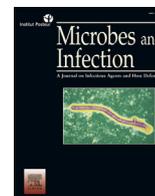




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## Editorial

# Improving access to essential tests for infectious diseases



### A B S T R A C T

Recently, WHO published the first ever Essential Diagnostics List (EDL), which includes 113 tests, including tests for HIV, TB, malaria, hepatitis B and C, human papillomavirus (HPV) and syphilis. The EDL is a welcome first step in ensuring that diagnostics are a key part of all health systems. The impact of the list, however, will depend greatly on how countries adopt and implement the EDL.

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Despite the ongoing, rapid epidemiological transition in many low and middle-income countries (LMICs), infectious diseases continue to account for substantial morbidity and mortality, as shown by the Global Burden of Disease project [1]. For example, 1.8 million people were newly infected with HIV in 2017 [2], and 1.7 million people died of tuberculosis in 2016 [3].

Recent outbreaks of Ebola, Zika, and influenza have underscored the threat posed by emerging and re-emerging infections [4]. To make matters worse, estimates suggest that by 2050, 10 million lives a year and a cumulative 100 trillion USD of economic output are at risk due to antimicrobial resistance [5].

Early and accurate diagnosis is the first critical step in the management of all infections and outbreaks. But diagnostics and laboratories have received little attention in LMICs for decades. The global health community has, by and large, settled on cheap rapid tests as the most viable solution for poor countries, and has failed to build strong, tiered, network of laboratories within healthcare delivery systems [6]. This has resulted in widespread use of empirical antibiotic therapies, growing concerns about antimicrobial resistance, and limited capacity to deal with outbreaks [7].

At long last, 40 years after publishing the first Essential Medicines List (EML), the World Health Organization (WHO), has taken a bold step to highlight the importance of essential diagnostics, as part of the push to achieve Universal Health Coverage (UHC) [8]. In May 2018, WHO published the first ever Essential Diagnostics List (EDL), a list of the tests needed to diagnose the most common conditions as well as several global priority diseases [9].

The first EDL includes 113 tests. Of these, 58 are basic tests (e.g. blood glucose, hemoglobin, blood cell counts) intended for a wide range of common infections and non-communicable diseases.

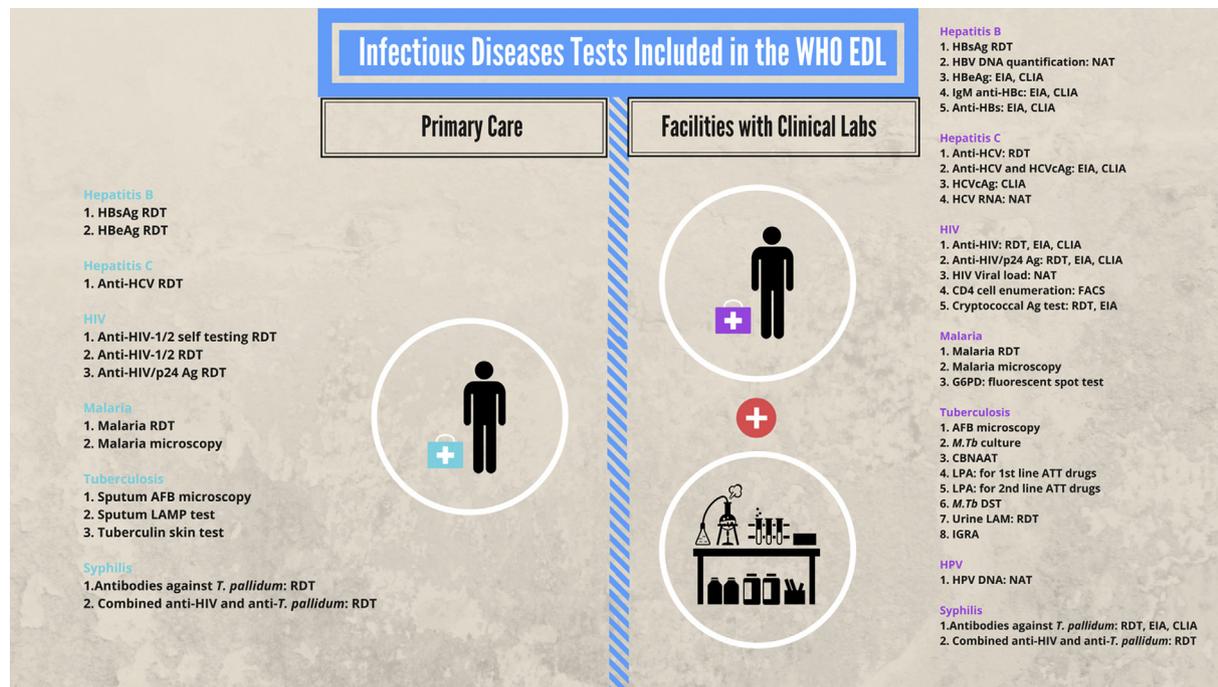
These basic lab tests form the basis for an essential package of tests at the level of primary care and higher. The remaining 55 tests are for the detection, diagnosis and monitoring of “priority” infections — namely HIV, TB, malaria, hepatitis B and C, human papillomavirus (HPV) and syphilis [9].

All tests included in the EDL are backed by existing WHO guidelines and manuals, or included in the WHO Prequalification program for in-vitro diagnostics. Tests in the EDL are grouped in two categories: tests at the level of primary health care (with no or basic laboratories), and tests intended for health care facilities with clinical laboratories. Fig. 1 shows all the tests in the first EDL that are focused on infectious diseases, stratified by level of healthcare. The WHO EDL itself provides additional information for each test included, such as test purpose, assay format, specimen type, facility level, link to the relevant WHO guidance, and link to WHO prequalified products, where relevant.

While several infectious diseases are covered in the first EDL, there are big needs that are yet to be addressed by the list. For example, sepsis, antimicrobial resistance, pneumonia, diarrheal diseases, and neglected tropical diseases are yet to make the list. Although tests for malaria are included in the EDL, there are many other causes of fever, and lack of good diagnostic capacity is a major reason for overuse of antimicrobials.

Thankfully, WHO will update the EDL on a regular basis, has already published a call for applications for the second edition of the EDL that will be released in 2019 [10]. All applications will be considered by the WHO Strategic Advisory Group of Experts on In Vitro Diagnostics (SAGE IVD). Applications can be made to add new categories of tests, to update the existing ones, or to remove tests or indications. While the call is open to all diseases areas, WHO has expressed a strong interest in receiving applications for categories of tests for antimicrobial resistance, neglected tropical diseases, noncommunicable diseases, outbreaks/emergencies as well as sepsis [10].

How can we make the most of the first EDL and improve access to important tests? The first big step would be for countries to adopt and adapt the WHO EDL and develop their own national EDLs. Only then can the EDL be implemented to increase access to tests.



**Fig. 1.** Infectious diseases tests included in the first edition of the WHO Essential Diagnostics List. Abbreviations: AFB- acid fast bacilli; ATT- anti-tuberculosis therapy; CBNAAT- cartridge-based nucleic acid amplification test; CLIA- chemiluminescence immunoassay; DST- drug susceptibility testing; EIA- enzyme immunoassay; FACS- fluorescence-activated cell sorting; G6PD- glucose 6 phosphate dehydrogenase; HIV- human immunodeficiency virus; HPV- human papillomavirus; IGRA- interferon gamma release assay; LAMP- loop-mediated isothermal amplification; LPA- line probe assay; M. Tb- *Mycobacterium tuberculosis*; NAT- nucleic acid amplification; RDT- rapid diagnostic test.

As reviewed elsewhere [7,11], there are several potential benefits for countries to develop and implement national EDLs. These include improving patient care, helping detect epidemics, increasing affordability of tests, reducing out-of-pocket expenses for laboratory testing, reducing antibiotic overuse, improving regulation and quality of diagnostic tests, strengthening accreditation and quality of laboratories, improving supply chain and guiding the R&D of new diagnostics.

Another key step would be for countries to go beyond simple rapid tests and invest in developing laboratory capacity [12]. It is time to reject the mindset that rapid tests and syndromic treatments are “enough for poor countries,” and work towards ensuring that all countries have a functional, tiered, quality-assured laboratory infrastructure [6]. This will require serious investments in laboratories, equipment, human resources, as well as quality assurance systems [12].

Although the EML has been around for over 40 years, access to essential medicines is still a challenge in many countries [8]. So, to make the most of the EDL, the global health community needs to learn from the lessons of EML implementation, shorten the learning curve, and achieve greater impact.

The fight against infectious diseases will require all countries to achieve UHC. UHC, in turn, requires essential diagnostics as well as essential medicines. The WHO EDL is a welcome first step in ensuring that diagnostics are a key part of all health systems. The impact of the EDL will depend greatly on how LMICs adopt the list and implement them for maximum impact.

### Conflicts of interest

MK and PS have no conflicts to disclose. MP served on the WHO SAGE IVD Group that drafted 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.

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