Q&A from the webinar:

How to develop a national list of essential in vitro diagnostics

This webinar delved into the WHO Model list of essential in vitro diagnostics (EDL) scope and contents, including the criteria for selecting IVD tests categories and the Strategic Advisory Group of Experts on In Vitro Diagnostics (SAGE IVD). We also presented the proposed process for developing or updating a national EDL (NEDL) based on the evidence based EDL and the experience of Nigeria.

No.	Question	Answer
1	Many countries have a National Laboratory Working Group. They can serve as the committee, maybe with some additional epidemiological support, no need to install yet another committee in countries	We recommend that to develop a national EDL (NEDL) the ministry of health appoints a national high-level committee for IVDs or use an existing high-level unit, agency or working group that is usually charged with selecting IVDs and prioritizing health products for the population. This strategic committee is in turn responsible for appointing a technical committee (NEDL committee) for technical leadership and guidance on evaluating and selecting essential IVDs for the country by adapting and applying the WHO EDL process. If countries have a National Laboratory Working Group installed, then this group could be used as a base to form the high-level committee and the NEDL committee. More details on the suggested members of the committees and their roles and responsibilities are available in the guidance document: https://www.who.int/publications/i/item/9789240030923
2	Is this list going to be made into an interactive tool? Would be much easier to search. For example: disease, level, infrastructure requirements, price,	The WHO Model list of essential in vitro diagnostics (EDL) is also available as an user-friendly web-based application called electronic EDL (eEDL), it became available in Beta format in January 2021 and allows searching for tests using various filters such as disease, setting, assay format, IVD purpose and specimen type. The eEDL also provides information on the characteristics of tests and a summary of SAGE IVD recommendations. You can consult the eEDL here: https://edl.medevis.test.evidenceprime.com
3	What role do/should country FDA/FBB/Pharmacy and poison boards play in the development of the country EDL, especially since they approve any drugs and diagnostics that are used in-country? Should they lead the process since they are empowered	The ministry of health should lead the processes of national EDL development and future implementation. Representative(s) of the national regulatory agency for health products and testing providers are expected to be part of the national ministry of health high-level committee. More details on the suggested members of the committees and their roles and responsibilities are

	by the Government or this must go through the Ministry of Health?	available in the guidance document: https://www.who.int/publications/i/item/9789240030923
4	The barriers show the importance of having a strong laboratory system with sufficient funding available	As part of the steps in organizing testing services after publication of a national EDL, budgets should be assessed by the ministry of health, and the approved amount should be within the available resources. The implementation plan should be revised, and the final list of items for procurement, enhancement of infrastructure and supply chain and recruitment of human resources should be prepared in accordance with the final approved budget.
5	How survey of labs has helped in Nigeria? Is survey must?	For us, the survey was a must because there was no better way of capturing the information we needed such as tests available, important tests, available infrastructure and human resources.
6	How is this EDL expected to solve the absence of any kind of diagnostic support in health care	The WHO EDL was developed to provide evidence-based guidance to countries for creating or updating their national EDL (NEDL) and to guide policy on access to clinical laboratory services. It can be used by countries to prioritize the IVDs that should be available at different levels of the health-care system and to support them in allocating often scarce resources to essential IVDs for ensuring a healthier population. Once a NEDL has been approved by the ministry of health it should be implemented. When the NEDL is available and used to guide procurement and reimbursement in Universal Health Coverage priority benefits packages, it can serve as the basis for improving the availability and quality of IVDs for patients and for reducing out-of-pocket expenditure for these tests.
7	Question for Dr Ana Aceves Capri. Do you see a role for relevant civil society organizations in the development of the national EDL?	People should be at the center of health care and health systems. Inclusion and participation of all stakeholders should be guaranteed during the development of a national EDL (NEDL), including patients, their families and civil society organizations advocating for them. The NEDL committee should take pertinent measures to ensure an open, transparent application process widely disseminated throughout the country that includes a public consultation phase. Applications to the NEDL should be open to all, including health institutions, academia, manufacturers, nongovernmental organizations, professional associations, and patient advocates.

8	Does this list include veterinary diagnostics? Seeing as though some of these outbreaks are from zoonotic pathogens	The scope of the WHO Model list of essential in vitro diagnostics (EDL) does not include veterinary IVDs.
9	Can the EDL be expanded to include advice on method verification and the importance of internal quality control and external quality assurance	The EDL is a policy document, and its scope does not include method verification and/or quality control management. WHO has other publications addressing these topics: https://www.who.int/ihr/publications/lqms_en.pdf
10	Please comment on role of evidence synthesis in developing national EDLs	The EDL is a policy document based on scientific evidence. The review of submissions to the EDL covers the following main types of evidence: systematic reviews and primary studies of the clinical accuracy of the test when used in clinical practice; systematic reviews and primary studies of the clinical utility and impact of the test on patient management and care; recommendations from guidelines issued by WHO or other recognized expert bodies on use of the diagnostic test; and available evidence on comparative cost and cost–effectiveness. The update of the EDL is a rigorous evidence-based process and countries that are considering inclusion of tests categories for their NEDL can be assured that any diagnostic test in the EDL has been thoroughly considered. When the national EDL committee considers that EDL recommendations are applicable to the local context then national selection is advised to be in line with selection for the EDL without further evaluation of evidence, however, when national selection in line with EDL is not possible, the NEDL committee should have a process for standardized review and evaluation of applications. A rigorous process such as that used for the EDL should be considered. The assessment must be based on appraisal of robust evidence on the performance, utility, availability and cost-effectiveness of the tests and assay formats.
11	How do we involve the other ministries, such as Ministry of Finance? They would be important from the beginning to ascertain the cost-effective and cost benefit analysis of including more diagnostics at the public level. This would be crucial in developing the infrastructure and capacity building to roll out these new additions to the current under-resourced health systems.	Evidence on cost-effectiveness is part of the criteria for selecting IVDs categories for a national EDL (NEDL) and should be part of the evidence requested for the application process. The technical committee (NEDL committee as per the guidance document) should be responsible for assessing available published evidence on comparative cost and cost–effectiveness submitted by the applicants. The ministry of finance, among other relevant ministries, should be part of the high-level committee, the role of this committee is to provide strategic leadership for development of the list, including final approval and guidance on the availability of resources for

		implementation. More details on the suggested members of the committees and their roles and responsibilities are available in the guidance document: https://www.who.int/publications/i/item/9789240030923
12	Good Job Nigeria. From the National EML selection of essential medicines there has been a concern on less involvement of health workers in this process while developing the list in LMICs. What are the challenges faced during development of the EDL? Was the EDL committee selection structured? Please share the use of evidence synthesis and economic evaluations in selection of diagnostics for EDL?	Different cadres of health professionals were involved. The EDL committee was a subcommittee of the National Laboratory Working Group. Aside the challenge of the geographical size of Nigeria, security challenges, and the reluctance of some health workers to respond to questions in course of the survey, it was also a bit challenging getting the professionals to agree on the list.
13	Q: The EDL is a great tool; often country specific "EDL" already exist, which cover quite some ground. The big challenge is however at the implementation phase, especially in more decentralized parts of countries, where the diagnostics from the EDL are absent or insufficient (in terms of menu and/or quantity). Can the panelists comment on how to address these gaps?	Some countries may already have some lists that include IVDs, for example a list of minimum diagnostic tests, a national list for procurement and reimbursement, a national reference list, a national basic list or a national essential list, these lists could be drawn up by a national or regional committee, an agency or unit in the ministry of health or an insurance agency. A national list of essential in vitro diagnostics (NEDL) should be a policy document that lists categories of tests that are considered by the ministry of health as high priorities for availability at appropriate levels of the national health-care system, such a list should be based on scientific evidence and defined according to the country's context and needs. Once the ministry of health has authorized and approved an NEDL, it should be implemented within a defined period. A national implementation committee could be appointed by the ministry of health, which would be responsible for the development of an implementation plan and future roll out. Details regarding the recommended steps in organizing testing services after publication of an NEDL can be consulted in the guidance document at https://www.who.int/publications/i/item/9789240030923
14	Why not simply use the National Laboratory Working Group?	To develop a national EDL (NEDL) the ministry of health should appoint a national high-level committee for IVDs or use an existing high-level unit, agency or working group that is usually charged with selecting IVDs and prioritizing health products for the population. This strategic committee is in turn responsible for appointing a technical

		committee (NEDL committee) for technical leadership and guidance on evaluating and selecting essential IVDs for the country by adapting and applying the WHO EDL process. If countries have a National Laboratory Working Group installed, then this group could be used as a base to conform the high-level committee and the NEDL committee. More details on the suggested members of the committees and their roles and responsibilities are available in the guidance document: https://www.who.int/publications/i/item/9789240030923
15	What role do/should country FDA/FBD/pharmacy and poison boards play in the development of country EDL, especially since they approve any drugs and diagnostics that are used in-country?	The ministry of health should lead the processes of national EDL development and future implementation. Representative(s) of the national regulatory agency for health products and testing providers are expected to be part of the national ministry of health high-level committee. More details on the suggested members of the committees and their roles and responsibilities are available in the guidance document: https://www.who.int/publications/i/item/9789240030923
16	Should they lead the process since they are empowered by the Government or this must go through the Ministry of Health?	The ministry of health should lead the processes of national EDL development and future implementation. Representative(s) of the national regulatory agency for health products and testing providers are expected to be part of the national ministry of health high-level committee. More details on the suggested members of the committees and their roles and responsibilities are available in the guidance document: https://www.who.int/publications/i/item/9789240030923
17	Excellent work in Nigeria. A section on method verification in the clinical setting is important as is attention on staff training and quality assurance. This is particularly important when IVDs are used outside the laboratory	Very correct. Method verification, Staff training and quality assurance are important quality issues but not critical issues for essential diagnostic listing. It does not specify the desirable minimal performance characteristics for each test category, nor does it state the minimum quality standards to be considered in selecting specific brands of the test types listed.
18	Thank you for the presentation Mrs Nkechi, my friend. Nigeria had a lot of IVDs in the market according to your presentation: Did you find any challenges of performance of some of them and did anyone of them miss out getting into the list? If so how was this taken by the players?	The purpose of the survey was not targeted on the performance of the IVDs and as such none missed getting into the list based on performance. Rather what was discovered was that some tests were initially missed out in the survey tool.

19	Assuming the EDL will drive inclusion of specific tests in Ministry of Health National Local Tender: should not Ministry of Finance be involved in the finalization of the document	The ministry of finance, among other relevant ministries, should be part of the high-level committee, the role of this committee is to provide strategic leadership for development of the list, including final approval and guidance on the availability of resources for implementation. More details on the suggested members of the committees and their roles and responsibilities are available in the guidance document: https://www.who.int/publications/i/item/9789240030923
20	Is there a position paper on the importance of co-development of diagnostics and therapeutics as a health-care package?	No, but WHO acknowledges the importance of considering both diagnostics and therapeutics as a package.
21	What data support and technical support does WHO provide to help countries decide on regulatory approval for a given diagnostic test/ equipment?	Please see: https://extranet.who.int/pqweb/vitro-diagnostics/regulatory-agencies
22	The IFBLS is supportive of the EDL and is seeking to promote it globally, regionally, and nationally among its members. The EDL would benefit by consideration of reference ranges and guides to interpretation. In addition, consideration of whether tests are screening or diagnostic. What are front line tests and what are used as second line.	The EDL is a policy document developed to provide evidence-based guidance to countries for creating or updating their national EDL (NEDL) and to guide policy on access to clinical laboratory services. It can be used by countries to prioritize the IVDs that should be available at different levels of the health-care system and to support them in allocating often scarce resources to essential IVDs. The scope of the EDL does not include reference ranges and guides to interpretation, however, tests' purpose (e.g., screening or diagnosis) is included in the list, as well as specimen type and assay format. The EDL Secretariat is currently working on technical specifications for the IVDs listed in the EDL. WHO has other publications addressing technical and clinical issues with regard to IVDs recommended for use in the context of several diseases here: https://apps.who.int/iris/?locale-attribute=en&
23	Will the in vitro diagnostics be accessible to public health systems in near future?	The WHO EDL was developed to provide evidence-based guidance to countries for creating or updating their national EDL (NEDL) and to guide policy on access to clinical laboratory services. It can be used by countries to prioritize the IVDs that should be available at different levels of the health-care system and to support them in allocating often scarce resources to essential IVDs for ensuring a healthier population. Once a NEDL has been approved by the ministry of health it should be implemented. When the NEDL is available and used to guide procurement and reimbursement in Universal Health Coverage priority benefits packages, it can serve as

		the basis for improving the availability and quality of IVDs for patients and for reducing out-of-pocket expenditure for these tests.
24	Strategies on implementation strategy will be very useful as we have developed and signed off our National EDL in Nigeria	WHO has recently published the guidance document "Selection of essential in vitro diagnostics at country level: using the WHO model list of essential in vitro diagnostics to develop and update a national list of essential in vitro diagnostics" https://www.who.int/publications/i/item/9789240030923 which addresses NEDL implementation and provides suggestions to be considered by countries when organizing testing services after publication of their NEDL.
25	Is there any work in progress to evaluation genomics and sequencing technologies to include it in EDL?	Not for now.
26	I'd to know if at all there is bond between WHO and Medical Laboratory Government Regulatory Agencies across the globe especially in the area of IVD reagents and equipment calibration and validation. Thank you	Please see: https://extranet.who.int/pqweb/vitro-diagnostics/regulatory-agencies