Diagnostics Webinar Q&A: Questions answered online

Note: names of those asking the questions are not given here, since we didn't explicitly get permission. However, panelists are named in the responses. Responses have been edited slightly for grammar but not content.

Q: I wonder if FIND is also interested in including diagnostic imagine in its analysis and proposals?

A: **Willo Brock**: Yes, we organized a meeting with our scientific advisory committee last year to develop a plan and strategy, and have started on for instance TB imaging. It is dependent of course on a wider governance sign off and funding, but WHO has just presented diagnostics across the scope.

Q: (for Dr. Fleming): Why did the committee developing the SDG's not consider diagnostics? And on the Malawi example (see slide) is the HIV siloed approach a contributor to the deprioritisation of diagnostics?

A: **Ken Fleming**: The SDGs not addressing diagnostics is just an illustration of the invisibility of diagnostics. On the silo issue, this certainly does impact on prioritisation as it allows people to say that the issues are being tackled. It also tends to siphon off staff and resources away from broader diagnostic needs.

Q: May I have access to the tools presented on slide #23?

A: **Adriana Velazquez**: https://www.who.int/health-topics/in-vitro-diagnostics#tab#tab_1

Q: for Dr. Brock, given that Dr. Fleming mentioned that "Without diagnostics, Medicine is blind", do we see the UHC as the holy grail that will resolve this issue? Current UHC modalities still require "out of pocket" payment for diagnosis of some disease. How will we address this issue?

A: (not addressed due to time constraints). **Sue Horton**: UHC will help, if we apply the principle that diagnostics should be covered for those conditions for which treatment is covered under UHC. Of course, this doesn't eliminate out-of-pocket costs by patients who need to travel for diagnosis, etc.

Q: for Dr. Brock: the lack of a gendered approach to access to diagnostics is worrisome, given that women are the ones who present at HCFs. What about children, for instance point-of-care early infant diagnosis? There is a case to be made, given the increasing numbers of babies born who are HIV+?

A: **Willo Brock**: Certainly, specific attention for pediatric tools is essential too and we see also for instance proper TB tools for children are a priority. And to be clear: FIND does work strongly to ensure all aspects that may influence equitable and high quality diagnostic tools. We do however want broad recognition for these issues and the resolution could be a great tool. Adriana Velazquez: In the draft resolution, per Member States comments, as of 13 January includes considering age to ensure children are considered.

Q: TO our WHO colleagues, what about multiplex diagnostic tools? Will we consider these? Given the expensive nature of these tools, lack of support from international partners, including IP barriers and lack of tech transfer, we are concerned that these will not be something that comes to fruition before 2030. Do we hope that this resolution will address the issues?

A: **Willo Brock**: Maybe not the resolution directly, but the work by FIND and many partners including WHO will see the introduction of multiplex tools as well as the development and expansion of "menus of tests" for these tools as a key part of workplans from 2023-2026.

Q: Which member states (MS) currently support the resolution?

A: **Sue Horton**: this information is not public. But there have been over 50 participants in each session, not necessarily the same MS each time. There is broad support, but MS are working to fine-tune the language.

Q: To Philo Simelane: what role will local production play in the resolution? And/or what's the current discussion or position of the African group on local production of diagnostics?

A: **Willo Brock**: Please also note that India is kicking off the G20 this week with a strong focus on supporting the expansion of local production of diagnostics. **Adriana Velazquez**: Local production is one of the topics being discussed by MS.

Q: WHO recommended Gene Xpert as the first point of TB modlecular diagnostics but Cepheid has not brough the price of cartridges to $5, making it inaccessible for LIC. How can the stalemate be broken?

A: Willo Brock: part of the answer is creating "competition". We have seen in Covid-19 that having multiple companies with equal quality tools leads to quick reduction of prices. We see this in TB playing out from some new platforms and will continue to purse this approach to "force" prices down to affordable levels.

Questions answered live (or not answered, due to time constraints)

Q: Expressed concern re change of wording between the 10th November and 25th November drafts of the resolution and mention of involvement of civil society and the appointment of a WHO focal point on diagnostics; important given WHO's intention to create a WHO CSO Commission in 2023.

A: This question was not answered – most participants in the webinar did not have access to the draft text, which is restricted mainly to MS at present.

Q: For WHO again, we need enabling regulatory environments and we currently have weak EDLs at country levels. Does WHO support countries across the value chain?

Q: For WHO colleagues, in the case of local production, what are we going to do to support countries with quality assurance, given how expensive WHO PQ (prequalification) is for local manufacturers?

Q: May I ask how will WHO or FIND plan to work with the private sector to speed up innovation of diagnostics? Are there any work plans in 2023?

Q: Will the resolution be explicit on the role of WHO to support the development of products in different regions so as to support local research and production? How will produce price issues be addressed (we know some products are still very expensive (service and maintenance). If not, this could be a huge burden for countries.

Q: Excellent topics and initiatives! It is also important to consider new testing environments (that depending on the country also need regulation for places like pharmacies or clinics to undertake

screening. This would be important to consider in order to integrate all diagnostic systems and structures.

Q: Another point to consider is that diagnostics is a very important leveraging tool in: a) economics b) education and c) access. So whatever incentives countries can give, will lead to large benefits.

Q: A few questions to all speakers: will the Resolution address the issue of “cost of goods” as these should be global public goods? Secondly are there lessons from the mRNA hubs that we have in some African countries. Last, the production capacity of Dx in Senegal and Morocco mentioned by Ambassador Aboualatta is a game changer. Does the Ambassador see the African Continental Free Trade Agreement and the African Medicines Agency playing a role in the Resolution and future discussions?

Q: Does the resolution address priorities in R&D because right now there is much focus on the next pandemic, yet we are not done with the current one in terms of access to innovative tools.

Q: While regional manufacturing has been discussed, a critical element is how MS are considering building capacity to support this effort, including training and education for a broad range of expertise that today is limited on the continent.

Q: I am particularly interested in regulatory harmonization. Would regional harmonization schemes like IMDRF/GHWP be helpful to speed up access to diagnostics, particularly in APAC region, with not only demand but also strong suppliers?