Industry Perspectives on the WHO Essential Diagnostics List

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Access to diagnostics is a key component of universal health coverage (UHC). However, healthcare systems in low- and middle-income countries (LMICs) have given little importance to diagnostics and laboratories.\textsuperscript{1,2} Disease management in such countries largely relies on empirical therapy and syndromic management. This poses challenges for tackling problems such as antimicrobial resistance, outbreaks, and non-communicable diseases.\textsuperscript{1,2}

This year, the World Health Organization (WHO) took the unprecedented step of releasing the first Essential In Vitro Diagnostics List (EDL)\textsuperscript{3}, highlighting the key role of diagnostics within UHC.\textsuperscript{4} The EDL includes 113 diagnostic tests. Of these, 58 are basic tests (e.g. hemoglobin, blood-cell counts, urine dipstick) for managing a wide range of conditions. The list also includes 55 tests for priority infections, such as tuberculosis, HIV, malaria, hepatitis, HPV, and syphilis.

The global in vitro diagnostics (IVD) industry is plays a pivotal role in developing and supplying quality-assured diagnostic tests. Industry perspectives on the WHO EDL have not been formally assessed. We conducted a short anonymous online survey to solicit industry opinions on the potential strengths and shortcomings of the EDL. Names of respondents and companies were not recorded and personal details were not sought.

Data were collected from 18 participants who attended the McGill Summer Institute in Infectious Diseases and Global Health (held in June 2018) and 12 responses were collected via email snow-balling. Therefore, 30 industry representatives out of the total 36 approached, responded to the questionnaire in their personal capacity. Representatives were affiliated with 19 companies of which 58\% (11/19) were multinational companies and 84\% (16/19) were manufacturers of IVDs. Among the companies represented by the survey participants, 63\% (19/30) had their products already listed in the EDL. Lastly, 90\% (27/30) of the survey participants had executive roles in either administration, marketing, or research and development.

As shown in Figure 1, 93\% (28/30) of the participants knew about the EDL and saw benefits to the diagnostics field. Also, 63\% (19/30) believed that the EDL served as a useful compendium and prioritized diagnostics in the healthcare system. The “EDL heightens the profile of diagnostics and [...] brings it to the forefront,” one respondent commented.

Seventy-seven percent (23/30) of the participants believed that EDL will improve access to diagnostics and 80\% (24/30) agreed that the EDL could help the diagnostics industry by identifying priority conditions for which tests need to be developed. Drawing parallels with the WHO Essential Medicines list (EML), one participant suggested that the EDL “will benefit [LMIC] governments, just as the EML has.”

Respondents also commented on benefits such as awareness of where tests are needed in the tiered health system, use of EDL as a quality metric and for standardization of test methodologies. “We do not have insight on [the levels where testing occurs]. Having a reference on what tests should/need to be available for each tier helps us know what the priorities are for the diagnostics,” commented one
respondent. Other participants commented that the EDL is “a quality metric, it gives people the confidence of the quality of tests” and “will help in bringing in some standardization in the testing methodology and eventually help in uniform accreditations across countries.”

Even though most of the participants welcomed the EDL and saw many benefits, 53% (16/30) had concerns that introduction of the EDL might have some negative consequences. Price capping was a major concern that 40% (12/30) of the participants raised. “If EDL becomes a mechanism to put pressure on pricing or local manufacturing, then it can serve as a disincentive,” one participant remarked.

Twenty percent (6/30) expressed concerns that if the EDL is not updated regularly, it will not be able to incorporate the latest technologies, thus limiting innovation. The EDL should be a “living” document, according to one survey participant. Interestingly, 83% (25/30) respondents believed that omitting specific company or brand names from the EDL was a good strategy.

The tests listed in the EDL are supported by WHO guidelines or included in the WHO Prequalification program for IVDs, when applicable. One participant commented that it takes “money to get WHO approval.” WHO endorsement or prequalification is difficult to attain for smaller companies, whose products may be ultimately excluded from the EDL. Another potential concern was that some countries “might be reticent to adopt new technologies so the barriers to enter the market may be higher” for newer companies or products.

Although our survey did not cover all IVD companies, the data suggest that the industry largely welcomes the WHO EDL initiative and agrees that it will help improve access to diagnostics in LMICs. WHO can use our findings to address some of the concerns raised. To address the need for frequent updates, WHO has already published a call for applications for the second edition of the EDL that will be released in 2019. While WHO EDL does not include any recommendations on pricing, it will be up to LMICs on how they adapt and implement the EDL to ensure access. Industry concerns about price controls will need to be balanced by the need for LMICs to make tests affordable and accessible.
Conflicts of interest

PS and MK have no conflicts to disclose. MP serves on the WHO SAGE IVD Group that oversees the Essential Diagnostics List. He is a member of the Scientific Advisory Committee of Foundation for Innovative New Diagnostics (FIND). He has no industry or financial conflicts.

Acknowledgements

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<th>Statement</th>
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<th>No</th>
<th>Not Sure</th>
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<td>Knew about the WHO EDL</td>
<td>93%</td>
<td></td>
<td>7%</td>
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<tr>
<td>WHO EDL is beneficial</td>
<td>93%</td>
<td></td>
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<td>WHO EDL will make diagnostics more accessible</td>
<td>77%</td>
<td>23%</td>
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<td>Company products are already listed in the EDL</td>
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<td>Company products could be included in future EDL editions</td>
<td>97%</td>
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<td>3%</td>
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<td>WHO can identify conditions for which tests are needed</td>
<td>80%</td>
<td>20%</td>
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<td>WHO EDL brings forth negative consequences</td>
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<td>Concerns about EDL resulting in price controls</td>
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<tr>
<td>Not listing brand names is favourable</td>
<td>83%</td>
<td>17%</td>
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Figure Legend:

Figure 1. Responses of industry representatives to the WHO Essential Diagnostics List online questionnaire (n = 30).

*Not Sure: Not all questions had this option.