The WHO Model List of Essential In Vitro Diagnostics (EDL) and other Priority medical devices Lists

Medicines and Health Products Division
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December, 2019
Health technologies are required to achieve the 13th WHO Global Programme of Work: “Triple Billion” targets
Health technologies include Medical devices, which include in vitro diagnostics

Medical devices are used all along the health life cycle.

Medical devices

Vaccines

IVDs

MD

Medicines
To support the registration, selection and supply, WHO has developed guidance:
To ensure improved access of safe, quality medical devices

R&D
- Industry and Academics: Research and development should be based on needs

Assessment
- Health Technology Assessment
  - Lists of MD for reimbursement or procurement

Regulations
- Regulation process of medical devices
  - Lists of approved MD for marketing in country.

Management
- 1. Needs Assessment, 2 (procurement, donations, loan…)
- Installation, inventories, training, maintenance, operations
- Safe use, operating costs and clinical effectiveness
- Post market surveillance and adverse event report
- Decommissioning, Replacement

Common elements in dossier
WHO Medical Devices Technical Series

Needs assessment

Selection  Priority lists…

Donations

Procurement

Supply and access:
  • Installation, training
  Maintenance, Use
  Decommissioning.
Priority Medical Devices (PMD) and essential in vitro diagnostics (EDL)

2015, 2017, 2018, 2019 .....
Priority Medical Devices and Essential in vitro aim to inform national lists for procurement / reimbursement

Fig. 3.6-1: Available national standards or recommended lists of medical devices for public procurement or reimbursement.

Sustainable development goal 3: good health and well being

Health Technologies are required to achieve SDG3:
universal health coverage,
including financial risk protection,
access to quality essential health-care services.
Essential in vitro Diagnostic List

Strategic Advisory Group of Experts (SAGE IVD) oversight:

- 18 members annual or biannual membership.
- Scope, prioritisation, inclusion criteria, process

Annual Review: Add tests for disease priorities

First EDL 2018:

- 62 tests: (no brand names nor specific products)
- TB, Malaria, HIV, hepatitis B & C, HPV & Syphilis
- General laboratory tests

Source: Image from iStock.com
# Example of an EDL entry

## Disease specific In Vitro Diagnostic Tests

<table>
<thead>
<tr>
<th>I.b Disease-specific IVDs for primary health care</th>
<th>Diagnostic test</th>
<th>Test purpose</th>
<th>Assay format</th>
<th>Specimen type</th>
<th>WHO prequalified or recommended products</th>
<th>WHO supporting documents</th>
</tr>
</thead>
</table>
### Process for review of applications for inclusion in the 2nd EDL

#### Changes to an existing EDL
- Changes submitted
- Proposed list of changes
- Review by SAGE IVD and EDL secretariat
- Proposed list published on WHO website
- SAGE IVD recommend inclusions & exclusions to WHO
- SAGE IVD recommendations presented to WHO DG

#### Full submission process
- Application screened by EDL Secretariat
  - Full submission requested
- Submission assessed by experts selected by WHO
- Expert reviews and comments published on WHO website
- Assessment reports presented at SAGE IVD meeting
- SAGE IVD recommend inclusions & exclusions to WHO
- SAGE IVD recommendations presented to WHO DG

#### General and anatomical pathology IVDs
- Available WHO guidance, recommendations by SAGE members, research commissioned by WHO
- Proposed list of general laboratory tests
- Review by SAGE IVD working group on General Lab tests and EDL secretariat
- Proposed list published on WHO website
- SAGE IVD recommend inclusions & exclusions to WHO
- SAGE IVD recommendations presented to WHO DG

#### Therapeutic drug monitoring tests
- Review of evidence commissioned by EDL and EML Secretariats
- Report and proposed list of tests and suggested prioritization
- Review by independent external group, SAGE IVD and EDL / EML Sec.
- Proposed report and list published on WHO website
- SAGE IVD recommend inclusions & exclusions to WHO
- SAGE IVD recommendations presented to WHO DG
## Full submissions – information requested

<table>
<thead>
<tr>
<th>Information requested</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identification of the applicant</td>
<td>Name, organization, professional societies</td>
</tr>
<tr>
<td>Disease burden</td>
<td>Prevalence, QALYs, economic impact of the disease addressed</td>
</tr>
<tr>
<td>Public health impact</td>
<td>The impact of introducing the diagnostic test – more cases diagnosed, early detection, early treatment</td>
</tr>
<tr>
<td>Clinical utility of the test</td>
<td>The place of the IVD in diagnostic algorithms</td>
</tr>
<tr>
<td>Evidence related to test accuracy</td>
<td>Primary studies, trials, systematic reviews, meta-analyses etc on test function and utility</td>
</tr>
<tr>
<td>Guidelines</td>
<td>WHO recommendations on use of the test</td>
</tr>
<tr>
<td>Commercial IVD kits and prices</td>
<td>To link with procurement – approved or prequalified IVDs</td>
</tr>
<tr>
<td>Infrastructure requirements</td>
<td>Point-of-use, laboratory containment, equipment requirement, HR training required, electricity etc</td>
</tr>
<tr>
<td>Equity and human right issues</td>
<td>Impact to reduce inequity and increase accessibility</td>
</tr>
</tbody>
</table>
Assessment elements for inclusion in the 2nd EDL

Basic test characteristics

- Test purpose
- Test format
- Specimen types
- Equipment required
- Regulatory status
- Global availability
- Price per test range
- Instrument price range

Ethics, equity and human rights issues

Evidence for clinical usefulness and impact

Evidence for economic impact and/or cost-effectiveness
Disease/disciplines or health conditions Contents of 2nd EDL

Section Ia & II.a
General IVDs

Section I.b, II.b & II.c
Disease Specific IVDs

Organized by Disease:
- HBV, HCV, HIV, TB, Malaria, HPV
- Cancer (12)
- Syphilis, CT/NG
- Cholera
- Dengue, Schisto, VL
- Zika
- Influenza
- Histoplasmosis
- Blood screening section
I. Community and health settings without laboratories, with two sections:
   a. General IVDs for community and health settings without laboratories
   b. Disease-specific IVDs for community and health settings without laboratories

II. Health care facilities with clinical laboratories, with three sections:
   a. General IVDs for clinical laboratories
   b. Disease-specific IVDs for clinical laboratories
   c. Disease-specific IVDs for blood screening laboratories

Total number of test categories: 122
   46 general IVD tests
   69 IVDs intended for the detection, diagnosis and monitoring of specific diseases.
   7 test categories intended for screening of blood donations
Global Implementation: From EDL to access of IVDs

**WHO HQ**
- Call for new tests to be added general and disease specific
- Review by WHO Public consultation
- Recommendations by SAGE IVD
- Publication of a list including test type, test purpose and link to WHO guidance

**Country and health facilities**
- WHO EDL
- Local needs: epidemiology, resources, committee
- Prioritized national list

**Final users**
- National reference lab
- 2nd and 3rd level
- Primary care (self testing)
IVD and Laboratory website, to integrate all work done by WHO


<table>
<thead>
<tr>
<th>Policies and strategic plans</th>
<th>Laboratory management</th>
<th>IVDs in primary care</th>
</tr>
</thead>
<tbody>
<tr>
<td>WHO/EURO</td>
<td>IARC</td>
<td>WHO/DR Andy Crapps</td>
</tr>
<tr>
<td>Providing adequate laboratory services to support basic healthcare requires the implementation of a national strategy for the development of appropriate laboratory infrastructure.</td>
<td>Diagnostics services in a given country depend on an integrated, connected, tiered laboratory system with laboratories of varying technical sophistication at different levels of the healthcare delivery system.</td>
<td>A broad set of IVDs is available for testing patients in the primary care setting where laboratories are not available.</td>
</tr>
<tr>
<td>WHO has resources available to assist with the development of national health lab policies, as well as strategies for strengthening lab capacity.</td>
<td>WHO documents are available offering guidance on lab set up as well as testing methods for a wide range of diseases.</td>
<td>Evaluations of the use of various Rapid Diagnostic Tests are available from WHO</td>
</tr>
<tr>
<td><strong>General laboratory policy</strong></td>
<td><strong>Laboratory test selection and method manuals</strong></td>
<td><strong>Regional laboratory policy and strategy</strong></td>
</tr>
<tr>
<td>- Technical consultation on the development of national health laboratory policies: meeting report</td>
<td>- A guide to aid selection of diagnostic tests</td>
<td>- Regional laboratory policy and strategy</td>
</tr>
<tr>
<td>- Development of medical device policies</td>
<td>- Manual of basic techniques for a health laboratory</td>
<td>- Regional laboratory policy and strategy</td>
</tr>
<tr>
<td><strong>Disease-specific laboratory policy and strategy</strong></td>
<td><strong>Basic laboratory procedures in clinical bacteriology</strong></td>
<td></td>
</tr>
<tr>
<td>- Framework of indicators and targets for laboratory strengthening under the End TB Strategy</td>
<td></td>
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<tr>
<td>- Implementing tuberculosis diagnostics policy framework</td>
<td></td>
<td></td>
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<tr>
<td>- Role of Laboratory Detection of Human Papilloma Virus</td>
<td></td>
<td></td>
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<tr>
<td>- Protecting health through global epidemic control</td>
<td></td>
<td></td>
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<tr>
<td><strong>Laboratory biosafety guidelines and support</strong></td>
<td></td>
<td></td>
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<tr>
<td>- Documents relevant to laboratory biosafety guidelines</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Disease-specific testing resources</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ebola</td>
<td>HIV</td>
<td>HPV</td>
</tr>
<tr>
<td>Meningitis</td>
<td>MERS</td>
<td>Polio</td>
</tr>
</tbody>
</table>
2019-2020 Current projects in development to support EDL up-take:

1. e EDL
2. WHO Nomenclature of IVDs
3. Country implementation guidance
4. Laboratory manual update
5. Support regulatory agencies
6. Develop tech specifications for procurement
WHO working on an international nomenclature of medical devices including IVDs for use by regulators, procurers, supply and use.

Source: WHO global atlas of medical devices


https://icd.who.int/browse11/l-m/en
WHO working on an international nomenclature of medical devices including IVDs for use by regulators, procurers, supply and use.

Discussion on Nomenclature of Medical Devices
145th session of the Executive Board

Developing and adapting a global standard for naming medical devices is a perfect example of WHO's core normative standard-setting work

Tedros Adhanom Ghebreyesus
Guide & Technical specifications for different Devices

Blood pressure measurement
Radiotherapy equipment
Oxygen delivery systems
Devices for screening and treatment of precancerous lesions

2019
Interagency technical guidance to support access to good quality products

WHO-UNICEF TECHNICAL SPECIFICATIONS AND GUIDANCE FOR OXYGEN THERAPY DEVICES

WHO MEDICAL DEVICE TECHNICAL SERIES

Table 4.1 Description and comparison of oxygen sources

<table>
<thead>
<tr>
<th>Type of Oxygen Source</th>
<th>Uncompressed Oxygen</th>
<th>Compressed Oxygen (BO)</th>
<th>Oxygen Plant (OP)</th>
<th>Liquid Oxygen (LO)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Description</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Flow Control</strong></td>
<td>Volumetric flow meters, flowmeters and pressure gauges.</td>
<td>Volumetric flow meters, flowmeters and pressure gauges.</td>
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<td><strong>Flow Monitor</strong></td>
<td>Volumetric flow meters, flowmeters and pressure gauges.</td>
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<td><strong>Flow Indicator</strong></td>
<td>Volumetric flow meters, flowmeters and pressure gauges.</td>
<td>Volumetric flow meters, flowmeters and pressure gauges.</td>
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<td><strong>Flow Rate Control</strong></td>
<td>Volumetric flow meters, flowmeters and pressure gauges.</td>
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Box 4.2 Cost of oxygen supplies

- Initial capital costs and operating costs vary greatly and cannot be easily compared between oxygen sources.
- The total cost of oxygen supplies and equipment includes purchasing oxygen delivery systems, and operating costs.
- Operating costs can be minimized.
- The capital costs of oxygen supplies and equipment vary with available options.
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Figure 4.1: Oxygen flow meter with different pressure regulators and safety features. (a) Main features: (b) Safety features (c) Main features: (d) Safety features.

Box 4.3 Considerations for oxygen delivery systems

- For emergency services, respiratory with premixed oxygen, large (≤250 m³/h) or small (≤250 m³/h) pumps.
- The flow of oxygen supplies and equipment must be correctly set and monitored.
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Box 4.4 Total cost of oxygen supplies

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https://apps.who.int/iris/bitstream/handle/10665/329874/9789241516914-eng.pdf?ua=1
Develop Technical specifications for better procurement of EDL

<table>
<thead>
<tr>
<th>IN VITRO DIAGNOSTIC MEDICAL DEVICE TECHNICAL SPECIFICATIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>NAME, CATEGORY, AND CODING</td>
</tr>
<tr>
<td>INTENDED USE</td>
</tr>
<tr>
<td>PERFORMANCE CHARACTERISTICS</td>
</tr>
<tr>
<td>TECHNICAL AND OPERATIONAL CHARACTERISTICS</td>
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<tr>
<td>INSTRUMENT PHYSICAL AND TECHNICAL CHARACTERISTICS</td>
</tr>
<tr>
<td>INFRASTRUCTURE REQUIREMENTS</td>
</tr>
<tr>
<td>ACCESSORIES, CONSUMABLES, SPARE PARTS AND OTHER COMPONENTS</td>
</tr>
<tr>
<td>DOCUMENTATION</td>
</tr>
<tr>
<td>ENVIRONMENTAL AND SAFETY REQUIREMENTS</td>
</tr>
<tr>
<td>TRAINING, INSTALLATION AND UTILISATION</td>
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<tr>
<td>WARRANTY AND MAINTENANCE</td>
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<tr>
<td>DECOMMISSIONING</td>
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<td>QUALITY AND REGISTRATION</td>
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<tr>
<td>PRICING</td>
</tr>
<tr>
<td>PROCUREMENT CONSIDERATIONS</td>
</tr>
</tbody>
</table>
Timeline and next steps

2019

- **Mar**: 2nd SAGE IVD Meeting
- **May**: Open call for pre-submissions for 3rd EDL
- **Jun**: 2nd Edition of the EDL announced at WHA
- **Jul**: Call for new SAGE members
- **Aug**: 2nd Edition of the EDL announced
- **Sep**: EDL Secretariat review of pre-submissions for 3rd EDL
- **Oct**: Deadline for full submissions for 3rd EDL
- **Nov**: SAGE IVD review and web publication of submissions for 3rd EDL
- **Dec**: EDL Secretariat review of pre-submissions for 3rd EDL

2020

- **Mar**: Pilot national EDL in selected countries
- **Apr**: Secretariat to develop web based platform for EDL (e-EDL) and IVD nomenclature
- **May**: WG and SAGE draft guideline for country implementation
- **Jun**: Consultation with member states, industry & non-state actors. Regional and country workshops
- **Jul**: Review SAGE applications
- **Aug**: Renewed SAGE IVD commences work
- **Sep**: 3rd SAGE IVD Meeting
- **Oct**: Deadline for pre-submissions for 3rd EDL
- **Nov**: Renewed SAGE IVD commences work
- **Dec**: 3rd SAGE IVD Meeting

04/12/2019
Essential in vitro diagnostic List (EDL) Objective:

To increase to IVDs for patients to have diagnostics-informed treatment at various health care levels.

EDL provides evidence-based guidance to:

1. **Member States**
   
   for the development of local/national essential in vitro diagnostics lists to define regulatory, supply and use of IVD to their population

2. **United Nations (UN) agencies and non-governmental organizations (NGOs)**
   
   who support provision of in vitro diagnostics

3. **Provide guidance to the medical technology private sector** on diagnostics priorities needed to address global health issues

WHO looks forward to working with all stakeholders of this meeting, the challenge is enormous but together we can overcome it..
Remember a patient is at the end of all our activities, they deserve our:

- Technical knowledge
- Passion
- Honesty
- Hard work
- Collaboration