Progress report in implementing WHA 70.12 on Cancer Control

Member State Information Session

25 April 2023
Objectives of MS Briefing

- Present WHO’s programme of work in cancer including WHO cancer initiatives through an integrated approach
- Progress in cancer control planning – nationally, regionally and globally – tracking progress and impact of programmes
- Proposal for mapping, expected output and strengthening cancer control mandate, in line with the request from Slovak Republic and other EB members (EB 143)
- Next steps including reporting on progress to Governing Bodies

<table>
<thead>
<tr>
<th>Time</th>
<th>Agenda Item</th>
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<tbody>
<tr>
<td>11:30</td>
<td>Welcome addresses</td>
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<tr>
<td>11:40</td>
<td><strong>Item 1</strong>: WHO programme of work in cancer control:</td>
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<tr>
<td></td>
<td>Progress in the implementation of initiatives in childhood, cervical and breast cancers</td>
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<tr>
<td>12:05</td>
<td><strong>Item 2</strong>: Reporting on progress in cancer control:</td>
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<tr>
<td></td>
<td>Mapping current status and data gaps</td>
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<tr>
<td>12:20</td>
<td><strong>Item 3</strong>: Methodology for stock-take and setting a strategic direction for 2025 and beyond</td>
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<td>Review of proposed approach, sharing of best practices and results</td>
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<td>12:30</td>
<td><strong>Item 4</strong>: Moderated discussion with Member States</td>
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<tr>
<td>12:50</td>
<td>Wrap up and end of session</td>
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Opening Remarks

Prof Dr Jérôme Salomon
Assistant Director-General,
Division of Universal Health Coverage,
Communicable and Noncommunicable Diseases

Dr Maria Neira
Assistant Director-General (a.i.),
Division of Universal Health Coverage/Healthier Populations
Agenda item 1:

WHO programme of work in cancer control

Progress in the implementation of initiatives in childhood, cervical and breast cancers

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<tr>
<td>11.40 – 11.50</td>
<td>Current status of strategic priorities in cancer control</td>
<td>Dr Bente Mikkelsen, Director, Noncommunicable Diseases Department/HQ</td>
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<tr>
<td>11.50 – 11.55</td>
<td>WHO cancer initiatives and inclusion of communities with lived experience</td>
<td>Dr Rogério Pinto de Sa Gaspar, Director, Regulation and Prequalification Department/HQ</td>
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<tr>
<td>11.55 – 12.00</td>
<td>Cancer control link to health system strengthening with focus on access to medicines</td>
<td>Dr Meg Doherty, Director, Global HIV, Hepatitis and STI Programmes/HQ</td>
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<tr>
<td>12.00 – 12.05</td>
<td>Integrated approach to cancer management with co-morbid conditions</td>
<td>Dr Meg Doherty, Director, Global HIV, Hepatitis and STI Programmes/HQ</td>
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</table>
Current status of cancer control: *major burden, marked by inequalities*

20 mil
Diagnosed with cancer per year; 1 in 3 lifetime risk of being diagnosed with cancer in HIC; Lifetime risk in LMIC is 1 in 6

14 (of 196)
Countries on track to reduce premature mortality from cancer by one-third by 2030

1 in 3
Cancer deaths in men in Europe associated with educational inequalities; 1 in 6 deaths in women in Europe

Cancer & CVD ranks as the two leading causes of premature death in 127 countries (2019).
Cancer may be the leading cause of premature death this century.
Generational harm: premature deaths & impoverishment

>60% People with cancer experience anxiety or depression

>70% Experience financial distress or hardship

GDP loss 0.5-2%

2.1 Maternal orphans per cancer death. Cancer affects women 2.7 million women aged 25-54 years old

>30% People affected by cancer and caregivers experience unemployment after diagnosis.
## Overview
Launched 3 integrated cancer initiatives (cervical, childhood and breast cancers)

## Technical guidance
Produced 10 strategic guidance documents and 2 implementation tools

## Country support
Increased country support from 5 (2017) to 75 (ongoing)

## Leadership & advocacy
Increased partner networks including 10 MoUs, 300 implementing partners; Launched network for people affected by cancer

## Implementation capacity
Increased WHO capacity in RO and CO to >40 new staff & consultants Voluntary contribution – mainly, non-state actor

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### Cancer prevention and control in the context of an integrated approach

The Seventieth World Health Assembly,

Having considered the report on cancer prevention and control in the context of an integrated approach,

Acknowledging that, in 2012, cancer was the second leading cause of death in the world with 8.2 million cancer-related deaths, the majority of which occurred in low- and middle-income countries;

Recognising that cancer is a leading cause of morbidity globally and a growing public health concern, with the annual number of new cancer cases projected to increase from 14.4 million in 2013 to 21.4 million by 2030;

Aware that certain population groups experience inequalities in risk factor exposure and in access to screening, early diagnosis and timely and appropriate treatment, and that they also experience poorer outcomes for cancer; and recognising that different cancer control strategies are required for specific groups of cancer patients, such as children and adolescents;

Noting that risk reduction has the potential to prevent around half of all cancers;

Aware that early diagnosis and prompt and appropriate treatment, including pain relief and palliative care, can reduce mortality and improve the quality of life of cancer patients;

Recognising the critical importance of the introduction of new pharmaceutical products based on investment in innovation for cancer treatment in recent years, and noting with great concern the increasing cost to both society and patients;

Emphasising the importance of addressing barriers in access to safe, quality, effective and affordable medicines, medical products and appropriate technology for cancer prevention, diagnosis, screened diagnosis and treatment, including coverage, by strengthening national health systems and international cooperation, including under the Sustainable Development Goals for cancer patients, including through increasing the capacity of the health systems to provide such access;

Resolving to observe WHA82.22 (2020) on cancer prevention and control;
### Overview of major milestones by MS request

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
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<tbody>
<tr>
<td>2018</td>
<td>DG announces call for Cervical Cancer Elimination</td>
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<tr>
<td>2018</td>
<td>Launch of WHO Global Initiative for Childhood Cancer</td>
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<td>2018</td>
<td>Pricing of cancer medicines and its impacts</td>
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<td>2019</td>
<td>Guidelines for pain management</td>
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<td>2019</td>
<td>Monitoring system for cervical cancer</td>
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<tr>
<td>2020</td>
<td>Launch of WHO Global Report on Cancer</td>
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<tr>
<td>2020</td>
<td>Launch of Global strategy to accelerate elimination of cervical cancer with technical guidance</td>
</tr>
<tr>
<td>2021</td>
<td>WHO guidelines for screening and treatment of cervical cancer; AI evidence</td>
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<tr>
<td>2021</td>
<td>CureAll Framework for GICC</td>
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<td>2021</td>
<td>Launch of GBCI using resource-stratified approach</td>
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<tr>
<td>2021</td>
<td>Announce Global Platform for access to childhood cancer medicines</td>
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<td>2022</td>
<td>Cancer centre document with IAEA</td>
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<td>2022</td>
<td>Amplifying the lived experience of people affected by cancer</td>
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<tr>
<td>2023</td>
<td>Launch of implementation guidance for Global Breast Cancer Initiative</td>
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<tr>
<td>2023</td>
<td>Position paper on breast cancer &amp; alcohol use – integrated RF and management</td>
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<td>2023</td>
<td>WHO-IARC workplan established</td>
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Global Initiative for Childhood Cancer

>80% children with cancer in HIC survive

<20-30% children with cancer in LMIC survive
CureAll Country Showcase: GICC Milestones

$12,000,000
Funding support distributed to major WHO Budget Centres, Years 1-4

150+
Childhood cancer centres supported in providing care across 6 WHO Regions

35,000+
Children newly diagnosed with cancer accessing care improved care in 70+ countries
CureAll Country Showcase: GICC Milestones
Global Platform for Access to Childhood Cancer Medicines

Platform vision: a **comprehensive** solution engaging **global partners** to provide an **uninterrupted** supply of **quality** childhood cancer medicines

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<th>Initial Phase</th>
<th>Growth Phase</th>
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<td>2022</td>
<td>2023</td>
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<tr>
<td>Countries</td>
<td>6</td>
<td>12</td>
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<tr>
<td>Children</td>
<td>5,000</td>
<td>12,000</td>
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<tr>
<td>Budget (USD)</td>
<td>2 mil</td>
<td>11 mil</td>
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* 50,000 children per year by 2027 represents approximately:
  • 25% of all children with cancer in the world
  • 60% to 70% of children with cancer in low- & lower-middle income countries

By 2027, the Global Platform will have provided medications for > 120,000 children
The Global Strategy

**THRESHOLD:** < 4 cases per 100,000 women per year

**2030 Control Targets**

- **90%** of girls fully vaccinated with HPV vaccine by age 15 years.
- **70%** of women are screened with a high-performance test by 25 years of age and again by 45 years of age.
- **90%** of women identified with cervical disease receive treatment (90% of women with pre-cancer treated, and 90% of women with invasive cancer managed).

**LIFE-COURSE APPROACH:**

Three pillars provide a comprehensive strategy to ensure lifetime benefits are maximized.
Cervical Cancer Elimination Initiative: timeline & progress

Flagship launched by WHO Director-General (2018)

"One woman dies of cervical cancer every two minutes... Each one is a tragedy, and we can prevent it."

Partnership, advocacy, and monitoring and evaluation

- Adoption & Launch of Global strategy 2020
- Guidance updated & expanded 2021-2022
- Regional implementation / action plan 2022

Implementation guidance & support
Strengthened leadership & accelerated impact
CCEI Implementation

COORDINATION

Building on existing UN coordination mechanism – dialogues with UNFPA, UNICEF, GAVI, Unitaid and others

Partner networks
Developing WHO implementation network with South-South engagement

Expanding stakeholder dialogue
For example, African Union Commonwealth, Union for Mediterranean, cancer institutes

ADVOCACY

17 November: day of action

Uzbekistan: Great Silk Road

WHO Ambassador
CCEI led a history-making endeavour to honor Henrietta Lacks

First Spouse Network
>10 First Spouses engaging with CCEI

Knowledge repository & exchange
including communities of practice

CCEI direct support to 20 Member States, leveraging implementation partners for impact.
Global Breast Cancer Initiative

**OBJECTIVE:** reduce breast cancer mortality by 2.5% per year, to avert 2.5 million breast cancer deaths globally by 2040.

**Pillar 1**
Pre-diagnostic interval
Early detection

**Pillar 2**
Diagnostic interval
Definitive diagnosis

**Pillar 3**
Treatment interval
Integrated care

**AGE-STANDARDIZED BREAST CANCER MORTALITY RATES**

**ESTABLISHED CANCER SYSTEMS**
(2% Annual Mortality Reduction)

**EVOLVING CANCER SYSTEMS**
(Mortality Reduction in Transition)
Global Breast Cancer Initiative

3 pillars

- **Pillar 1**
  - Health promotion for early detection (pre-diagnostic interval)
  - Achieve diagnosis of at least 60% of invasive breast cancers at stage I or II

- **Pillar 2**
  - Timely breast diagnostics (diagnostic interval)
  - Evaluation, imaging, tissue sampling and pathology completed within 60 days

- **Pillar 3**
  - Comprehensive breast-cancer management (treatment interval)
  - 80% undergo full courses of multimodality treatment and successfully return home

3 implementation strategies

- Convene multi-sectoral stakeholders
- Develop operational guidance
- Accelerate & monitor implementation
Launch of campaign to engage communities affected by cancer

**Primary objective:**
- to **understand and support** impact of cancer in the medium to long-term, in a diversity of settings

**Secondary objectives:**
- to **define and innovate** ways stakeholders support people facing a cancer diagnosis and their families.

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**Survey (English)**
73%
Wanted to speak with their health professional about their emotional health

**Survey (French)**

**Survey (Spanish)**
30%
Had any discussion on emotional well being
Levers in access to oncology medicines

Policy, including National Essential Medicines Lists (nEML) and treatment guidelines, reflect oncology medicines, including biosimilars.

Procurement, pricing and financing strategies are in place to ensure sustainable access.

Regulatory affairs are enabled, including pharmacovigilance, to ensure safe distribution and use of medicines.

- Normal levers along the value chain for access to medicines may not be well developed for oncology medicines if treatment options have been limited to private institutions.

- All of these areas will need to be assured. In some cases, regulators require support, which can be available from WHO Prequalification Programme for many situations.
Access to medicines: prequalification & regulatory pathway

- The regulatory environment can be complex, particularly for oncology medicines and especially in LMIC markets.

- To stabilize markets, it will be critical to ensure products have market authorization from National Medicines Regulatory Authority.

- If the products have been imported through informal means, or if they are being used “off label”, availability and quality are often unstable.

- In some cases, regulators require support, which can be available from WHO Prequalification of Medicines Programme for many situation.

PQ pilot for biosimilar oncology medicines ongoing

- Trastuzumab (breast cancer): 4 manufacturers
- Rituximab (non-Hodgkin’s lymphoma & leukemia): 3 manufacturers

PQ will expand to include additional oncology medicines

- Identification and prioritization for products included into the WHO Prequalification Programme is based on ongoing recommendations from technical department.
- Work is in progress

Support is available for the best regulatory pathway

- WHO Collaborative Registration Procedure is an option for products prequalified by WHO
- Other reliance mechanisms may be used, where available, for other products
Cervical cancer and HIV are intricately linked

Women and girls living with HIV have:
- Higher risk of getting HPV infection
- Lower chances of clearing the infection
- Faster progression from infection to cancer
- Lower regression of pre-cancer lesions
- Higher recurrence following treatment
- Younger age at presentation

Our goals are to:
- Better understand this relationship & prioritize resources
- Develop guidance relating to cervical cancer & HIV
- Support woman-centred program integration and expansion of coverage
Risk for cervical cancer among women living with HIV is 6x higher (RR = 6.07)

Population attributable fraction of women with cervical cancer living with HIV, 2018

Over 15 million women on ARVs provide an opportunity for screening and treatment.

Two Important WHO Guidelines

Screening and treatment to prevent cervical cancer
- Age of screening initiation
- Interval of cervical cancer screening
- Optimal algorithm for screening and treatment
  - Limited data for multiple test/treatment algorithms in WLHIV
  - Modeling of ~30 scenarios with differing screening tests and treatment options

Consolidated HIV Guidelines
- Clinical services
- Service delivery
  - Focus on people-centered care
  - Integration and linking services
  - Section on cervical cancer screening for women living with HIV
WHO suggests using either of the following strategies for cervical cancer prevention among the general population of women:

- HPV DNA detection in a screen-and-treat approach starting at the age of 30 years with regular screening every 5 to 10 years.
- HPV DNA detection in a screen, triage and treat approach starting at the age of 30 years with regular screening every 5 to 10 years.

WHO suggests using the following strategy for cervical cancer prevention among women living with HIV:

- HPV DNA detection in a screen, triage and treat approach starting at the age of 25 years with regular screening every 3 to 5 years.
Awareness of cervical cancer prevention

Low levels of knowledge on cervical cancer, its association with HPV and the ability to prevent it

High acceptability (70% or higher, several with 90%) across studies for self-sampling, VIA, HPV DNA tests or triage-based methods

Clear and strong preference for immediate treatment following a diagnosis of a cervical intraepithelial lesion among all women

Single-visit based approach and multi-visit approach feasible across multiple intervention types – self-sampling, HPV test, VIA, cryotherapy, LEEP and thermocoagulation
  ◦ An online survey found that women stated they were likely to have difficulties returning for follow-up

Clear request from the community for better counselling, patient education, availability of choices of treatment and screening tests
Policy & Program Implementation

Support ministries of health in adopting guidelines
- Increase country-level impact
- Improve awareness in communities

Bi-directional integration of HIV and cervical cancer services
- Improve service provision in settings with high HIV prevalence
- Facilitate referrals between programs
- Early identification of STIs

Further strengthen links with the community
- Advocate for better counselling, patient education, availability of treatment and screening tests
- Involve community of women in all aspects of programme development

Address knowledge gaps with implementation science
Agenda item 2:

Monitoring progress in cancer control

Current reporting on core indicators and data gaps

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<tr>
<td>12.05 – 12.10</td>
<td>Mandate to report on programme of work in cancer</td>
<td>Dr Bente Mikkelsen, Director, Noncommunicable Diseases Department/HQ</td>
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<td>12.10 – 12.15</td>
<td>IARC Global cancer observatory</td>
<td>Dr Freddie Bray, Head, Cancer Surveillance Branch</td>
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<tr>
<td>12.15 – 12.20</td>
<td>Reporting social and economic impact of cancer</td>
<td>Dr Tessa Edejer, Director (a.i.), Health Financing and Governance Department/HQ</td>
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<td>12.20 – 12.25</td>
<td>Using data to shape innovation in cancer control</td>
<td>Dr John Reeder, Director, Research for Health Department/HQ</td>
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World Health Organization
Reporting to WHA on progress in cancer control: current mandate

Monitoring framework

In development

“MS adopt strategy with associated goals and target”

Cancer indicators

(1) Cancer incidence
(2) Proportion screened for cervical cancer
(3) HPV vaccination availability
(4) Hep B vaccination coverage

Frequency & End Date

(1) Yearly Progress Monitor to WHA until 2031
(2) 2024 Progress report to UN SG, preparation for 4th HLM on NCDs

No cancer targets among 9 NCD voluntary targets

None requested

None

(1) Narrative reporting in line with WHA 66.12 (yearly)
(2) “Periodic” global report on cancer

(1) HPV vaccination coverage
(2) Proportion screened for cervical cancer
(3) Proportion with cervical disease receiving treatment

Two indicators related to GMF for NCDs
Core indicators for WHO Cancer initiative: data gaps

- **Cervical cancer incidence**
  - <4 per 100,000

- **Childhood cancer survival >60%**
  - (collected by 30-50 MS)
  - (1) Number of children completing treatment
  - (2) Inclusion of childhood cancer in benefit packages/policies
  - (3) Number of public childhood cancer centres

- **Annual ↓ breast cancer mortality (2.5%/yr)**
  - (1) Stage of diagnosis
    - (collected by 70-90 MS)
  - (2) Time to diagnosis
  - (3) Treatment completion rate
Noncommunicable disease facility-based monitoring guidance

Framework, indicators, and application

**Current guidance & capacity building in NCDs**

**1st phase:** Meta-data provided for 20 facility-based (primary care) indicators

**2nd phase:** Selection and finalization of facility-based data for cancer centres

**Implementation approach (sample):**
- Integration of indicators into DHIS-2
- Pilot testing planned; broad engagement of implementation partners
NCD Data Portal & visualization platform

- **1st phase**: NCD indicators routinely collected and reported to WHO including RF and disease burden

- **2nd phase**: data visualization platform to support adoption of “NCD best buys” and to demonstrate the value (impact and cost-effectiveness) of implementation
Sample implementation monitoring: draft approach from GICC

CureAll Country Projects

OVERVIEW:

Use this page to display visualizations of main collaborative country projects (to be completed by June 2024). All data shown was reported by country teams.

Projects Across Pillars

115 TOTAL PROJECTS

Projects Across Enablers

14 Countries Reporting

World Health Organization

Draft content with credit to Dr Catherine Lam, St Jude Children’s Research Hospital
Cancer Surveillance at WHO/IARC

- consolidate and expand IARC’s role as a global reference for cancer data
- ensure locally recorded data are of high quality available for cancer control and research
- conduct research that illustrates the transitional nature of cancer and the benefits of interventions
Cancer Surveillance Framework

Core Surveillance Measures
- Risk Factors
- Risk factor reduction
- Screening programme

Survival
- Incidence
  - By cancer type
  - By stage
- PBCRs

Mortality
- PBCRs
- Vital Statistics

Surveillance Strategy
- Population Surveys
- Vaccine registry
- Screening registry

Extended Surveillance Measures
- Attributable Risk
- Prevalence
- DALYs

Associated Economic Costs

Population
- Healthy
- New Diagnosis
- Living With Cancer
- Dying From Cancer

Cancer control continuum
- Prevention
- Early Detection
- Treatment Care
- Palliative End-of-Life Care
Global Initiative for Cancer Registration (GICR) – data for action

- A global partnership to improve the quality, availability and use of data from population-based cancer registries (PBCR) worldwide
- Six IARC Hubs created with support of 13 IARC-GICR Centres of Expertise

GICRNet
- ‘Train the trainer’ + model to form subject specific networks to deliver regional courses and provide support to registries
- Move towards greater responsibilities of regional trainers in courses and support
- Integration of learning materials to develop certification programme in-person; E-learning modules; and technical reports

Electronic medical health data linkages
- DIHCS – Health Information System v2 (DHIS2) cancer module to link data with CanReg5+
- Piloted in the Caribbean with the OBCA and the IARC Caribbean Hub (14 countries)
- CanReg5+, enhanced to take advantage of modern technology using insights gained from users and the CanReg5 GICRNet

GICR Partner Countries
- Identify and develop joint work plans to improve the registry in selected countries; clear opportunity with commitment from the country and agreement to monitor progress towards goals
- Up to an additional 30 Partner Countries in next five years
IARC global data launches 2023

Cancer Incidence in Five Continents

- Compendium of comparable data on cancer incidence in different subpopulations
- Reference source for studies exploring cancer variations
- Volume XII (2013-17) online end-June 2023

GLOBOCAN

- Incidence, mortality and prevalence estimates in 185 countries, 36 cancers, by sex and age
- Estimates derived from best available information in each country
- GLOBOCAN 2022 launched end-May 2023 on the Global Cancer Observatory (GCO)
How do we get robust national estimates of the cancer burden?

PBCR in the African Cancer Registry Network (AFCRN)

Methods of national incidence estimation, GLOBOCAN 2020

35 national or subnational population-based cancer registries (PBCR) in 25 countries

PBCR data used directly in 25 SSA countries to estimate national incidence

The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or of its authorities, or concerning the delimitation of its frontiers or boundaries. Stippled and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.
How do we get robust national estimates of cancer survival?

1- and 3-year survival differences by region and HDI, colon cancer

The social and economic impact of cancer: lack of prioritization

• In addition to being a leading cause of mortality and morbidity, cancer also negatively affects countries’ economies and impose a heavy economic burden to patients and families.

• The burden of cancer affects a country's economy because of premature mortality, absence from work and lost productivity.

• Cancer impacts patient and families due to out-of-pocket expenditures, in particular in settings with no or limited universal health coverage, but also due to psychological and subjective financial distress.
  • Worldwide, only 41% of national benefit packages include core childhood cancer services.
  • 50% of health benefit packages in low-income countries include screening, but only 20% cover treatment.
WHA mandate and response

• Development of a cancer priority setting and costing tool
• Use cases:
  • Support to Member States in costing the national cancer control plan
  • Development of investment cases (e.g. Mozambique, Kenya, Senegal, Palestine, Honduras, five in pipeline)
  • Update of appendix 3 of Global NCD Action Plan → 24% of all assessed interventions are related to cancer prevention and control.
  
  • A majority of these interventions represent very good value for money and should be a priority for inclusion in health benefit packages.
Gaps and priorities

- Ensure optimal use of resources by prioritizing cost-effective and affordable interventions to promote universal access to comprehensive cancer care.
  - There is a need to expand the evidence-base on cost-effectiveness of cancer control interventions and consider additional criteria such as equity.
- There is limited evidence on the macro–and microeconomic impact of cancer.
  - Several systematic reviews on the economic burden of cancer are ongoing to better understand the determinants of financial hardship experienced by patients and families.
  - There is a need to estimate the global economic cost of cancer and to make an investment case for cancer prevention and control.
    - Initial analysis has shown that for each US$1 invested in cancer care, the direct productivity return is US$2.30
  - We are currently updating EPIC, a tool to estimate the burden of ill-health, to better capture the economic impact of cancer (e.g. loss of employment to caregivers)
R&D processes at WHO

Outcomes: development of health products that address global health needs and accelerated implementation and uptake in countries
What is the Global Observatory on Health R&D?

- **Established through resolution WHA66.22** (2013) “to consolidate, monitor and analyze relevant information on health research and development activities” to identify gaps and opportunities in health R&D and coordinate actions.
- **Supports evidence-informed decisions related to R&D gaps, funding and capacity.**
- **Scope:** all health and health-related fields and all types of research
- **Target users:** Governments, policy-makers, funders, researchers.

A comprehensive source for up-to-date global information and analysis on health R&D, including resources, processes and outputs.

url: https://www.who.int/observatories/global-observatory-on-health-research-and-development
Analysis example – Research Investments

- Who is funding what and where?
- In Europe 8.37% of research funding spent on cancers,
- In Europe $USD 282 million spent on research for malaria, HIV and TB
**Analysis example – Research topics funded**

**Grants on NCDs:**
- 17 million USD to LMIC
- 19,673 million USD to USA

**Cancer:**
- In LMIC: < 1 million USD in on cancers (in only 6 cancer topics)

**Despite**

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**Source:** Centre for global health strategic plan 2021-2025
A concerted response across the product life-cycle

Prioritizing and Evaluating:
Developing a prioritized drug portfolio of the most needed formulations and assisting in the design and implementation of efficient, and high-quality clinical trials.

Developing:
Establishing and maintaining relationships to launch effective products and supporting regulatory submission activities to facilitate paediatric medicine approvals.

Delivering:
Supporting efforts to introduce new, adapted formulations in an equitable, accelerated, safe and coordinated manner.

Accelerating priority paediatric drug formulation development and uptake
**Agenda item 3:**

Methodology for stock-take and setting strategic direction

Review of proposed approach, sharing of best practices

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<tr>
<td>12.25 – 12.35</td>
<td>Current and planned reports, in response to Member State mandates</td>
<td>Dr Bente Mikkelsen, Director, Noncommunicable Diseases Department/HQ</td>
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<td></td>
<td>Performing stock-take to inform strategic priorities in WHO’s programme of work for cancer</td>
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<td>Childhood cancer as a tracer in NCD agenda to inform and contribution to current mandates (e.g., clinical trials, access to medicines, social determinants)</td>
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Next steps: stock-take methodology

Objectives:

(1) Present current best practices and gaps/inequalities in cancer control

(2) Gather and present MS with models and tools to improve outcomes through an integrated approach

(3) Promote incorporation of key indicators for WHO cancer initiatives into routine national NCD reporting

Anticipated Outputs:

(1) Stock takes for WHO cancer initiatives presented to EB 154 (2024) in annual NCD report (cervical ca, May 2023; childhood ca Q3 2023; breast ca Q3 2024)

(2) WHO global status report (in line with WHA 70.12) to be presented to EB 156 (2025)

(3) Communication events (eg, WHA side events)

(4) Updated mandate / programme of work for 2024-2025
Cancer & broader health agenda: *Example of childhood cancer*

Mapping current strategies and gaps in cancer.

**Objectives**

1) Demonstrate how progress in and implementation of WHO Global Initiative for Childhood Cancer *tracer for NCDs & strengthen health systems through an integrated approach*

2) Track progress, drive innovation

3) Leverage recent commitments *(eg, Global Platform for Access to Childhood Cancer Medicines to ↑programmatic investments)*
**Stakeholder engagement: partners for stock-take/mapping**

<table>
<thead>
<tr>
<th>Stakeholder Group</th>
<th>Responsibilities</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>WHO, IARC</strong></td>
<td>Responsible for full process of mapping to dissemination and implementation of recommendations</td>
</tr>
<tr>
<td><strong>UN agencies</strong></td>
<td>Close collaboration throughout process including data inputs, review and communication</td>
</tr>
<tr>
<td><strong>Affected communities</strong></td>
<td>Consultation on priority indicators, summaries of best practices and presentation of results</td>
</tr>
<tr>
<td><strong>Civil society</strong></td>
<td>Inputs on priority indicators, participation in communities of practice, dissemination of findings</td>
</tr>
<tr>
<td><strong>Private sector</strong></td>
<td>Dialogue as advised in WHA 70.12 (2017) and in line with FENSA</td>
</tr>
<tr>
<td><strong>Professional society &amp; academia</strong></td>
<td>Including participation of WHO Collaborating Centres including data collection and dissemination of results</td>
</tr>
<tr>
<td><strong>Philanthropic foundations</strong></td>
<td>Participation in development of investment cases / business plans</td>
</tr>
</tbody>
</table>
Horizon: Strategic opportunities in cancer

Advocacy & leadership

- Anticipate multiple side events during World Health Assembly 2023 to further elevate cancer agenda

- UN High-Level Meeting on UHC including event(s) on childhood cancer (Q3/4 2023): launch of Global Platform and stock-take of GICC

- Global partners forum (Nov 2023) with multi-sector engagement (provisionally 16-17 Nov), and Civil Society Dialogue

Capacity building & communities of practice

- WHO expanding Knowledge Action Portal for cancer control as community of practice to gather best practices & accelerate implementation

- Number of countries engaging in WHO cancer initiatives continue to increase, likely to reach 100 countries by 2024

- Additional MoUs, partner engagement strategy: WHO working with UN agencies and >300 implementing partners for coordinated support

Expanding mandate

- Dialogue on strategic priorities for 2024-2025 Programme of work ongoing with MS through three-level WHO approach

- Align cancer mandate with relevant resolutions including on research & innovation (clinical trial), access to medicines, quality of care, workforce optimization
Next steps & conclusion

• Methodology on stock-taking/mapping
  • Initiate consultative process in Q2/3 2023
  • Stock-take (narrative) – cervical cancer in May 2023; childhood cancer in Q3 2023
  • Progress toward global status report in 2024

• Communicate data gaps & priority targets
  • Increase and standardized reporting frequency
  • Expand reporting to include socioeconomic impact of cancer & horizon scanning

• Accelerate integration of cancer with other programmes, leveraging cervical cancer as entry point

Thank you for your commitment to cancer control
Questions ?
Moderated discussion
Wrap-up & Closing
Thank you

Further information on cancer is available at: https://www.who.int/health-topics/cancer.

Should you require additional information please do not hesitate to contact
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Dr André Ilbawi, Technical lead, cancer control, Department of NCDs (ilbawia@who.int).
Annex

Additional slides
Current status of NRAs based on WHO GBT Performance Maturity Levels

1. **No formal approach**
   - Some elements of regulatory system exist
   - Evolving national regulatory system that partially performs essential regulatory functions
   - Can ensure the quality of products if rely on ML 3/ML 4 regulatory systems
   - 98 Countries
   - 70% of countries

2. **Reactive approach**
   - Stable, well-functioning and integrated regulatory system
   - Target of WHA Resolution 67.20
   - 38 Countries
   - 30% of countries

3. **Stable formal system approach**
   - Regulatory system operating at advanced level of performance and continuous improvement
   - Advanced and well resourced regulatory systems
   - 58 Countries
   - 58% of countries

4. **Continual improvement emphasized**
   - 40% of countries
What is WHO Prequalification?

• WHO prequalification aims to ensure access to key health products that meet global standards of quality, safety and efficacy/performance, in order to optimize use of health resources and improve health outcomes.

• Today, there are almost 1,500 WHO prequalified products — in vitro diagnostics (IVDs), male circumcision devices, medicines, vaccines, immunization devices and cold chain equipment, and vector control products — that have assisted in improving public health in low- and middle-income countries (LMIC).

• WHO prequalification has become a trusted and reputed symbol for safety, quality and efficacy across stakeholders.
Cancer medicines in PQ

- EoIs are disease area-focused (except for trastuzumab/rituximab and insulin which are product-focused)

- There has never been an EoI in PQ focusing on cancer as a therapeutic area.

- Up to Nov 2010 certain medicines against cancers associated with HIV/AIDS were invited in the HIV/AIDS EoI (etoposide, bleomycin, vincristine, vinblastine) but these medicines were subsequently dropped from the EoI. Two products (vincristine and vinblastine) were prequalified in 2002 but were later withdrawn by the company. Palliative therapies continued to be invited for a while, but not any longer.
The prequalification of rituximab and trastuzumab
Background to pilot

BTP/SBPs quality, safety and efficacy, product handling and post-prequalification requirements differ greatly compared to small molecules. Trastuzumab and rituximab were selected as model biotherapeutics in the pilot for the below reasons.

- Disease prevalence, evidence of efficacy and safety, and comparative cost-effectiveness
- One of the first monoclonal antibody therapies listed in the WHO Model List of Essential Medicines
- Existence of established WHO technical guidance for evaluation of biotherapeutic protein products prepared by recombinant DNA technology and on evaluation of MAbs
- Some SRAs have extensive experience in evaluating these molecules.

Pilot for PQ of rituximab & trastuzumab and their corresponding SBPs: EOI published on 5 July 2018 (first dossier received on 24 Oct 2018)
Access to medicines: prequalification & registration (provisional)

After identification of supplier and product: In-country Registration of the product

- All pharmaceutical products should be used in a country only after approval by the national or regional authority. *(WHA Resolutions: WHA 67.20 (2014); WHA 67.21 (2014); WHA63.12 (2010))*

1. Tender process
2. Identification of supplier and product
3. Registration of the product in the country by the NRA (National Regulatory Authority)

- Depending on the nature of product and supplier, the National Regulatory authority (NRA) of each country may follow one of the following regulatory pathways to accept the introduction of the product in the country:

1. **One-time waiver or only Import Permit for the first allocations**, particularly if those are small allocations: Country to decide on the acceptability of this pathway, NRA to inform on the requirements for the supplier to meet and to issue the regulatory clearance - No product registration, regulatory clearance only

2. **Collaborative Registration Procedure (CRP)** - for full registration/approval or marketing authorization of the product: WHO supports the NRA to get access to the relevant product data to accelerate the assessment and registration of a product (within 90 working days)
   - SRA CRP: products approved by SRAs
   - PQ CRP: products prequalified by WHO

3. **Mix of the 2 above - Import waiver + CRP (in parallel)**: NRA and WHO

4. **National registration pathway**: Accelerated or standard registration pathway following NRA timelines (sometimes above 50 days for product assessment and registration): NRA only
Access to medicines: prequalification & registration (provisional)

CRP Process (PQ CRP or SRA CRP)

1. Source of Information to rely upon:
   - WHO PQ
   - Reference Authorities (SRAs)

2. Documentation to be shared:
   - Full Product Dossier (ICH CTD format)
   - Detailed Assessment reports (scientific evaluations and inspections reports)
   - QIS validated by SRA or WHO

3. Actions for different stakeholders
   - Applicant
     - Submission
   - NRA
     - NRA Review: Recognition or Reliance - 90 working days (regulatory time)
   - Approval / Rejection
     - Variations
     - NRA Review: Recognition or Reliance - 30 working days (regulatory time)

World Health Organization
PQ has been proven as an effective mechanism for facilitating access to quality assure health products

Key findings of the independent external impact assessment:

- WHO Prequalification (PQ) programme enables a core market of approximately US$3.5 billion with the majority coming from vaccines
- WHO PQ has a Return on Investment of 30-40 to 1 for the PQ-enabled donor-funded market (US$ million)
- Most donors and procurers and implementing partners view PQ approval as equivalent to approvals by stringent regulatory authorities
- 340-400 million more patients have access thanks to resources freed up by PQ
- National regulatory authorities (NRAs) relying on Collaborative Registration Procedure (CRP) have achieved significant acceleration of approval timelines vs pre-CRP registrations
WHO Listed Authorities
A new concept introduced to replace SRAs

Following ICH structural changes in 2015, need for replacing the term Stringent Regulatory Authority (SRA) and eligibility criteria based on the pre-reform membership to ICH

ICDRA 2016 & 2018 Recommendations regarding SRAs

Recommendations from 51st ECSPP in 2017 and 61st ECBS in 2018

Feedback from international consultations and virtual meetings on developing the GBT

WLA

Authorities listed by WHO following a consistent, documented, transparent and accountable assessment
WHO Listed Authorities

...and to promote reliance

- Listing can be achieved by ML3 and ML4 NRA/RRS and implies ADVANCED PERFORMANCE
  - i.e., consistent adherence to international standards and guidelines, as well as good regulatory practices, by ensuring the attainment of key regulatory outputs over time
Definition of a WHO Listed Authority
Adopted by the ECSPP in October 2020, TRS 1033

A WHO Listed Authority (WLA) is a regulatory authority or a regional regulatory system which has been documented to comply with all the relevant indicators and requirements specified by WHO for the requested scope of listing based on an established benchmarking (GBT) AND a Performance Evaluation process.

[Diagram showing GBT, PE, and WLA connected with arrows labeled ML and delinked from ML]
Objectives of WLA initiative

01 To provide a transparent and evidence-based pathway for RAs to be globally recognized

02 To promote access and the supply of safe, effective and quality medical products

03 To optimize use of limited resources by facilitating reliance

Policy document:
Describes the purpose, definitions and high-level operating principles related to the evaluation and public listing of authorities

Link: https://www.who.int/publications/i/item/9789240023444