An Audit of the Infectious Disease Diagnostic Landscape of the University of Benin Teaching Hospital

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INTRODUCTION

The World Health Organisation (WHO) recently updated an Essential diagnostics list (EDL) first released in 2018 (WHO, 2019). Analogous to the Essential Medicines List, the EDL is a catalogue of tests required to diagnose the most common conditions as well as a number of global priority diseases such as Human Immunodeficiency Virus (HIV), malaria, tuberculosis and sexually transmitted infections. This list provides a benchmark against which diagnostic services can be measured and improved (Kohli et al., 2018)

The University of Benin Teaching Hospital (UBTH) has the vision of becoming a leader in providing quality healthcare solutions in West Africa (Obaseki et al., 2018). Infectious diseases remain a major cause of morbidity and mortality in the sub-region, and indeed the entire continent. Without access to in vitro diagnostics, health care providers cannot effectively diagnose infectious diseases and provide prompt, appropriate treatment. To realize this vision, tests deemed essential for the diagnosis of infectious diseases should be readily available in UBTH.

The objective of this study was to assess the available diagnostics for infectious diseases in UBTH against the WHO EDL for health facilities with clinical laboratories, identify the gaps and make appropriate recommendations.

MATERIALS AND METHODS

The EDL is presented in two tiers based on health care facility level namely (1) community and health settings without laboratories and (2) health care facilities with clinical laboratories (WHO, 2018). The latter is further presented in three sections namely: (a) general in vitro diagnostics (IVD) for clinical laboratories presented per disciplines including microbiology; (b) disease-specific IVDs for clinical laboratories and; (c) disease-specific in vitro diagnostics for blood screening laboratories.

Diagnostics useful for infectious diseases were identified from the WHO EDL for health care facilities with clinical laboratories. A scoring system was designed based on availability of concerned tests. Points were awarded based on availability of these diagnostics in the Department of Medical Microbiology main laboratory and other satellite laboratories in UBTH where infectious disease testing is conducted.

Each item in the general category was stratified and points were allotted based on currently recommended global best practice. For instance, with respect to blood culture, automated methods are recommended, manual method is less desirable, while total lack is least desirable; these categories were assigned points of 2, 1 and 0 respectively. The total score was expressed as a percentage of the maximum possible score. For disease specific categories, the number of diagnostics available in UBTH was expressed as a percentage of the total

number of tests in each disease category. Results for the various categories were presented as figures and charts.

RESULTS

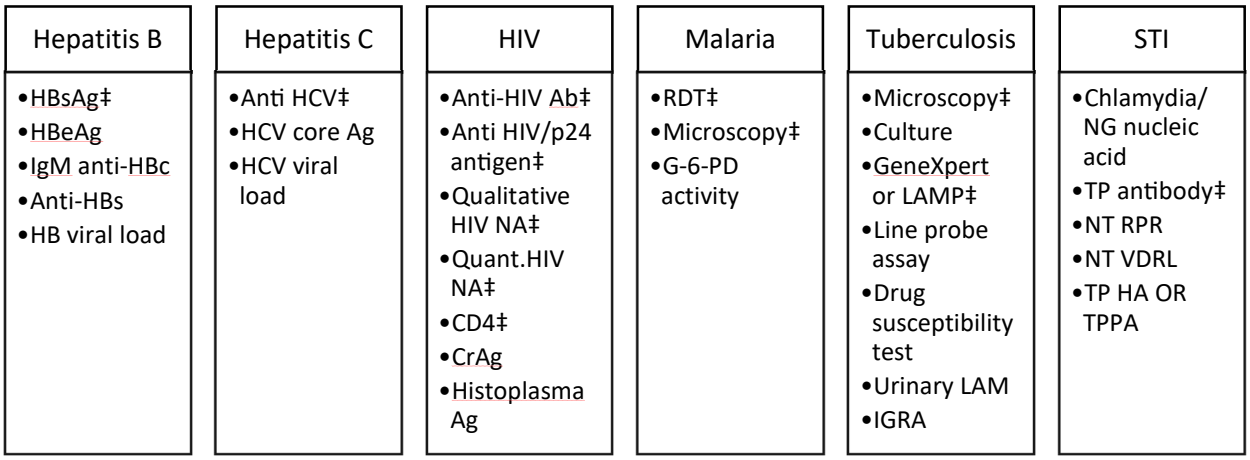
Of the maximum 14 points for general in-vitro diagnostics for infectious disease testing on the WHO EDL (Table 1), UBTH scored 10 (71.4%).

In the disease specific categories, availability of diagnostics was 71.0% for HIV, 66.6% for malaria, 20.0% for Hepatitis B, 33.3% for Hepatitis C, 28.6% for tuberculosis and 20.0% for STI (Figure1, Table 2). Diagnostics for Dengue fever and Zika virus were not available.

Table 1: Scoring model based on the General IVDs for clinical laboratories in the WHO EDL

Diagnostic test	Categories	Points	Maximum score	UBTH score
Urinalysis test strips	Available	1	1	1
	Not available	0		
Microscopy	Available	1	1	1
	Not available	0		
Culture	Bacteriological media and fungal media	2	2	2
	Bacteriological media only	1		
	No culture available	0		
Blood culture	Automated (BacTalert®, BACTEC® etc.)	2	2	2
	Manual	1		
	Not available	0		
Bacterial identification	MRSA determination+ GPC panel + GNB panel available	3	3	1
	GPC panel + GNB panel	2		
	GNB panel only	1		
	None available	0		
Fungal identification	Chromogenic medium or yeast identification panel	2	2	1
	Germ tube testing only	1		
	None available	0		
Antimicrobial sensitivity testing (AST)	AST available with interpretation using CLSI or EUCAST	2	2	2
	AST without interpretation	1		
	AST not available	0		
Procalcitonin	Available	1	1	0
	Not available	0		
Total			14	10

*MRSA= Methicillin Resistant *Staphylococcus aureus*, GPC= Gram positive cocci, GNB= Gram negative bacilli, CLSI= Clinical laboratory standards institute, EUCAST= European Union Committee on antimicrobial sensitivity testing



‡ Available in UBTH

Figure 1: Essential diagnostics in the Disease specific categories and availability in UBTH (Dengue virus and Zika virus categories not shown).

Table 2: Availability score of UBTH for the various disease specific in-vitro diagnostics

Category	No. of tests in category	No. available in UBTH	Score (%)
Hepatitis B[1]	5	1	20.0
Hepatitis C[2]	3	1	33.3
HIV[3]	7	5	71.0
Malaria[4]	3	2	66.6
Tuberculosis[5]	7	2	28.6
STI[6]	5	1	20.0
Dengue[7]	2	0	0.0
Zika[8]	2	0	0.0

1. Hepatitis B sAg, HBeAg, IgM anti-HBc, anti-HBs, HB viral load
2. Anti-HCV, HCV core antigen (HCVcAG), HCV viral load (qualitative or quantitative)
3. Anti-HIV Ab, Anti-HIV/p24 antigen, Qualitative HIV virological nucleic acid test, Quantitative HIV nucleic acid, CD_4 cell enumeration, Cryptococcal antigen, Histoplasma antigen
4. Malaria: Plasmodium spp antigens (species specific and pan-species specific), Microscopy, Glucose-6-phosphate dehydrogenase activity
5. Tuberculosis: Microscopy for *Mycobacterium tuberculosis*, Culture for *M.tuberculosis*, *M.tuberculosis* DNA (using GeneXpert OR loop-mediated isothermal amplification (LAMP)), *M.tuberculosis* DNA mutations associated with resistance using molecular line probe assays, Drug susceptibility testing with *M.tuberculosis* culture, Urinary lipoarabinomannan (LAM) antigen, Interferon-gamma release assay
6. Sexually transmitted infections: Qualitative nucleic acid test for *Chlamydia trachomatis* and *Neisseria gonorrheae* infections, antibodies to *Treponema pallidum*, Non-treponemal rapid plasma regain, Non-treponemal veneral disease research laboratory (VDRL), *T.pallidum* haemagglutination test OR *T.pallidum* particle agglutination test
7. Denguevirus: Qualitative dengue virus nucleic acid test, Dengue virus antibody (IgM), Dengue virus antigen (NS1)
8. Zika: Zika virus IgM antibodies, Zika virus nucleic acid test

DISCUSSION

Although general in vitro diagnostics for infectious diseases are largely available in UBTH, deficiencies in fungal identification and procalcitonin estimation present opportunities for improvement. With the emergence of drug resistant yeast species, identification and speciation is becoming increasingly important for appropriate patient management and surveillance purposes. Ample evidence supports using procalcitonin to guide antibiotic therapy in sepsis and lower respiratory tract infections (Jin *et al.*, 2010). Thus, it is desirable to have this test, especially in a tertiary care facility, to aid antibiotic stewardship (WHO, 2019).

HIV diagnostics are the most readily available disease specific diagnostics in UBTH. This is expected as UBTH is a designated treatment facility with donor agency funding. Nevertheless, deficiencies in testing for opportunistic infections in HIV/AIDS such as cryptococcosis exist and need to be addressed because they can result in mismanagement of this vulnerable population. Key gaps also exist for tuberculosis, the viral hepatitides and sexually transmitted infections as diagnostics required for adequate management and monitoring the progression of these conditions are not available. For instance, drug testing in tuberculosis and monitoring of hepatitis B and C viral loads cannot be conveniently achieved in UBTH.

Diagnostics for emerging viruses like Dengue virus are completely lacking. Studies have shown that dengue fever is often misdiagnosed as malaria. Despite dengue being endemic in Nigeria, the disease is not reportable and routine diagnosis is neglected countrywide (Ayukekbong, 2014). Provision of dengue diagnostics, would promote the rational use of anti-malaria agents.

CONCLUSION

Key gaps have been identified in the essential infectious disease diagnostics landscape of UBTH with regards to fungal diagnosis, disease management of viral hepatitides and tuberculosis, amongst others. These deficiencies need to be addressed if UBTH is to attain her vision of being a leader in healthcare in the West African sub-region.

RECOMMENDATIONS

1. Clinicians, laboratory staff and other stakeholders should deliberate on the cost-effectiveness of introducing non-available tests to the test menu.
2. Public-private partnerships can be exploited to bridge existing gaps in infectious disease testing.
3. Ultimately, it is desirable that the federal government and the federal ministry of health identify with, and implement the WHO EDL. Setting priorities is necessary to adapt the list to meet the specific needs of the country as has been done in India. National laboratory networks also need to be strengthened.
4. To remain relevant, this assessment scheme must be as dynamic as the essential diagnostics list which is expected to be updated yearly. If and when a national EDL is drawn, such a list would be the preferred benchmark.

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Conflict of interest

The authors declare that they have no conflicts of interest.

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