Platform for ACT-A Civil Society & Community Representatives

Hosted by WACI Health, STOPAIDS & Global Fund Advocates Network (GFAN)

Statement on the ACT-Accelerator Strategic Review (12 October 2021)

Over a year and a half into the COVID-19 pandemic and the establishment of the Access to COVID-19 Tools Accelerator (ACT-A), questions about future pandemic preparedness responses are dominating global public health discussions. The ACT-A recently undertook a review for the stated purpose of potentially extending its mandate until the end of 2022, primarily on the basis of an assessment of performance against stated goals, with the final report, 'ACT-Accelerator Strategic Review' published on 8 October 2021.

The review was conducted by Dalberg, who executed the report in line with the Terms of Reference (ToR) with efforts to ensure the civil society and community representatives to ACT-A were consulted through interviews, focus groups and written submissions. However the nature and scope of this review developed by ACT-A partners has neglected fundamental questions and lacked adequate time for public consultation with stakeholders impacted by ACT-A.

Lack of meaningful involvement of low and middle income countries governments, civil society and community organisations most impacted by the ACT-A

The ACT-A did not begin with a structure that was fit for purpose. Whilst we understand that this structure was built under urgent circumstances, if "equity" had been prioritised by the global community in our approach to global health prior to this pandemic, a responsive structure would have already been in place. Instead there is a lack of transparency and clear decision-making structures within ACT-A and a complete absence of mechanisms or tools for accountability, with an acute lack of meaningful inclusion of LMICs, CSOs and the communities for whom equity is at risk at all levels of decision-making. Moreover, there is a tremendous wealth of public health expertise in low and middle income governments, universities, and civil society that has been systematically excluded from ACT-A. Instead, ACT-A has turned to organizations, predominantly in high-income countries and their network of public health professionals to develop and review ACT-A initiatives. Whilst the ACT-A review acknowledges, and recommends improving the meaningful inclusion of civil society and communities, it relies on existing governance structures to ensure this engagement without acknowledging the varying governance structures of the lead agencies; this is not lessons learned but more of the same. Civil society and community engagement at the governance level of select agencies (Global Fund, Unitaid and Gavi) does not ensure meaningful engagement across the ACT-A structure and overlooks decisions being made between agencies. A clear decision-making structure is foundational to accountability and good management - without this it will be status quo. The absence of this structure overall has had a significant negative impact on civil society, communities and compromised the ability of some low and middle income countries to meaningfully engage in the work of ACT-A. Without the accountability that

inclusion and transparency engenders, ACT-A cannot fully realise its potential and legitimacy to serve those most in need.

Lack of ambition and underachievement of even limited ambition

Targets set across the ACT-A pillars were a gross underestimation of what was and is needed, and their production was not based on wider consultation. In part, the ACT-A's lack of ambition rested on the assumption that interventions would be needed during the acute phase of the pandemic only and that normal market forces would address post-acute phase needs for LMICs. Because the flaws in these assumptions have been repeatedly exposed in the systemic gaps such models have left in other disease responses, it was predictable that status quo responses to the pandemic would result in the unjust, unbalanced, and inequitable global vaccine /therapeutics/diagnostic/PPE/oxygen we currently see, a situation where equitable access is still years away. It is magical thinking that the market would right itself to suddenly ensure equitable access, even more so when the threat of new variants has arisen. The lack of ambition was not just reflected in the planned short duration of ACT-A, but also in its ambition to support access only to a relatively smaller proportion of LMIC needs even during the acute phase of the pandemic. The failure of ambition and the reluctance to challenge flawed-but-politically-sensitive decisions is consistent with the longstanding conservatism of the lead institutions involved in ACT-A, most of which are reluctant to support reforms that are unpopular with their primary (and overwhelmingly high-income country) financial backers.

Equity

ACT-A has not adequately addressed equity needs, particularly those affecting access to COVID-19 health technologies by socially marginalized populations. Inequalities within states based on gender, LGBTQ+, race/minority group, refugee/migrant status, disability, age, religion, and other intersecting vulnerabilities must be addressed through the Health System Connector (HSC) and other means. Although ACT-A has voiced consistent rhetorical concern about global inequalities in access, it has done so largely without naming culpable parties, corporate and governmental. ACT-A needs a broad intersectional and equity strategy across all its activities.

Resource mobilization

ACT-A has been significantly underfunded since its inception. Although most of the blame for its resource shortfalls falls at the feet of donors, its resource mobilization strategies have led to moderately robust funding of its vaccine work, but gross underfunding of vital work in the diagnostics, therapeutics, and health systems pillars. This underfunding and maldistribution of funding must be urgently addressed so that necessary work can be undertaken to ensure greater availability to tests and treatments in health and community systems as well as investment in health workforce upon which service delivery depends.

Vaccines pillar (COVAX)

CEPI has not adequately undertaken to mandate technology transfer from vaccine producers it has invested in and has further neglected to enforce those access provisions that it did negotiate. Although

recent efforts to expand vaccine production capacity are noteworthy, much remains to be done, especially with respect to expanding regional hubs for independent vaccine manufacturing capacity in LMICs. ACT-A should use its leverage and power to ensure expansion of production and access of vaccines, diagnostics and therapeutics based on need, prioritising the worst off, and promoting local action. ACT-A as a collective of influential stakeholders should support the TRIPS waiver and call on producers of vaccines and other life-saving commodities to share their knowledge and technology with C-TAP and the WHO mRNA vaccine technology transfer hub.

COVAX has dramatically underperformed in its first year in securing vaccine supplies even for its inadequate goal of 20% coverage in AMC countries by the end of 2021. COVAX's pivot to "donations" allowed face-saving by countries that hoarded vaccines, but dose-sharing promises have not been fulfilled and are inadequate to meet the supply needs of LMICs. The vaccine pillar should establish much more ambitious coverage goals, including 70% coverage of LMIC populations in each country by mid-2022. It should redouble its efforts to secure vaccine supplies, to make them available at no cost to AMC eligible countries, and to invest in vaccination programming and service delivery at the local level.

Diagnostics

The pillar continues to be held back by conservatism on the support for widespread community-based use of antigen RDTs. The lack of access to community-based antigen RDTs is both a key driver of diagnostics inequity for individuals and a key reflection of systematic inequity of country-level access to markets. In the Global North, rapid antigen self-tests are available in pharmacies and in homes, and in some countries they are available for free. The reliance of low and middle income countries on WHO guidelines for testing policy—and the WHO's delayed and relatively muted promotion of community-based testing—means that a large proportion of low and middle countries are not sufficiently empowered to self-manage COVID-19 risk. This has been made complicated by late and ambiguous WHO guidelines which are liable to misinterpretation thus losing opportunity for the C19RM window. The lack of involvement of LMIC and LIC reps in ACT-A in any meaningful way has meant that they are not even aware of the potential of the utility of the tools developed by the pillar to change the trajectory of the pandemic in their own countries. The failure of the Health System Connector to bridge that gap of inclusion and information sharing has also contributed to the problem.

In addition, the emerging trend of discussing 'absorptive capacity' of LMICs towards deployment of antigen RDTs is grounded in the same principle of doing FOR rather than WITH that infuses the entire structure of ACT- A and defeatism. 'Absorptive capacity' is a term that implies and normalizes restricting volumes of tests deployed rather than encouraging and facilitating necessary steps towards community-based use of antigen RDTs, regulatory harmonisation, and demand creation.

Therapeutics

The therapeutics pillar needs to focus much more intently on expanding the supply of promising medicines, including with respect to promising antivirals appropriate for out-patient use. Although expansion of access to outpatient monoclonal antibodies (mAbs) would be desirable if problems of supply, price, and mode of administration could be addressed, those barriers restrict reliance on mAbs

for major investments. However, given positive readouts on Merck's molnupiravir, and impending readout on two other novel small molecule antivirals, attention should be urgently focused on licensing to expand generic production and export with more affordable pricing. To optimize use of outpatient therapies, the pillar in conjunction with the Dx pillar needs to adopt a vigorous test-and-treat strategy that greatly increases use of community-based and self-testing with antigen RDTs followed by near immediate connection to treatment for those who test positive. This will reduce disease progression, demand on health services, risks of long-covid, and economic and social disruption.

The pillar will increasingly need to turn its attention to overcoming regulatory barriers that will interfere with rapid deployment of new medicines, especially biosimilar and generic medicines where accelerated WHO Prequalification pathways should be established.

Health Systems

The findings and recommendation for this pillar are presented as separate to the work of diagnostics, therapeutics and vaccines without acknowledging that these three pillars rely on strong health systems to function and deliver their work. It is important for all pillars to note and address the need to invest in the recruitment and remuneration of health workers rather than limit their focus on PPE and vaccination of healthcare workers. There is an urgent need to invest in the recruitment and remuneration of additional health workers as an investment priority; leaders must acknowledge deaths and burnout rates among health workers, which has impacted the delivery of COVID-19 services and is already reversing the impact of investments in other diseases. Recruitment, training, and remuneration of health workers at all levels (including community health workers) must be a core recommendation to improve the delivery of diagnostics, treatment and vaccines.

The Health Systems Connector must clearly prioritize sustainably strengthening health systems, which includes existing community health systems and structures, that can address long-standing gaps and build a more resilient future. To minimize duplication and competition for limited resources, the lead agencies of the Health Systems Connector must ensure coordination, alignment and harmonisation at the country level with the input and leadership of in-country civil society included as a key step in decision-making.

The delay in the Health Systems Connector pillar to host full group meetings and consultations is concerning as health systems challenges stand to threaten progress on vaccines, diagnostics and treatment roll-outs and risks further investments and financing in the pillar. The Health Systems Pillar must articulate an investment case that goes beyond PPE and vaccination of health workers, but rather focuses on broader investment in and protection and care of the health workforce. The lead agencies must include civil society from the start in shaping priority actions, objectives and budgets.

RECOMMENDATIONS

In addition to those recommendations in the formal review (which CSOs find inadequate), changes must be made to ensure the ACT-A is legitimate, accountable, relevant and effective. Going forward, a more

rigorous assessment of the impact and effectiveness of ACT-A must be included in any strategic review, based on a broad public and transparent consultation with both governments and affected communities.

As civil society and community organisations, we call on ACT-A lead agencies to:

- Establish a consultative process for developing a central accountability mechanism framework for the ACT-A to ensure meaningful inclusion of LMICs, civil society and communities and a clear decision-making structure (led by an independent neutral party)
- Revise resource mobilization efforts to dramatically increase funding levels for the under-resourced therapeutics, diagnostics and health systems pillars and ensure transparency in how decisions for allocation of resources per pillar are made
- Revise targets to more ambitious levels that reflect the urgency and magnitude of the problem with an equitable consultative process to formally reset the goals of ACT-A, specifically with representatives from LMIC governments and communities
- Establish an equity framework across all its work addressing not only global inequity but in-country inequitable access to COVID-19 health technologies.
- Review and revise the structure of the ACT-A mechanism in order to ensure democratic representation, permanent seats and votes, and consistent input by LMIC, including civil society and affected communities, at all levels of decision-making.
- Revitalise the work of the diagnostics pillar toward major expansion of antigen RDTs, including community-based and self-testing. xpand the focus of the therapeutics pillars to increasing the supplies of promising new medicines, particularly antivirals appropriate for outpatient use.
- Diagnostics and Therapeutics pillars will need to accelerate and collaborate on an urgent test-and-treat strategy for outpatient detection and treatment of early disease to mitigate clinical progression and reduce risk of transmission. Additionally, health systems challenges and solutions must be mapped in partnership with HSC simultaneously as new tools and treatments are being developed in order to effectively and equitably reach communities.
- Ensure transparency of any and all contracts negotiated by an ACT-A partner regarding research or procurement with pharmaceutical companies
- Publish full disclosure and statement of conflicts of interest of all ACT-A partners
- Publish documents and minutes from key strategy meetings throughout the pre-launch and post-launch periods of the ACT-A, as knowledge about key reasonings, alternative scenarios, and identity of decision makers / policy voices remains almost totally hidden to date
- Broaden the Health Systems Connector from focusing only on PPE and vaccination, to investment in and protection and care of the health workforce. ACT-A should conduct an impact and gap analysis and investment case and funding for the recruitment of additional health workforce needs to deliver COVID-19 services and adequate technical assistance to maintain sustainable health services to ensure that other programs e.g HIV, TB, Malaria, Vaccinations are not impacted by the shift and focus of the already severely limited and overstretched limited health care workers to COVID-19 response.

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