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Causes of late diagnosis and treatment delay of breast, cervical cancers and childhood cancer of different localisations

Submission date 23/11/2021	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 07/02/2022	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 16/01/2025	**Condition category** Cancer	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims
In light of the launched global initiatives on cervical and childhood cancer and preparations for the launch of a similar initiative on breast cancer, new research projects are being developed to achieve the goals of these programs. One of them is a project aimed to identify the determinants of late diagnosis and delayed treatment of three above-described cancers. The aim of this study is to develop and apply questionnaires to identify the barriers to diagnosis and initiation of cancer treatment in different countries and analyze the results.

Who can participate?
Patients aged over 18 years with breast or cervical cancer and patients aged under 21 years with childhood cancers

What does the study involve?
Participants will be interviewed using a structured questionnaire that will evaluate their personal and medical journey throughout the disease, assessing the main three-time variables: a) access delay (time between self-noticed first symptoms and the first consultation by a doctor); b) diagnosis delay (time/delay between the first consultation by the doctor and effective diagnosis), and c) treatment delay (time between the diagnosis and beginning of treatment). The study questionnaire has been designed to explore health staff behaviors well as patient behavior and beliefs. Medical information about disease sub-types, stage, and tumor size at diagnosis will also be collected for each patient from their medical records. The questionnaire will also permit the identification of or measure the factors that potentially influence these time variables and their associations with patient and health service factors.

What are the possible benefits and risks of participating?
Participants may benefit from the identification and possible reduction of time intervals in the diagnosis and initiation of cancer treatment, raising awareness about cancer. There are some possible harms also related to participating in the study (psychological discomfort).

Where is the study run from?
International Agency for Cancer Research (IARC) (France)

When is the study starting and how long is it expected to run for?
September 2021 to December 2026

Who is funding the study?
World Health Organization Regional Office for Europe (Denmark)

Who is the main contact?
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Additional identifiers

Protocol serial number
IEC 20-18-A1

Study information

Scientific Title
Determinants of late diagnosis and delayed treatment cancer

Acronym
DEDICA

Study objectives
Early diagnosis programs are defined by WHO as “a set of public health measures aiming at ensuring rapid diagnosis and care of cancer”. Today the majority of cancer (breast, cervical, lung, childhood, colon, etc) is curable when detected at the early symptomatic stage therefore early diagnosis is key to decreasing cancer mortality and improving survival. Early diagnosis programs that aim at ensuring diagnosis of the symptomatic patient at an early stage are much less resource-intensive and more sustainable than screening programs and are in any case a prerequisite to efficient screening programs. Tailored to each national/local situation, early diagnosis programs may include training of health staff, improvement of referral procedures and /or diagnosis guidelines, awareness campaigns for the public, etc. “Tailored” is a key feature of early diagnosis programs and therefore the first step of such programs is to clearly identify the causes (determinants) of late diagnosis in a country/region, in order to adequately tackle them. The WHO regional office for Europe (EURO) together with IARC has developed a framework and tools (questionnaire, protocols) to help countries through this first phase.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 30/09/2021, IARC Ethics Committee (IARC Ethics Committee: 150 cours Albert Thomas, 69372 Lyon cedex 08, France; +33 (0)4 72 73 83 41; iec-secretariat@iarc.fr), ref: IEC 20-18-A1
2. Approved 28/10/2021, the Academic Council meeting (N.N. Alexandrov National Cancer Center of Belarus: 223040 Lesnoy, Minsk District, Republic of Belarus; +375 (0)17 265 39 52; evmenenkoalesya88@gmail.com), ref: 177
3. Approved 25/10/2021, the Academic Council meeting (NMRC of Oncology named after N.N. Petrov of MoH of Russia: 197758, 68 Leningradskaya str., Pesochny, Saint Petersburg, Russia; +7 (0)812 43 99 555; md.komarov@gmail.com), ref: 18

Primary study design
Observational

Study design

Observational prospective cohort study

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Breast, cervical and childhood cancers

Interventions
This is a prospective study that will include breast, cervical or childhood cancer patients recently diagnosed with all stages of the disease who are referred for treatment.

It is envisaged that at least 200 patients with confirmed cancer each of the three locations will be interviewed using a structured questionnaire that will evaluate their personal and medical journey throughout the disease, assessing the main three time variables: a) time between self-noticed first symptoms and the first consultation by a doctor; b) time/delay between the first consultation by the doctor and effective diagnosis, and, c) time between the diagnosis and beginning of treatment. The study questionnaire has been designed to explore health staff behaviors well as patient behavior and beliefs. Medical information about disease sub-types, stage, and tumor size at diagnosis will also be collected for each patient from their medical records. The questionnaire will also permit to identify or measure the factors that potentially influence these time variables and their associations with patients' domain and health services' domain factors.

The study can be conducted by non-governmental/patient organizations, academic groups, hospitals, or cancer centers with access to cancer patients. All patients fulfilling the inclusion criteria should be selected as potential study participants. Patients will be invited to participate in the study after a pre-screening is done for their eligibility. The invited patients or their legal representative will provide contact information (name, national ID number where available, detailed address and telephones, and name of contact person with address and telephone) and eligibility will be evaluated by interviewers.

Eligible cancer patients will be informed of the study and will be given the chance to participate. Eligible patients can refuse to participate or may ask for additional time to consider their participation in which case a later appointment will be given to them. Reasons for refusals will be documented if agreed by eligible patients.

Those who agreed with the informed consent (orally or by signing the informed consent form) will be assigned a study number and will then be interviewed following a structured questionnaire designed to document the patient's medical and personal journey throughout the disease and describe the type and scale of medical and social experiences faced. Participants will agree to be interviewed and may agree to have their medical records revised by clinicians or researchers or to have the interview recorded.

The interviewers will be conducted by trained personnel, preferably with previous experience working with oncological and advanced cases and who have some experience interviewing patients/relatives in other surveys or scientific studies. The interviewers should not be involved directly in the diagnosis and treatment of the cancer cases or other activities related to their diagnosis, in order to encourage the openness and trust of the participants.

The interviewers will foresee that the conditions to conduct the face-to-face interviews are adequate to ensure a calm atmosphere and allow for sufficient time to conclude the interview. Interviews will be conducted in the participant's language whenever possible. If a study participant is willing to provide more details about their story, additional time will be offered to do so in an effort to increase the quality of the survey and data collection.

Participants can withdraw from the study at any time, including while having the interview, in which case their data will be deleted, and this will not affect their clinical management.

Data from the questionnaire and medical records of the participants will be registered, collected, and analyzed.

Intervention Type
Other

Primary outcome(s)
Barriers of late diagnosis and delayed treatment of patients with breast, cervical, and childhood cancers by interviewing patients (parents/ guardians in cases of childhood cancer) in accordance with developed questionnaires. There are two interviews for each participant: the first - no later than 3 months after the first visit to the treatment center, the second - 6 months after the first interview.

Key secondary outcome(s)
There are no secondary outcome measures

Completion date
01/12/2026

Eligibility

Key inclusion criteria
1. Patients who have confirmed breast, cervical, or childhood cancer
2. Older than 18 years (for adult cancers) or younger than 21 years (for childhood cancers)
3. Histology report available and confirms precancer lesion or invasive malignant cancer
4. New presented cases, up to 3 months from the day of first medical visit at the center
5. Agreed with informed consent to participate in the project

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
All

Sex
All

Key exclusion criteria

1. Cognitive or social disorder that impairs the ability to understand the interview
2. Ideally, a patient who is halfway through treatment should NOT be newly enrolled. An exception can be made in study sites with a low number of new cases or for low prevalent cancer types

Date of first enrolment
01/12/2021

Date of final enrolment
01/12/2023

Locations

Countries of recruitment
Belarus

Moldova

Romania

Russian Federation

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Sponsor information

Organisation
World Health Organization Regional Office for Europe

ROR
https://ror.org/01rz37c55

Funder(s)

Funder type
Research organisation

Funder Name
World Health Organization

Alternative Name(s)
, , Всемирная организация здравоохранения, Organisation mondiale de la Santé, Organización Mundial de la Salud, WHO, , ВОЗ, OMS

Funding Body Type
Government organisation

Funding Body Subtype
International organizations

Location
Switzerland

Results and Publications

Individual participant data (IPD) sharing plan
Data will be entered and stored at REDCAp. Personal data will be available only for interviewers and local PIs in each participative countries, only anonymized patient data (medical information about their disease and filled questionnaires) will be available for study monitoring and statistical analysis. Each participant will sign the informed consent form.

IPD sharing plan summary
Stored in non-publicly available repository