

# Tapping into existing policy and regulatory synergies to facilitate scale-up of HIV self-testing in Malawi: challenges & opportunities

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# Outline

- Who are the key players ?
- Current synergies and interactions
- Opportunities for self-testing
- Roles and responsibilities in getting started at country level
- Questions for reflection in relation to scale-up





# Who are the key players?

- Key informant interviews conducted in Malawi
- Formal qualitative methods used to conduct a policy analysis (actors, process, content, context)
- Important to understand the actors involved when getting started at country level – think widely and use ‘snowballing’ e.g.
  - HIV policymakers
  - Implementers
  - Lab sector
  - Regulators
  - Also academics, bilaterals, donors, civil society





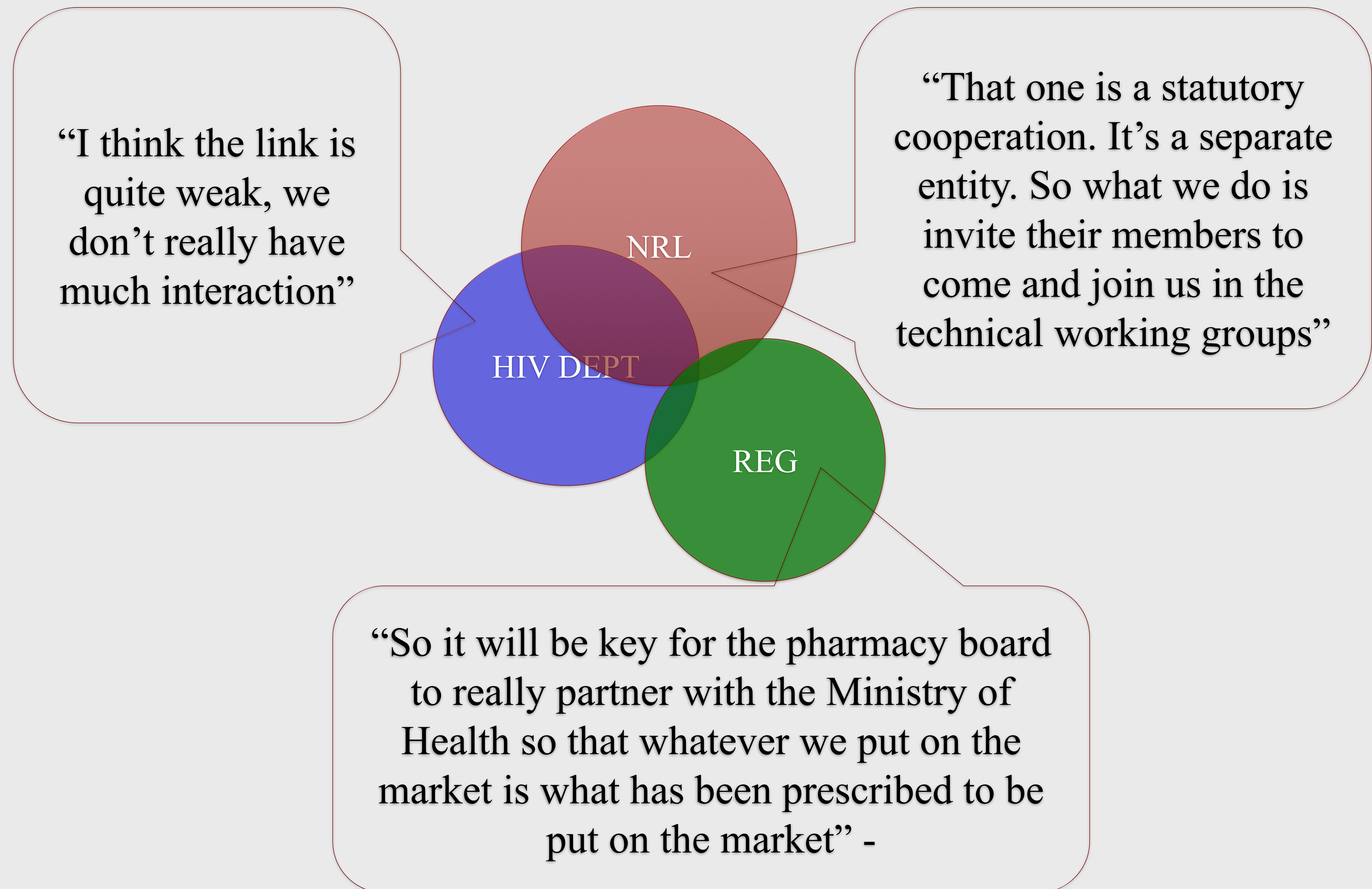


## Current synergies and interactions:

- Current relevant interactions happening among HIV programme and reference lab in Malawi
- But less involvement of regulatory bodies such as Pharmacies, Medicines and Poisons Board (PMPB) in these when we started.
- Significance of informal interactions should not be ignored



# Constituency interaction





# Challenges with interactions

- HIV programme and reference lab currently sit on same committees e.g. HIV testing.
- But Pharmacy, Medicines and Poisons Board (PMPB), a regulator, doesn't sit there.
- Currently regulatory vacuum as PMPB has no clear mandate but are addressing it







## Opportunities for self-testing regulation in Malawi:

- PMPB Bill in the process of getting to Parliament; to enable PMPB regulatory mandate for medical devices (and diagnostic tests)
  - Prequalification from WHO/Global Fund Expert Review Panel for Diagnostics
  - Capacity strengthening and support interactions between policy, reference lab and regulators
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# Strategies for getting started

- To deliberately include funding the participation of key stakeholders in working groups that focus on HIVST
- Having identified challenges, working under STAR to address them by bringing the 3 key constituencies (policy, regulatory and lab) together.
- Meanwhile, engaging the three through action planning and workshops; to continue process next phase of STAR
- Capacity building process to continue in skills building workshop (tomorrow)
- To also engage more with community health departments and civil society partners involved with HIV testing.







## Roles and responsibilities of key constituencies in getting started

- **Policy:** clarifying current policy environment and research needs to inform policy and practice
  - **Reference laboratory:** ensuring quality control; getting informed by initiators of process about expectations.
  - **Regulatory bodies:** noting capacity gaps within institution and regulatory framework. Clear mandates of responsibility for *in vitro* diagnostics
  - **Researchers:** engaging policy makers, regulators and lab groups at initial stages and retaining the engagement
  - **Civil society:** engaging constituencies, community engagement and demand creation
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- **Note:** expectations must be clear. Who should clarify?





## Opportunities to facilitate scale-up in Malawi:

- Technical working group brings together key actors
  - Key informants state that research evidence is keenly awaited and there is opportunity for researchers to engage directly with policy, regulators and reference lab.
  - Process to also engage more with key stakeholders such as community health and civil society.
  - Health systems operations research to investigate integration of self-testing into public health sector – e.g. the system of Health Surveillance Assistants
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## Questions for reflection in relation to scale-up:

- How to support capacity of PMPB?
  - How can regulation and policy development work in tandem? Addressing this is regulatory workshop tomorrow
  - What about post-market surveillance?
  - How should researchers and implementers better engage with policymakers and regulators?
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