The WHA resolution on diagnostics: what comes next?
Kenneth Fleming & Susan Horton
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Diagnostics should be:

- Available
- Accessible
- Acceptable
- Quality (incl safety)

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?

<table>
<thead>
<tr>
<th>GOAL</th>
<th>METHODS TO REACH GOAL</th>
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<tbody>
<tr>
<td>AVAILABLE</td>
<td>Invest (2 steps)</td>
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<tr>
<td></td>
<td>Localize (5 steps);</td>
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<td></td>
<td>Address needs of conflict situations (1 step)</td>
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<tr>
<td>SAFE</td>
<td>Regulate (1 step);</td>
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<td>Manage Technology/Quality (2 steps);</td>
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<td></td>
<td>Ensure safety of imaging (1 step)</td>
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<tr>
<td>AFFORDABLE</td>
<td>Prioritize (5 steps)</td>
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<td>Deploy market mechanisms (3 steps)</td>
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<tr>
<td>OVERARCHING</td>
<td>Develop a national strategy (1 step)</td>
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<td>Provide better information (6 steps for WHO)</td>
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Invest in an integrated tiered network

Referral hospital
CT, MRI, other specialised imaging; high-performance liquid chromatography; culture and antimicrobial susceptibility testing; microbial identification; automated nucleic acid analyser; flow cytometry; immunohistochemistry

First-level hospital
X-ray; ultrasound; automated chemistry, immunoassay, and haematology analysers; microscopy with stains; benchtop analysers; slide agglutination

Primary health centre
POC ultrasound; POC laboratory tests; microscopy

Nucleic acid testing
Chemistry analyser
Glucose meter
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.
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
### l.b Disease-specific IVDs for primary health care

<table>
<thead>
<tr>
<th>Disease</th>
<th>Diagnostic test</th>
<th>Test purpose</th>
<th>Assay format</th>
<th>Specimen type</th>
<th>WHO prequalified or recommended products</th>
<th>WHO supporting documents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hepatitis B</td>
<td>e antigen (HBeAg)</td>
<td>Staging to assess the need for HBV treatment in chronic HBV infection</td>
<td>RDT</td>
<td>Capillary whole blood</td>
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</tbody>
</table>
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
World Health Assembly nod signals revolution in Africa’s diagnostics

WEDNESDAY JUNE 07 2023

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?