

Suzanne Hill
Director, Essential Medicines and Health Products Department
World Health Organization
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24 October 2016

Open letter re: Urgent need for an Essential Diagnostics List

Dear Dr. Hill,

We greatly appreciate the continued work of the Essential Medicines and Health Products Department of the World Health Organization (WHO) in establishing and maintaining updated Model Lists of Essential Medicines (EMLs). A similar list for diagnostics would be extremely helpful, as a recent *New England Journal of Medicine* article suggests.¹ **We echo this suggestion and respectfully request the WHO's leadership in establishing a Model List of Essential Diagnostics (EDL).**

The WHO EMLs have been fundamental in guiding countries on the appropriate medicines to include in national guidelines and procurement. An EDL would do the same for diagnostic tests, which are crucial for management of all forms of diseases (communicable and non-communicable), surveillance of emerging infections and management of public health. An EDL would complement the EMLs, as accurate diagnosis is critical to linking patients to appropriate treatment. Countries can then tailor the list to align with their burden of disease as many already do with the EMLs. An EDL could also facilitate pooled purchasing, which has the potential to lead to cost reductions and to enable access to laboratory testing, especially in low- and middle-income countries. An EDL would further help policy makers to better prioritize their countries' laboratory testing and infrastructure needs, leading to improved health care delivery and better patient outcomes.²

Moreover, these lists provide other interested stakeholders a powerful tool to advocate for availability of recommended medical products, so as to best maximize health resources. For example, an EDL would allow advocates to hold country governments accountable for providing access to recommended TB diagnostic tools, the very same way the EML does. Yet no equivalent resource currently exists for diagnostics. As advocates for access to evidence-based, quality diagnosis and treatment for tuberculosis (TB) and other diseases, we are particularly eager for the establishment of an EDL. There have been several instances where countries continue to allow the marketing and use of inappropriate diagnostic tests for TB and other diseases, which are at best ineffective and costly, and at worst detrimental to the patient and ultimately the public health system. Simultaneously, many settings are failing to implement some of the best new diagnostic tools.

¹ Schroeder LF, Guarner J, Elbireer A, Castle PE, Amukele TK. Time for a Model List of Essential Diagnostics. *N Engl J Med*. 2016 Jun 30;374(26):2511-4. doi: 10.1056/NEJMp1602825.

² Ibid.

Since the WHO already hosts the EML, develops guidance on diagnostic tests and laboratory accreditation schemes for low income countries,³ we believe that it is extremely well-positioned to lead on the development of an EDL. We therefore urge the WHO and partners to hasten the establishment of an EDL. The world should not continue with existing mediocrity in implementing potentially life- and cost-saving diagnostic tools. A WHO EDL would efficiently and proactively communicate to country governments the diagnostic tests that are worthy and indeed essential for approval and use.

We appreciate your consideration of this request and would like to set up a time to schedule a teleconference to discuss further. We look forward to what we hope will be a favorable response by 7 November 2016. Kindly direct your response to Wim Vandavelde at wim@eatg.org.

Thank you,

Organizational endorsements

ACTION Global Health Advocacy Partnership

AVAC

Foundation for Innovative New Diagnostics (FIND)

Global Coalition of TB Activists (GCTA)

Global Health Strategies (GHS)

Global Tuberculosis Community Advisory Board (TB CAB)

Infectious Diseases Society of America (IDSA)

The Latin American Alliance for the Development of In Vitro Diagnostics (ALADDiV)

McGill Global Health Programs & McGill International TB Centre

RESULTS International (Australia) Inc.

Socios en Salud Sucursal Perú (SES)

Stop TB Partnership (STBP)

TB Proof

Treatment Action Group (TAG)

University of Michigan Medical School Global Reach Program

UPMC Center for Health Security

Individual endorsements

(Institution listed for affiliation purpose only)

Lee Schroeder, University of Michigan Medical School, USA

Madhukar Pai, McGill University, Canada

³ Ibid.