

## Global Health Advocacy Coalition Calls for WHO to Develop Essential Diagnostics List

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NEW YORK (360Dx) – The Global Health Technologies Coalition, an advocacy organization focusing on global health R&D for new tools and technologies, has joined other healthcare groups and professionals in requesting that the World Health Organization establish an essential diagnostics list that would provide guidance about vital tests in low- and middle-income countries.

Doctors and healthcare workers in these nations frequently don't have access to the tools they need to properly diagnose patients, GHTC said.

The essential diagnostics list would identify the most relevant diagnostics tools by disease area, and nations would then decide which tools they need based on the disease burden of that country, Matthew Robinson, policy and advocacy officer for GHTC, told 360Dx.

Importantly, the diagnostics tools list would also identify gaps in capabilities and could stimulate research and development into diagnostic tools that could in the future mitigate some of the unmet needs of those countries' healthcare programs, GHTC said.

"We have not seen a shred of resistance in our advocacy for the essential diagnostics list," Robinson said. "It's supported by the global health R&D community and our membership."

In November, Marie-Paule Kieny, the WHO's assistant director-general for health systems and innovation, replied to a letter from GHTC requesting that the world health entity lead the development and implementation of an essential diagnostics list. WHO said in response to the letter that it was "pursuing analysis of the idea and outlining next steps," and GHTC said that it "will continue to monitor progress and engage with WHO in support of this initiative."

In its letter, GHTC — a coalition of 27 nonprofit organizations advancing policies to accelerate the creation of new health technologies — commended the WHO's work in creating the Model Lists of Essential Medicines, which provides guidance to healthcare workers about the types of drugs, therapies, and treatments that meet basic public health needs and that should be made available to citizens. GHTC, which is funded by the Bill and Melinda Gates Foundation, said that a Model List of Essential Diagnostics would "provide a vital tool to help increase access to the diagnostic tests necessary to maximize the use of limited health resources and improve health outcomes."

Robinson said that WHO is determining how to implement an essential diagnostics list and who would staff it. "Our position is that there should be a diagnostics list, and we trust that the WHO will figure out the mechanics of how to create and support it," Robinson added.

He pointed to neonatal sepsis as one disease area that would benefit from an essential diagnostics list. Neonatal sepsis is frequently misdiagnosed in sub-Saharan Africa for neonatal malaria based on symptoms because healthcare practitioners don't have access to rapid tests that would help them differentiate between the two conditions.

"Antimalarial therapies are ineffective against bacterial sepsis," Robinson said. "Both antimalarial and antibacterial therapies are on the essential medicines list, but the condition can't be diagnosed correctly because of the lack of a diagnostic."

GHTC's letter to WHO stated that "Improved diagnostic capacity, such as point-of-care tests, could enable earlier identification of disease outbreaks, saving the lives and costs associated with epidemics. In the fight against antimicrobial resistance, rapid diagnostics are needed to specify treatment, and improved antibiotic susceptibility testing would enable treatment to be better targeted to the patient's specific infection, as well as to ensure appropriate regimen use."

Robinson said that GHTC is open to whether the technology on an essential diagnostic list is molecular or employs other types of technology, as any tests included on the list would identify gaps in diagnostic tools development and make the case for investments into R&D.

"This really is both disease and technology agnostic," he said.

The essential diagnostics list would be separate from the essential medicines list, Robinson said. However, the diagnostics list would begin with companion diagnostics to treatments on the essential medicines list. Whether the diagnostics list would expand beyond that would be decided later. WHO's Expert Committee on the Selection and Use of Medicines, which determines the essential medicines list, is working on identifying diagnostics that would complement the medicines on the essential medicines list, Robinson added.

GHTC's work to request an essential diagnostics list was spurred by a series of articles and papers, including a [paper in the \*New England Journal of Medicine\*](#) written by Lee Schroeder, director of point-of-care testing at the University of Michigan School of Medicine, and others.

The paper describes several tests that are required for use of medicines on the WHO Model List of Essential Medicines, including tests based on nucleic acid, blood count, lipid panels, electrolytes, liver enzymes, and antigens, among many others.

The authors noted that improved access to diagnostics has been shown to quadruple the number of detected HIV cases and double the rate of glycemic control. Meanwhile, the overtreatment of malaria was reduced by 73 percent.

"That paper laid out what we think is a very smart and cost-effective idea that could improve access to existing diagnostics tools and highlight where there are gaps in current technologies," Robinson said. "And that could then provide the business case or donor funding case to help fill those gaps.

"When you can effectively articulate in a scientifically sound and globally respected fashion where there are gaps in current technologies, it makes it easier to argue the business case because there will likely be a market there once you've gone through the research pipeline," Robinson said.

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