

A Critical Systems Heuristics approach exploring new TB vaccine (M72) implementation in a high-burden African context.

Julia Ruokomäki, MD, MSc Global Health

Prof. Benjamin Kagina (VACFA)

Prof. Rudzani Muloiwa (VACFA)



Agenda

- 1 Background & Introduction
- 2 Methodology
- 3 Results
- 4 Discussion
- 5 Summary



Introduction



- TB is the leading cause of death from a single pathogen worldwide.
- In 2023, an estimated **10.8 million** people **fell ill with TB worldwide**. **1.25 million** people **died from TB** in 2023.
- **2.5 million** people **fell ill with TB in the African region**, accounting for a **quarter of new TB cases** worldwide.
- **424,000** people **died** from TB in the **African region** in 2022. Over **33% of TB deaths** occur in the **African Region**.





- South Africa has one of the highest burdens of TB globally.
- In 2021, South Africa alone had **over 56 000** (153/day) **people dying due to TB.**
- **TB has bimodal distribution:** peaks occurring in early childhood and among adolescents and adults.
- **HIV** is the most important risk factor.
 - In 2021, the WHO estimated that **71% of TB** were in **people living with HIV.**



Reference: NICD South Africa

Current TB vaccination

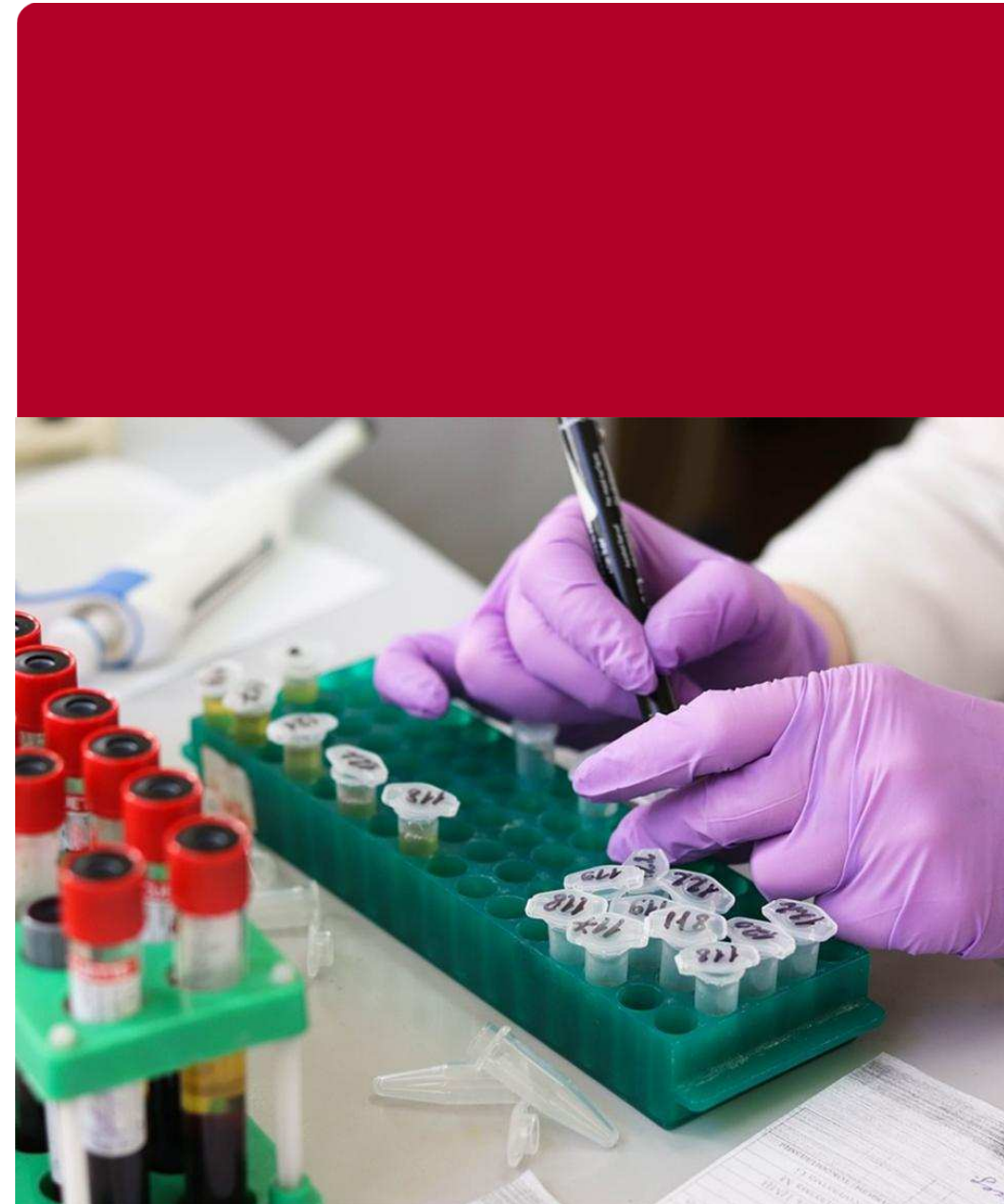
- **Childhood vaccination:** Bacillus Calmette-Guérin (**BCG**) is the **current TB vaccine** in South Africa's immunization schedule.
- Given at birth since 1973 to protect **infants** from severe TB (e.g. miliary TB, TB meningitis).
- Limited and variable protection against **pulmonary TB** in adults.



**Invented in
1921**

New TB vaccine: M72/AS01E

- This vaccine candidate consists of the **M72 fusion protein** and the proprietary GSK **adjuvant** system **AS01E**.
- **Primary Indication: Prevention of TB disease**
- **Target Population(s):** Adolescents, Adults, People living with HIV, People with TB infection

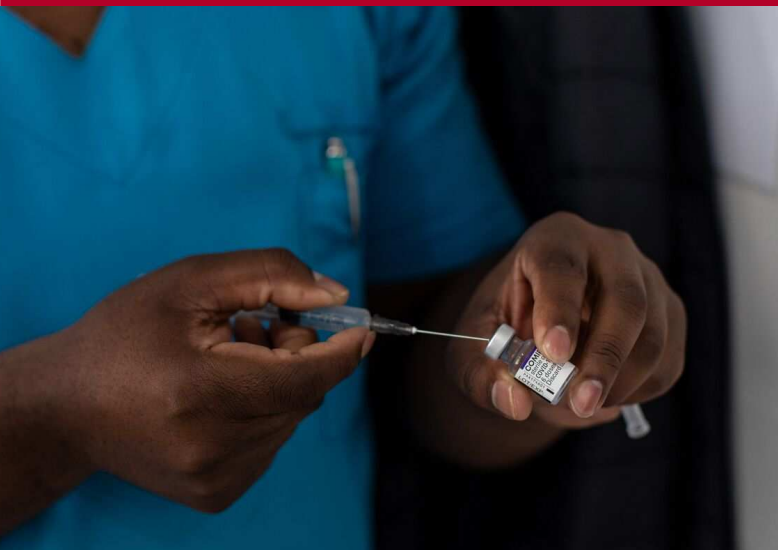


Why M72 TB Vaccine?

- **M72/AS01E** vaccine candidate showed **50% efficacy** in phase 2 trials (Kenya, SA, Zambia) in **preventing pulmonary TB**.
- **Phase 3** multi-country trial is currently underway.
- Promising for **individuals with latent TB**, offering potential impact in high-burden settings.
- Could **reduce TB incidence** by targeting adult pulmonary TB, the main source of transmission.



Vaccine Delivery Landscape in South Africa



The Expanded Program of Immunisation focuses mainly on childhood vaccination.

Adolescents and adults are not usually included in routine vaccination efforts (except HPV for adolescent girls).

Vaccine delivery is managed through top-down approach from **National to Local levels**.

Challenges: fragmented governance, health system constraints, and infrastructure (e.g. cold chain)

Research Question:



How can the M72 vaccine for adolescents and adults be **effectively implemented** into **South Africa's health system** through collaborative efforts between stakeholders, while **addressing systemic barriers, promoting equity, and ensuring sustainability** in high TB-burden settings?



Methodology

Method:

- Interviews with key stakeholders involved in TB/vaccination research, immunisation policy, and delivery.



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Participants



Number of Participants	Role
3	Technical Advisor
2	Provincial EPI Manager
3	TB Physician/Researcher
1	Vaccinologist
2	TB Vaccine Researcher
1	TB Implementation Researcher
1	TB Vaccine Researcher/Physician
Organization	
2	Philanthropic Organization
2	Ministry of Health
1	NITAG
2	NGO
5	Academia
1	WHO

Semi-Structured Interviews

Online (Microsoft Teams)

Critical Systems Heuristics

Critical: Reflectively inquiring into the validity of current thinking with a quest to uncover **improved ways of perceiving and viewing the situation.**

Heuristics: A process where all participants in the situation collectively learn their way towards a **shared understanding and alignment around action.**

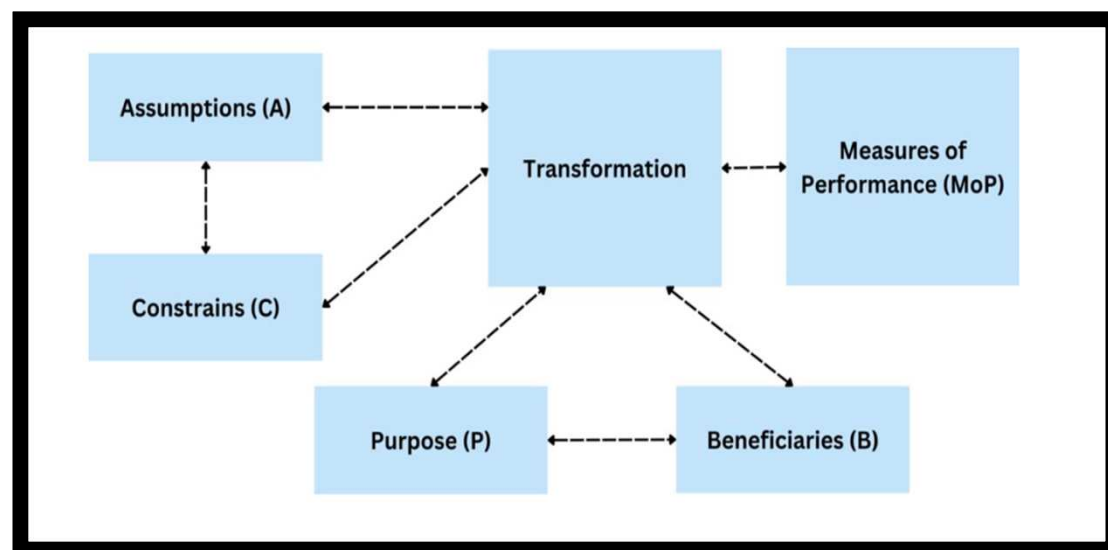
Systems: Seeking a holistic view and solution, one connected with past reality but also seeking future relevance. The process itself is one of **sewing in views as opposed to seeking one ultimate correct view** and solution.

Originally developed by Werner Ulrich, adapted by Strümpfer, J. P. (2022)

Critical Systems Heuristics

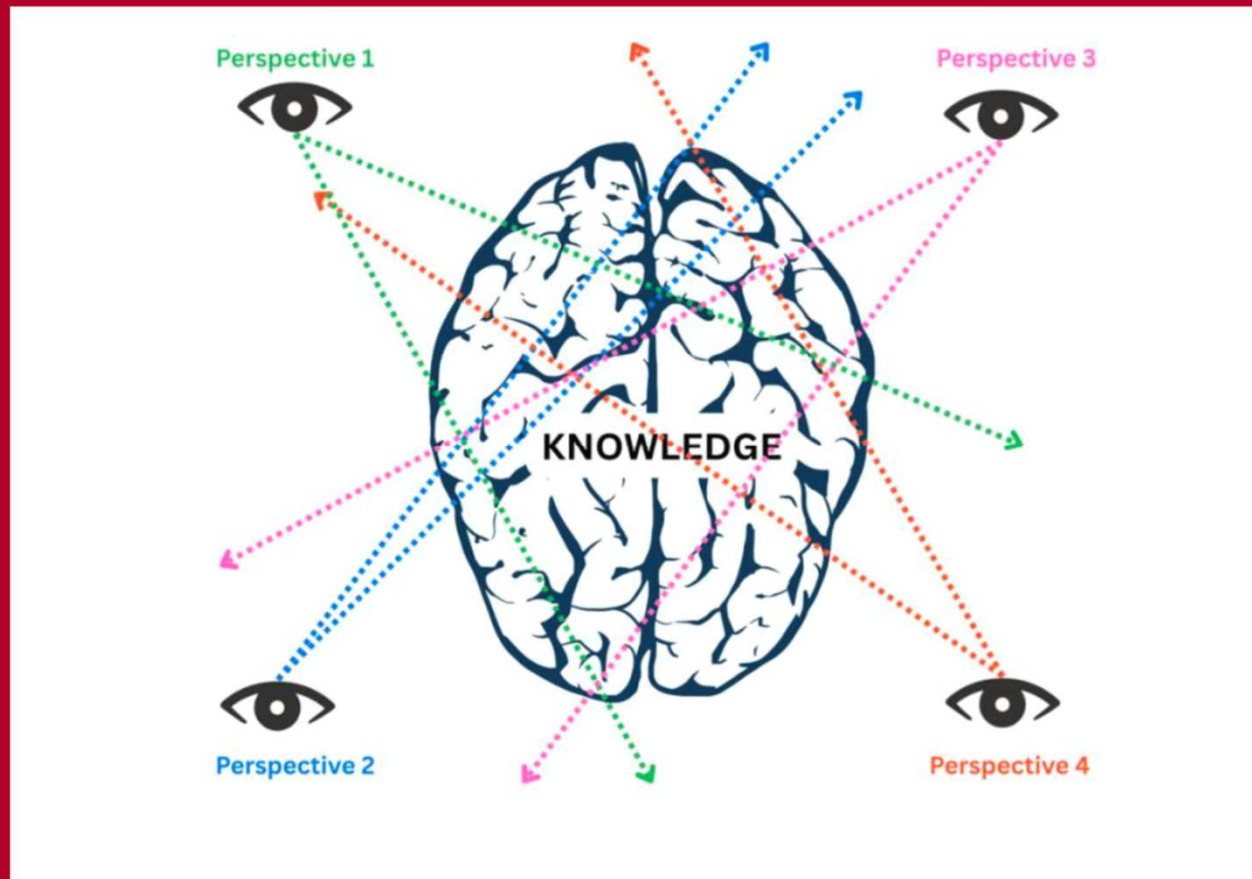
Sub questions:

1. What is the perceived **purpose and value of the M72** vaccine according to key stakeholders in South Africa?
2. Who are identified as the intended **beneficiaries** of the M72 vaccine, and who risks **being excluded** from M72 **vaccine access**?
3. What **assumptions** are made about the feasibility, financing, and health system readiness for M72 rollout?
4. What **constraints** are identified as **potential barriers** to equitable and effective M72 vaccine implementation?
5. What **inputs and outputs** are necessary to ensure the success of the M72 vaccine rollout?
6. How should **success be measured**, and what mechanisms are needed to **ensure accountability and legitimacy in decision-making**?

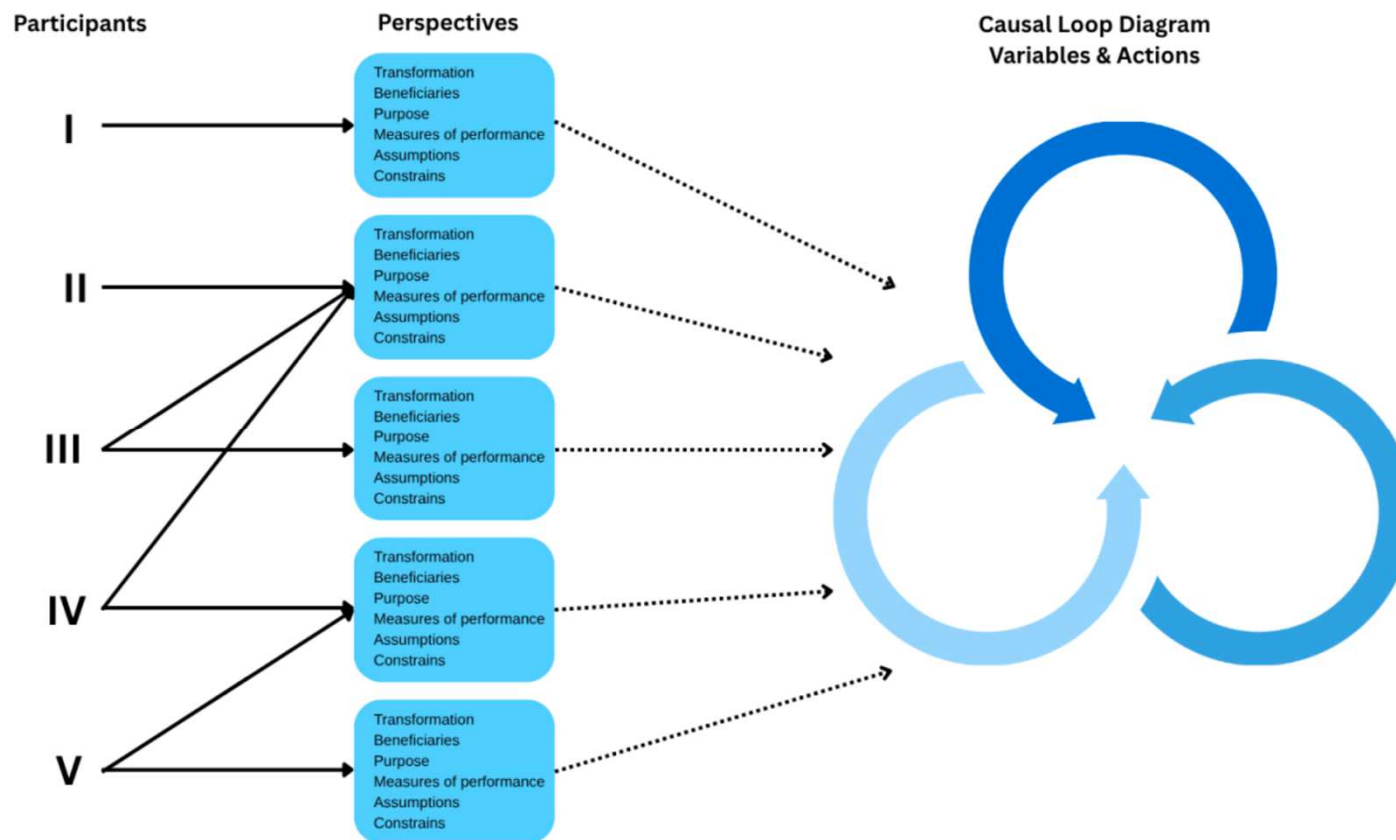


Modified Critical Systems Heuristic Framework into six boundary categories and their interactions.

Multiple Perspectives



Research approach based on Strümpfer's multiple perspectives





Multiple Perspectives formed from the interviews

	High Vaccine Coverage for Target Population	Hybrid Delivery Models
Transformation	In: Absence of TB vaccine program for adolescents and adults Out: Protection of high-risk groups with M72	In: Multiple different delivery models Out: Broader population coverage
Beneficiaries	<ul style="list-style-type: none"> • People living with HIV • Underserved communities • High burden areas 	People living with high-risk of TB
Purpose	Ensure fair allocation and maximum impact from limited vaccine supply	Improve accessibility and equity of M72 delivery
MoP	<ul style="list-style-type: none"> • Equity indicators • Population coverage on high-risk areas 	<ul style="list-style-type: none"> • Coverage rates across diverse delivery channels • Reach of underserved populations
Assumptions	High-burden communities are a priority target to reduce TB incidence	Taking services to communities increases vaccine uptake
Constraints	<ul style="list-style-type: none"> • Limited experience outside infant vaccines • Inadequate data systems 	<ul style="list-style-type: none"> • Lack of coordination • Lack of funding • Lack of resources

Multiple Perspectives formed from the interviews

	System Capacity for Scale Up	Adequate Vaccine Supply
Transformation	In: Adequate funding, workforce Out: Timely rollout of M72 without compromising other services	In: IP reform, pooled procurement Out: Stable supply, affordability, increased equity
Beneficiaries	HCW, target communities, national health system	TB-endemic countries, underserved populations
Purpose	Ensure that rollout does not overburden existing health services	Ensure affordable access to M72 for high TB burden countries
MoP	<ul style="list-style-type: none"> Health system readiness Minimised disruption of routine care 	<ul style="list-style-type: none"> Vaccine price transparency Licensing agreements Proposition of M72 supply manufacture domestically
Assumptions	Current health system is under pressure and cannot do a major vaccine rollout without extra support	<ul style="list-style-type: none"> Global stakeholders will act in solidarity Manufacturers will agree to shape IP
Constraints	<ul style="list-style-type: none"> HCW shortage Funding limitations <ul style="list-style-type: none"> Existing service burdens 	<ul style="list-style-type: none"> IP protection laws Profit driven manufacturing Lack of accountability for global equity

Excerpts: Decision Making

“Manufacturers are the ones making the key decisions...the profits and losses are the main determining factors of vaccines and how they progress along the pipeline.”

(TB Vaccine Researcher)

Excerpts: Equity

“Achieving equity is complex: marginalised groups have historically been the last to benefit from new vaccines, despite often participating in clinical trials.”

(TB Vaccine Researcher)

“You would definitely not want a situation where low TB burden countries suddenly decide they want to vaccinate all their people at the expense of high TB burden countries.”

(TB Researcher/ TB Physician)

Excerpts: Logistical Barriers

**“Local manufacturing would be a big advantage. If you can manufacture (M72 vaccine) locally, it's closer to where you want to distribute it as well.”
(Technical Officer)**



Discussion: Strategies for Sustainable Implementation



1 Early Planning

- **Local manufacturing** strengthens preparedness and distribution.
- Early **community engagement** builds trust and counters misinformation.

2 Vaccine Delivery

- Target group for rollout is **people with highest risk to TB.**
- **Leverage existing platforms** (EPI, HPV programmes, other health services) for M72 delivery

3 Equity

- Target high-risk groups using **local data**, not just broad national strategies.
- **Promote community involvement** in planning to avoid top-down approaches.

Summary

1

M72 vaccine seen as a crucial tool for reducing TB burden, especially in high-risk groups like people living with HIV, adolescents, and healthcare workers.



2

Decision-making shaped by power dynamics, with strong influence from manufacturers, global actors, and limited community input.

3

Hybrid delivery platform: recommended by combining school-based programmes, health facilities, mobile outreach, and integrated services to reach diverse groups and maximise equitable access.

4

CSH describes how better outcomes emerge when decisions involve **diverse perspectives, power imbalances, and include** those who are **most affected**. It is a reminder that **effective vaccine policy is ultimately a matter of both public health and social justice.**



1. What would your health system need to do to successfully implement new TB vaccine?

2. When making decisions about new vaccine implementation, whose knowledge should matter the most?

3. When program like this gets rolled out, some people might benefit more than others. Who do you think might be left out – and how this could be addressed?

**Thank you
Everyone!**

Questions?

