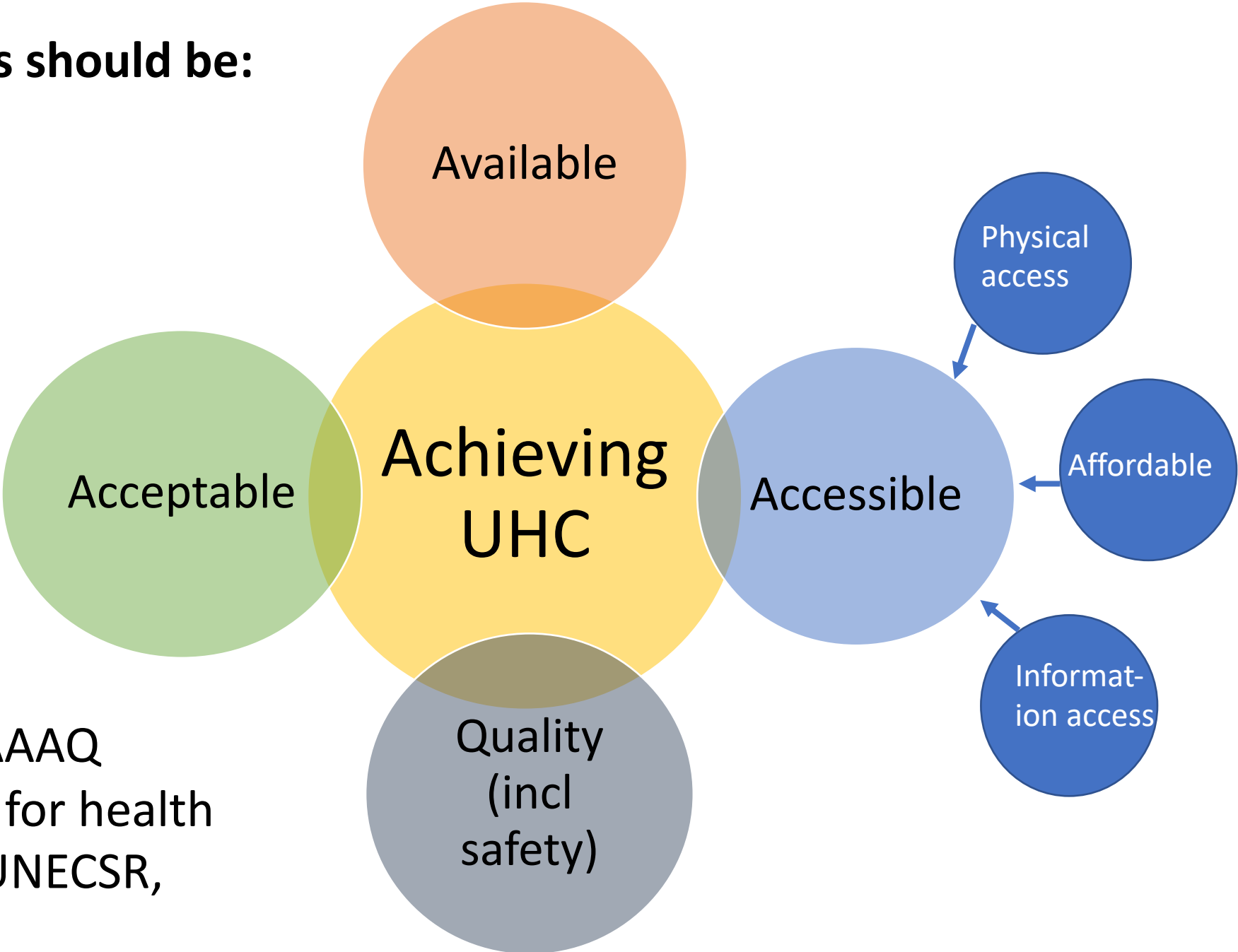


THE LANCET COMMISSION ON DIAGNOSTICS



**The WHA resolution on diagnostics: what comes next?
Kenneth Fleming & Susan Horton
Thursday June 7, 2023**

Diagnostics should be:



Using the AAAQ framework for health products (UNECSR, 2000)

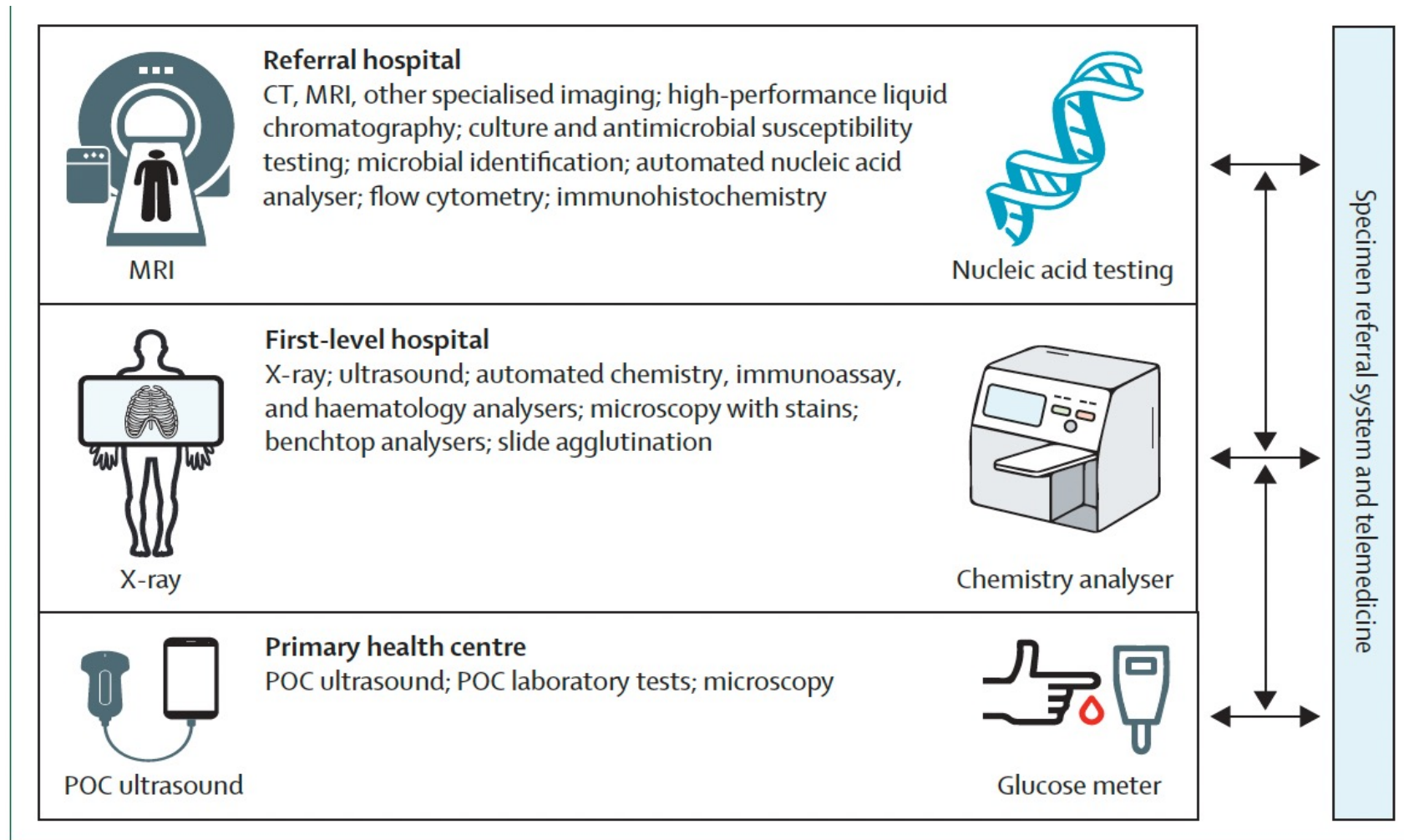
The Lancet Commission on Diagnostics: Progress on WHA Resolution

- The Resolution was proposed by the Kingdom of Eswatini, coordinator for AFRO region, and Indonesia; other countries expressing support included Germany, France, Bangladesh, Canada
- The text of the resolution urges member states to take 15 different actions, and requests Director General to take 15 actions as well as to report progress in 2025
- Draft at https://apps.who.int/gb/e/e_eb152.html#confpaper

How can the resolution help reach Dx goals?

GOAL	METHODS TO REACH GOAL
AVAILABLE	Invest (2 steps) Localize (5 steps); Address needs of conflict situations (1 step)
SAFE	Regulate (1 step); Manage Technology/Quality (2 steps); Ensure safety of imaging (1 step)
AFFORDABLE	Prioritize (5 steps) Deploy market mechanisms (3 steps)
OVERARCHING	Develop a national strategy (1 step) Provide better information (6 steps for WHO)

Invest in an integrated tiered network



Invest in workforce expansion & upskilling

- Estimates of global shortfall by 2030 are 840,000 to 1,008,000
 - 57% of these are in pathology and laboratory medicine, 43% medical imaging
- Unrealistic to expect LMICs to increase their workforce capacity to HIC levels
- New approaches to work are needed: team-based, task sharing, changes in educational and training programs that are shorter and more adaptable
 - AI in Decision Support systems to guide use and interpretation
 - Internet links for primary and second opinion
- In all countries, improved continuing professional development to adapt to rapid changes in technology, especially informatics

Localize

- 4 steps in the Resolution urge member states to:
 - Invest resources in R&D and local production
 - Consider including clauses regarding R&D in funding agreements
 - Promote joint development and technology transfer (on mutually agreed terms – TRIPS language)
 - Utilize TRIPS and the Doha Declaration on public health
- And call upon WHO to assist with technology transfer and local production



Address needs of conflict situations

- WHO should develop a subset of the Essential Diagnostics List for emergency situations, including the Interagency Emergency Health Kits



Emergency health kits

Regulate for quality and safety

- For pathology and laboratory medicine, national or regional accreditation and EQA (external quality assessment)
- For diagnostic imaging, regular and systematic review of all diagnostic processes, procedures, and safety standards
- For both, ensure professional certification, competency, and continuing professional development
- Import and use of diagnostics. A BIG factor for manufacturers

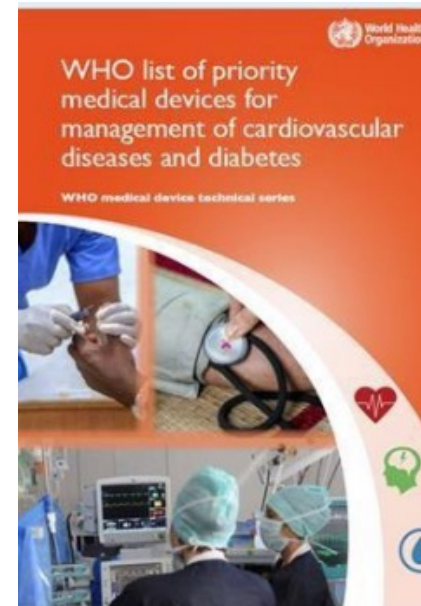
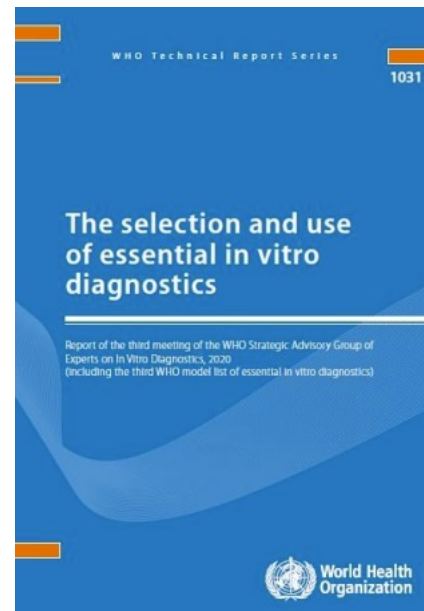


Prioritize to help affordability: WHO EDL

I.b Disease-specific IVDs for primary health care						
Disease	Diagnostic test	Test purpose	Assay format	Specimen type	WHO prequalified or recommended products	WHO supporting documents
Hepatitis B	Hepatitis B surface antigen (HBsAg)	Screening for acute and chronic hepatitis B (HBV) infection: infants > 12 months of age, children, adolescents, adults	RDT	Oral fluid Capillary whole blood	Public reports of WHO prequalified IVDs (http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hbsag/public_report/en/)	Guidelines on hepatitis B and C testing (February 2017): http://apps.who.int/iris/bitstream/handle/10665/254621/9789241549981-eng.pdf?sequence=1
	Hepatitis B e antigen (HBeAg)	Staging to assess the need for HBV treatment in chronic HBV infection	RDT	Capillary whole blood		
Hepatitis C	Hepatitis C virus antibody (anti-HCV Ab)	Screening for HCV infection: infants > 18 months of age, children, adolescents, adults	RDT	Oral fluid Capillary whole blood	Public reports of WHO prequalified IVDs (http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hcv/public_report/en/)	Guidelines on hepatitis B and C testing (February 2017): http://apps.who.int/iris/bitstream/handle/10665/254621/9789241549981-eng.pdf?sequence=1

Other actions on prioritization:

- Assist Member States to develop national diagnostics lists
- Member states to use health technology assessment to choose cost-effective diagnostics
- Make links between WHO EDL (in vitro) and Priority Medical Devices lists (in vivo)



Deploy market mechanisms → affordability

- Success of Global Fund in making RDTs for malaria more affordable
- Success of South Africa (as very large HIV diagnostics kit purchasers) in achieving lower prices
- PAHO undertakes pooled procurement of diagnostics and other medical supplies
- Africa CDC undertook pooled procurement of COVID-19 tests
- Resolution calls on WHO to support national procurement efforts
- And for Member States to prevent anticompetitive measures
- And collect data on market shaping and effective use of Dx

Overarching actions

- Director General of WHO:
 - To collect data on affordability of diagnostics
 - To develop an official definition of in-vivo diagnostics
 - To avoid silos in WHO (e.g. WHO has lists of priority medical devices for RMNCH, cancer, COVID-19 and CVD and diabetes; as well as the EDL for in-vitro diagnostics; but India's national EDL contains both in-vitro and in-vivo diagnostics
 - And assist Member States also to avoid silos
- Member States to strengthen collaboration, including during pandemics and emergencies, aligned with International Health Regs.

Some recent developments:

- WHO is developing a definition of “in vivo” diagnostics; there are no FDA or European definitions as a starting point
- WHO is going to have diagnostics experts from different disease areas meet regularly (avoid silos)
- Device manufacturing associations are connecting (joint letter of support from 5 professional associations in imaging, along with RAD-AID, GMTA and DITTA)
- At least one manufacturer in pharmaceutical sector has established a diagnostics division (Roche); currently there is no clear association representing manufacturers of in-vitro devices, separate from pharma

COLUMNISTS

World Health Assembly nod signals revolution in Africa's diagnostics

WEDNESDAY JUNE 07 2023

ET Healthworld.com
From The Economic Times

THE TIMES OF INDIA

WHA member states vote to adopt 'Resolution on strengthening diagnostics capacity'

International Diagnostics Alliance

Multiple partners/stakeholders

Roles include:

International Alliance for Diagnostics

Preliminary discussions

- Lancet Commission on diagnostics
- FIND
- CHAI
- Africa CDC
 - Widespread consultations with potential stakeholders over next few months
 - Aims, objectives, governance, etc

Aims, governance - personal thoughts:

- Equitable access to safe, affordable, quality-assured diagnostics, across health system tiers, with focus on primary care.
- Leadership and governance from countries where unmet needs are greatest
- Transparent decision making
- Existing mechanisms leveraged
- *in vitro* and *in vivo* diagnostic technologies
- Use pandemic preparedness investment for “every day” diagnostics
- *Et cetera*

Launch within year?

Comments? Questions?

