Priority technologies for Pathology

Adriana Velazquez
Senior Adviser Medical Devices
Essential Medicines and Health Products Department
World Health Organization
WHO leadership priorities

Universal health coverage
Increasing access to medical products
Social, economic and environmental determinants
Non-communicable diseases
Health-related Millennium Development Goals
The International Health Regulations (2005)
SDG3: Achieve universal health coverage, including financial risk protection, access to quality essential health-care services
Challenges on health technologies for Universal Health Coverage

- Quality and available health services:
  - Promotion, prevention
  - Treatment, rehabilitation
  - Palliative care

- Without financial hardship

- Principles:
  - Equity,
  - Accountability
  - Integrated health services
  - People oriented care

- Good clinical practice
- Safe quality interventions
- Medical devices
  - Early Diagnostics (IVD, imaging)
  - Effective Treatment technologies (surgical, non-surgical)
  - Affordable interventions
- Safe use of medicines
Challenge: Low and Middle Income Countries

- Difficult to select, procure and use medical devices
- 55 countries *do not have* regulatory authority for medical devices
- 97 countries *do not have* a list of medical devices for public procurement or reimbursement
- Continuous request, “Does WHO has a list of Essential Medical Devices”? 
- Where can I find it?

- The need to target cancer is enormous but there is lack of appropriate infrastructure, specialized human resources.
- The need to define medical devices priorities based in a reference guidance from WHO.
10,000 Types of medical devices what to chose for cancer management?

- Diagnostic imaging
- Laboratory and pathology equipment
- Implantable medical devices
- Medical equipment for patient
- Personal protective equipment and clothing
- Quality assurance
- Radiation protection
- Solutions and reagents
- Surgical instruments
- Single use devices (IV)

500,000 different products commercially available
Rational allocation of resources is a big challenge, depending on setting, infrastructure and human resources available.

1. Health Post
2. Health centers
3. District Hospitals
4. Provincial/Regional Hospitals
5. Teaching or tertiary level or National specialized Hospital
9 Global NCD targets to be attained by 2025 (against a 2010 baseline)

- **A 25% relative reduction in risk of premature mortality from cardiovascular disease, cancer, diabetes or chronic respiratory diseases**
- **A 30% relative reduction in prevalence of current tobacco use**
- **Halt the rise in diabetes and obesity**
- **At least a 10% relative reduction in the harmful use of alcohol**
- **A 30% relative reduction in mean population intake of salt/sodium**
- **A 25% relative reduction in prevalence of raised blood pressure or contain the prevalence of raised blood pressure**
- **An 80% availability of the affordable basic technologies and essential medicines, incl. generics, required to treat NCDs**
- **A 30% relative reduction in prevalence of insufficient physical activity**
- **At least 50% of eligible people receive drug therapy and counselling to prevent heart attacks and strokes**

9 Global NCD targets to be attained by 2025 (against a 2010 baseline)
Percentage of countries with generally available cancer diagnosis and treatment services in the public sector, by WHO region and World Bank income group.

- **Cancer centres or cancer departments at a tertiary level**
- **Pathology services (laboratories)**
- **Cancer surgery**
- **Subsidized chemotherapy**
Defining, Guidelines, Interventions, and medical devices by levels of care
Work on priority medical devices 2014-2016
Methodology to select medical devices,
(Cancer 2015)
Considering international guidelines

<table>
<thead>
<tr>
<th>Leukemia</th>
<th>Lung Cancer</th>
<th>Prostate Cancer</th>
</tr>
</thead>
<tbody>
<tr>
<td>National Institute for Clinical Excellence</td>
<td>2011</td>
<td>Lung cancer. NICE clinical guideline 121. 2013</td>
</tr>
<tr>
<td>National Institute for Clinical Excellence</td>
<td>2014</td>
<td>Prostate cancer. NICE clinical guideline 175. 2014</td>
</tr>
</tbody>
</table>
Cancers considered in this project

- Breast
- Cervical
- Colorectal
- Leukemia
- Lung
- Prostate
- All cancers
Priority medical devices through the continuum of care

- Prevention
  - Vaccination
- Screening
  - Clinical assessment
- Diagnosis
  - Clinical laboratory
  - Medical imaging
  - Endoscopy
- Treatment
  - Surgery
  - Palliative care
- Palliative care

Level of Care:

Secondary & tertiary

Pathology

Primary, secondary & tertiary

Nuclear medicine

Radiotherapy
4.1 General description of the unit
4.2 Priority medical devices for clinical laboratory
   4.2.1 General medical devices for clinical laboratory
   4.2.2 Specific medical devices for clinical laboratory by cancer type
4.3 Priority medical devices for pathology
   4.3.1 General medical devices for pathology
   4.3.2 General medical devices for histopathology
   4.3.3 General medical devices for cytology
   4.3.4 General medical devices for immunohistochemistry
4.4 Other health system components
   4.4.1 Human resources and training
   4.4.2 Infrastructure
   4.4.3 Quality management
   4.4.4 Guidance documents
### 4.3.4 General medical devices for immunohistochemistry

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Device category</th>
<th>Medical devices (for specialized hospitals)</th>
<th>Accessories/hardware/software/consumables</th>
</tr>
</thead>
<tbody>
<tr>
<td>IHC staining</td>
<td>Laboratory and Pathology Equipment</td>
<td>Gravity-convection laboratory oven, Refrigerator, laboratory, Microscope, binocular, Mechanical balance, Precision electronic balance, Timer, 60 min, mechanical, Timer, digital, Oven (37°C), Immunohistochemistry (IHC)/In situ hybridization (ISH) staining platform, semi-automated, Humid chamber</td>
<td>Adequate space should be planned for cabinetry to store treatment devices, immobilization devices, blocks and daily used quality assurance equipment</td>
</tr>
<tr>
<td>Furniture</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Instruments</td>
<td></td>
<td>Forceps</td>
<td></td>
</tr>
<tr>
<td>Solutions and reagents</td>
<td></td>
<td>Distilled water, Haematoxylin, Acetic acid, Methanol, Mounting medium, Xylene, Antibodies diluent</td>
<td></td>
</tr>
</tbody>
</table>
4.4 Other health system components

### 4.4.1 Human resources and training

The personnel required depends on the anticipated volume of material to be handled by the laboratory. Individuals required are:

<table>
<thead>
<tr>
<th>Professional</th>
<th>Role</th>
<th>If not available</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biomedical Laboratory Scientist</td>
<td>• Tissue handling/transportation, tissue assessment, sectioning and staining, analysis of tissue sections</td>
<td>Laboratory Technician</td>
</tr>
<tr>
<td>Pathologist/Cytopathologist</td>
<td>• Gross and microscopic analysis of tissue and cytologic specimens with diagnosis</td>
<td>Trained Physician</td>
</tr>
<tr>
<td>Cytotechnologist</td>
<td>• Review Pap smears and non-gynaecologic cytology preparations</td>
<td></td>
</tr>
<tr>
<td>Biomedical Engineer</td>
<td>• Management of medical devices</td>
<td>Biomedical Technician</td>
</tr>
</tbody>
</table>
| Laboratory Manager             | • Ensure Quality of all Procedures, that all SOP are followed, and that all staff maintain professional standards and certification.  
                                 | • Plan job descriptions and hire an appropriate number of staff to cover workload.  
                                 | • Verify that items on the job application are correct.  
                                 | • Train each employee in his or her specific duties.  
                                 | • Provide orientation for new employees.  
                                 | • Conduct and record ongoing competency assessments on all personnel.          |                        |
| Quality Manager                | • Ensure that relevant Standard Operating Procedures (SOPs) are provided, updated and followed.  
                                 | • Ensure that sufficient internal and external quality control procedures are in place and followed.  
                                 | • Provide employees with orientation and training.  
                                 | • Keep track of employee records and make sure they are confidential.  
                                 | • Include policies relevant to personnel in the quality manual.              |                        |
### 4.4.4 Guidance documents

<table>
<thead>
<tr>
<th>Title</th>
<th>Link</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laboratory Quality Management System</td>
<td><a href="https://globalhealthlabatories.tghn.org/site_media/media/articles/WHO_Laboratory_quality_management_system_1.pdf">https://globalhealthlabatories.tghn.org/site_media/media/articles/WHO_Laboratory_quality_management_system_1.pdf</a></td>
<td>Achieving, maintaining and improving accuracy, timeliness and reliability are major challenges for health laboratories. This handbook is intended to provide a comprehensive reference on Laboratory Quality Management Systems for all stakeholders in health laboratory processes, from management, to administration, to biomedical laboratory scientists. This handbook covers topics that are essential for quality management of a public health or clinical laboratory. They are based on both ISO 15189 and CLSI GP26-A3 documents.</td>
</tr>
<tr>
<td>Laboratory Assessment Tool</td>
<td><a href="https://globalhealthlabatories.tghn.org/site_media/media/articles/WHO_Laboratory_Assessment_Tool_1.pdf">https://globalhealthlabatories.tghn.org/site_media/media/articles/WHO_Laboratory_Assessment_Tool_1.pdf</a></td>
<td>This document offers guidance to assess individual laboratories and the national laboratory system. It describes a general process for assessing laboratories and provides questionnaires to help assess laboratories. The document and its questionnaires can be used as is or after an adaptation to meet local requirements or specificities to better fit the assessment context. The intended audience of the document is any stakeholder performing laboratory assessments, including: national health authorities, multilateral agencies, non-governmental organizations (NGOs), laboratory managers, etc.</td>
</tr>
<tr>
<td>The Pathology Request-Test-Report Cycle - Guidelines for Requesters and Pathology Providers</td>
<td><a href="https://www.rcpa.edu.au/getattachment/cb14bc34-0a0f-4c09-853c-614e09c84b56/Pathology-Request-Test-Report-Cycle-Guidelines.aspx">https://www.rcpa.edu.au/getattachment/cb14bc34-0a0f-4c09-853c-614e09c84b56/Pathology-Request-Test-Report-Cycle-Guidelines.aspx</a></td>
<td>These guidelines have been developed for use by medical practitioners when requesting pathology tests and by Pathology Providers operating in both public and private practice.</td>
</tr>
<tr>
<td>Quality Systems for Medical Laboratories. Guidelines for</td>
<td><a href="http://applications.emro.who.int/dsaf/rka33.pdf">http://applications.emro.who.int/dsaf/rka33.pdf</a></td>
<td>The document provides guidance for laboratories to introduce, maintain and improve appropriately specified levels of service quality and to provide a basis for assuring an adequate quality of</td>
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Pathology... beyond the medical devices:

• Communication to patient and medical doctors
• Link in the cancer diagnostic and treatment process
• Consider innovative technologies like tele-pathology
• Even the smallest medical device is important, to support patient care and avoid delays
• Due to enormous gap, WHO is working with NGOs: WASPaLM, IFCC, IFBLS and institutions: NCI, CC, to support pathology guidance, capacity building and increased availability in all Member States.
Innovation, regulations, Health technology Assessment, Health technology management and lists of priority medical devices.
Conclusions

• WHO requires methodology and working tools to be used by experts and MoH, to select and prioritize medical devices.
• Cancer and other NCDs require many clinical areas and thus includes many technologies, which becomes complicated.
• Important to consider each and the link among them:
  – The “big ticket” technologies
  – As well as minor instruments or accessories or consumables or
  – Specialized human resources
  – Infrastructure
  – Required to avoid delay in diagnosis or treatment
• So still challenges ahead but first steps have been given.... Lets continue!
• Provide better health care for all, specially today to cancer patients!
Thank you to all that have made this project possible...

- **150 global experts in:**
  - Laboratory and Pathology
  - Medical Devices
  - Medical Imaging
  - Palliative Care
  - Radiotherapy
  - Systemic Therapy
  - Surgery
- **Academic Institutions**
- **Ministries of Health**
- **Professional Associations & Non-Governmental Organizations**
  - AORTIC, ASCO, BHGI, DITTA, ESMO, EUROSCAN, GMTA,
  - GIEESC, HUMATEM, IAPO, IFCC, IFBLS, IFMBE, IOMP,
  - ISRRT, NCCN, SLACOM, UICC, WASPaLM, WFUMB.
- **UN Agencies:** IAEA, UNOPS

www.who.int/medical
velazquezberumena@who.int
Medical_devices@who.int