Editorial

Giuseppe Lippi, Mario Plebani and Emmanuel J. Favaloro

The Model List of Essential In Vitro Diagnostics: nuisance or opportunity?

<https://doi.org/10.1515/dx-2018-0035>

The World Health Organization (WHO) has recently published its Model List of Essential In Vitro Diagnostics [1]. The listed tests encompass a minimum set of in vitro diagnostic (IVD) tests that should be made available in primary health care settings, hospitals and reference laboratories, with the aim of ensuring access to good quality, affordable and appropriate routine patient care worldwide.

Although all would probably agree that this WHO endorsed initiative can be seen as an important step forward for guiding governments in the indispensable processes of developing or updating national inventories of essential diagnostic tests and medical devices, we feel that there are some critical considerations.

Before discussing the sense and widespread applicability of the WHO List of Essential In Vitro Diagnostics, a necessary premise should be made. Albeit not easily quantifiable, due to the many factors involved, it is now unquestionable that laboratory diagnostics provides a vital contribution to most clinical decision-making. For certain diseases, such as non-ST elevation myocardial infarction (NSTEMI) [2] or bleeding disorders [3] for example, the impact of laboratory tests on the diagnosis and managed care of these conditions is suggested to be even higher than the standard “70% claim” [4] as clinical history, physical examination and other non-IVD tests do not allow a final etiological diagnosis to be reached nor can they reliably drive clinical management. Interestingly, this clear-cut concept is not actually mirrored by the global cost of IVD testing, inasmuch as the total expenditure for diagnostic testing usually comprises between 1.2 and 2.4% of the total healthcare costs in many countries around the world [5, 6], and thus is moderate compared to other expenditures. Therefore, we would argue that the added value of diagnostic testing is perceivably much higher than its costs [7, 8], and efforts (reasonable or not) by governments or administrators to reduce laboratory expenditure would only have a modest impact on the overall budget of national healthcare systems and healthcare facilities, and be at risk of adverse medical care proportionally higher to any cost savings.

The WHO Model List of Essential In Vitro Diagnostics basically entails 58 general IVD tests which can be used for diagnosing several communicable and non-communicable diseases, along with 55 other tests used for detecting, diagnosing and monitoring infectious diseases such as hepatitis B (HBV) and C (HCV), human immunodeficiency virus (HIV), human papilloma virus (HPV), tuberculosis, malaria and syphilis. Some of the listed tests are duplicated, and although it is unclear if the tests are double counted, the list is almost a list of the ‘top 100’ (up to 113) tests according to the views of the formulating committees. From a genuine clinical perspective, however, this inventory is indeed incomplete. Some notable examples of essential laboratory tests lacking from the list include activated partial thromboplastin time (APTT), D-dimer, fibrinogen, lactate dehydrogenase (LDH), creatine kinase (CK), uric acid, as well as a vast array of indispensable immunochemistry tests such as fecal occult blood test (FOBT), prostate specific antigen (PSA), thyroid-stimulating hormone (TSH) (Table 1). These are only some of the most relevant examples, but many other important tests could be cited.

The so-called “pyramid of testing” proposed by the Strategic Advisory Group of the WHO, and encompassing the classification of laboratory services in four main categories (i.e. national reference laboratories, regional/provincial/specialized laboratories, district/hospital laboratories and primary care setting), is indeed commendable as it actually mirrors the modern organization of laboratory facilities according to the well-known “hub and spoke” paradigm [9]. Hitherto, the widespread implementation of this clear-cut concept necessitates a preliminary reorganization and networking of all clinical laboratories, a process which has not been completed, or it has not even commenced, in many countries around the globe. Finally, the list of essential IVD diagnostics will obviously depend on the model and level of healthcare delivered in individual countries. The capacity of resource-limited countries to deliver the same level of diagnostic testing as developed countries is questionable, although creating separate lists based on economics has ethical implications. However, as laboratory testing is an important part of the diagnostic and

Table 1: Some vital laboratory tests lacking from the World Health Organization (WHO) Model List of Essential In Vitro Diagnostics.

Test	Test purpose
Activated partial thromboplastin time (APTT)	Inherited and acquired bleeding disorders
Fibrinogen	Inherited and acquired bleeding disorders
D-dimer	Diagnostics of venous thromboembolism
Lactate dehydrogenase (LDH)	Cell injury, hemolysis
Creatine kinase (CK)	Muscular injuries
Uric acid	Hyperuricaemia
Fecal occult blood test (FOBT)	Screening of colorectal cancer
Prostate specific antigen (PSA)	Screening of prostate cancer
Thyroid-stimulating hormone (TSH)	Screening of thyroid disorders

therapeutic process, the term “essential” (referred to either country Medicine or Diagnostics Lists) is strictly related to the local organization of the healthcare systems in terms of number and quality of services provided, access to care and treatment pathways, public or private funding, refunding policies, epidemiology and local regulations for quality (i.e. certification or accreditation).

Although the WHO Model List of Essential In Vitro Diagnostics should hence be regarded as a valuable enterprise for some countries to strive toward, in particular those in which establishing an inventory of essential IVD tests remains problematic for a kaleidoscope of economic, organizational or technical factors, we fear that many policymakers in more advanced countries may use this Model List as an expedient for further reduction of available laboratory resources, by revising downward the current national inventories of allowable or refundable IVD tests. In other words, countries that are challenged to provide laboratory testing support should strive toward the list and beyond; however, countries that currently manage to undertake testing that currently exceeds this ‘minimal’ dataset should not use the list to dumb-down currently advanced diagnostics in developed countries.

Notably, the Strategic Advisory Group of the WHO has perceptively concluded the Executive Summary with a statement that the Model List will be significantly revised and expanded over the next few years, for addressing other prevalent or emerging health priorities [1]. Indeed, the request made by the WHO to the applicants for providing information on clinical accuracy or impact of the proposed list should be accomplished. It is hence advisable that both the international and national Federations

or Societies of Laboratory Medicine rather than the individual scientists should establish a prompt and effective communication with the WHO, supporting the Strategic Advisory Group with expert recommendations to finally make the Model List of Essential In Vitro Diagnostics an opportunity and not a nuisance.

Author contributions: All the authors have accepted responsibility for the entire content of this submitted manuscript and approved submission.

Research funding: None declared.

Employment or leadership: None declared.

Honorarium: None declared.

References

1. World Health Organization. World Health Organization Model List of Essential In Vitro Diagnostics, 1st ed. Geneva, Switzerland: World Health Organization, 2018.
2. Mueller C, Giannitsis E, Möckel M, Huber K, Mair J, Plebani M, et al. Rapid rule out of acute myocardial infarction: novel biomarker-based strategies. *Eur Heart J Acute Cardiovasc Care* 2017;6:218–22.
3. Lippi G, Favaloro EJ. Laboratory hemostasis: from biology to the bench. *Clin Chem Lab Med* 2018;56:1035–45.
4. Hallworth MJ. The ‘70% claim’: what is the evidence base? *Ann Clin Biochem* 2011;48:487–8.
5. Rohr UP, Binder C, Dieterle T, Giusti F, Messina CG, Toerien E, et al. The value of in vitro diagnostic testing in medical practice: a status report. *PLoS One* 2016;11:e0149856.
6. Lippi G, Plebani M. The add value of laboratory diagnostics: the many reasons why decision-makers should actually care. *J Lab Precis Med* 2017;2:100.
7. Plebani M. Clinical laboratory: bigger is not always better. *Diagnosis (Berl)* 2018;5:41–6.
8. Lippi G. Weighting healthcare efficiency against available resources: value is the goal. *Diagnosis (Berl)* 2018;5:39–40.
9. Lippi G, Bassi A, Bovo C. The future of laboratory medicine in the era of precision medicine. *J Lab Precis Med* 2016;1:7.

Corresponding author: Prof. Giuseppe Lippi, Section of Clinical Biochemistry, University Hospital of Verona, Piazzale LA Scuro, 37100 Verona, Italy, E-mail: giuseppe.lippi@univr.it. <https://orcid.org/0000-0001-9523-9054>

Mario Plebani: Department of Laboratory Medicine, University Hospital of Padova, Padova, Italy. <https://orcid.org/0000-0002-0270-1711>

Emmanuel J. Favaloro: Diagnostic Haemostasis Laboratory, Department of Haematology, Institute of Clinical Pathology and Medical Research (ICPMR), NSW Health Pathology, Westmead Hospital, Westmead, NSW, Australia