Enablers and barriers to scaling up infectious diseases POC testing in the primary care setting in Australia

Lise Lafferty, Sophie Lewis, Kerryn Drysdale, Rob Monaghan, Angela Kelly-Hanku, Rebecca Guy, Carla Treloar

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Background

- RAPID-funded project
- POC testing streamlines care cascades, enables prompt response
- Existing infectious disease POC testing programs (e.g., STI, hepatitis C) currently funded by government

Methods

- 30 semi-structured in-depth interviews
- Participants: decision-makers within key stakeholder organisations
- Stakeholders identified/nominated by RAPID Chief Investigators
- Interviews conducted between July 2021 and Feb 2022

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RAP:D

POCT ID Scale Up: Participant expertise

- Federal and state-level health departments
- Peak national NGOs
- Clinicians
- Pathology
- Technology
- Accreditation

- Academics
- Health economists
- Workforce training
- Prison health
- Aboriginal and Torres Strait Islander health

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RAP:D

Scale up considerations

- Who (population groups)?

- What (infectious diseases)?

- When (routine screening / symptomatic)?

- Where (primary care / settings)?

- Why (disease management / streamlining care cascades)?

- How…?

Aim

What are the barriers and enablers to <u>country readiness</u> for sustainably scaling up an infectious diseases point-of-care testing model in the primary care setting in Australia?

Unitaid Scalability Framework

CREATE GLOBAL CONDITIONS FOR SCALE-UP

- **Create sustainable access conditions**
  Evidence, normative guidance, regulatory approval, affordable pricing, adequate supply base, delivery models…

- **Align and coordinate with global donors and partners**
  Strategic gaps/priority needs, recommended approaches/tools, planning/budgeting cycles, procurement…

- **Generate and disseminate knowledge and evidence**
  Study results and other evidence, project/program progress, lessons learned, investment case, global advocacy…

ESTABLISH COUNTRY READINESS FOR SCALE-UP

- **Secure political and financial support**
  Political engagement and buy-in, donor/domestic funding, national advocacy…

- **Ensure programmatic and operational readiness**
  Supportive policies, integration into national programs, effective supply-chain systems, adequate health system capacity, timely registration of products…

- **Create community-driven demand**
  Civil society engagement, grassroots advocacy …

TRANSITION (PROJECT-SPECIFIC)

- **Transition services critical to vulnerable populations' health**
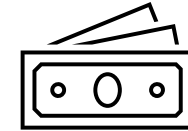
SCALE-UP

COMMITMENTS FOR SCALE-UP COUNTRIES
Agreements signed, recommendations made, orders placed, funding secured, policies adopted

Regulatory Approvals

*From a registration perspective for these companies registering, they probably need some sort of **guarantee on volumes** or alternatively need to **lower the barrier to registering** a particular product in terms of those **costs for them to recoup** or, obviously, they need to sell so many devices or tests before they can recoup that. **I think that's the big barrier for them at the moment.*** (Participant #2)

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Therapeutic Goods Administration (TGA)

We are Australia's government authority responsible for evaluating, assessing and monitoring products that are defined as therapeutic goods. We regulate medicines, medical devices and biologicals to help Australians stay healthy and safe.

Funding Models / Sustainability

The first, the biggest, and **the most important enabler is the funding model**. *(Participant #1)*

I do think that the **decision of what goes on the Medicare reimbursable list** *and what does not* **requires lobbying and requires real engagement** *from probably the biggest influences in healthcare. (Participant #15)*

National Advocacy

*I think **Australia having signed** up to the **WHO [hepatitis C] global targets** is probably a **system enabler**. (Participant #8)*

*The capacity that the **national [HIV, STI, and BBV] strategies** are very well put together and so it **provides a really strong roadmap for which point-of-care testing could be implemented**, because once you have those policy frameworks in place, that makes it a little bit easier to … for the **government funders to then align funding and apply implementation efforts** along the direction of the national strategies, so I think **having a policy framework in place is really critical**. (Participant #22)*

*I think obviously **someone needs to take on the regulatory and policy-based push** and that's kind of hard to pick. […] It needs to be **some sort of invested yet widescale party that is willing to drive** through things like the TGA regulatory stuff and the MSAC funding stuff at sort of a **sustained level over time**. I don't really know who that would be. [laughs] I don't think we really have anyone. (Participant #30)*

Advocacy: Who is responsible for pushing the agenda?

*I think the biggest difficulty for the reimbursement of point-of-care testing is there is not really a precedent yet for us to build on [...] and **point-of-care testing doesn't really fit** nicely into the existing Medicare Benefit Schedule where there is **a strict pathology arm and a strict service arm, whereas point-of-care testing is a bit of both**. So it creates a bit of **a policy dilemma** for [government] as to well, **"where does this fit?"**. (Participant #8)*

***Who should be doing this?** Someone should be doing this but it kind of **falls between the cracks**. [...] Our **advocacy muscle** as a public health community **is pretty weak** and I think we are **not doing our job properly**. (Participant #12)*

Other (stakeholder) barriers

*The other policy dilemma […] is of course the **pathologists don't want [government] to remove their income** from the [Medicare Benefits Schedule], so there is a sensitivity I guess there as well. (Participant #8)*

*I think the **biggest roadblock is the funding issue** and so and I think that is interconnected with the fact that right now **laboratories would be set to lose quite a bit of income** from remote communities with testing. (Participant #15)*

COVID-19: Case example of system readiness

COVID has offered a new opportunity for the potential expansion of the use of point-of-care tests for infectious diseases that government has recognised an important need for being able to have tests that people can do at the point-of-care or at near the point-of-care […]. And I think that that has generated momentum in terms of being able to get political commitment to figure out a mechanism by how do we sort out where the point-of-care tests fit. (Participant #22)

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