Webinar: Open session day - 4th Meeting of the Strategic Advisory Group of Experts on IVDs
Q&A Session

Haemoglobin A1c (HbA1c) may be misleading for people in LMICs where there is higher burden of hemoglobinopathies.

As it pertains at the diagnosis Diabetes Mellitus (DM) we agree that the glycosylated haemoglobin may be suboptimal in some settings, but this is acknowledged by the WHO guidelines on the management of DM and in other WHO technical packages for the management of DM. It is also important to clarify that the EDL is not a clinical practice guide or a guideline, but a policy document intended to support the development, update, and implementation of national EDL (NEDL) by Member States. Countries will need to consider their local epidemiology, disease priority areas and the population addressed among other local characteristics, and in doing so the implementation committee is expected to consider clinical guidelines when recommending the ideal or more appropriate in vitro diagnostic tests to be implemented in the local setting. Furthermore, and taking into consideration that the EDL is not a comprehensive list, the national committee in charge of the development of the NEDL could propose the addition of IVD tests not included in the EDL.

Are the publications mentioned during the webinar available?

Yes, all the publications are available online and you can download them directly from WHO Website. For IVD topics: https://www.who.int/health-topics/in-vitro-diagnostics#tab=tab_1 and for other medical devices: https://www.who.int/health-topics/medical-devices#tab=tab_1

What type of support is available for Member States working in developing a national EDL?

The publication "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" is available in English here: https://www.who.int/publications/i/item/9789240030923 and the EDL Secretariat will keep its coordinated work with the WHO regional offices and with the country offices to support Member States in the development, update and implementation of their national EDL.

The Technical Report Series books include the EDL, and a complete description of every submission, a summary of the evidence appraised by specialist methodologists and a summary of the deliberations and recommendations of the SAGE IVD. It is a useful resource, providing Member States with the evidence for considering national selections in line with selections for the EDL without further evaluation of evidence. These publications are available here: https://www.who.int/teams/health-product-policy-and-standards/assistive-and-medical-technology/medical-devices/selection-access-and-use-in-vitro

Do you involve the applicants during the SAGE IVD meeting while taking the decisions?

No, during the SAGE IVD meeting the applicant is not involved, these are closed discussions only involving SAGE IVD members.

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The applicant is involved during the pre-submission phase in the case of the applications for addition of new IVDs to the list, and for the full submission too, we usually have communications through emails. The applicants send their submission/application, and we will review for completeness, it is very important to be sure that the applicants have answered all the questions required in the application form and that there are no missing responses. The same interaction between us and the applicants occurs for the other type of applications such as edits, delisting or the addition of do not do recommendations. We are available to support applicants if they have questions regarding how to prepare the application. Once the application has been submitted and it is with the SAGE IVD members to be reviewed the applicants won't be involved because at this point the application is already complete and it is the turn of the SAGE IVD members to review it. The outcome of the review we will be shared in due time with the applicants. There are several outcomes, for example, SAGE IVD members can accept the IVD for listing, or they can recommend for conditional listing of the IVD, or they could recommend to re-submit for a further edition of the EDL depending on the quality of the application or on the availability of the evidence submitted with the application. The applicant will learn about the outcome, however, during the actual SAGE IVD meeting the applicant is not involved, these are closed discussions only involving SAGE IVD members.

What is the process to review the EDL and how this process was developed? Could you elaborate on the reviews that are available online and how they have been produced by the SAGE IVD? And could you explain about the public consultation and the comments that everyone is invited to provide.

When the EDL Secretariat receives an application to add a new IVD category to the EDL, the first step is to circulate it among WHO colleagues working in applicable diseases programmes to identify in the IVD considered in the application is high priority from a programmatic point of view. If the IVD is considered as high priority, then we will invite the full submission. For the applications for edits, do not do recommendations or delisting, we also circulate these applications with the applicable WHO focal points to check on the relevance of this application. Once the application has been accepted the review will be done by the SAGE IVD members. Each application will be reviewed initially by at least two SAGE IVD members and by an expert methodologist. We will thus have at least three detailed reviews of each application and they will be shared for public comments along with the application on the WHO website. During this stage of the process all interested people and stakeholders have the possibility to comment on the applications and on the reviews of the applications, the comments should be sent by email and using applicable forms available in the WHO website. The EDL Secretariat then shares all the public comments received, in addition to the three initial reviews for each submission, with the SAGE IVD members for their review during the closed sessions of the SAGE IVD meeting. The SAGE IVD committee members will have also reviewed all the submissions before the meeting. The SAGE IVD committee then makes recommendations for each submissions received. Finally, and when applicable, the EDL Secretariat will respond to the public comments once SAGE IVD members have provided their recommendations and final comments.

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How do you harmonize a health systems approach at country level, particularly on diagnostics, but also taking into consideration the treatment (e.g., the medicines)?

WHO has developed publications to support countries to develop, to update and to implement their national essential/priority lists and for the selection of interventions relevant to different diseases or conditions according to their local context. These guidance documents complement each other and cover different health products such as medicines, medical devices, in vitro diagnostics, and assistive technologies, and provide recommendations for their use at the different levels conforming health systems.

In the case of the EDL, the IVDs recommended for use at community settings and health facilities without laboratories are the first opportunity for the population to access IVD testing, for example at the primary level, but the list also includes IVD tests recommended for use at higher levels of the health system. WHO recommendation to countries is that the IVD tests in the EDL are intended to be available in the context of functioning health systems and when developing or updating a national EDL other national essential lists should be considered, for example, the IVD tests in the national EDL could complement or correspond to the medicines listed in the national essential medicine lists (national EML).

There is a continuous effort from WHO to ensure that all the efforts are canalized and brought together to provide consistent guidance, one example is the Universal Health Coverage Compendium that includes health services and intersectoral interventions covering medicines, in vitro diagnostics, other medical devices and associated human resources. Additional information available here: https://www.who.int/universal-health-coverage/compendium

Furthermore, WHO has developed an approach to health planning called One Health approach which is a multi-dimensional approach that involves stakeholders from multiple sectors and recognize that the health of humans, domestic and wild animals, plants, and the wider environment (including ecosystems) are closely linked and interdependent. Additional information available here: https://www.who.int/health-topics/one-health#tab=tab_1

How do you bundle the different diagnostic tests when addressing different diseases for which you may need multiple tests?

Different conditions or diseases will require different IVD tests. The EDL list individual IVD tests with the aim to provide greater clarity regarding the recommendations provided, mainly the test purpose, assay format, specimen type, and available prequalified products as well as other WHO supporting documents. However, the EDL does list groups of tests that are recommended for specific diseases for non-laboratory settings and for laboratory settings, the EDL 3 covers 24 different diseases, and the scope of diseases may increase for the EDL 4. Of course, the implementation process is more complex at country level and other factors should be considered when planning to bundle different tests to address local health priorities.

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Is there a plan to include in the EDL a nomenclature system?

In the short term the EDL won't include a nomenclature system, however, the nomenclature for medical devices includes the nomenclature for in vitro diagnostics and WHO is working towards a globally accessible, transparent, and harmonized nomenclature system. Currently only MEDEVIS includes some nomenclature codes. Nomenclature mapping will start in 2023 and the IVDs are one of the topics that will be seen in the mapping exercise, and we are working with four nomenclature agencies (EMDN GMDN, UMDNS, UNSPSC). More information available here: https://www.who.int/teams/health-product-policy-and-standards/assistive-and-medical-technology/medical-devices/nomenclature

How is the EDL implementation happening in the PAHO region and what are the anticipated timelines?

I would say that we will start on 2023 once we have the translations (Spanish and Portuguese) of the guidance document on how to use the EDL to develop and update a national EDL and we will start by organizing a second webinar to increase the EDL awareness in the region.

What are the eligibility criteria and the process to apply for the PAHO capacity building program?

The PAHO capacity building program is open for regulatory authorities and for anyone nominated by the authority. PAHO shares the announcement of the program with country offices and then they obtain the nominations from the health authorities. In addition to the program, PAHO also offers webinars on this topic that are open for everyone.

Could you share your ideas about how countries could switch from a hospital-based approach to a primary health care or community-based approach when thinking in the planning of their national EDL or when updating their national EDL?

I think that one thing to think about for the EDL is that this is not about what can we do with resources available, but this is a human rights question that's being answered, it's what is essential for care, regardless of what resources we have, it is according to the disease burden in the country and the hard work after writing an EDL and publishing it is implementing it. And that really gets to what you are asking, how do you determine what test will be available, at which facility level, and with all the focus and hard work that needs to happen at the hospital level, how do we bring in the primary care level? And I think you need to go to the human rights issue, and to the commitment of Member States that have recognized that if you do not adjust primary care it is going to bite you in years to come, because all of the NCDs and all the other diseases burden, if you don't address it at primary health care level it's going to be overwhelming from a human cost standpoint but also the economics. So, I think that Ministries of Health in making these decisions have to take all that into consideration. Primary health care and facilities without labs cannot be ignored. And so, even if you start small and say, ok, you've got to have haemoglobin available, you've got to have blood glucose, you have to get HIV testing and

syphilis testing available in the non-lab settings. I mean, you know, to me there are no question you have to include those.

How can we bring uniformity across the theme of regulatory requirements?

WHO formulates recommendations but it is not a regulatory agency, however, WHO works with regulators to improve and to optimize decision making, and to pursue the global standards. EDL is a global standard and hence it could be considered as the level of which all the countries should pursue to deliver population health benefits. WHO advice regulators with the aim to harmonize decision making towards high value and population health benefits but cannot make regulatory decisions.

When transferring diagnostic test to the community how can we ensure the quality assurance?

Patient safety and quality assurance is health care delivery a high priority for WHO in general. For clinical laboratory services is a key feature. The quality and safety of the IVD tests should be considered from the moment of selection and procurement and should continue through all the phases of the laboratory process. Quality assurance is without doubt an important component of IVD testing implementation at both laboratory and non-laboratory settings.

For IVD tests that are recommended for use in the community, a good way to ensure the quality is that the personnel running the test (being health personal or lay users) have completed the training regarding the appropriate sampling process, the actual testing, and the interpretation of the results. These personnel should be able to demonstrate their correct understanding of the testing process for the IVD test that they will be working with prior going out to the community.

Assuring the quality of laboratory testing is a big responsibility at country level, particularly for the lab manager or the medical director, and WHO has several resources on this topic, including trainings and publications available for laboratory professionals in charge of quality assurance, these resources are available here: https://www.who.int/activities/strengthening-public-health-laboratory-services