Transactions of the Royal Society of Tropical Medicine and Hygiene 2026; **0:** 1–3
https://doi.org/10.1093/trstmh/trag052
Published: 0 2026
Commentary

Diagnostics and the 100-day mission: why preparedness cannot wait

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Abstract

The 2025 International Panel for Pandemic Surveillance Report and the G7 100-day mission emphasise rapid deployment of diagnostics, but preparatory infrastructure is vital to achieve this goal. Drawing on lateral flow development and haemorrhagic fever case studies, we highlight the requirement for pre-established diagnostic building blocks, including monoclonal antibodies, antigens, biological reference materials and regulatory pathways. Persistent funding imbalances and inequitable global investment threaten timely outbreak response. Sustained preparedness investment, strengthened biobanking and equitable access frameworks will ensure that diagnostics can be delivered within meaningful response timelines.

Keywords diagnostics, global health equity, lateral flow tests, pandemic preparedness

Commentary

The release of the 2025 IPPS (International Panel for Pandemic Surveillance) Report[1] and the recent release of the Fifth 100 Days Mission Implementation Report[2] have once again focused global attention on the role of diagnostics in pandemic preparedness. Although the IPPS does not call for fully deployable diagnostics within the first 100 days of a novel outbreak like the G7's earlier 2021 '100-day mission', it stresses the necessity of rapid post-100-day scale-up and highlights how current gaps in diagnostic R&D, biological reference materials and manufacturing capacity continue to undermine early response efforts. These findings provide an important context for the G7 '100-day mission', which sets out specific ambitions for medical countermeasures, including vaccines, therapeutics and diagnostics within 100-days once a new pandemic threat is identified.

Lateral flow tests (LFTs), specifically rapid antigen-detecting point-of-care tests that detect pathogen infection, illustrate why the 100-day ambition cannot rely on reactive development. Key scientific components, including monoclonal antibodies, recombinant antigens and well-characterised biological samples, must have already been developed, whether for a specific pathogen of pandemic potential or through pathogen-family preparedness. These diagnostic 'building blocks' cannot be created amid an emergency within this timeframe. Instead, they must be prepared, characterised and stored in advance. Establishing such resources during pandemic 'peacetime' periods is therefore essential if the global community is to pivot effectively to diagnostic development when the next crisis emerges. Although antibody-based LFTs can still play a complementary role in serosurveillance and retrospective assessment of population exposure, they are generally less suited to early outbreak detection.

Our experience developing a prototype LFT for Crimean–Congo haemorrhagic fever virus (CCHFV)[3] illustrated the inherent challenges of this approach. Even under favourable conditions, developing the necessary reagents typically requires around 6 months, followed by a further 2 or 3 months to produce the first prototype in the standard development pipeline. For the CCHFV LFT, the absence of pre-existing, well-characterised antibodies and samples substantially delayed these timelines, with the first prototype meeting the WHO's minimum sensitivity threshold,[4] taking 1 year to achieve. Furthermore, the WHO's 2019 Research and Development Roadmap for CCHFV emphasised the need for well-characterised isolates and biobanks to support diagnostic evaluation, yet this remains a largely unrealised goal. Achieving it will depend on strengthening laboratory capacity and biobanking infrastructure in endemic countries, harnessing local expertise and encompassing pathogens of epidemic or pandemic potential. Additionally, biosafety infrastructure and the safe handling of specimens are critical components of this capacity, particularly in settings where laboratory containment facilities may be limited. Building research capability and diagnostic infrastructure in endemic areas is fundamental to pandemic preparedness and a vital component of meeting G7 and IPPS expectations.

The need for preparedness is made starkly apparent by the recent outbreak of Marburg virus disease in Ethiopia.[5] The outbreak of a haemorrhagic fever with no licensed vaccine or approved treatment highlights how quickly a pathogen can emerge and cause severe morbidity and mortality. Diagnostic capacity for Marburg virus remains limited, relying primarily on molecular

Received: 13 February 2026. **Revised:** 30 March 2026. **Accepted:** 6 April 2026

testing in reference laboratories requiring specialised biosafety infrastructure. The outbreak demonstrates the value of pre-prepared 'libraries' of diagnostic building blocks. Without these, reactive development of rapid point-of-care tests would be too slow to influence early containment, underscoring the importance of investment during pandemic 'peacetime'.

The COVID-19 pandemic demonstrated both what is possible in rapid diagnostic development and where systemic barriers persist. Once antigen targets were identified and monoclonal antibodies were produced, LFTs were developed and deployed rapidly, largely enabled by emergency use mechanisms in place by WHO and in the USA and Europe. However, some manufacturers still reported an inability to get their tests to market due to regulatory delays. Multiplex tests, to identify more than one pathogen, will be a valuable part of diagnostic response. However, regulatory challenges to evaluate multiplex technologies, including rare pathogens, need to be addressed for manufacturers to respond effectively. The COVID-19 pandemic highlights the need to ensure national emergency authorisation frameworks continue to be applied proportionally, to ensure rapid availability of diagnostics in future crises and potentially support pre-licensure routes. Cross-collaboration between government, industry and stakeholders will be essential to strengthen these pathways while maintaining product quality and public trust.

In addition to practical barriers to diagnostic development and despite the global consensus on the importance of preparedness, funding trends have moved in the opposite direction. A recent *Lancet Global Health* analysis found that post–COVID-19 support for pandemic preparedness represented only 12.2% of the recommended target set by the High-Level Independent Panel on Financing the Global Commons for Pandemic Preparedness.[6] This is reflective of a pattern of increasing resources immediately following an epidemic or outbreak followed by a dramatic decline only a few years later as demonstrated in a 2019 analysis of the 2014–2016 Ebola outbreak in which funding declined from US$1.0 billion to $477.8 million 2 years after the outbreak.[7] We are firmly back in the cycle of 'panic and neglect'.

At the same time, the allocation of pandemic preparedness funding remains heavily skewed towards vaccine development. While investment in vaccines is vital, this focus has come at the expense of diagnostic preparedness, the single tool that enables early detection, surveillance and outbreak containment. If even a fraction of this funding had been directed towards diagnostic R&D and validation, we would already possess a suite of rapid, field-ready tests covering the majority of WHO priority pathogens. Balancing investment between all medical countermeasures is essential for a credible and effective 100-day response.

In addition, lower- and middle-income countries (LMICs) are consistently the most disproportionately affected by such funding reductions.[8,9] Since most, if not all, WHO priority pathogens disproportionately impact LMICs, lessons must be learned and decisive action taken, not only to increase funding for pandemic preparedness but also to ensure equitable distribution to guarantee diagnostic availability for all. This was shown starkly in a review of diagnostic accessibility during the COVID-19 pandemic, which found that only about 35% of all diagnostic tests administered worldwide (as of February 2023) were used in LMICs despite these countries containing 75% of the population.[10]

Preparing for 'Disease X' (the placeholder term for an as-yet-unknown pathogen with pandemic potential) may require a shift from pathogen-specific to family-level preparedness as highlighted in the 2024 pathogens prioritisation report by the WHO.[11] Building libraries of conserved antigens, monoclonal antibodies and validated assay templates for pathogens potentially headed for pandemic outbreaks would permit rapid adaptation once a novel pathogen is identified. Emerging tools in synthetic biology, computational antigen design and AI-driven epitope prediction may further accelerate this process, provided that global data sharing and equitable access frameworks are in place.

Ultimately, the challenge is not scientific but structural. Without consistent and equitable resourcing in preparedness, ongoing development and banking of the necessary diagnostic 'building blocks' and a dynamic regulatory framework, we must be honest and acknowledge that the 100-day target is aspirational. As the IPPS makes clear, only by embedding diagnostics within a continuous preparedness framework, rather than relying on reactive mobilisation, can we hope to respond swiftly and effectively when the next pandemic threat appears. Preparedness must be seen as a continuous, globally distributed endeavour, one that integrates research, regulation and capacity building long before the next pandemic begins. Diagnostics cannot be constructed overnight. If we wait until an outbreak to begin development, the 100-day clock will already have run out.

Authors' contributions

Caitlin R Thompson (Conceptualization [lead], Investigation [lead], Resources [lead], Writing – original draft [lead], Writing – review & editing [lead]), Emily R Adams (Conceptualization [supporting], Writing – original draft [supporting], Writing – review & editing [equal]), Tom E Fletcher (Conceptualization [supporting], Writing – original draft [supporting], Writing – review & editing [equal]https://credit.niso.org/).

Acknowledgements

The views expressed are those of the author(s) and not necessarily those of The Pandemic Institute.

Funding

The research was funded by The Pandemic Institute, formed of seven founding partners: The University of Liverpool, Liverpool School of Tropical Medicine, Liverpool John Moores University, Liverpool City Council, Liverpool City Region Combined Authority, Liverpool University Hospital Foundation Trust and Knowledge Quarter Liverpool.

Competing interests

E.R.A. works for Global Access Diagnostics, a diagnostic development company. C.R.T. and T.E.F. have had shared projects with Global Access Diagnostics in the past.

Ethical approval

Not required.

Data availability

Data sharing is not applicable to this article as no datasets were generated or analysed during the current study.

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Received: 13 February 2026. **Revised:** 30 March 2026. **Accepted:** 6 April 2026