The WHO Model List of Essential In Vitro Diagnostics (EDL)

Access to Medicines and Health Products Division

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Objectives of the EDL

The EDL is intended to support IVD policy development, to support patients having diagnostics-informed treatment.

The EDL lists a set of priority IVD categories for use at various levels of the healthcare system.

The EDL:

1. Provides evidence-based information to Member States for the development of local/national essential in vitro diagnostics lists
2. Informs United Nations (UN) agencies and non-governmental organizations (NGOs) who support selection, procurement, supply, donations or provision of in vitro diagnostics
3. Provides guidance to the medical technology private sector on diagnostics priorities needed to address global health issues
EDL scope and oversight

Scope:

No brand names or specific products but categories of tests
Includes categories of tests for both infectious diseases and NCDs
Also includes general laboratory tests
Process generally similar to that for EMLs but adapted for IVDs

SAGE IVD review

First meeting April 2018
Second meeting 18 – 22 March 2019
Third virtual meeting June - July 2020.

Source: Image from iStock.com
Inclusion Criteria for EDL

Criteria:

• Primary care: For patients at entry level care facilities

• Higher level facilities: Laboratory based technologies/methods

• Public health relevance: High burden diseases, affordable, appropriate

• Evidence based: Supported for example, by WHO guidelines & guidance.

• Free of conflict of interests

• Have commercially available tests with regulatory approval

Priorities and direction are set by the SAGE IVD every year.
Organization of the EDL 3

Section I

Community and health settings without laboratories

I.a. General tests (arranged by discipline)
I.b. Disease-specific tests (arranged by disease)

Section II

Health care facilities with clinical laboratories

II.a. General tests (arranged by discipline)
II.b. Disease-specific tests (arranged by disease)
II.c. Blood screening tests

Section III

Do Not Do
Recommendations: recommendations against the use of certain test categories

New
### Example of an EDL entry

**Disease specific In Vitro Diagnostic Tests**

<table>
<thead>
<tr>
<th>HIV</th>
<th>Diagnostic test</th>
<th>Test purpose</th>
<th>Assay format</th>
<th>Specimen type</th>
<th>WHO prequalified or endorsed products</th>
<th>WHO supporting documents</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>Diagnostic Test:</strong></td>
<td>To aid in the diagnosis of HIV infection: adults, adolescents, children and infants over 18 months of age</td>
<td>RDT</td>
<td>Oral fluid</td>
<td><a href="http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hivrdts/public_report/en/">link</a></td>
<td><a href="http://apps.who.int/iris/bitstream/handle/10665/2544621/9789241549981-eng.pdf?sequence=1">link</a></td>
</tr>
</tbody>
</table>

**Diagnostic Test:** The analyte being measured

**Test Purpose:** Brief outline of the common reasons for performing the test

**Assay format:** Recommended method(s) for performing the test (no brand)

**Specimen type:** Typical specimen used for this test

**WHO Prequalified or endorsed product:** Link to public report for the product

**WHO supporting documents:** Link to guidelines, guidance.
The Strategic Advisory Group of Experts (SAGE IVD)

- Serve as a principal advisory group to the WHO Director-General on all aspects of IVDs, including the WHO Model List of Essential in vitro Diagnostics
- Adequate representation of expertise (varies from year to year depending on needs)
- Geographical representation
- Gender balance
- Strict management of conflict of interest
- Serve for a specified amount of time and can be renewed for consecutive terms as outlined in the Terms of Reference
Strategic Advisory Group of Experts (SAGE) members (2021)

- Prof. Abdul-Ghani, Rashad (Yemen)
- Prof. Bhargava, Anurag (India)
- Prof. Chanoine, Jean-Pierre (Belgium)
- Dr Fleming, Kenneth Anthony (UK)
- Prof. Garcia, Patricia (Peru)
- Dr Grenwal, Ravnit (South Africa)
- Dr Hançali, Amina (Morocco)
- Dr Kelly-Cirino, Cassandra (Canada)
- Dr Ndowa, Francis Jim (Zimbabwe)
- Mr Offutalu, Paulinus Nnamdi (Nigeria)
- Prof Schroeder, Lee (USA)
- Prof. Sewell, William (Australia)
- Dr Trapani, Dario (Italy)
- Prof. Shakoor, Sadia (Pakistan)
- Dr Yunfeng, Lyu (China)
Five different types of submission:
• Addition of a test category
• Edit to an existing EDL entry
• Removal of a test category
• Do not Do recommendation
• Submission of additional evidence to reverse a conditional listing
### The update of the EDL is a rigorous evidence-based process

#### 2-step process: **pre-submission** and **full submission**

<table>
<thead>
<tr>
<th><strong>Applicant’s information</strong></th>
<th><strong>Disease or conditions addressed</strong></th>
</tr>
</thead>
</table>
| • Name/info of applicant organisation(s)  
  • Name/info of Institutions consulted or supporting the application  
  • Name of WHO focal point | • Disease or condition addressed by diagnostic test (ICD-11 code)  
  • Public health impact of disease/condition  
  • Public health impact of diagnostic test  
  • Use of the test (i.e. diagnostic testing algorithm) |

<table>
<thead>
<tr>
<th><strong>IVD description</strong></th>
<th><strong>Evidence available</strong></th>
</tr>
</thead>
</table>
| • Category of test  
  • Intended use, detection target  
  • Intended user  
  • Training, equipment requirements  
  • Annex I: examples of commercially available tests | • Diagnostic accuracy SR or primary studies  
  • Clinical utility/impact SR or primary studies  
  • Existing guidelines supporting the use of the test  
  • Technology landscapes |

<table>
<thead>
<tr>
<th><strong>Societal impact information (as appropriate)</strong></th>
<th><strong>Budget and resources</strong></th>
</tr>
</thead>
</table>
| • Ethical issues  
  • Human rights issues  
  • Equity issues | • Comparative test costs and cost effectiveness  
  • Resources and budget impact on health care systems (specialised HR, training etc) |
Annual face to face meeting (whenever possible)

Possible outcomes of the discussion by SAGE IVD:
- Not listing
- Conditional listing
- Listing

Additional considerations documented in the meeting report (caveats, conditions, statements from the SAGE IVD) along with the full submissions and evidence considered.

Moving to an electronic platform (the eEDL)

The TRS report is a very useful tool for countries developing a national EDL
EDL 3 update: main highlights

- 28 applications received
- 26 changes suggested (non editorial)
- 5 sets of additional data to lift conditional listings
- List contains **175 test categories** and 2 Do Not Do recommendations
- Some highlights:
  - Addition of SARS CoV-2 NAT and antigen tests
  - Addition of a section on endocrine disorders (LH, FSH, prolactin, cortisol, progesterone, estradiol, TSH)
  - Addition of point-of-care sickle cell testing
  - Additional cancer test (EGFR mutation)
  - Additional fungal diseases: Aspergillosis, *Pneumocystis* pneumonia
  - Vaccine preventable diseases: measles and rubella
  - Changes made to the general tests
Development of National EDL (NEDL)

- Currently finalizing guidance document to help countries develop their own national EDL
- The guidance document also includes basic elements to consider for implementation of the national EDL.

Input: country’s documentation and data

Step 1. Review of country’s documentation and data on disease burden

Output: list of candidate IVDs available in the country

Step 2. Comparison exercise: WHO EDL vs list of candidate IVDs available in the country

Input: WHO EDL and output from step 1

Output: draft composite list of candidate IVD not requiring further evaluation

Output 1: draft list of candidate IVD requiring further evaluation

Step 3. Public consultation

Input: outputs 1 & 2 from step 2

Output 2: revised list of candidate IVD requiring further evaluation

Output 3: revised composite list of candidate IVD not requiring further evaluation

Step 4. Call for submission to the NEDL

Input: output 1 from step 3 and applications accepted from step 4

Step 5. Systematic review and evaluation of applications

Output 4: revised list of candidate IVD requiring further evaluation

Step 6. Selection of IVDs for the NEDL

Input: output 3 from step 3 and applications accepted from step 4

Step 7. Submission of NEDL to MOH for final approval

Step 8. NEDL embedded as policy and disseminated

Step 9. NEDL periodic update
Next steps for the EDL/SAGE IVD

Currently discussing strategy and direction of the EDL with SAGE IVD

Some suggestions made:

- Survey countries about how they use the EDL and what are their needs
- Focus on the implementation of the EDL in countries (already discussing this with FIND and others)
- Closer alignment with the EML
- Perhaps, future calls for submission should focus on companions IVDs to the EML
- Link eEML and eEDL
- Greater focus on primary care
- Use EDL to advocate for research where evidence is lacking (e.g. on utility or impact of various IVDs)