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DIPARTIMENTO DI
SCIENZE MEDICHE E CHIRURGICHE

The object of the research grant activity:

He/she will be involved in the following studies of DCIMIT: (1) a mixed-methods study to explore the barriers to early detection of cervical cancer among immigrant women, and (2) a community-based interventional study to improve participation in cervical screening for healthy immigrant women.

- Literature search and appraisal
- Write research protocols
- Address ethical requirements for the study protocol's approval by the Ethics Committee
- Collect quantitative and qualitative research data
- Analyse collected data according to study protocols
- Write research reports

Preferential titles:

- Proficiency in Italian and English
- Master's Degree in Nursing and Midwifery Sciences
- Previous experiences in healthcare research, design, and conduction of investigations to improve patient outcomes and healthcare delivery
- Previous experiences in enrolling participants in research studies
- Competences in mixed-methods research
- Competences in writing scientific articles
- Ability to promote public and patient engagement
- Teamwork skills
- Transcultural competences

Disparities in cervical cancer prevention and early detection among immigrants in Italy (DCIMIT)

Proposal Main Body

Impact

Proactive prevention and early detection are crucial in the fight against cervical cancer, as persistent infection with Human papillomavirus (HPV) is the primary cause. Despite being preventable and curable, cervical cancer ranks as the 4th most common form of cancer among young women worldwide and the 5th most common in Italy. This disease reflects global inequities to a significant extent. Screening programs for cervical cancer aim to reduce inequalities based on factors such as age, education level, socioeconomic status, and citizenship. Promoting universal participation in cervical cancer screening has the potential to reduce disparities in cancer mortality rates among individuals with lower socioeconomic and educational backgrounds. Disparities in health outcomes may be even more pronounced among immigrant populations. In particular, immigrant women, who are defined as foreign-born, have a higher risk of cervical cancer compared to Italian-born women (OR=3.54)¹ but they participate in screening at lower rates (72% vs. 78%)² and are less likely to follow up after abnormal results,³ leading to a higher cancer burden and delayed diagnosis.⁴ Therefore, it is important to narrow the disparities in cervical cancer prevention and early detection among immigrants in Italy. By reducing inequities in timely access to care, diagnoses, and disease management, we can decrease avoidable mortality and costs for the healthcare system. There is a need not only to collect reliable national data on cervical cancer incidence in immigrants from registries but also to better understand the barriers to early detection. By doing so, we will contribute to scientific advances in epidemiological research and enhance social justice, as well as policies for vulnerable populations. Moreover, a culturally sensitive intervention for immigrants,⁴ such as the one proposed in this project, has the potential to reduce the cancer burden among immigrant women by improving their participation in cervical cancer screening programs.⁵ Focusing on reducing inequalities in cervical cancer prevention and early detection among immigrants in Italy, by promoting screening and early treatment, aligns with the World Health Organization's initiative to eliminate cervical cancer worldwide. As Italy's birth rate continues to decline and the population becomes more diverse due to increased immigration, most cases of diagnosed cervical cancer will likely involve immigrant women. Therefore, to eliminate cervical cancer in Italy, it is crucial to narrow the disparities in cancer prevention and early detection among immigrants. This research effort is essential from humanitarian, social, and economic perspectives, and it will also pave the way for narrowing disparities in other types of cancer among immigrants in Italy.

Rationale and feasibility

a) Research questions, study design, and methods

Research questions. This project aims to narrow the disparities in cervical cancer among immigrants in Italy. Specific research questions are: (1) What barriers do immigrant women face in the early detection of cervical cancer? (2) What are the cervical cancer incidence, mortality, and survival rates for immigrants compared to non-immigrants in Italy? (3) Can a

community-based intervention improve immigrants' participation in cervical cancer screening?

Study design. Overall, we will conduct three sub-studies in this project, including (1) a mixed-methods study, (2) a register-based study, and (3) a community-based interventional study.

Study 1 - This will be a mixed-methods study with a two-phase explanatory design involving a sequential collection of quantitative and qualitative data in a nested sample.⁶ First, we will survey immigrants with cervical cancer to identify barriers and disparities in screening participation and access to care. Second, we will conduct semi-structured interviews with a sub-group of participants to further explain the results. Overall, study 1 will take five years.

Study 2 – This will be a register-based study. We will collaborate with AIRTUM (the Italian Association of Cancer Registries) to obtain and analyze data collected since the year of inception from regional population-based cancer registries (PBCRs) across Italy, to measure the cervical cancer burden among immigrants. In particular, we will compare cervical cancer incidence, mortality, and survival rates between immigrants and non-immigrants to assess disparities in access to prevention and care. Overall, this study will take three years to complete.

Study 3 – This will be a community-based interventional study. We will design and implement a culturally and linguistically tailored community-based intervention, based on Heron's six-category intervention framework,⁷ to mitigate barriers and improve participation in cervical screening among immigrant women. In the intervention and control groups, we will measure the participation in cervical cancer screening programs among immigrant women in two communities. Overall, this study will last five years, with 18 months for intervention and two years for follow-up.

Methods.

Study 1 - We aim to recruit 300 immigrant women with cervical cancer from 10 clinical centers across Italy. To be eligible, participants must meet the following criteria: a) have been diagnosed with cervical cancer at any stage, or high-grade squamous intraepithelial lesion (HSIL), within the past year; b) be aged between 25 and 65; and c) be born in Eastern Europe, Asia, and South-central America, as they have been shown to be at higher risk for cervical cancer;^{2,8} and d) living in Italy. Data collection will last for about two years. During follow-up visits for cervical cancer, participants will be asked to complete a self-report questionnaire in Italian or their native language about socio-demographic and clinical characteristics, barriers experienced in accessing early detection, the experience of discrimination in healthcare (CARE), and the Health Care System Distrust Scale. The data will be collected in an anonymized manner. The data collection period will span approximately two years. Out of the 300 participants, 60 women will be purposefully selected to participate in semi-structured individual interviews lasting about one hour in Italian or their native language. The scope of the interviews is to explore the experiences of immigrant women with cervical cancer in accessing screening and care, in order to identify potential additional barriers to early detection.

Study 2 – We will obtain cervical cancer incidence data from the regional PBCRs across Italy. PBCRs regularly collect and store data on cancer patients, including date of diagnosis, topography and morphology of tumors, age at the diagnosis, country of birth, pathologic stage at the diagnosis (if available), vital status, date and cause of death (if died). We will estimate crude and age-standardized incidence rates (ASR) for cervical cancer among immigrants

compared to the Italian population. We will stratify the analyses by country of birth and age. We will estimate the incidence rate ratio (IRR) of cervical cancer in immigrants compared to Italian-born populations. We will also employ survival analysis models to estimate hazard ratios (HR) and compare the cancer survival rates between immigrants compared to Italian-born patients.

Study 3 – We aim to enroll 205 healthy immigrant women to participate in a community-based intervention in Rome. The geographic area was selected based on the number of immigrants residing there. To be eligible, participants must meet the following criteria: a) be aged between 25 and 65; b) be born in Eastern Europe, Asia, and South-central America, c) live in Rome (in the municipality ASL Roma 2), and d) have not participated in cervical cancer screening in the last 5 years. Overall, about 12 groups will be organized based on country of origin, availability, and residence. Recruitment will occur at the local level with the help of four research assistants from each immigrant community. They will contact women via local organizations, community activities, and social media. We will also identify three key informants from each immigrant group to help with recruitment. To encourage interactive participation, we will conduct the intervention in small groups of 15-20 participants, separately for each immigrant group. Each in-person educational session will last for two hours, including a presentation of the project goals, cervical cancer diagnosis, treatment, and prevention; questions and answers with researchers; and education on navigating the healthcare system. Before the educational intervention, participants will be asked to complete a self-report questionnaire covering sociodemographic characteristics, clinical data (including history of cervical cancer screening, risk factors such as smoking, education, and number of partners), as well as knowledge about the health system and cervical cancer screening. Following the educational intervention, women will be asked to complete again a questionnaire to assess any improvements in their knowledge about the health system and cervical cancer screening. Women will be encouraged to participate in cervical screening through the national program, and up to two reminders will be sent. Additionally, after each educational session, an Open Day of the screening service will be organized with healthcare professionals available to perform cervical screening on willing women. To evaluate the effectiveness of the intervention, we will gather information on the screening status at baseline and two years after the intervention from the screening databases in the Rome – ASL Roma 2 (intervention group) and Milan (control group) screening centers. In particular, to prevent cross-contamination, immigrant women from the same original countries residing in the control area (Milan) will be the control participants. We will compare the number of women who had done the screening in the previous 5 years at baseline and 2 years after the intervention.

b) Preliminary data

Free regional screening programs for cervical cancer are available across Italy. Women aged 30/35 to 64 can receive an HPV test every 5 years, while younger women aged 25-30/35 have access to a Pap test every 3 years. According to the PASSI national surveillance system,^{*} in Italy, in 2021-2022, 77.7% of women between 25 and 64 years old participated in cervical screening for preventive purposes, whether within organized programs or through personal initiative.⁹ Cervical screening coverage varies significantly from north to south, and the COVID-19 pandemic led to a substantial decrease in both the availability and participation of screening. Overall, the screening procedure has not been able to achieve the desired level of adherence,

^{*} PASSI is based on questionnaires administered through telephone interviews

especially among immigrant women, who show lower participation. In particular, a study conducted in northern Italy found that attendance rates in young immigrant women ranged between 36.5% for women born in Asia and 45.5% for women born in Eastern Europe.² Moreover, immigrant women are at a higher risk of cervical cancer due to limited access to screening in their home countries and higher rates of HPV infection. In European countries, studies have found significant variations in cancer-related indices among immigrants and the host population,^{10,11} along with different subtype-specific incidences.¹² In Italy, there is little information on cervical cancer incidence rates in immigrants. In our initial study, we analyzed data from the Eastern Sicily Cancer Registry collected between 2004 and 2019. We discovered that immigrants have a higher risk of cervical cancer (OR=3.54) compared to non-immigrants.¹ Additionally, a recent study examining data from the Veneto region also found an almost double incidence of cervical cancer in women born in countries with high migratory pressure (11.8 per 100,000 compared to 6.5 per 100,000), with women from Eastern Europe, Asia, and South-Central America having the highest risk.⁸ Furthermore, data from northern Italy revealed a higher detection of CIN2+ among women from Central and Southern America (23.0%) and Eastern Europe (17.9%).² This paves the way for a national epidemiological study involving other Italian registries.

Italy has one of the highest numbers of migrants in Europe, with foreign people comprising 8.6% of the population. Romania, North Africa, Albania, and China are the top regions of origin.¹³ Due to various factors, foreign-born individuals may experience additional difficulties in accessing early detection in Italy. These may include language barriers, challenges in assessing their health status, difficulties in navigating the healthcare system, higher likelihood of behavioral risk factors (e.g., smoking and alcohol consumption¹⁴), inadequate social support, stigma, and lower socioeconomic status.¹⁵ As a result, despite the "healthy immigrant effect" and lower cancer incidence in some immigrant groups,¹⁶ immigrants may experience a higher cancer burden due to less participation in screening programs and delayed diagnosis.¹⁷ For example, a study found that African American women were 45–53% less likely to schedule a follow-up appointment after a low-grade abnormal screening, compared to other women.³ Numerous intervention studies have attempted to increase cervical screening uptake among immigrant women worldwide, including health promotion campaigns and HPV self-sampling.¹⁸ Overall, we believe that community-based interventions using different modes of information delivery are the most effective and useful from a public health perspective. For example, a community-based intervention in Norway resulted in a 5% increase in participation in cervical cancer screening.¹⁹

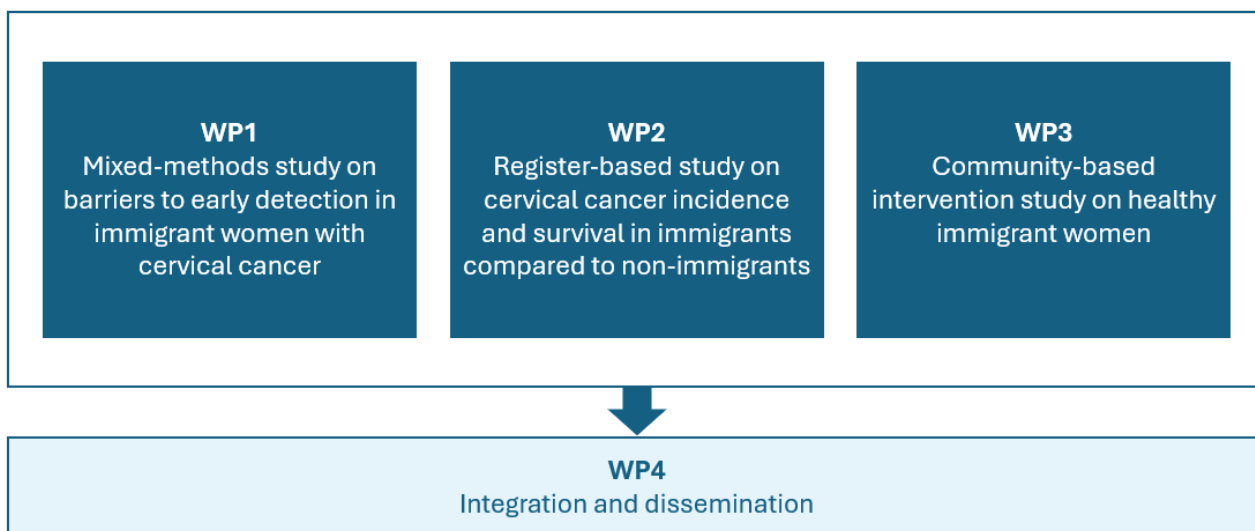
c) Power analysis

Study 1 - We aim to collect quantitative data to study the prevalence of barrier factors, targeting a range of 20-30% with a precision of 5%. This requires a sample size of 242 to 320 patients to adequately assess the prevalence of various barriers to participation in cervical screening among immigrants. To meet this requirement, we plan to recruit approximately 30 patients from each of the 10 collaborating centers, resulting in a total of 300 patients overall.²⁰ For our qualitative data collection, we plan to enroll 60 participants from the 10 collaborating centers, with 6 immigrant women from each center. The participants will represent three major immigrant groups: Eastern Europe, Asia, and South-central America.^{2,8} We anticipate achieving data saturation by including 20 women from each immigrant group.

Study 2 - Based on our study conducted in Sicily¹ and preliminary analyses performed by Friuli PBCR, we estimate that upon approval of the project by the AIRTUM steering committee and sending the call for data across the country, we expect that at least 10 PBCRs will collaborate with this project and more than 2000 cases will be shared for the analyses. With $\alpha=0.05$ and 80% power, we can detect an IRR of about 1.10. Since the expected IRRs will be larger than 1.10, we could perform subgroup analyses by country of birth.

Study 3 - The screening participation rate was 40% among immigrants and 62% among non-immigrants in central Italy in 2013.²¹ To study the effect of our intervention on screening participation, we aim to increase the participation rate by about 15% within the intervention group.^{18,19} To achieve 80% power at a 5% significance level, we will require at least 171 women in each group. Assuming a dropout rate of 20%, we will recruit 205 immigrants in the intervention group. Controls will be all women from Eastern Europe, Asia, and South-central America living in Milan who will receive no interventions.

Research plan



WP1: Mixed-methods study on barriers to early detection in immigrant women with cervical cancer

Specific objectives:

1. To collect quantitative data on the barriers to early detection of cervical cancer among immigrant women with cervical cancer.
2. To collect qualitative data on the experiences of immigrant women with cervical cancer in accessing screening and care.
3. To integrate and compare qualitative and quantitative data in order to convey a comprehensive understanding of the factors affecting equal access to screening and care among immigrants.

Task 1. Protocol for the mixed-method study: A research protocol will be developed for the mixed-methods study aimed at identifying barriers to early cervical cancer detection among immigrant populations. The protocol will be developed based on findings from a systematic literature review, which will include both qualitative and quantitative studies. This will help us in creating questionnaire items for the study.

Task 2. Ethics: The protocol will be submitted to the Ethics Committee for approval at each of the 10 clinical centers involved after receiving approval from the coordinator center.

Task 3. Quantitative data collection: Each of the 10 clinical centers will gather quantitative data (n=300). In particular, each center will enroll 30 immigrant women who have been diagnosed with cervical cancer at any stage or high-grade squamous intraepithelial lesion (HSIL) within the past year. They should be aged between 25 and 65 and born in Eastern Europe, Asia, and South-central America. These women will be administered a self-report questionnaire that includes questions about potential barriers to early detection (e.g., language), experiences of discrimination in healthcare (CARE), and the Health Care System Distrust Scale. Socio-demographic and clinical data will also be collected (e.g., screening/vaccination status, length of stay in Italy, age at immigration). A cultural intermediary will be available to assist in completing the questionnaire in their native language.

Task 4. Qualitative data collection: Each of the 10 clinical centers will gather qualitative data (n=6). A purposeful sub-sample of 6 patients per center will be invited to participate in semi-structured individual interviews conducted in their native language. These interviews aim to explore disparities in accessing screening and cancer care (e.g., “How easy has it been for you to access early detection for your condition?”).

Task 5. Data synthesis and writing: PI from each clinical center will be involved in data synthesis and reporting of the results, as well as the preparation of specific manuscripts. In particular, quantitative data will describe the burden of the potential barriers and patients' attitudes using descriptive statistics and associations. Qualitative data from individual interviews will reveal immigrant patients' experiences of accessing screening and care in Italy. All interviews will be analyzed in their native language to retain typical expressions of their language's etymological and semantic meanings. Therefore, six coders (two from each native area) will perform the complete analysis. Codes, subcategories, and themes will be developed in English to facilitate discussion among the multilingual research team. Mixed methods analysis will be conducted using the merging integration technique which entails a comparison of the qualitative and quantitative data after separate analysis.

Specific milestones:

1. Approval of the mixed-methods study by the Ethics Committee
2. Enrollment of 30 immigrant women with cervical cancer at each of the 10 centers
3. Interviews with 6 immigrant women with cervical cancer at each of the 10 centers
4. Report on the results of the mixed-methods analysis

WP2: Register-based study on cervical cancer incidence and survival in immigrants compared to non-immigrants

Specific objectives:

1. To evaluate disparities in cervical cancer incidence and mortality among Italian and immigrant populations by country of birth in Italy.
2. To evaluate disparities in survival of cervical cancer among Italian and immigrant populations by country of birth in Italy.

Task 1. Collaboration agreements with registries: We will finalize the collaboration agreements with the already involved PBCRs. In addition, we will submit a research proposal to the steering

committee of AIRTUM for their approval. Once approved, we will invite all Italian PBCRs to participate in this study. We will establish individual collaboration agreements with each participating PBCR to ensure confidentiality and allow for data sharing between each PBCR and the University of Bologna. Each PBCR will be asked to provide us with anonymized raw data on cervical cancer incidence and mortality from the date of inception.

Task 2. Data acquisition: Anonymized data from each registry will be shared with the University of Bologna for pooled analysis, using standard definitions. A standard record layout will be defined for the creation of homogeneous databases by all participating PBCRs.

Task 3. Data analysis on incidence and mortality: We will estimate crude and age-standardized incidence rates (ASR) for cervical cancer, using the standard Italian population among immigrants compared to non-immigrants. We will stratify the analyses by country of birth, age, and calendar period. We will then estimate immigrants' incidence rate ratio (IRR) of cervical cancer in immigrants compared to non-immigrants. In addition, we will utilize the data on the vital status (dead/alive) of cancer patients from the PBCR databases to study cancer mortality and survival. We will calculate mortality to incidence ratio to assess the impact of diagnosis and care.

Task 4. Data analysis on survival: We will employ the Cox regression model to estimate hazard ratios (HR) and compare the survival rates between immigrant and non-immigrant cancer patients. The expected survival estimates for this analysis will be obtained from the regional life tables provided by ISTAT, stratified by age and calendar year. Furthermore, we will perform a sub-analysis using the available data on pathologic staging (optional variable) to study the disparities in stage distribution and the stage-specific survival between Italian and immigrant populations.

Task 5. Interpreting results and writing reports: We will review the data analysis results within the steering group to interpret them and understand their relevance. We will prepare a summary of each registry's results for local reporting. Each registry manager will participate in reporting the results and preparing specific manuscripts.

Specific milestones:

1. Approval of the project of the register-based study by AIRTUM
2. Obtain data from collaborating PBCRs
3. Report on the incidence and mortality of cervical cancer
4. Report on cervical cancer survival

WP3: Community-based intervention study on healthy immigrant women

Specific objectives:

1. To design and implement a community-based, culturally-targeted intervention for healthy immigrant women to improve their participation in cervical screening, ensuring a comprehensive approach for effective engagement
2. To obtain information on cervical screening status at baseline and after the intervention from the Local Health Authorities and PASSI, for both the intervention and control groups
3. To evaluate the effectiveness of the community-based intervention using generalized estimation equations

Task 1. Protocol for intervention study: The protocol for a quasi-experimental study involving a community-based intervention to promote cervical screening participation in immigrant women will be developed. The intervention groups will include 205 healthy immigrant women residing in ASL Roma 2, while the control group will consist of women from the same original countries residing in Milan. Authorization to conduct the study will be obtained from the local authorities.

Task 2. Community-based intervention: Healthy immigrant women will receive invitations to take part in a community-based intervention in Rome if they have not participated in cervical cancer screening in the last 5 years. Female researchers and fieldworkers with relevant ethnic backgrounds will assist in recruiting participants. Based on Heron's six-category intervention framework, we will be organizing an educational intervention in small groups of 15-20 participants, separately for each immigrant group. Our approach will be informed by previous studies, focus-group discussions, and theoretical concepts. The intervention will be tailored to each group based on their country of origin, possibly involving a 20-25-minute PowerPoint presentation, a brief video demonstrating the screening test, and information about Italian cervical cancer screening guidelines. We will also explain how to navigate the healthcare system and schedule appointments. Female researchers and fieldworkers fluent in the participants' languages will discuss their understanding of cervical cancer screening with them. Participants will be asked to fill out a brief questionnaire before and after the intervention.

Task 3. Evaluation: We will obtain data from the Local Health Authorities and PASSI to evaluate the effectiveness of the intervention. The main outcome measure will be screening status two years after the intervention compared to screening status before the intervention. We will define a woman as screened if she has taken a cervical screening test within two years after the intervention. We will compare the number of women who had done the screening in the previous 5 years at baseline and 2 years after the intervention in the Rome – ASL Roma 2 (intervention group) and Milan (control group) screening centers.

Task 4. Data analysis: We will use statistical data analysis to estimate the impact of the intervention. We will apply generalized estimation equations (GEE) with a binomial distribution and an identity link function. The outcome will be the screening status, and we will use long-format data with two binary measurements of screening status per person.

Task 5. Report: We will prepare a detailed report of our findings, including the effectiveness of the intervention after adjusting for key covariates such as age, income quartiles, and educational level. The report will offer detailed conclusions and recommendations based on the data analysis.

Specific milestones:

1. Approval of the quasi-experimental study by local authorities
2. Enrollment of 205 healthy immigrant women in the intervention group
3. Conduction of about 12 educational sessions with immigrant women in Rome
4. Acquisition of data on cervical screening status in the intervention and control group at baseline and after two years
5. Report on the results of the quasi-experimental study

WP4: Integration and dissemination

Specific objectives:

1. To harmonize and integrate the three components of the proposed research.

2. To create a comprehensive plan for project communication to effectively convey research findings, outcomes, and progress to relevant stakeholders.
3. To develop and implement a strategy to effectively disseminate project results to a wide audience, including healthy foreign communities, patients with cancer, health professionals, policymakers, researchers, and the general public.
4. To explore ways to use project results for additional research, policy changes, or innovative solutions.

Task 1. Integration: We will ensure that the three components of the proposed research, studies 1, 2, and 3, are coordinated and consistent across work packages. We will combine quantitative and qualitative data from different sources to provide a cohesive overview of the project's overall outcomes. The results will be integrated into a framework aimed at reducing disparities in cervical cancer prevention and early detection among immigrants in Italy.

Task 2. Prepare a dissemination strategy: We plan to create a holistic approach to engaging with national, European, and international stakeholders. In addition, we intend to create a project website that will act as a central platform for sharing our project's goals, updates, publications, and educational materials. This website will allow us to interact with stakeholders and the public, providing information about the project's objectives and outcomes.

Task 3. Present at conferences and workshops: We will present our research findings from studies 1, 2, and 3 to health professionals and researchers at national and international scientific conferences. We also plan to conduct workshops at the local level with health professionals from each center involved in the study.

Task 4. Communication of findings to the public: We will communicate our study findings to the general public, including healthy foreign communities, patients with cancer, and policymakers. Additionally, we will create educational resources, such as audiovisual content, to educate various audiences about cervical cancer among immigrant populations and preventive strategies. These resources will be crucial in promoting awareness about cervical cancer and encouraging screening among immigrants.

Task 5. Interim and final reports: We will perform interim analyses and reports to inform the stakeholders about the progress of the project. We will integrate the results of the three components of the proposed research and prepare a summary of the research findings, and their exploitation and dissemination.

Specific milestones:

1. Integration of the three components of the project
2. Dissemination plan and website
3. Attendance to scientific conferences to present study findings
4. Organization of educational events for immigrant communities and the general public
5. Interim and final reports

Table 1. Gantt chart

WP	Task	2025				2026				2027				2028				2029			
		Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
1	1. Protocol for the mixed-method study	■	■	■																	
	2. Ethics				■	■	■	■	M1												
	3. Quantitative data collection					■	■	■	■	■	■	■	■	■	M2						
	4. Qualitative data collection					■	■	■	■	■	■	■	■	■	M3						
	5. Data synthesis and writing															■	■	■	■	■	M4
2	1. Collaboration agreements with registries	■	M1	■	■																
	2. Data acquisition					■	M2														
	3. Data analysis on incidence and mortality							■	■	■	■										
	4. Data analysis on survival							■	■	■	■										
	5. Interpreting results and writing reports											■	M3	■	M4						
3	1. Protocol for intervention study	■	■	■	M1																
	2. Community-based intervention					■	■	M2	■	■	M3										
	3. Evaluation										■	■	■	■	■	■	■	■	■	M4	
	4. Data analysis										■	■								■	■
	5. Report																			■	M5
4	1. Integration	■	■	■	■	■	■	■	M1												
	2. Prepare a dissemination strategy	■	■	■	■	■	■	■	■	■	■	M2									
	3. Present at conferences and workshops											■	■	■	■	■	■	■	■	■	M3
	4. Communication of findings to the public															■	■	■	■	■	M4
	5. Interim and final report				■				■			■	■			■	■				M5

Innovation: This will be the first comprehensive research on disparities in cervical cancer among immigrant women. The multi-level approach, encompassing mixed-method research on determinants of participation in screening and care, population-based registry data analysis, and community-based, culturally tailored intervention will represent an original effort to address the key components of the burden of cervical cancer in immigrant women. The mixed-methods study will identify the reasons behind the unequal access to care and barriers to participation in cervical screening among immigrants. Based on the register-based study, we expect to provide a comprehensive assessment of the gap in the incidence and survival of cervical cancer between immigrants and non-immigrants and provide an overview of the accessibility of cervical cancer prevention and care services for immigrant women. Based on the interventional study, we will develop an educational program to increase cervical screening participation by 15% in the intervention group compared to the control group. Our community-based intervention model would have the potential to be implemented at the national level in the future and decrease the burden of cervical cancer screening in all immigrant women in Italy. Overall, this project will reduce the cancer burden among immigrant women by enhancing their participation in cervical cancer screening programs. It will also pave the way for conducting research on ways to reduce disparities of other cancer types among immigrants in Italy.

Resources: We will utilize the University of Bologna resources, including scientific and administrative support at the school and departmental levels [<https://dimec.unibo.it/en/index.html>]. In addition, we will employ human and logistic resources from Prof. Boffetta's lab.

Risk assessment and contingency plans: The inclusion criteria related to the country of origin of the women to be enrolled in studies 1 and 3 may be revised based on preliminary findings. For the mixed methods study, if enrolling patients within the hospital setting is challenging, immigrant women with cervical cancer will be actively recruited from patient associations. In the register-based study, if AIRTUM does not approve the study protocol, contact will be made with single registries at the national level. For the community-based intervention study, if ASL Roma 2 does not agree to organize an Open Day for the screening service after each educational session, women will be encouraged to participate in cervical screening through the national program.

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