ACTaccelerator
ACCESS TO COVID-19 TOOLS

Hosted by World Health Organization

Pre-Council technical briefings

Summary of major takeaways

3rd Facilitation Council meeting
14 December 2020

ACT now, ACT together to accelerate the end of the COVID-19 crisis

Objectives of the technical briefings

Understand **details and urgency of ACT-A priorities for 2021**

Enhance the Council members' **ability to advocate for ACT-A**

Goals of the technical briefings

1. Provide an update on the **current strategic priorities** of each Pillar and the Health Systems Connector, as outlined in the most recent ACT-A investment case

2. Share identified **priorities / activities that may be adjusted for 2021**, as a result of recent or expected developments

3. Provide a description of **any costs that may be incurred in 2022**

Technical briefings

Diagnostics & Therapeutics (*07 December, 12:00-14:00 CET)*

Chair: Anban Pillay (South Africa)

Principals: **Dx**: C Boehme (FIND), P Sands (Global Fund), H Balkhy (WHO)
Tx: P Duneton (Unitaid), M Simão (WHO)

Representatives: **Tx**: N Cammack for P Schreier (Wellcome Trust)

Vaccines / Health Systems Connector *(09 December, 12:00-14:00 CET)*

Chair: Anban Pillay (South Africa)

Principals: **Vx**: S Berkley (Gavi), S Swaminathan (WHO), R Hatchett (CEPI)
HSC: Z Jakab (WHO), P Sands (Global Fund)

Representatives: **HSC**: F Zhao for M Pate (World Bank)

Technical briefings: some overall takeaways for 2021

An **integrated approach** (Dx, Tx, Vx, PPE) remains critical to end the pandemic, even as vaccines become available

ACT-A's multibillion dollar financing gap is now the key constraint to realizing its full impact, as it is limit immediate scale-up & delivery of existing tools and further innovation

The **supply/demand imbalance** also requires urgently creating in-country demand (esp. Dx, Dexa, PPE, O2), including through:

- Ensuring timely & clear, **dynamic technical guidance/tools** to optimize product use
- Rolling out **rapid in-country assessments and plans** to foster demand creation

Overall, ACT-A's focus on **country delivery** is escalating massively (incl. for Vx readiness)

With the evolving priorities of all Pillars, across the value chain, **ACT-A's strategy and budget will need to be refreshed for 2021**

Diagnostics (Dx) – specific takeaways

Current priorities & challenges

Scale up **mass AgRDT use** and **POC testing,** and improving **equitable supply** in LMICS

Gap in 2020 procurement target of 85m tests for LMICs (PCR + RDT)

Total **funding gap** for the pillar of **$5.3Bn** for innovation, procurement & deployment

Shift in priorities & activities for 2021-22

Testing for normality: Country support to develop testing strategies are key

- Innovative design for quality lower-cost AgRDTs, self-testing & multi-pathogen platforms
- Ensure demand for high quality, affordable tests at the country level

Q&A top topics

Increasing demand, market shaping for mass production (incl. in LMICs) and tech transfers

Therapeutics (Tx) – specific takeaways

Current priorities & challenges

Demand generation for dexamethasone

Monitoring of trial read outs for mAbs and small molecule antivirals

Shift in priorities & activities for 2021-22

Ensure fit-for-purpose clinical trials; continue to monitor and act on R&D gaps as needed

Shift to **adapt to the changing target population** with vaccine roll-out

- Anticipate shift towards non-high-risk populations/mild infections

Accelerate LMIC access to any approved novel therapeutics

Q&A top topics

Equitable and universal access, and dexamethasone stockpile

Vaccines (Vx) – specific takeaways

Current priorities & challenges

Current focus on **finalizing deals, country readiness** & **roll out** of first doses

Key challenges (esp. for country readiness)

- Procurement and funding gaps ($5Bn)
- Regulatory processes & EUL/PQ, liability & indemnification agreements
- Global safety monitoring & info systems / post-intro implementation & impact assessment
- Potential need for ultra-cold chain

Country support for development of national vaccination strategies

Shift in priorities & activities for 2021-22

(Preparing for) scale up and supporting country readiness (Q1/Q2 2021)

Supplying to countries and securing second wave of Vx and deployment at-scale to achieve the 2Bn goal (Q3/Q4 2021)

- Aiming for options better suited to LMICs (e.g. heat stable, 1 dose) and specific groups

Q&A top topics

Roll-out timelines; donations of 'additional doses' via COVAX; role of MDBs; understanding immunity acquired after natural infection vs. vaccine induced immunity

Health Systems Connector (HSC) – specific takeaways

Current priorities & challenges

Support countries w. vaccine readiness assessment

- Vaccines: guidance & tools developed (e.g. VIRAT & NDVP); technical assistance provided
- Collection real-time country data

Identify bottlenecks through country assessments

Funding gap of $9.5Bn, with urgent need of $1.7 Bn for rapid scale up of essential health system commodities and tools (e.g. PPE, O2, policies, training)

Shift in priorities & activities for 2021-22

Broader country assessment and **address country-specific bottlenecks** to enhance readiness for delivery of new tools

Country support for planning process, guidance and policies and global coordination

Continued provision of PPE and O2

Top topics Q&A

Country preparedness, country specific costs for health system enablers, basic health system financing

Technical workstream planning

Next steps

Incorporate comments from Council members and Pillar leads

Refresh each Pillar's strategy and budget considering the context of the 'vaccines era' (January)

Pre-Council technical briefings (mid-January)

4th Facilitation Council (proposed in February, TBC)

Goal

Understand & agree on ACT-A Pillars' refreshed strategy, priorities & budget for 2021

Annex

Further detailed takeaways by Pillar

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Recap Council Pre-Briefing: Diagnostics (Dx)

Key messages

Test for normality: Living with COVID-19 requires novel testing strategies in 2021 and beyond

- Innovative design for quality lower-cost AgRDT, low-cost self-testing & multi-pathogen platforms
- Market shaping for mass production, incl. in LMICs
- Rapid access & deployment at-scale with country policies & testing strategies in place

Significant progress in Dx innovation, at risk due to gaps in procurement financing & country uptake

Relevant gap remains to reach 85m procurement target for LMICs by end 2020

- **40%** of 2020 target of **85m** procurement target for LMICs reached (PCR + RDT), target for **mid-2021: 500m tests**
- Daily tests / 100k population is **4x lower** in UMICs (excl. China), LMICs, LICs than HICs
- **Total funding gap** for the pillar of **$5.3Bn** for innovation, procurement & deployment

ACT-A Dx work to date is laying the foundation for broader health emergencies preparedness

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Recap Council Pre-Briefing: Diagnostics (Dx)

Highlights Q&A

Very immediate funding gap: **Critical concern**, alignment needed on how to close the gap

Importance of balance across pillars: Need for **holistic approach**, funding gaps in Dx / Tx / HSC may jeopardize efficient service delivery on all pillars

Barriers to uptake: **Resources,** and difficulties to adopt **coherent strategy** with evolving Dx technologies and variety of use cases. Need to provide **implementation guidance / clarity, integrated guidelines** and work on **capacity building**

Demand generation gap: Need for **timely, clear and dynamic technical guidance**, HSC working on in-country assessments / rapid planning / demand generation

Diversification of manufacturing: Has been important focus, investments made in manufacturing and innovation in Africa, Latin America and Asia will pay off in 2021-22

Strategy on IP and access: **Global access** has been **foundational to partnerships**, there has been openness from companies and manufacturers. Smaller innovators will need to enable tech transfers and collaboration with large-scale companies (e.g. self-testing: redesign to low-cost high-performance tests for scale-up)

Recap Council Pre-Briefing: Therapeutics (Tx)

Key messages

Tx Partnership 2021 strategy focuses on accelerating LMIC access to effective therapeutics, especially mAbs and SM NAVs

- **Tx priorities** reflect evolving clinical status, access challenges for each potential therapeutics product, and how and when these become available in 2021
- **Upcoming results mAbs:** phase 3 data Regeneron (end Q3 '21) and Lilly (Q2 '21); **preliminary novel SM NAVs**: Merck (phase 2 data Dec '20, interim phase 2-3 Q2 '21)

Tx Partnership product focus is driven by clinical readouts, viability of equitable access, and added value of ACT-A intervention

Tx expected to continue to play a pivotal role in 2022, even with Vx deployment. Tx Partnership 2022 strategy will shift to adapt to the changing population needs

- **Anticipate shift in Tx towards non-high-risk population** (e.g. small molecule anti-virals and host-directed Tx)
- **Anticipate decrease in Tx needs for high-risk populations** (e.g. IV mAbs) – however need remains not protected
- **Ensure fit-for-purpose clinical trials**; continue to monitor and act on R&D gaps as needed

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Recap Council Pre-Briefing: Therapeutics (Tx)

Highlights Q&A

Strategy on IP and access: Key to have all tools available, **help coordinate country preparations**, IP sensitive topic but discussions on how to speed up tech transfer – **more thought needed on mid and long term**

Equitable access: interventions to increase volume and decrease price ongoing, two main barriers: **scientific** and **accessibility** (**manufacturing scale up**)

Updated version of **ACT-A charter** for guiding principles **for equitable and universal access for Dx / Tx / Vx** to be endorsed at Council meeting in Jan/Feb

Focus on integrated guidance to drive better use: need for **timely and clear technical guidance**, **dynamic** in light of rapidly evolving scenarios

Stockpile dexamethasone: stockpile exists, uptake not as rapid as anticipated, **progress in clinical care needed**, response capacity to be built up

Recap Council Pre-Briefing: Vaccines (Vx)

Key messages

COVAX's needs are evolving along different phases until first Vx are released to the world

- **Securing access** to Vx candidates and planning (until EOY 2020)
- **(Preparing for) scale up and supporting country readiness** (Q1/Q2 2021)
- **Supplying to countries and securing second wave of Vx** (Q3/Q4 2021)

With aspirational timelines, COVAX is facing a set of near-term challenges

- Procurement and **funding gaps ($5Bn)**
- Need for **ultra-cold chain**
- Regulatory processes & EUL/PQ, liability & indemnification agreements
- Global safety monitoring & information systems / post-introduction implementation & impact assessment

COVAX is considering 3 waves of candidates depending on the expected EUL – 2nd generation expected for 2022

- **First efficacy data available** for Pfizer/BioNTech, Moderna, AstraZeneca and Gamaleya
- Additional vaccine candidates expected in 2021-22 to achieve **2 billion** goal, with aim to provide options better suited to **LMICs**
- Supply and demand equilibrium not expected to be reached until **2022**

Recap Council Pre-Briefing: Vaccines (Vx)

Highlights Q&A

2Bn doses target in 2021: 700 mn doses commitments, behind it many times more doses in option, awaiting more information to come in. Target of 2bn still in reach, but inherent uncertainties (e.g. scientific, manufacturing at scale, tech transfers) could impact delivery

Role of development banks: Coordination with World Bank ($12Bn package announced), strongly liaising with regional development banks for synergetic support, cost-sharing

Test and vaccine strategies: Support countries on setting own policies, and implementation. Frameworks available for countries to adapt and adopt on values, distributing scarce resources, and prioritization of population groups to be considered for early vaccination

Excess doses: Donation of doses would be very welcome for equitable distribution, COVAX can channel doses through the facility's allocation mechanism. Early contributions of doses would prevent equity gap from emerging

Recap Council Pre-Briefing: Health System Connectors (HSC)

Key messages

The HSC aims to enable effective deployment of COVID-19 tools by addressing country specific bottlenecks and rapidly scaling up essential health system commodities and tools

Funding gap of $9.5Bn, of which an urgent need of $1.7Bn for rapid scale up of essential health system commodities and tools (e.g. PPE, O2, policies, training)

7 workstreams to address bottlenecks identified in country assessments

- Health financing, in-country supply chains, data/health services monitoring, protecting FLHW, clinical care, community response and private sector

Countries supported with vaccine readiness assessment, but broader assessment also needed

- **Technical guidance and tools** developed (e.g. VIRAT & NDVP) and technical assistance provided
- **Real-time country data** collected

Recap Council Pre-Briefing: Health System Connectors (HSC)

Highlights Q&A

Country preparedness: Ongoing assessments at national level, to sharpen strategic direction for support on strengthening country preparedness

$8-10Bn funding for health systems: Not included in ACT-A investment case, as these are country-specific costs such as catalytic investments for the enablers (e.g. supply chain, community response and clinical care). Resources to be mobilized at country-level from domestic funds available from World Bank and other external sources

Donor support: Support that donors might bring at country level needs to be seen part as overall package of ACT-A support

HSC Connector Funding in light of basic health system finance: Overall investment to foster collaboration globally across partners. The strategic direction for the World Bank is to have a sharp focus on COVID-related tools and Health System enablers tied to COVID response. The focus is on country gaps in order to deliver tools, while complementing ongoing work for system strengthening initiatives