevant staff were interviewed Site visits were conducted Data were collected on the tool on paper and entered in the RedCap platform
Key informant interviews	CFIR constructs • Intervention characteristics • Outer setting • Inner setting • Characteristics of individuals • Implementation process Discrepancies observed between desk review and facility visits' findings	Social scientists from the local teams (Romania, Portugal), IARC team (Estonia)	Interviewees were selected by the local team according to their availability, interest and by snowball method *Macro level* A policy-maker (someone with an executive role, such as a health secretary) Professionals involved in programme management *Meso level* Professionals involved in the screening registry, laboratory performing HPV tests, screening services, diagnostic and treatment services delivery A representative of organizations or a healthcare provider looking after the interests of vulnerable population

CCS, cervical cancer screening; MoH, Ministry of Health

resources; (6) essential support services; (7) monitoring and evaluation; (8) supply chain management; and (9) infection control and waste management (see Additional file: Appendix S2 and S3). Issues related to improvement of screening in vulnerable women were addressed using specific questions in the survey tool.

The questions in the facility visit tools are categorized by 10 dimensions relevant to assess the facility's readiness to provide screening and related services. For each dimension, a readiness index score was calculated through adaptation of the methodology from the WHO toolkit for cervical screening prevention and control programme [17]. Response to each question had a three-scale score (2: satisfactory; 1: needs improvement; and 0: needs significant improvement). An average readiness score was ascribed to each dimension by

dividing the total score for that dimension by the number of questions.

Key informant interviews

Semi-structured interviews of key informants were the last step of the *CervScreen-SARA* protocol (see Additional file: Appendix S5). It aimed at clarifying findings from facility visits, discussing discrepancies observed between reviewed documents and data collected at the facilities and understanding the potential implementation climate in key institutions involved in the CCS and management pathways, including the perspective of the facility in-charge. Key stakeholders were selected for these discussions from the macro and meso levels, comprising screening programme managers at both national and regional levels, officials from both the Ministry of Health and private healthcare sectors, those in charge of health facilities and laboratories, etc. In addition, representatives from civil society organizations were included, particularly those championing women's health and vulnerable populations. Trained investigators engaged with these key informants in interviews utilizing an interview guide (see Additional file: Appendix S4), anchored in the constructs of the Consolidated Framework for Implementation Research (CFIR) [18].

The CFIR is a comprehensive theoretical framework that identifies factors that might influence intervention implementation. Divided in five domains – intervention characteristics, outer setting, inner setting, characteristics of the individuals involved and the process of implementation – the CFIR provides a structured approach to support the design and execution of robust implementation strategies [19]. The guide we prepared needs to be tailored to the specific requirements on the basis of the information gathered through desk review and facility visits.

Adaptation made

Tools used for the capacity assessment underwent pretesting and enhancement via a Plan-Do-Study-Act (PDSA) cycle [20] through preliminary visits of IARC team to Estonia, Portugal and Romania. Adjustments were made to the desk review checklist to enhance understanding of the different items to be collected. Questions in the facility evaluation survey found irrelevant were omitted, and necessary modifications were made to render the tool more fitting during the visits. Noteworthy modifications comprised: addition of response options to more accurately mirror reality (beyond just yes or no), incorporation of a free text section for health providers to voice their thoughts on improving screening services and an adjustment in the questions related to user fees to account for the fact that the countries may have different mechanisms for charging and/or reimbursing such costs.

Interview guides with key informants were modified after discussions with experts from each target country. Changes were made to fit the local context and language.

Pilot implementation of CervScreen-SARA protocol in three European countries

The new protocol and tools were used as part of a situational analysis in the CBIG-SCREEN project [11]. Within this project, three representative countries (Estonia, Portugal and Romania) were selected to gain insights into the diverse landscape of health systems in Europe as presented in Table 2. Cervical cancer burden, organization of health systems and quality and coverage of CCS were quite different between the three countries. We implemented the *CervScreen-SARA* protocol to grasp a comprehensive picture of the challenges and opportunities present in different countries to switch to HPV detection-based screening. The CBIG-SCREEN project did not have the capacity and resources to conduct nationwide implementation of capacity assessment. Therefore, the principal investigators from each country selected the administrative region(s) to implement the project. The selected regions were areas where (i) a substantial proportion of women in vulnerable situations (according to the in-country definition) resided and (ii) the health systems were representative of broader national health infrastructure. Some of the regions were stratified as rural and urban (e.g. in Portugal). The capacity assessment exercise was kept limited to these regions selected for CBIG-SCREEN project.

Table 2 Overview of cervical cancer burden and cervical screening programmes in the European countries included in the study

Country	Age-standardized cervical cancer incidence (2020)[a]	Cervical screening organization	Estimated screening coverage in the last 5 years for women aged 24–65 years[a] (%)	Status of introduction of HPV-based screening
Estonia	18.5/100 000 women	Population based with active invitation	54	Yes, nationwide
Portugal	10.7/100 000 women	Population based with active invitation	80	Yes, nationwide
Romania	22.6/100 000 women	Opportunistic	35	Piloted in specific regions

[a] https://hpvcentre.net/, Fact sheet 2023

To ensure optimal use of the tools and the protocol, we developed an implementation guide addressing every facet of the assessment process (Additional file: Appendix S5). This guide, including the specifics on team formation, obtaining administrative authorization, determination of suitable sample size (described later) and use of data collection tools, was shared with the country partners before initiating the capacity assessment.

The implementation of *CervScreen-SARA* protocol was led by a team from IARC (P.B., I.M. and K.M.) and a team formed in each country composed of epidemiologists, social scientists, clinicians and public health experts. The national investigators collected and shared with IARC team all documents relevant for desk review. IARC team performed further literature search and filled out the desk review form.

As a first step for facility visits, the national collaborators prepared a list of clinics and hospitals involved in CCS and management within the selected region. This list, obtained from national or regional master facility lists, encompassed public, private and NGO facilities offering invitation, screening, colposcopy, treatment, laboratory and pathology services related to CCS. Private facilities providing CCS services were also included if they were part of the national or sub-national screening programme in the concerned countries.

In each country the services were categorized into those (1) providing screening and related services; (2) colposcopy and related services (including pre-cancer treatment); and (3) laboratory services. Calculation of the number of facilities to be sampled was done using the standard formula for a proportion using expected percentage of health facilities offering a given service as the outcome [21]. An expected proportion of 95% of service availability was used, with 95% confidence intervals to be within an error margin of 15%, and assuming a non-response rate of 10% of the selected facilities. An adjustment was made [$\alpha = 1.25\%$ (2.5%/2)] taking into consideration the planned stratified analysis based on geographical areas (counties) to be able to remain with a two-tailed 5% level of significance for the overall effect. The design effect was 1 as no clustering of facilities was done.

Once the required number of screening and colposcopy facilities to be visited was decided on the basis of above sample size estimation, these were selected randomly from the master list. While laboratories were originally scheduled to be included in a similar sampling procedure, preliminary visits disclosed a high degree of organization and automation in the analysis procedure in the limited number of laboratories providing centralized service in each country. Thus, it was resolved that detailed interviews with the laboratory heads would generate more insightful revelations and be more efficient than visits to the laboratories that provide a range of services in addition to performing HPV testing and cervical cytology. An interview guide for such interviews was formulated to collect information on the sample trajectory – from its arrival at the facility to the distribution of results, involving questions related to cervical screening delivery and the implementation of evidence-based interventions (Additional file: Appendix S4).

A team was formed for facility visits in each country and approval from the appropriate authority was obtained. Facility visit was planned in advance with the facility in charge. The team physically verified the services being provided including the process of documentation and physical infrastructure, and discussed with the providers (doctors, nurses, administrative and support staff) involved in the delivery or supervision of services to complete the survey questionnaire.

National teams identified the key informants to be interviewed. Depending on the country, informants included policy-makers, screening programme coordinators, heads of laboratories, screening registry managers, heads of screening/diagnostic/treatment services and representatives from associations serving specific vulnerable groups. Interviews were conducted either in English, or in local language by one or two national team representatives at a predesignated time and date. A verbal or written consent was obtained from each interviewee after explaining the objectives and procedure of the project. Interviews were audio recorded, fully or partially transcribed and when conducted in a local language, translated into English.

Data analysis

Data on service availability from the three steps were analysed independently in each country before being triangulated to perform a country-specific SWOT analysis in the context of readiness of the health system to roll out HPV detection-based screening ensuring coverage to the vulnerable women.

Data obtained through desk review underwent meticulous editing, cleansing and consistency evaluations. We prepared a descriptive analysis that consolidated information on CCS governance, policies, protocols, guidelines, information systems, monitoring, quality assurance and any special policy to improve screening of vulnerable women. These assembled data were then shared with respective national team to solicit their feedback. The resultant report, verified by national collaborators, was utilized in the SWOT analysis. Furthermore, this analysis aided in adding or refining the questions to be asked subsequently during in-depth interviews with key informants as described above.

A facility visit report was prepared by the team summarizing the key observations after each facility visit highlighting the readiness of each facility for HPV based screening. Descriptive analyses were performed and summarized by the two types of service categories (screening and colposcopy/treatment). The output tables were separated by countries. For each facility and dimension, an average readiness index score was calculated. For an item in the facility visit tool that could not be completed due to inability of the responders to provide the information, a score of 0 was ascribed. All data were analysed using R software.

To analyse the outcomes of key informant interviews, we applied a qualitative data analysis approach, using the CFIR implementation readiness codebook. After coding certain interviews, qualitative researchers convened to discuss coding definitions and inclusion and exclusion criteria. A single researcher performed the coding of five interviews which was then discussed with each national team to enhance accuracy and reach a consensus. Coding and analysis were conducted without any software assistance (in Estonia and Romania) or using Nvivo software (in Portugal) according to local practices. Upon receipt of all codes through the CFIR dimensions, outcomes were summarized by K.M. and I.M. to compose an interview report.

Upon completion of the desk review, facility visits and interviews, key findings were triangulated and categorized and noteworthy themes frequently echoed across data sources were highlighted. These findings were then systematically condensed and categorized by K.M. and I.M. into a SWOT analysis, tailored to each country. The SWOT analysis covered the six WHO building blocks [22]. The SWOT analysis was shared with national collaborators for feedback prior to finalization, ensuring a comprehensive understanding of the landscape.

The study was approved by the institutional ethics committees of IARC. In Portugal, ethical approval was needed and obtained from the Instituto de Saúde Pública da Universidade do Porto (ISPUP) Ethic Committee regarding the key informant's interviews. In Romania and Estonia, no ethical approval was needed.

Results

The study was implemented in two counties in Estonia (Harjumaa and Ida-Viru), two districts in Portugal (Porto and Vila Real) and one county in Romania (Cluj).

Outcomes of desk review

Between September 2021 and February 2022, we reviewed and analysed a total of 36 documents from Estonia, Portugal and Romania, revealing diverse approaches in implementing CCS across these nations. In Estonia, the documents analysed ($N=11$) included guidelines from scientific societies, national cancer plans, laws and decrees related to data protection and the health system and research papers contextualizing cervical cancer within the Estonian health system. In Portugal, we assessed 10 documents, all sourced from national or regional authorities. These encompassed decrees, laws, cancer plans and screening guidelines, painting a comprehensive picture of the nation's official position on CCS. In Romania, our analysis of 15 documents revealed the role of the government in screening programmes' organization, funding and evaluation, as all such activities were supported through national decrees. Guidelines on CCS process and management were issued by two different scientific societies in the country.

At the time of our analysis, HPV-based screening had been adopted as the standard of care in Estonia and Portugal. In Romania, it was being pilot-tested in the county of interest (Cluj), while the standard of care remained cytology for the rest of the country.

Analysis of these diverse documents uncovered common themes and differences in the countries' CCS approaches, setting the stage for an in-depth examination of their health facilities.

Outcomes of facility visits

We visited a total of 27 screening centres and 16 colposcopy and treatment centres from the 86 screening and 17 colposcopy and treatment centres. Visits took an average of 1.5 h, which included time for informal discussions with healthcare providers about the strengths, weaknesses of CCS services and the key areas for improvement. The characteristics of the facilities visited are summarized in Table 3

In all countries, when CCS services were offered on specific days, it was due to internal scheduling (screening services) or colposcopists' availability (colposcopy and treatment services).

Our facility visits uncovered strengths and potential areas for improvement on the basis of readiness scores in 10 dimensions of the screening and colposcopy services that have been summarized in the country-specific spider graphs (Fig. 1).

Outcomes of key informant interviews

A total of 15 key informant interviews conducted as a third step of the capacity assessment (six in Estonia, seven in Portugal and two in Romania) revealed different barriers and facilitators to implement HPV detection-based screening services within the three countries. The results are structured according to the CFIR dimensions and presented in Table 4. These insights shed light on country-specific contexts influencing the implementation

Table 3 Overview of the characteristics of the visited facilities

	Global (*N* = 43)	Country		
		Estonia (*N* = 18)	Portugal (*N* = 11)	Romania (*N* = 14)
Services offered				
Screening centres (%)	27 (62.8)	10 (55.6)	9 (81.8)	8 (57.1)
Colposcopy and treatment centres (%)	16 (37.2)	8 (44.4)	2 (11.2)	6 (42.8)
Localization (%)				
Urban	41 (95.3)	18 (100)	11 (100)	12 (85.7)
Semi-urban	2 (4.7)	0 (0.0)	0 (0.0)	2 (14.3)
Facility type (%)				
Primary care	14 (32.6)	5 (27.8)	9 (81.8)	0 (0.0)
District/tertiary care	16 (37.2)	5 (27.8)	2 (11.2)	9 (64.3)
Private sector	13 (30.2)	8 (44.4)	0 (0.0)	5 (35.7)
CCS services availability (%)				
All working days	28 (65.1)	7 (38.9)	9 (81.8)	12 (85.7)
On specific days	15 (34.9)	11 (61.1)	2 (11.2)	2 (14.3)

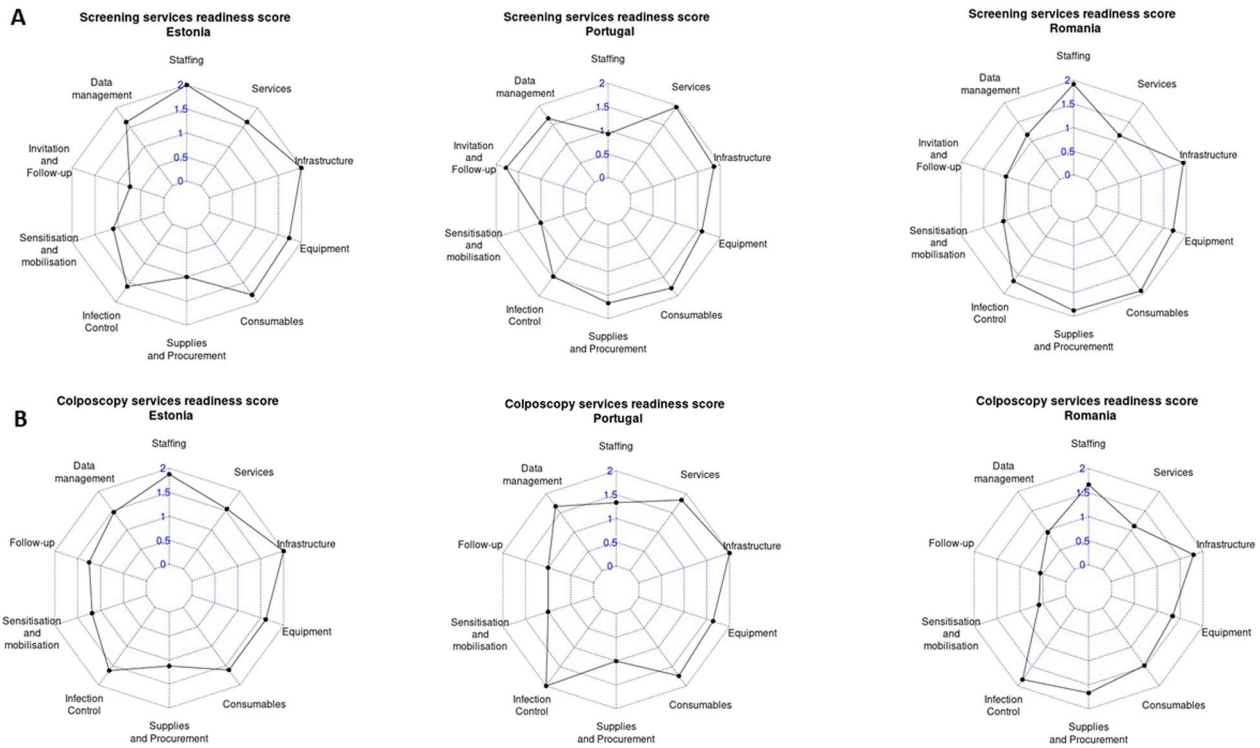

Fig. 1 Spider graphs depicting the readiness scores for two distinct services, namely screening services (**A**) and colposcopy services (**B**), across three different countries: Estonia, Portugal and Romania. These scores indicate the readiness and capacity of these countries to deliver the respective services as part of the cervical screening process

of HPV detection-based screening services and the commonalities that might serve as guiding principles for future implementation strategies.

Common barriers reported by key informants across the selected countries included issues with the information system, such as non-user-friendly interfaces and lack of tracking and follow-up mechanisms. There were also shared concerns about inadequate human resources to deal with scaled-up programmes, particularly insufficient training opportunities. Additionally,

Table 4 Synthesis of CFIR constructs identified in key informant interviews: cross-country commonalities and differences in implementing HPV detection-based CCS

CFIR domain/subdomain	Commonalities	Differences
Intervention characteristics		
Evidence strength and quality	All countries used updated guidelines and conducted pilots before scaling up HPV screening	
Relative advantage		Portugal reported preferences for cytology over HPV for some practitioners in the private sector
Outer setting		
Patient needs and resources	Concerns were expressed in all countries about effective communication between health providers and women, which could lead to fears and misconceptions about the new screening process	
External policy and Incentives	Shared political will to improve access to care, exemplified by initiatives to make HPV-based screening more accessible and efficient, including offering self-collection of samples	
Inner setting		
Structural characteristics	Common barriers included issues with information systems (e.g. non-user-friendly interfaces, lack of tracking and follow-up mechanisms)	Estonia had a robust e-health system aiding data centralization, while Portugal exhibited regional flexibility to make administrative decisions
Readiness for implementation	Limited human resources (e.g. inadequate training opportunities to handle scaled-up programmes)	
Characteristics of individuals		
Knowledge and beliefs about the intervention	Stakeholders shared the perception of a low level of literacy and awareness regarding CC among women	In Romania, there was a fear of job loss among cytologists due to the introduction of HPV-based screening. This indicates some resistance to the transition due to perceived negative personal impact
Process		
Planning	Systematic approaches to organizing screening, such as the use of updated guidelines and pilot tests, were common across the three countries	
Engaging	Shared perception of lessons learned from COVID-19 pandemic that can apply to a CCS organized programme and efforts regarding its implementation	

CC, cervical cancer; CCS, cervical cancer screening; HPV, human papilloma virus

each country highlighted issues with effective communication between health providers and women, which could lead to fears and misconceptions about the HPV-based screening process among the target populations.

On the facilitator side, all countries showed a strong political will to improve access to care, demonstrated through their various initiatives to make HPV screening more accessible and efficient, including offering self-collection of samples. Systematic approaches to organizing screening such as use of updated guidelines, conducting pilots prior to scaling up of HPV screening and research to identify appropriate implementation approaches were common across the three countries.

The interviews also revealed unique barriers in the countries such as preferences for cytology over HPV for some practitioners in the private sector in Portugal, or fear of job loss among cytologists due to introduction of HPV screening in Romania. The country-specific facilitators included a robust e-health system aiding data centralization in Estonia, regional flexibility to make administrative decisions in Portugal and wider use of HPV tests using molecular laboratory infrastructure built to mitigate coronavirus disease 2019 (COVID-19) pandemic in Romania.

Key observations from the SWOT analysis

Results from the previous three-step process were triangulated to provide a country specific SWOT analysis for each of the six health-system building blocks as specified by the WHO. The details of each country-specific SWOT analysis will be published later. Following is a summary of the key observations.

Governance and coordination

All three countries have national screening coordination bodies, and their existing screening guidelines are under review for the introduction or rolling out of HPV testing. In Estonia, coordination of the cervical screening

programme is divided between three organizations without clear delineation of responsibilities. In Portugal, HPV-based screening programmes are managed regionally, with implementation flexibility, on the basis of local contexts and expectations. Linkage with cancer registries is, however, perceived as inadequate. Romania is struggling with weak coordination between various levels of services crucial to reorganize screening programmes.

Financing

All three countries have allocated budgets for cervical screening programmes from their respective Ministries of Health. In both Estonia and Portugal, women undergoing HPV tests in the programme do not have any co-payment. However, the existence of different mechanisms for incentives to providers across different primary care models in Portugal is a limitation. A fixed budget for primary care may restrict expansion of services in Estonia. In Romania, the HPV-based screening programme relies heavily on funds obtained to support specific projects. Only a small percentage of health funding is allocated to prevention of non-communicable diseases in the country and scaling up of HPV test may face fiscal obstacles.

Health workforce

Staff trained in colposcopy to cover population needs is considered as inadequate in Estonia and Romania, while Portugal faces a lack of human resources at primary care (public health doctors and nurses). Family doctors' involvement in CCS varies between countries – they are at the forefront in Portugal, while gradually being integrated in Estonia and almost non-existent in Romania. The perception of HPV testing among cytologists differs, varying from positive (reduced workload) to negative (threat to their occupation).

Health infrastructure and access to services

Infrastructure, availability of consumables and supplies to provide CCS-related services were observed to be adequate during facility visits, though concerns were expressed on sustaining a scaled-up programme. Access to care for vulnerable populations was difficult in each country. Limited health literacy, fear of stigmatization, fear of screening procedures, and long waiting times for access to CCS-related services were the reported barriers for vulnerable women. Measures to mitigate geographical and social inequalities were not well defined, leading to disparities in screening coverage.

Delivery of care

All three countries have difficulties in identifying vulnerable women. Women have access to free-of-charge HPV tests in all countries. However, in Romania, women attending screening facilities not included in the project and un-insured women in certain regions have to pay for HPV tests. In Estonia, un-insured women will have to pay beyond HPV screening for diagnosis and treatment. The modalities for invitation to screening and follow-up, the strategies to cover vulnerable women and protocol for tracking the screen positive women vary among the countries. The process for screening invitation and recall is not standardized across the regions in Portugal, while in Estonia, eligible women are routinely invited to screening through a centralized facility. However, the process of recall and regular follow-up of women positive for HPV or those with missed appointments is not streamlined in any country. In Romania, active tracking of the screen-positive women for colposcopy and treatment is missing, and the system relies on individual health providers' initiative to do so. Moreover, the perception of self-sampling by women and stakeholders, and the acceptability of HPV screening among women and health providers, is heterogeneous among countries. In Estonia and Portugal, where previous HPV screening is already in place and self-sampling has been previously piloted, the acceptability was higher than in Romania, where screening relies on cytology.

Information system and quality assurance

All countries have guidelines and accreditation for laboratories involved in CCS. Key performance indicators for CCS are listed in programme guidelines in each country, but none of them include indicators to assess screening participation of vulnerable groups. There is a discrepancy between quality assurance protocols and their practices, and missing data related to cervical screening delivery outside the national screening programme (private sector or opportunistic screening). The level of centralization of health information systems, the linkage to population-based screening registries and the linkage between the different services involved in CCS (screening, colposcopy, laboratory, pathology) vary among the countries. In Portugal and Romania, the information system does not link screening, colposcopy and treatment data. In Estonia and Portugal there were no supervisory visits to the health facilities focussing on the screening cascade, while Romania incorporated it into their pilot programme. Moreover, Estonia's information system is not built to capture some indicators such as waiting times, delays

for appointments and results or missed appointments. Quality assurance in practice for screening, colposcopy and data is lacking in the country.

Discussion

The comprehensive three-step exercise we undertook to measure health systems capacity and readiness, a first of its kind, could unearth the operational realities in different European healthcare settings, thus proving the effectiveness and feasibility of applying these tools that would be of great benefits to the EU countries as they switch to HPV detection-based screening.

The European Council recommendation published in September 2022 to screen women aged 30–65 years [23] with an HPV detection test was based on outcomes of several randomized controlled trials (RCTs) demonstrating significant reduction in cervical cancer incidence and mortality among women screened with these tests [24]. Following the recommendation, it is expected that almost all EU countries will gradually switch from existing cytology-based screening to HPV detection-based screening. Rolling out of the new screening test will have a huge impact on the entire CCS pathway, and the programmes need to address several implementation aspects. These include educating women and healthcare providers, ensuring uninterrupted supply of test kits to the screening centres, transfer of samples to the laboratory and delivery of test results, having a fail-safe system to recall the women positive for HPV to appropriate triaging, (re) designing the information system to capture the new process of screening and ensuring high participation of the vulnerable women. The high degree of heterogeneity in available resources and system organization in the EU member states indicates that a one-size-fits-all solution is unlikely to be effective [10, 25]. The European Guidelines for quality assurance in CCS [26] recommend that countries should implement pilot studies before scaling up HPV detection-based screening. Such pilot implementation as well as subsequent scale-up would likely benefit from systematically evaluating the local health systems context using the new *CervScreen-SARA* tool.

The *CervScreen-SARA* tool is based on the CFIR framework and widely used to capture the contextual issues relevant to a particular healthcare setting. The piloting of the instrument demonstrated that our tool was capable of assessing several contextual factors within a short period of time in the following domains: intervention characteristics (e.g. availability of HPV tests, costs), inner setting of the organization delivering the intervention (e.g. integration of HPV testing within existing services, staff availability, training requirements), outer setting and external policies (e.g. national policies, prioritization of cervical cancer prevention), characteristics of target individuals (knowledge and beliefs, access to services by vulnerable women) and the phase of the implementation process (whether planning, piloting or scaling up HPV screening) [18]. Indeed, our findings from piloting this new tool underscored the crucial role of capturing several health-system-level contextual factors in optimizing on-the-ground CCS programmes. The organized information provided by the SWOT analysis facilitated strategic decisions related to HPV detection-based screening and subsequent management, identified areas for improvement and helped refine current efforts, paving the way for innovative solutions from stakeholders.

Our capacity assessment exercise also highlighted the key role of health providers in the success of CCS services delivery – from effective communication to involvement in follow-up of screen positives. Even their perceptions of the needs of the populations targeted by the interventions may have system-level impact. It aligns with literature showing that health programs are inherently intertwined with a wide spectrum of societal, cultural and health system determinants that can either obstruct or facilitate their success and failure to consider such determinants in programme planning may have significant implications [27, 28]. One such example in the field of cervical cancer prevention is failure to achieve a high coverage for HPV vaccination in several European countries. As shown in a systematic review [29], underlying factors such as personal behaviours, beliefs and ethical norms shape general practitioner's likelihood to advise parents for vaccinating their children.

All the countries assessed had a strong political will and policies to roll out HPV detection-based screening that are informed by outcomes of RCTs with or without cost-effectiveness studies. Unfortunately, outcomes of an RCT implemented in highly controlled research settings are not always generalizable in real-life healthcare environments. There are several contextual factors that play a crucial role in the successful translation of an evidence-based intervention to real life practice, and instances of such interventions failing to be introduced or scaled up in practice are not uncommon [30, 31]. The *CervScreen-SARA* protocol constitutes a practical tool to assess real-life conditions of CCS services before or during an HPV detection-based roll-out. Moreover, by triangulating our capacity assessment outcomes with observations of a parallel CBIG-SCREEN study assessing population level barriers, the national and local stakeholders' groups in each country were able to identify context-appropriate strategies.

The primary limitation of our capacity assessment tool is that it does not provide much insight into the barriers encountered by women targeted by screening programmes. A comprehensive assessment of individual-,

provider- and system-level barriers would usefully complement the capacity assessment on the basis of existing experience in the European context in assessing barriers from the health system perspective [32]. However, within the CBIG-SCREEN project, the collaborative efforts of various work packages have enhanced our understanding of the barriers that women face. This includes stakeholder meetings at micro, meso, and macro levels, along with literature reviews. The insights gained from these multiple sources will inform the development of the CBIG-SCREEN implementation strategies, specifically designed to improve the participation of vulnerable women in CCS.

Our tools were not validated as psychometric surveys; they were designed with adaptability and flexibility in mind. Going through multiple cycles of improvement and refinement allowed us to ensure accuracy of the image of the CCS-related services within each country.

Conclusions

Health systems capacity assessment is a prerequisite to any strategic action for stakeholders. It will help guide strategic actions, optimize investment allocation and ultimately aid in the design of a tailored capacity development plan for CCS. The *CervScreen-SARA* protocol and tools developed through the project can be used by any country contemplating introduction of HPV testing. Suitable adaptations would be necessary; however, our experience shows that changes needed require limited time. The developed resources, adaptable to various contexts, pave the way for further research and tool development, bearing promising implications for the improvement of cancer screening in Europe and elsewhere.

The foremost challenge identified in the assessed regions/countries is the follow-up and further management of screen-positive individuals. While screening is free of charge, this is not always the case for colposcopy and treatment. Addressing this should be a priority to reach the WHO's cervical cancer elimination goal.

High heterogeneity in resources and system organization necessitates an approach that acknowledges regional disparities and cautions against a one-size-fits-all strategy. The study also highlights the pivotal role of governance in refining on-the-ground CCS programs.

Abbreviations

CanScreen5	Cancer Screening in Five Continents
CCS	Cervical cancer screening
CervScreen-SARA	Cervical cancer screening related service availability and readiness assessment
CFIR	Consolidated Framework for Implementation Research
EU	European Union
HPV	Human papilloma virus
IARC	International Agency for Research on Cancer
PDSA	Plan-Do-Study-Act
SARA	Service Availability and Readiness Assessment
SWOT	Strengths, weaknesses, opportunities, threats
USAID	United States Agency for International Development
WHO	World Health Organization

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12961-024-01190-y.

Additional file 1.

Acknowledgements

We extend our sincerest gratitude to the various health centres and providers who generously took time out of their busy schedules to accommodate our visits. Their openness and collaboration were instrumental in the success of our facility assessments. Additionally, we appreciate the valuable time and effort contributed by the stakeholders during the interview process, their input significantly enriched our understanding. Finally, we express our profound thanks to our research partners whose insightful comments and guidance were invaluable to this study. Your collective contributions have substantially enriched our research and we are deeply grateful.
CBIG-SCREEN Consortium members. Institut national de la santé et de la recherche médicale (INSERM), France: Marc Bardou, Principal Investigator. Regionshospitalet Randers, Denmark: Berit Andersen, Pia Kirkegaard, Rikke Buus Bøje, Mette Tranberg. London School of Hygiene & Tropical Medicine, United Kingdom: Rosa Legood, Anna Foss, Li Sun, Martin McKee, Sadie Bell, Rachel Greenley, Samuel Rigby, Luke Vale. Azienda Unita Sanitaria Locale di Reggio Emilia, Italy: Paolo Giorgi Rossi, Luca Ghirottoo, Letizia Bartolini, Noemi Auzzi, Paola Mantellini, Giusy Iorio, Laura Bonvicini. Instituto de Saude Publica da Universidade do Porto, Portugal: Nuno Lunet, João Firmino-Machado, Margarida Teixeira, Ana Fernandes, Mariana Amorim, Inês Baía, Romeu Mendes, Cláudia Gouvinhas. Tartu Ulikool, Estonia: Anneli Uusküla, Anna Tisler. Universitatea Babes Bolyai, Romania: Adriana Baban, Diana Tăut, Nicoleta Jiboc. Institute of Oncology Cluj-Napoca, Romania: Florian Nicula, Alexandra Tolnai. European Institute of Women's Health, Ireland: Rebecca Moore, Vanessa Moore. International Agency for Research on Cancer, France: Partha Basu, Isabel Mosquera Metcalfe, Keitly Mensah, Eric Lucas. Ecole d'économie de Paris, France: Lise Rochaix, Camilla Fiorina, Violette Delisle. Health Psychology Research Center, Bulgaria: Irina Todorova, Yulia Panayotova, Tatyana Kotzeva, Raya Mihaylova. European Cancer Leagues, Switzerland: David Ritchie, Helena Ros Comesana, Meritxel Mallafré-Larrosa, Ginevra Papi, Wendy Yared, Arianna Khatchadourian. Inserm Transfert SA, France: Christiane Dascher-Nadel.

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Author contributions

I.M. and P.B. conceptualized and designed the study and the tools. A.U., A.T., A.B., D.T., F.N., N.L. and F.M. provided critical reviews of the tools. K.M. and I.M. conducted the desk reviews. K.M., I.M., A.U., A.T., F.N., N.L. and F.M. conducted the facility visits. A.B. and D.T. conducted the interviews in Romania, K.M. and I.M. conducted the interviews for the Estonian stakeholders. I.M. and K.M. adapted the tools and synthetized and analysed the data. K.M. completed the first draft of the manuscript. I.M., P.B., A.U., A.T., A.B., D.T., F.N., N.L. and F.M. provided critical reviews of the draft for publication.

Funding

CBIG-SCREEN has received funding from the EU Horizon 2020 Research and Innovation Programme under grant agreement no. 964049. Official starting date: 1 March 2021.

Availability of data and materials

The datasets generated and/or analysed during the current study are not publicly available due to confidentiality reasons but are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

The study was approved by the institutional ethics committees of IARC. In Portugal, ethical approval was needed and obtained from the ISPUP Ethic Committee regarding the key informant's interviews. In Romania and Estonia, no ethical approval was needed.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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Received: 31 August 2023 Accepted: 20 July 2024
Published online: 12 August 2024

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