



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, health care systems in low- and middle-income countries (LMICs) have given little importance to diagnostics and laboratories (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 noncommunicable diseases (1, 2).

This year, the World Health Organization (WHO) took the unprecedented step of releasing the first essential *in vitro* diagnostics (IVD) list (EDL) (3), highlighting the key role of diagnostics within UHC (4). The EDL includes 113 diagnostic tests. Of these, 58 are basic tests (e.g., hemoglobin, blood cell counts, and urine dipstick) for managing a wide range of conditions. The list also includes 55 tests for priority infections, such as tuberculosis, HIV, malaria, hepatitis, human papillomavirus, and syphilis.

The global IVD industry plays a pivotal role in developing and supplying quality-ensured 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 snowballing. Therefore, 30 industry representatives, of the total 36 approached, responded to the questionnaire in their personal capacity. Representatives were affiliated with 19 companies, of which 58% (11/19 companies) were multinational companies and 84% (16/19 companies) were manufacturers of IVDs. Among the companies represented by the survey participants, 63% (19/30 participants) had their products already listed in the EDL. Lastly, 90% of the survey participants (27/30 participants) had executive roles in either administration, marketing, or research and development.

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

Seventy-seven percent of the participants (23/30 participants) thought that the EDL will improve access to diagnostics, and 80% (24/30 participants) 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 and the use of the 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

Citation Sen P, Kohli M, Pai M. 2019. Industry perspectives on the WHO essential diagnostics list. *J Clin Microbiol* 57:e01637-18. <https://doi.org/10.1128/JCM.01637-18>.

Editor Alexander J. McAdam, Boston Children's Hospital

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Accepted manuscript posted online 5 December 2018

Published 18 January 2019

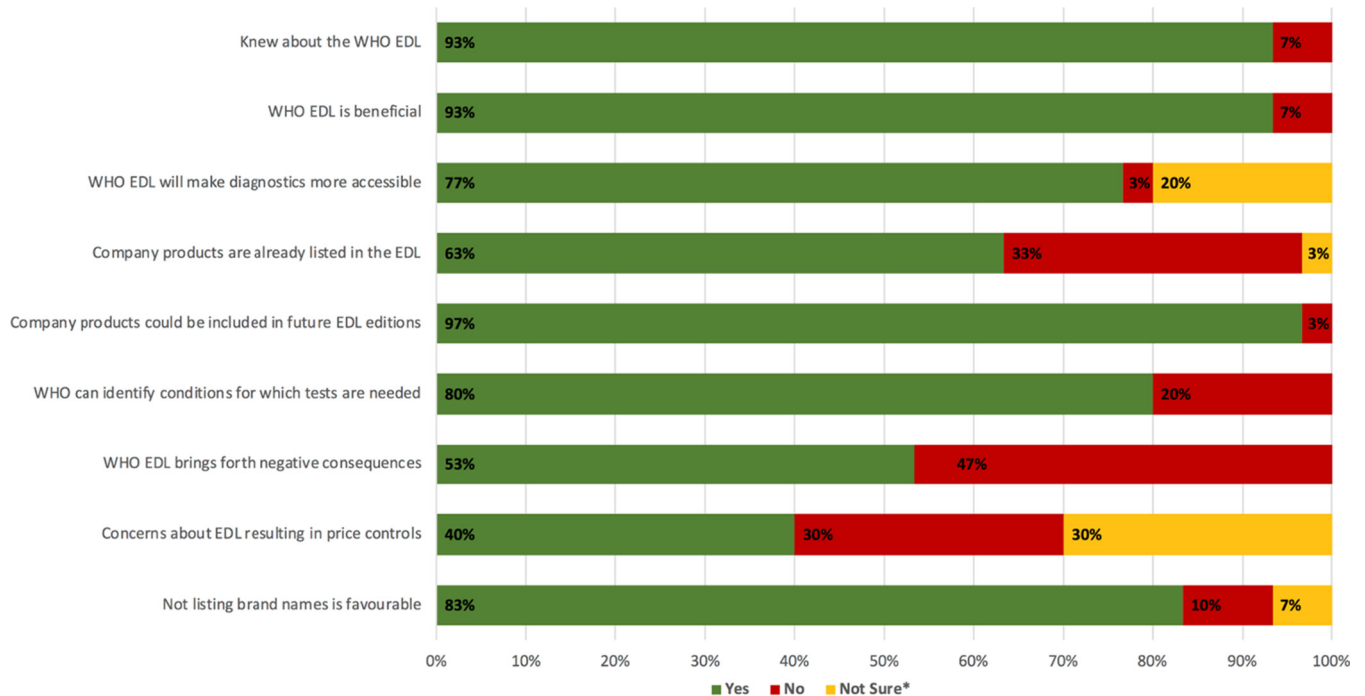


FIG 1 Responses of industry representatives to the WHO EDL online questionnaire ($n = 30$). *, not all questions had the option of “not sure.”

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 participants) had concerns that introduction of the EDL might have some negative consequences. Price capping was a major concern that 40% of the participants (12/30 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 participants) expressed concerns that, if the EDL is not updated regularly, then it will not be able to incorporate the latest technologies, thus limiting innovation. The EDL should be a “‘living’ [document] and updated as much as possible,” according to one survey participant. Interestingly, 83% of respondents (25/30 participants) thought that omitting specific company and 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 might ultimately be 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. The WHO can use our findings to address some of the concerns raised. To address the need for frequent updates, the WHO has already published a call for applications for the second edition of the EDL, which will be released in 2019. While the WHO EDL does not include any recommendations on pricing, it will be up to LMICs 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.

ACKNOWLEDGMENTS

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

P.S. and M.K. have no conflicts to disclose. M.P. serves on the WHO Strategic Advisory Group of Experts on IVD, which oversees the EDL. He is a member of the Scientific Advisory Committee of the Foundation for Innovative New Diagnostics. He has no industry or financial conflicts.

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