Are crosscutting initiatives the way forward for diagnostics and assays?

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COVID-19 - WHAT EXPERIENCE HAS TAUGHT US

CHALLENGES

Developers initially hindered due to:
• Slow access to samples / reference material
• Lack of clear product requirements
• Insufficient regulatory harmonisation

Lack of demand and supportive policy for affordable, fast and accurate diagnostics prior to COVID-19
• Limited evidence to inform policy
• Limited manufacturing capacity
• Market underprepared

Access to accurate tests in LMICs and integration into surveillance networks remain fundamental issues

SUCCESSES

Collaboration between academia and industry
• Automated PCR tests available in 64 days from PHEIC
• Rapid diagnostic tests approved in 236 days

Increased demand from governments, increasing manufacturing capacity and capabilities
• Reduced costs for diagnostics
• Increased access for LMICs
AN ALLIANCE TO REALIZE AN “APOLLO MISSION FOR THE MODERN AGE”
ENABLING EFFECTIVE PANDEMIC RESPONSE WITHIN 100 DAYS
OF A MAJOR OUTBREAK

Accelerate product development and R&D

1. Develop **novel diagnostic platforms**
2. Build prototype **diagnostic libraries** for 10 pathogens
3. Establish clinical **reference standards**

Streamline evidence generation and regulatory approval

4. Integrated **global biobanking network**
5. Establish **global clinical trial and product evaluation network**
6. Formalize pathway to enable **collaborative product authorization and registration**

Strengthen surveillance and community-based testing infrastructure

7. Strengthen **global disease surveillance**
8. Normalize **point-of-care testing programs**

Establish warm base for manufacturing and reliable pull mechanism

9. Support development of **regional manufacturing hubs**
10. Institute **reliable pull financing mechanisms**
SEQUENTIAL DEPLOYMENT OF SARS-COV-2 ASSAYS TO ADDRESS URGENT NEEDS AND PREPARE FOR THE FUTURE

1. Lab-based NAT kits for rapid implementation of accurate testing
2. Rapid Antigen Tests for increased accessibility through decentralized testing
3. POC molecular assay for accurate decentralized testing

INDEPENDENT EVALUATION
Generate independent analytical and clinical data to inform the global health community and support decision making on SARS-CoV-2 diagnostic testing approaches.

LOCAL MANUFACTURING
Build local capacity to increase accessibility to LMICs and reduce cost

TEST DIRECTORY
Build & maintain an updated product database to inform internal & external stakeholders on SARS-CoV-2 diagnostic pipeline and test features

DEVELOPMENT
Support the development of new tests that meet performance requirements and are more adapted to different use cases and target populations

ASSESSMENT & DUE DILIGENCE
Conduct product and company assessment to guide investment and support procurement strategy
TRANSFORMING TESTING BY LEVERAGING RAPID DIAGNOSTIC TESTS

Expand access to quality diagnostic tests for all patients, at primary care and community levels.

- Rapid tests for COVID-19 stable at high temperature
- Non-sputum based RDT for active TB incl. in children and people HIV+
- Next-generation malaria tests to improve *P. falciparum* and *P. vivax* management
- Combo RDT for HIV/syphilis and HBV for pregnant women
- RDTs for HCV, dengue, typhoid fever, schistosomiasis, Buruli ulcer, visceral leishmaniasis, Chagas disease

Expand access to quality diagnostic tests for all patients, at primary care and community levels.
CEPI Call for Proposal: Immunogen Design

**Machine Learning: Vaccine Antigen Design**

- Reverse engineering of monoclonal antibodies
- T-cell epitope prediction algorithms
- Structural protein folding models
- B-cell epitope prediction algorithms
- Mechanistic model for making subdominant antigens immunodominant and affinity maturation.

**Vaccine Design:**
1. Antigens that have fixed neutralizing epitopes.
2. Potentially broadly protective as a multivalent and/or chimeric antigen.
3. Contains both T and B-cell epitopes.
TRANSFORMING TESTING BY LEVERAGING
POC MULTI-ANALYTE TESTS

Bring accurate diagnostic testing for **multiple diseases** out of the laboratory, directly at the **point-of-care**

- Tests for **severity triage** and **differential diagnosis** at primary care
- Easy-to-use tests for **pathogen identification** and **antibiotic susceptibility** testing
- POC molecular **multi-pathogen** platforms **respiratory panel, AMR and HPV** for L1/L2 use
- True POC molecular platforms for L0/L1 use

- e.g. haematology devices, biomarker-based severity tests, clinical chemistry tests (for liver function)
- e.g. simplified blood culture system and ID and AST panel
Basic diagnostic capacity is available in only 1% of primary care clinics and 14% of hospitals in some LMICs\(^1\)

Appropriate tests do not exist for 60% of infectious agents with outbreak potential\(^2\) and 50% of the top 20 diseases responsible for most lives lost\(^3\)

\(^3\) Pai et al. Analysis from Global Burden of Disease Report 2020
Diagnostic testing is no longer confined to clinics and hospitals.

**Point-of-care multi-analyte tests**
Accurate testing for multiple diseases directly at the point-of-care.

**Rapid diagnostic tests**
Expand access to testing at primary care and community levels.

**Next-generation technologies (genomics, CRISPR)**
Sequencing for disease surveillance and rapid response.

**Wearables & home-use tools**
Self-monitoring, early detection and ambulatory management.

**Mobile devices & connectivity**
Reach the hard-to-reach; enable real-time monitoring of health status.

**Artificial intelligence & machine learning**
Quality diagnosis in areas without specialist healthcare workers.

**Sustainability**
Minimize environmental impact of single-use tests.
### Our Focus: Co-Creating Fit-for-Purpose Diagnostics

Adapted to use cases and capacity of LMICs

<table>
<thead>
<tr>
<th>Use setting</th>
<th>Level 0 (L0)</th>
<th>Level 1 (L1)</th>
<th>Level 2 (L2)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Use setting</strong></td>
<td>Community outreach, At home testing</td>
<td>Primary care facility</td>
<td>Near-patient laboratory, Referral hospital laboratory</td>
</tr>
<tr>
<td><strong>Testing infrastructure</strong></td>
<td>No mains power, No water, No lab equipment, No temperature control</td>
<td>No mains power (unreliable), Minimal lab equipment (may not support cold chain), BSL-1 containment</td>
<td>Mains power (may be intermittent), Basic lab equipment (biosafety cabinet, centrifuge, calibrated pipets, fridge), BSL-2/1 containment</td>
</tr>
<tr>
<td><strong>Technologies required</strong></td>
<td>Instrument free</td>
<td>True POC</td>
<td>Near POC</td>
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</table>
**CONCLUSIONS**

1. Dx innovation/product development can be accelerated dramatically when market opportunity is clear
2. Regulatory barriers remain significant
3. Strategic direction and ownership must be driven by countries
4. Private sector Dx access is an untapped opportunity
5. Financing for test & platform procurement is essential, but not sufficient, to generate demand and drive uptake
6. Pandemic preparedness will fail unless it is integrated with routine primary care atop strong surveillance systems
7. Forthcoming multiplex molecular platforms are potentially transformative for UHC and GHS
8. Close coordination of multiple agencies with clear strategic objectives, regular engagement through working groups, collective resource mobilization, and individual agency autonomy is an effective alliance structure

**CROSSCUTTING INITIATIVES**
The Diagnostic Pillar is co-convened by FIND and Global Fund, with participation from a coalition of 50 standing partners across 3 working groups. WHO leads on regulatory, policy, product procurement, and allocation.

More than 50 organizations support the Dx Pillar on strategy, product development, policy, and implementation across the Dx value chain.

- Market shaping, procurement, supply & access
- R&D, Product assessment, Policy
- Country support, advocacy & implementation