**RFP MVP/EMP/eEDL2019\_1 :****WHO Medical Devices Information system (MEDEVIS) and electronic Essential In Vitro Diagnostics list (eEDL)**

**APPENDIX 1: MEDEVIS and eEDL Detailed Requirements Specifications**

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# Business case – Vision, Targets, and Outline

## Vision

This RFP shall allow WHO to identify a bidder who shall establish a Medical Devices Information System (MEDEVIS) solution and online platform and in particular, transform the [Second EDL](http://gsm.who.int:8100/OA_HTML/OA.jsp?page=/oracle/apps/fnd/framework/navigate/webui/NewHomePG&homePage=Y&_ti=750584321&retainAM=Y&addBreadCrumb=N&OAMC=G&WFEBizWorklist=Y&oapc=5) into an **electronic** Essential In Vitro Diagnostics List within a timeline of 5 months after signature of the agreement.

The MEDEVIS online portal shall allow managing the various workflow processes for creation and maintenance of Medical devices lists, and under Phase one of this project, all processes related to the eEDL (electronic Essential In Vitro Diagnostics List) which is a subset of MEDEVIS. These processes include various detailed workflow interactions of internal and external actors, via processes such as online data submission, online commenting, reviewing and web publishing of applications and ultimately, the eEDL.

The vision is that the eEDL (electronic Essential In Vitro Diagnostics List) shall be made accessible online for the purpose of data searches and downloads; in addition, editing and updating the EDL and related information shall also be carried online and greatly facilitate the efficiency and effectiveness of the EDL review and dissemination process.

In conclusion, the new eEDL business solution shall greatly improve and automate aspects of information retrieval and reporting for the different audiences. It shall also replace the current manual process of web publishing.

## Project scope, organization and timelines

The scope of this project comprises all activities phases for establishing the WHO Medical devices lists and online platforms. With respect to the scope, organization and timelines, we wish to highlight that highest priority is to be given to the early delivery of the web based eEDL and related online portal for its management. Within the overall project plan, the eEDL would ideally become operational by end January 2020, to be followed by the remaining Medical device components.

## Project management approach

The project’s phases and activities such as requirements gathering/validation, design, development, configuration and implementation require use of proven business and IT project management capabilities and sound experience in applying them.

Potential challenges for this project which are beyond control of the eEDL business owner are, for example, and not limited to:

* Availability of staff dedicated to the approval, validation of information and data entry.
* Change of processes and/or lack of clearly documented processes for maintaining all EDL and related contents;
* Lack of clarity or coordination between the two phases of the project
* Establishing purpose and nature of linkages to external partners and their data sources and permissions for reuse/connecting to/integrating external resources from non-WHO entities.

## Project deliverables and outputs

This project is expected to deliver the following outputs:

### Deliverable 1: MEDEVIS for EDL

#### Output 1.1: Convert EDL into eEDL and create a public internet facing web portal (see tables 1 and 3)

* The EDL shall be transformed from a static, manually edited PDF document into a modern web-based information solution and managed via a comprehensive online platform with simple, yet powerful user interface for EDL content, reference data maintenance and administration (user data entry, creation of categories and attributes, links to the list).
* The eEDL will incorporate evidence from WHO documents, such as guidelines or other third parties (e.g. CDC), must be easily searchable, visually intuitive and allow for data extraction and download.
* The eEDL will include all the elements of the Second EDL plus 10 other variables (nomenclature, technical specifications for each assay format, evidence, recommendations, disease targeted, use, among others)
* The reference information will serve as a WHO knowledge repository, offering seamless integration of data shared with other WHO tools and classification systems partners (e.g. [ICD-11](http://gsm.who.int:8100/OA_HTML/OA.jsp?page=/oracle/apps/fnd/framewohttps://icd.who.int/en/), [ICHI](https://mitel.dimi.uniud.it/ichi/), [EML](https://apps.who.int/iris/bitstream/handle/10665/273826/EML-20-eng.pdf?ua=1) -future eEML-, WHO health facility assessment tools, WHO repository of guidelines and interventions -UHC menu).
* Access to the information provided in the eEDL online portal will be public and free of charge.
* Use of its information is subject to the acceptance of WHO corporate copyright and licensing schemes.

#### Output 1.2: Develop a secure online portal for the submission, review and publishing of information relevant for the eEDL (see figure 1)

* The eEDL secure online portal shall provide access to standardized and highly automated workflow processes facilitating a continuous EDL review and update process with two key components:

1. Online submission for changes to the list, activities include for example

* + - submitting proposals for changes by the public,   
      (similar to ICD11 under ‘be involved’: https://icd.who .int/en/
    - review by experts
    - decision to change or not the eEDL list
    - updating and publishing the eEDL

2. Online submissions for new IVDs to the EDL, review and update process

* + - Online workflow processes established and configured (see figure 3)
    - Submission forms developed
    - expert review process actions
    - publication for commenting from public
    - option to publish or not a new IVD on the list

### Deliverable 2: MEDEVIS

#### Output 2.1: Similar to output 1, expand the eEDL digital business solution and electronic platform for managing all WHO medical devices lists

Lists currently refers to the following lists of priority medical devices described in <https://www.who.int/medical_devices/priority/en/> including:

Priority medical devices for reproductive maternal, new born and child

<https://www.who.int/medical_devices/publications/interagency_med_dev_list/en/>

Priority medical devices for Ebola

<https://www.who.int/medical_devices/meddev_list_ebola_25nov_en.pdf?ua=1>

Priority medical devices for Cancer

<https://apps.who.int/iris/bitstream/handle/10665/255262/9789241565462-eng.pdf;jsessionid=12D5FECA9788B1F498052EA1CBC513F3?sequence=1>

* Priority Assistive Products List (APL) <https://www.who.int/phi/implementation/assistive_technology/global_survey-apl/en/>

#### Output 2.2: Implement a secure web interface for system administration to allow creation and maintenance of multiple categories for interlinking with other WHO information sources to all WHO medical devices lists

As per examples on Table 2 and 4, categories include nomenclature, medical device (name, type and subtypes), delivery of care, intended health intervention and sub interventions, health condition, disease, link to WHO guideline and other WHO sources, capital/consumable, technical specifications, etc.  
  
MEDEVIS

## General non-functional requirements

### Platforms

The MEDEVIS business solution shall be hosted either as WHO on-premise solution or in the WHO cloud. ¨

For WHO on-premise solutions, Microsoft IIS/.net and SQL as well as Linux/Apache/MySQL/PHP are available via virtual instances. WHO on-premise hosting is suggested for Drupal solutions (with PHP 7.23, Apache/Linux, SOLR).

WHO Cloud hosting is suggested for solutions using 0365 and MS Azure platform components (Microsoft and non-Microsoft solutions); this includes the Microsoft Active Directory Federation Services (ADFS) support.

### Web browser

The MEDEVIS and eEDL business solutions must

* be browser independent (must support MS IE11+, MS Edge, Firefox, Google Chrome;
* support latest versions for desktops computers and mobile computing devices (various Operating systems for handheld devices (Android, iOS, Apple, Microsoft);
* shall not require installation of software components on the client-side (i.e. the user’s computer/device).

## General Functional requirements

#### Managing data element and entity categories and tags, reference tables

The EMP Department wishes to overcome the current device lists’ business and information management processes which are time consuming, and entirely manual. The department therefore wishes to implement a web-based IT solution, which shall allow for efficient data management, data retrieval, and online searches dependent on user needs. The web-based IT solution has to link to other computerized (online) reference information such as WHO guidelines, and other WHO information databases (UHC Menu, ICD-11, ICHI, etc.)

Ideally, the new web-based IT solution shall be comprehensive and allow for updating and disseminating the information and provide features for web-based data maintenance, online data queries and reporting, generating PDF, excel or word documents, and connecting to/with other scientific data resources.

## eEDL – The EDL and essential workflow processes

The following outlines the concept and relevant workflow processes of the eEDL and provides a description of major functional and non-functional requirements for the design and implementation of the eEDL online platform.

#### EDL concept and Background:

On behalf of WHO, the Department of Essential Medicines and Health Products EMP is responsible for maintaining the Priority Medical Devices Lists (PMD), Assistive Technologies list (APL) and Model List of Essential in Vitro Diagnostics (EDL), major reference documents for healthcare systems, health policy makers, health practitioners and medical devices supply organizations globally.

The EDL List is revised by the Strategic Advisory Group of Experts on In Vitro [Diagnostics (SAGE IVD)](https://www.who.int/medical_devices/diagnostics/sage-terms-of-reference/en/) every year. Following submission of applications for change of/addition to/removal from the list and the SAGE IVD deliberations, an updated version of the EDL is published as part of the WHO Technical Report Series with guidance and evidence information, on the WHO web site (<http://www.who.int/iris/handle/10665/311567> ) and in hard copy and distributed to various health related audiences.

The Second EDL is presented by health care facility level in two tiers and 3 sub areas, but this might increase in the subsequent EDL to include up to 5 tiers.

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

An example of the final listing of in vitro diagnostics is provided in **Table 1**.

**Table 1**: Example of some tests in the EDL



The second EDL list is published under <https://www.who.int/medical_devices/diagnostics/selection_in-vitro/en/>

## The process of EDL review and update – current and future

### Current process

The process of maintaining the WHO EDL as well as generation of the related publications (currently only manual) consists of:

* Receiving pre-submissions from internal/external stakeholders for changes, additions or deletions to existing IVDs in the EDL, including adding or adding to a “negative listing of in vitro diagnostics”;
* Review by WHO EDL Secretariat and relevant WHO technical area Validate/Reject
* Receiving full-submissions with relevant data and evidence from internal/external stakeholders;
* Review of submissions by experts or reviewers;
* On line publishing of pre/full-submissions, review and open for stakeholder’s comments;
* Decision making by SAGE IVD experts during the in-person meeting once a year
* Approving or rejecting proposals;
* Updating eEDL by publishing the decisions made by the expert group;
* Publishing the latest version of the EDL as well as the meeting report as a printed document for reference.

### The future eEDL workflow process and WHO Strategic Advisory Group of Experts (SAGE IVD) meeting

The web based eEDL online portal shall support all required EDL and WHO Secretariat workflow processes, enabling it to manage the decisions regarding IVDs, tracking changes to the list more efficiently, creating multiple output documents based on user needs (using the different filter options).

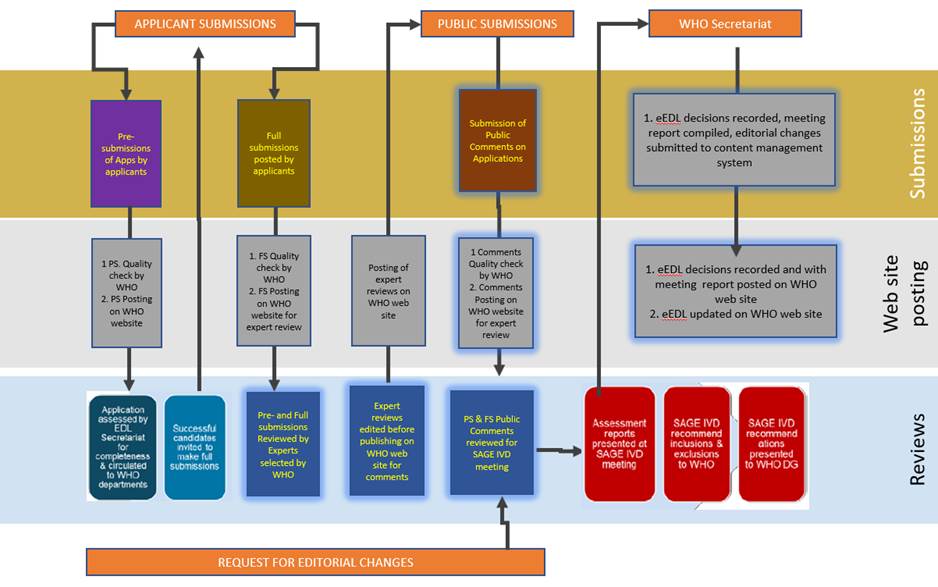
The overall EDL process consists of an annual review of the current listing, any submissions for change and expert’s reviews therefore, followed by a list update and publishing of the results.

The review process usually starts in June of each calendar year with the submission by applicants of new categories of tests to be added to the list, the revision of the submissions (off line Sept-Jan), the publication of all material by mid Feb, the discussion during the experts meeting in March and the publication of the list in May.

Updates to the published list outside the timeline will only happen under specific circumstances (e.g. additional important evidence that corroborate the decision of the panel), or criteria (i.e. updating links to most recently published WHO guideline). All other updates will follow the set timeline of only annual updates.

A scheme of the EDL application management process and various inputs and outputs is presented in **Figure 1**.

**Figure 1**. Management of EDL applications, outcomes and outputs.



### Online application for the WHO Essential In Vitro Diagnostics list

The eEDL online application shall provide all processes described in the Procedure to update EDL webpage: <https://www.who.int/medical_devices/diagnostics/selection_in-vitro/edl-model-lists/en/> including a pre-submission form, a full submission, posting for stakeholders comments and review by experts. This procedure is being updated for submissions for the third EDL starting in July 2019 and new forms will be posted soon under the mentioned URL.

### eEDL Inputs, outputs, actors

#### Inputs:

The eEDL business solution shall allow a process of reviewing, commenting and updating the current eEDL at its annual stakeholder meetings. The process also relies on capturing ongoing discussion via collaboration mechanisms. Managed user access is to be foreseen for WHO domain users, applicants, SAGE IVD members and expert reviewers defined by WHO. The new web based solution shall also allow for the submission of proposals for EDL list changes, allow to work off line and to publish once the approval procedure has been followed.

#### Outputs:

Validated and amended eEDL list. The following shows the current list of eEDL <https://apps.who.int/iris/bitstream/handle/10665/311567/9789241210263-eng.pdf>

The web based eEDL shall allow automated list consolidation, archiving and publishing and for online data queries and reporting.

#### Actors involved:

Major actors include General public, Applicants, Reviewers, Experts, WHO Secretariat and around 20, SAGE IVD members.

### eEDL user and online data management

#### Managing user rights and roles

To maintain accuracy, validity and relevance, the eEDL data contents must be annually updated as changes are implemented. Different actors and different data sets are defined and used/involved for completing the relevant activities: The processes and related data elements are divided into

* data and workflow processes related managing submissions and comments by the secretariat, submitters and reviewers, and the information that is subsequently approved and made live to the public part of the eEDL portal (not public, restricted access)
* data and workflow processes related to automated web publishing, which shall be automated but is subject to approval and promotion and completion of essential steps in the eEDL workflow processes portal (not public, restricted access)

The eEDL online portal must offer a simple and powerful user administration interface for granting and revoking WHO domain and non-WHO domain users the relevant right.

The eEDL must have inbuilt auditing of user actions (data value changes, system access logs); the audit trail must be understandable and exportable without further processing by a computerized system.

### Key feature sets

#### Key Feature Set 1: web-based tool for the EDL management

The eEDL shall allow managing, updating and tracking the applications of IVD tests, preparing the information resources used by experts for their reviews and at the SAGE IVD annual meeting. This comprises, among others,

* + Recording/viewing requests, applying requests and decisions
    - Background information for all changes are included and viewable
  + Automated Listing of EDL applications and decisions (outcome) including rejected applications
  + Automated Listing of applied decisions (these would not include rejected applications)
  + Versioning shall be enabled – all historical versions and actions must remain visible and need to be shown in a meaningful manner.

It is important to note the user interface must fulfill needs for two distinct user groups:

* users/actors involved in workflow processes and data management system for EDL applications;
* users/actors who consume the information resources shared via the public facing part of the online portal.

Both user groups must be provided with a clearly structured, quick and intuitive interface to navigate the EDL contents. The management of EDL applications and the automated publishing process as well as the data retrieval must be secured and yet seamlessly integrated.

#### Key Feature Set 2: online management of Committee decisions and EDL basic contents: applying and tracking additions, deletions, changes to the EDL

Managing APPLICATIONS and OUTCOME

Business rules for including additions, alterations of data and or removals of points of information are implemented in a controlled and auditable manner (version control and password identification).

#### WHO EDL Advisory group of experts (SAGE IVD) actions/options: list of recommendations

* **Addition**: IVD added to the list
* **Addition with condition**: IVD added or maintain on the list with requirement to review when further evidence is provided.
* **Deletion**: IVD previously listed which is then deleted
* **Rejection**: IVD not previously listed which is not recommended for inclusion
* **Change**: change is a log on requests for changes to an existing test on the list
* **Decision pending**: in few occasions decisions about listing/delisting have been postponed, as the ground to make the decision was in some respects problematic or due to lack of evidence.
* **Negative listing**: IVD not recommended by WHO.
* **Year:** year at which any decision has been taken.
* **History:** all modifications related to one item.
* **Evidence:** We will present brief summaries of evidence that supported the addition (or deletion/rejection) of an IVD to the EDL designed to make key information quickly available for policy makers, in order to understand why a decision was made. It will be structured in a format dividing the key information in criteria (see **Figure 2**). The evidence section will replicate the information that is developed for the WHO TRS and will be prepared and updated by the EDL Secretariat.

#### Key Feature Set 3: Public access to the Medical devices lists- Dissemination of information and knowledge, online searches and reporting

##### Dissemination of knowledge

All Medical devices lists PMD including the eEDL shall contain crucial WHO information which must be accessible to the public freely. WHO requires that the Medical devices public internet facing online portal can be searched, content presented or structured and downloaded at different level of granularity, ranging from individual devices or diseases or categories, to entities aggregated by device class, category, diseases, or the complete and detailed PMD or eEDL listing.

The successful bidder is expected to propose a configurable and powerful search and reporting functionality. A simplify and yet powerful web interface shall allow the different audiences to easily shape how contents will be prioritized, customized, and how different data elements will be linked for generating the required user outputs.

Examples of a possible formats presented in **Figure 2 and 3** below

The main objective is to create the optimum environment for partners to efficiently and effectively explore the WHO Lists. The explorer website should be designed to last for a period of five years without major updates, and with a minimal workload to be maintained.

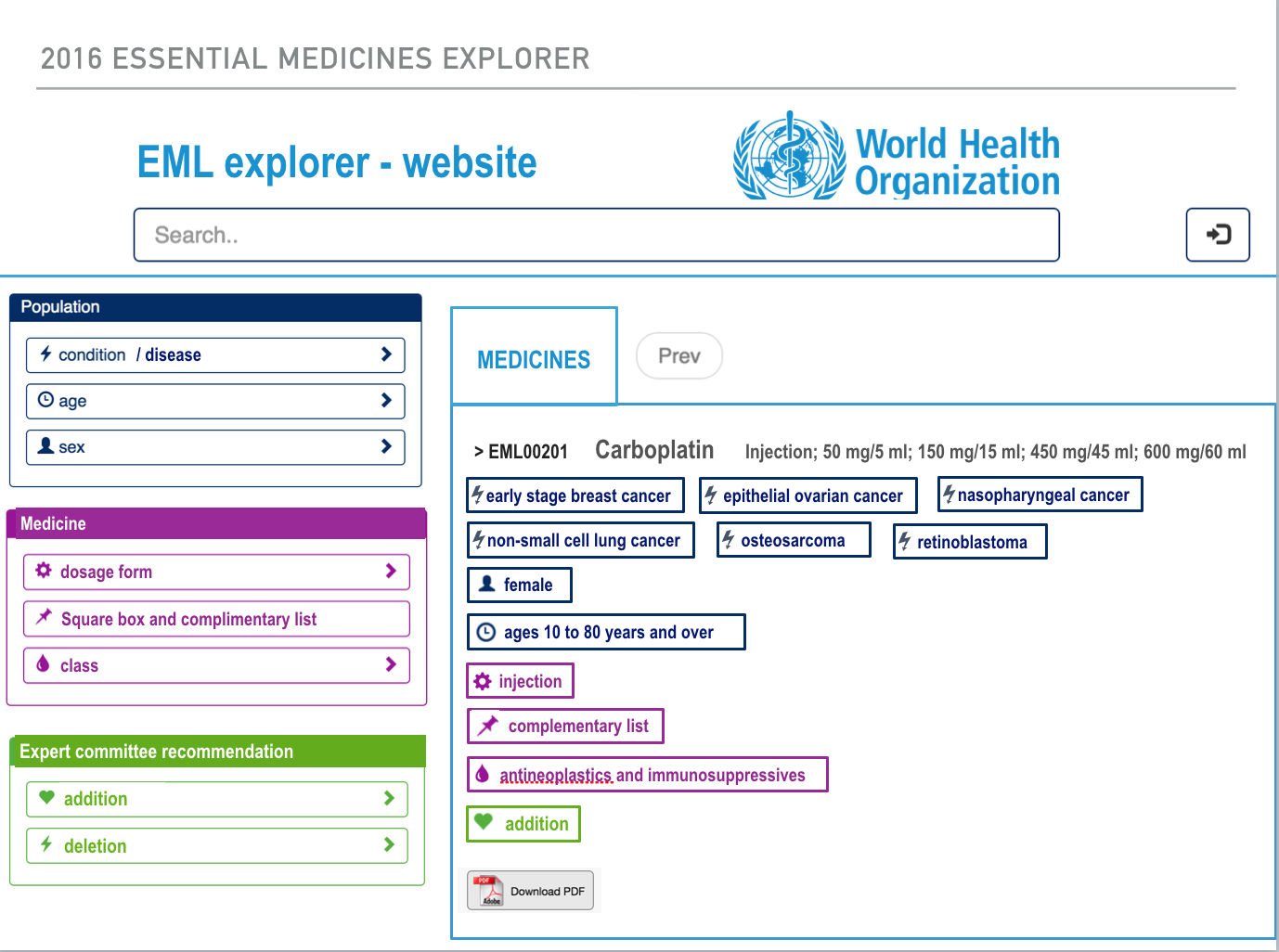
##### Permissions for reuse/connecting to/integrating external resources from non-WHO entities

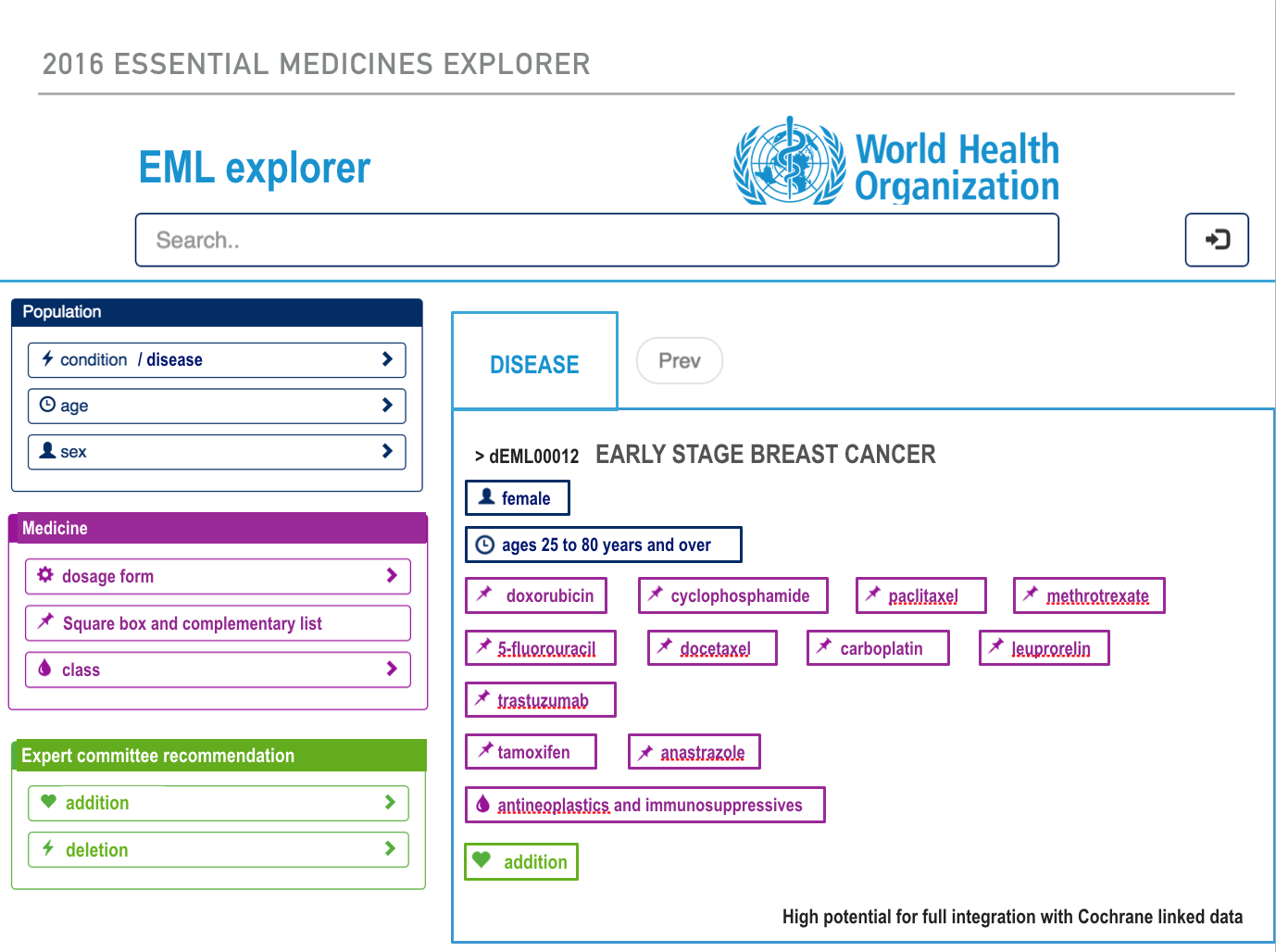
The eEDL and PMD will be released under the terms of a CC BY-NC-SA 3.0 IGO license. This license allows for redistributing and re-using eEDL contents for different purposes, including commercial purposes. Extracts or the entire eEDL or PMD can be integrated in National Lists and text books.

##### Online search and search options

The Medical devices list including the eEDL must provide powerful search features and make the retrieval of data useful, fast and simple; in addition, is shall allow to personalize the data output for each user including options to search using multiple tags, key words, categories, etc., and superimposing limits to searches.

* + Filter: multiple filters will be applied to the list: by level of care, by disease, by test type, by nomenclature, by name, by health condition, by intervention, by sample type, etc.
  + Search bar
* Search Field Tags: It is important that the tool provides a fast and flexible search and query engine, based on flexible search fields, using an ontology that will facilitate mapping data sources (see **Figures 2 and 3**).**Figure 2**: Example mock up proposals for the essential medicines list to be aligned with the approach taken by MEDEVIS.

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**Figure 3**: Mock-ups of the approach taken by EML for smart phone application to be aligned with MEDEVIS

#### Key Feature Set 4: Outputs, including EDL & WHO Technical Report Series (TRS) publications

* HTML pages, including Summaries divided in editorial sections (and references) by categories etc.
* Online (ad-hoc) generation of EDL body in PDF for all or selected categories

The eEDL online portal offers key information of more than 300 in vitro diagnostic tests contained in is database (with several (20) levels of information aggregations); it must provide powerful search features and make the retrieval of data useful, fast and simple; in addition, is shall allow to personalize the data output for each user. Also, as a global data repository, the eEDL should be easily translated into different languages, ensuring that non-English speaking audiences can access the best available information without language barriers.

**Weighted relevance:** Computation of weighted relevance order in search outputs will be a preferred option when results of searches are presented to users.

#### Key Feature Set 5: Integration with guidelines and other guiding documents

The proposal should present a strategy to export eEDL contents to third parties. This can be considered an automated way of sharing or transferring eEDL contents: any system receiver (e.g. external web platform, smartphone) can connect to the WHO eEDL platform/database to use/import the data and information. The EDL should be able to provide access to contents and links in a standardized and structured manner (e.g. predefined XML template). If the receiver is designed to be integrated with the eEDL, the updates of the eEDL will be read and processed by any third parties, and EDL contents shall efficiently populate target libraries.

The business solution should automatically transfer the data product of a search or the full list to third parties’ lists, such as National Formularies, National EDLs, National Guidelines or Regulatory agencies, in Excel, Word or PDF formats.

A key strategy regards the integration of WHO EDL and WHO guidelines, until now the contents of few WHO guidelines.

#### Key Feature Set 6: Integration with non EDL or external data providers (non-exhaustive):

* WHO repository of interventions and guidelines;
* WHO ICHI: the International Classification of Health Interventions;
* WHO ICD11 WHO International Classification of Diseases 11th Revision;
* WHO Prequalified medical products;
* WHO Guidelines;
* WHO EML: medicines that require a diagnostic before use;
* WHO PMD: Priority medical devices lists.

This work is a prerequisite to integrate WHO EDL contents and WHO Guideline contents. Particularly we envisage an Application Programing Interface (Web API, web service, etc.) that can handle the exchange of queries and responses messages, integrating Guidelines recommendations and Summary of Findings contents in the EDL output. The system should ensure a timely automated transferring and updating of contents, as far as guidelines are developed using the API/web service.

### Data elements /attributes (non-exhaustive list)

**Table 2:** The following is a non-exhaustive list of categories and data elements for MEDEVIS and EDL. Examples below.

|  |  |
| --- | --- |
| **Priority medical devices lists** | **Essential in vitro diagnostic lists** |
| TYPE OF MEDICAL DEVICE | TYPE OF MEDICAL DEVICE: in vitro diagnostic |
| DATE OF LATEST UPDATE | DATE OF LATEST UPDATE |
| NOMENCLATURE (to be provided in October link to ICD11 ICMD) | NOMENCLATURE (to be provided in October link to ICD11 ICMD) |
| NAME OF GENERIC TYPE OF MEDICAL DEVICE | NAME OF GENERIC IN VITRO DIAGNOSTIC TEST TYPE |
| TYPE OF MEDICAL DEVICE (assistive, medical equipment, surgical instrument, laboratory equipment, imaging, single use, protective equipment, solutions and reagents, implantable, software, eHealth device, other) | NAME OF SUBTYPE (manual, automated, single use, accessory of mobile phone) |
| PURPOSE/USE (prevent, screen, diagnose, treat, monitor, palliate, rehabilitate, assist) | PURPOSE/USE: Screening, Diagnosis, Aid to diagnosis, Staging, Prognosis, Monitoring, Surveillance, etc. |
| DISEASE (from ICD 11 catalogue active link) | DISEASE (from ICD 11) |
| HEALTH CONDITION | HEALTH CONDITION |
| CLINICAL INTERVENTIONS (can be multiple from ICHI) | CLINICAL INTERVENTIONS (many from ICHI) |
| ORGAN OR SYSTEM RELATED | SPECIMEN TYPE |
| TYPE OF TECHNOLOGY | ASSAY FORMAT |
| LINKS TO WHO GUIDELINES (can be multiple) | LINKS TO WHO GUIDELINES (can be multiple) |
| HEALTH FACILTY   e.g. primary, secondary, tertiary, outpatient, inpatient, self, community, emergency | HEALTH FACILTY: primary, secondary, tertiary, outpatient, inpatient, self, community, emergency |
| TARGET POPULATION (new born, child, adolescent, male, female, adult, ageing, pregnant, etc.) | TARGET POPULATION |
| UHC MENU: link to one or several interventions from WHO repository | UHC MENU: link to one or several interventions from WHO repository |
| TECHNICAL SPECIFICATIONS (free text) | TECHNICAL SPECIFICATIONS |
| REGULATORY CLASSIFICATION (risk level: class I, class II, class III, class IV or IIIB) | REGULATORY CLASSIFICATION |
| INFRASTRUCTURE NEEDS (water, electricity (power), air conditioned, vapour, gas (define), wifi, other) | INFRASTRUCTURE NEEDS |
| HEALTH CONDITION/SYMPTOMS | HEALTH CONDITION/SYMPTOMS |
| LEVEL OF TECHNICAL KNOWLEDGE REQUIRED | LEVEL OF TECHNICAL KNOWLEDGE REQUIRED |
| CONSUMABLES | SOLUTIONS AND REAGENTS |
| SUMMARY OF EVIDENCE | SUMMARY OF EVIDENCE |
| ELEMENT OF A KIT OR SET | ELEMENT OF KIT OR SET |
| QUALITY PRODUCT STANDARDS | QUALITY PRODUCT STANDARDS |
| LINK TO WHO ASSESSED PRODUCT (prequalified, endorsed, core, innovative, cost effectiveness, etc.) | LINK TO WHO ASSESSED PRODUCT (prequalified, endorsed, core, innovative) |
| EXTERNAL ASSESSMENT: link to studies and landscape analysis on HTA, costs, equity, ethics, patient benefits, special reports | EXTERNAL ASSESSMENT: link to external assessment studies on HTA, costs, equity, ethics, patient benefits |
| SAFE USE, TRAINING, MAINTENANCE, DECOMMISSIONING: link | SAFE USE, TRAINING, MAINTENANCE, DECOMMISSIONING: link |
| POSTMARKET SURVEILLANCE: links | POSTMARKET SURVEILLANCE: links |
| IMAGE | IMAGE |
| AFFORDABILITY (costs, prices, total cost of ownership, etc.) | AFFORDABILITY (costs, prices, total cost of ownership, etc.) |

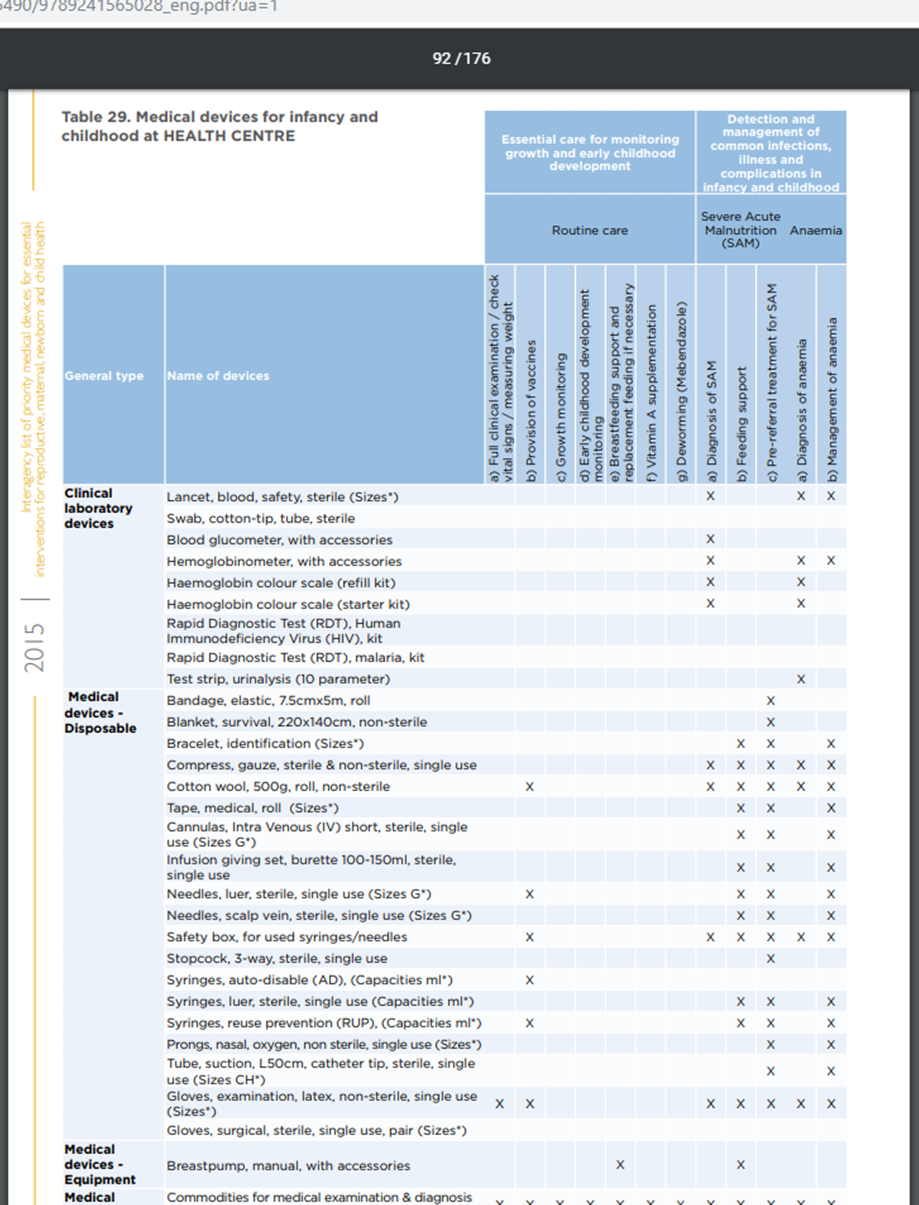
**Table 3**: Example of key information on IVD – prepared and updated by the EDL Secretariat.

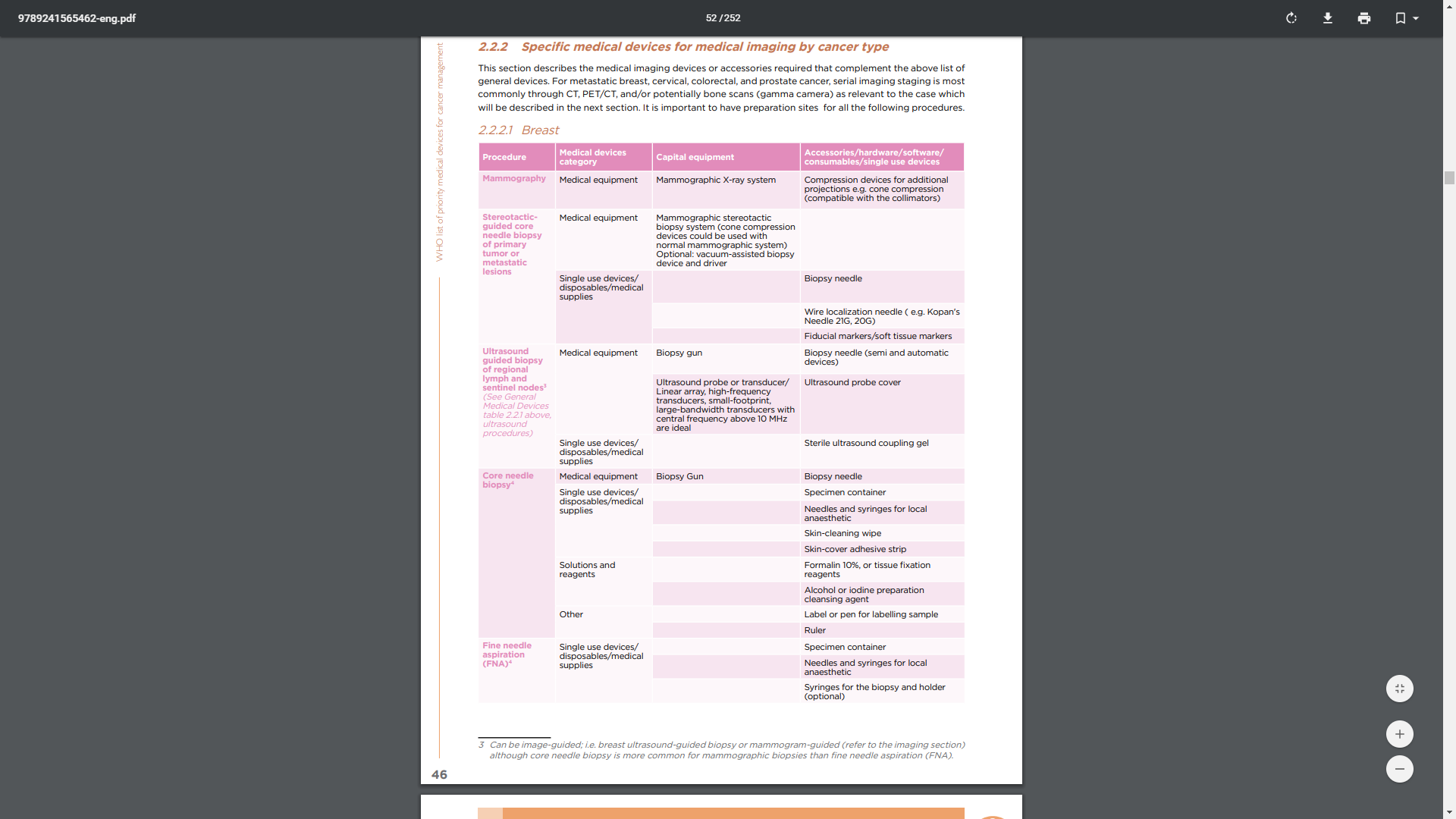
|  |  |  |
| --- | --- | --- |
| Basic panel of IHC for paediatric and adult solid tumours | | ICD11 code: xxx |
| Test category | Rapid diagnostic test for detection of Vibrio cholerae antigen | |
| Addition, change or deletion | Addition | |
| Year of decision | 2019 | |
| Test purpose | To screen patients with acute watery diarrhoea who present with the clinical case definition of cholera. A positive test should raise an alert while selected samples are sent for culture to confirm toxigenic V. cholerae. | |
| Applicant organization(s) | World Health Organization | |
| WHO technical department | Health Emergencies, Infectious Hazards Management | |
| Background: | *Disease condition and impact on patients: Cholera is an acute diarrhoeal disease caused by infection of the intestine with the bacterium V. cholerae, type O1 or O139 at any age. About 20% of people infected with V. cholerae have acute, watery diarrhoea, and approximately 20% have severe watery diarrhoea, many with vomiting. If these patients are not promptly and adequately treated, loss of fluid and salts can lead to severe dehydration and death within hours, with a case-fatality rate of 30–50%. Treatment (rehydration) is straightforward, and, if it is provided rapidly and appropriately, the case-fatality rate should remain < 1%. Cholera is transmitted by* *ingestion of faecally contaminated water or food and remains an ever-present risk in many countries. New outbreaks can occur in any part of the world where the water supply, sanitation, food safety and hygiene are inadequate. The risk is considerably increased in humanitarian emergencies, when there is significant population movement and crowding and frequent disruption of, or inadequate, access to health care services, clean water, sanitation and hygiene. The malnutrition status and health conditions of displaced populations can also lead to higher mortality. As the incubation period of cholera is short (2 h to 5 days), the numbers of cases and deaths can rise quickly and thus is an acute public health problem (1–3).*  *Does this test meet a medical need? The test is used to screen stool samples for detection of toxigenic V. cholerae O1 or O139 from patients presenting with the clinical symptoms of cholera. It is used at P primary care level for early detection of new cases and establishment of a cholera outbreak alert.* | |
| Public health relevance | *Prevalence*: In 2016, 38 countries reported a total of 132 121 cases of cholera and 2420 deaths to WHO. The global burden of cholera is, however, largely unknown because most cases are not reported, due to limited capacity for epidemiological surveillance and laboratories and also social, political and economic disincentives for reporting. Epidemiological reporting and spatial regression modelling indicate that there are 2.86 million cases of cholera annually and 95 000 deaths in 69 endemic countries.  *Socioeconomic impact*: Cholera often occurs in large explosive outbreaks that spread rapidly. From a public health perspective, the management of cholera outbreaks requires immediate identification, because of the pathogen’s potential for spread and the devastating consequences of epidemics. The economic impact of outbreaks has been estimated to be a loss of 1–2% of GDP in each outbreak year. WHO has estimated that US$ 26 billion will be lost each year in the next 10 years if the global cholera burden is not addressed. | |
| WHO or other clinical guidelines relevant to use of the test | Global Task Force on Cholera Control. Interim Technical Note. The Use of Cholera Rapid Diagnostic Tests. November 2016 (4) and Global Task Force on Cholera Control. Interim Guidance Document on Cholera Surveillance. June 2017 (5). | |
| Basic test characteristics | |  |  | | --- | --- | | Test purpose | Screening for cholera infection | | Test format | Lateral flow dipstick assay | | Specimen types | Fresh stool, rectal swab | | Equipment required | Dipstick cartridge, vial, buffer, dropper | | Regulatory status | No information | | Global availability | Broad | | Price per test range | US$ 2 per test | | Instrument test range | N/A | | |
| Evidence for clinical usefulness and impact | No direct studies of the impact of use of cholera RDTs have been reported. According to expert opinion, use of a point-of-care test for cholera can provide an initial indication of toxigenic V. cholerae transmission and thus reduce the danger of a nascent cholera epidemic. In the contexts in which cholera is most common, laboratory capacity and availability tend to be limited, and standard methods for cholera detection (culture and biochemical tests) are either unavailable or are available only after several days. As cholera outbreaks are explosive, the only realistic means of extinguishing an outbreak before it spreads is to raise an alert and begin a rapid response as soon as an RDT shows a positive result in an area known to be endemic for cholera. | |
| Evidence for economic impact and/or cost–effectiveness (from the application) | As is the case for other RDTs, the costs include that of the test (US$ 2) and of the supply chain system for monitoring and replacing stocks. In addition, although laboratory personnel are not required to perform the test, front-line health care workers should have a session of training and job aids for use, interpretation and follow-up of the results.  Cholera RDTs are not meant for individual diagnosis but rather to detect possible toxigenic cholera transmission in an endemic community and monitoring of the outbreak during its course. Thus, annual use in terms of the number of tests per year in an identified cholera hotspot (per 200 000 population) has been estimated at 50–100 tests. The cost per person living in an area at risk of cholera is estimated to be less than US$ 0.01 per year. Quality control and assurance and surveillance of proper RDT use must be included to ensure the most effective use of the test in a cholera surveillance system. | |
| Ethics, equity and human rights issues | As the test is intended for points of care in peripheral health centres and even for community health workers, the wide availability of cholera RDTs would improve equity in communities by providing evidence of an impending cholera outbreak for rapid protective measures. At present, the benefit is at community rather than individual level. | |
| SAGE IVD Evidence Review | A review of the development and evaluation of cholera diagnostics since 1990 included a systematic search for studies, analysis of methodological challenges observed across the studies, and tabulated limited details of evaluation studies, but did not assess study quality or undertake meta-analysis. Many methodological limitations and variation in accuracy between test kits was identified. Five tests are identified as promising, the studies report that the sensitivity of the RDTs may exceed 90% with specificity about 80%, although there is considerable uncertainty and variation among tests. | |
| SAGE IVD Considerations for Recommendation | Cholera outbreaks must be detected and monitored for rapid control. As they often occur in low-resource settings or in emergency situations, diagnostic tests that are simple to use at primary care level must be available. RDTs for cholera have been evaluated in many studies, many of which have methodologically limitations, but appear likely to have adequate sensitivity to be used for outbreak screening but not for making decisions about individual case management. | |
| SAGE IVD recommendations, with rationale | The SAGE IVD recommended inclusion on the EDL of the rapid antigen test for V. cholerae in the detection and monitoring of cholera epidemics at primary care level and for ruling out outbreaks.  The Group noted that it is rapid and easy to use and with acceptable diagnostic accuracy for the purpose. They recommended that an impact study should be performed in view of the high cost per test and further recommended that a systematic review of test accuracy studies be done to further investigate limitations in the primary research and the observed variability between studies | |
| Recommended test purpose | For early, initial detection or exclusion of a cholera outbreak (Not for use in case management). | |
| References | References  1. Clemens JD, Nair GB, Ahmed T, Qadri F, Holmgren J. Cholera. Lancet 2017;390:1539–49.  2. Ali M, Nelson AR, Lopez AL, Sack DA. Updated global burden of cholera in endemic countries. PLoS Negl Trop Dis. 2015;9(6):.  3. Keddy KH, Sooka A, Parsons MB, Njanpop-Lafourcade BM, Fitchet K, Smith AM. Diagnosis of Vibrio cholerae O1 infection in Africa. J. Infect Dis. 2013;208(Suppl.1):S23–31.  4. Interim technical note. The use of cholera rapid diagnostic tests. Geneva: GTFCC Surveillance Laboratory Working Group, Global Task Force on Cholera Control; 2016 (https://www.who.int/cholera/task\_force/Interim-guidance-cholera-RDT.pdf?ua=1, accessed April 2019).  5. Interim guidance document on cholera surveillance. Geneva: GTFCC Surveillance Laboratory Working Group, Global Task Force on Cholera Control; 2017 https://www.who.int/cholera/task\_force/GTFCC-Guidance-cholera-surveillance.pdf?ua=1 | |
| Other considerations |  | |
| Committee Recommendations |  | |

**2014 or closest year**

**Table 4**: Examples of key information on Medical Devices List

Example 1: for infancy and childhood at health centre



Example 2: PMD for cancer management: