



HEALTH **STRATEGY** INSIGHT **IMPLEMENTATION**

COULD GOOD POINT-OF-CARE TESTING REVOLUTIONISE ISSUES IN THE REGION?

TIM TUCKER

M.B.Ch.B – Ph.D. – F.C.Path(SA)Viro

PETER MANYIKE

B.Pharm – Ph.D.



26 OCTOBER 2018

- **No interest in any product mentioned**
- **Board member – National Health Laboratory Service**

National clinic and laboratory network

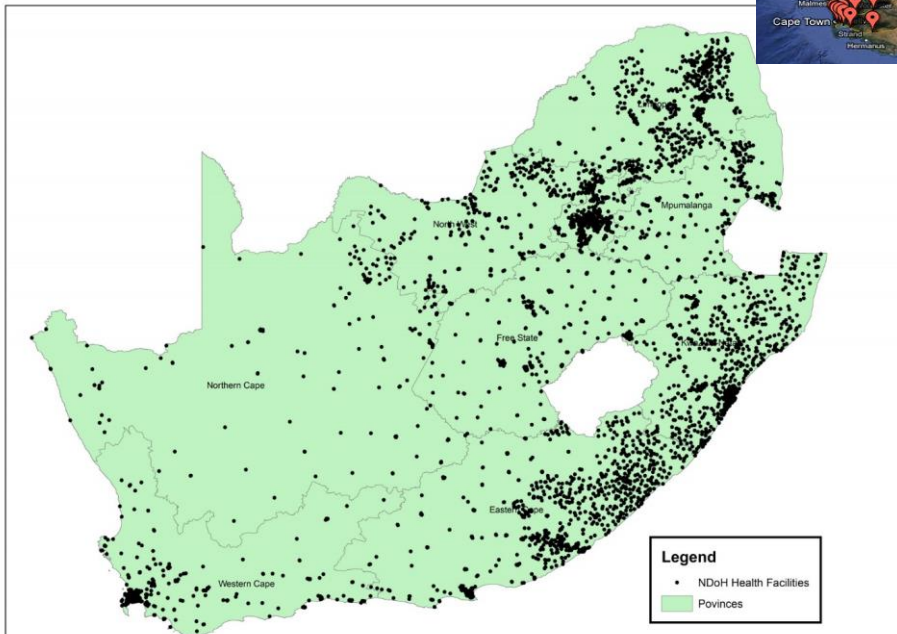


NATIONAL HEALTH
LABORATORY SERVICE

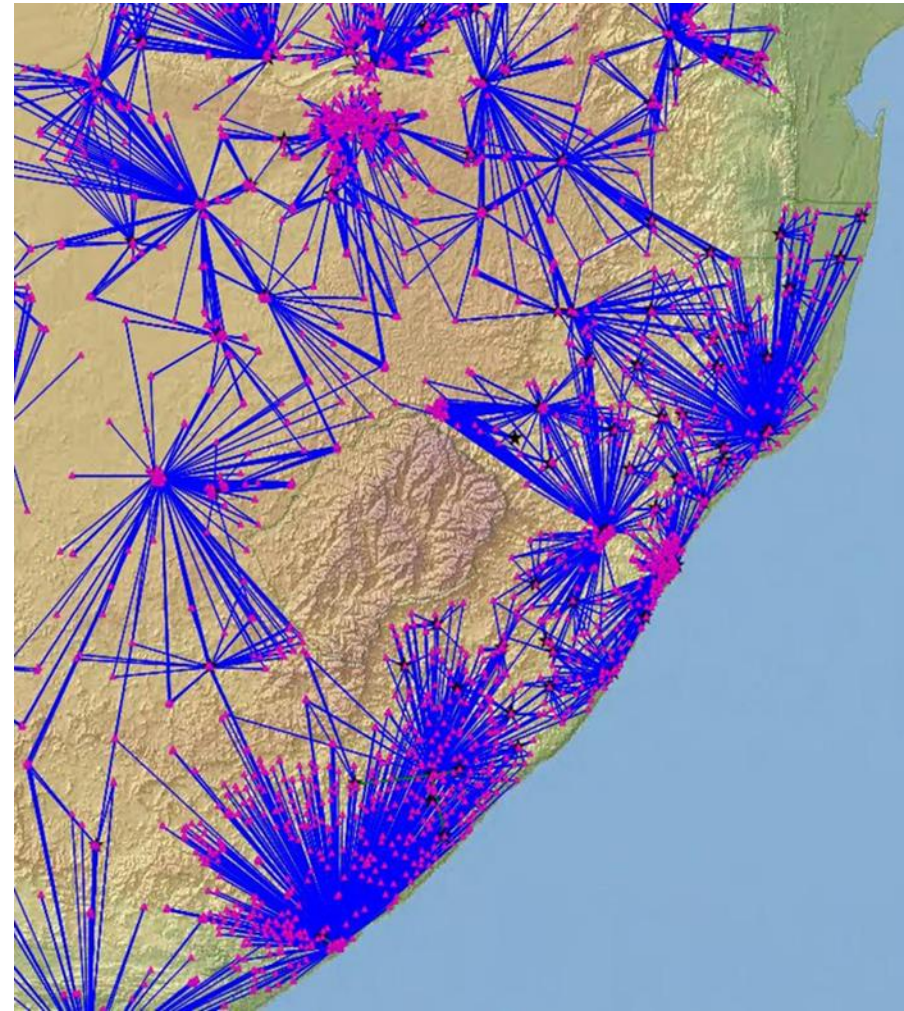
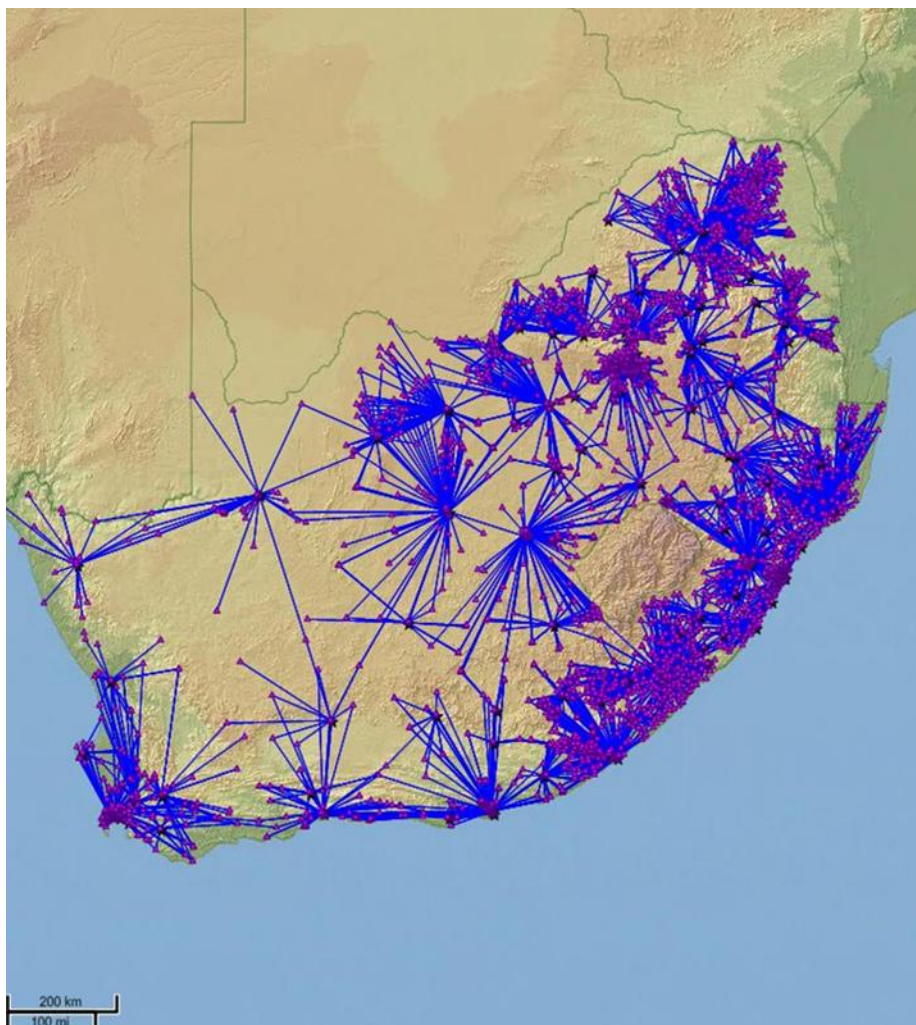


256 NHLS labs

NDoH Healthcare Facilities



National clinic and laboratory network

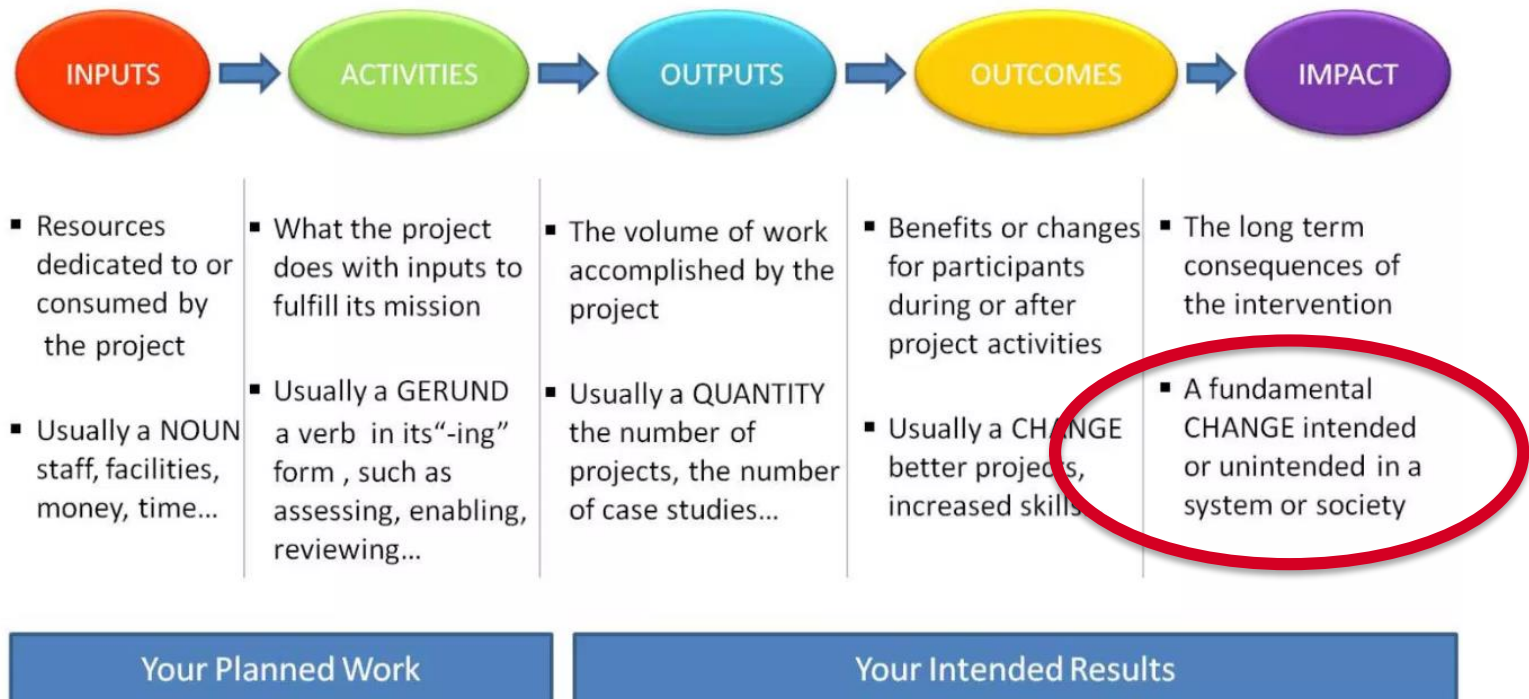


New POCTs - What are we trying to achieve?



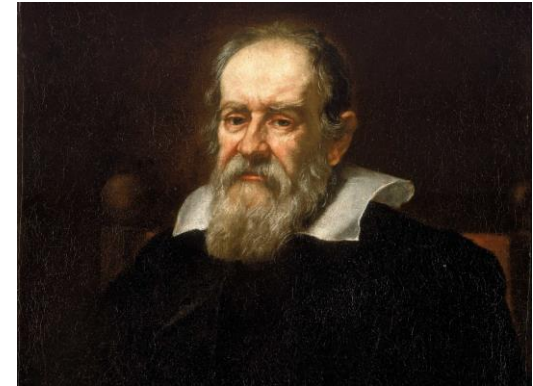
What are Inputs, Outputs, Outcomes and Impact?

The Logic Model Approach

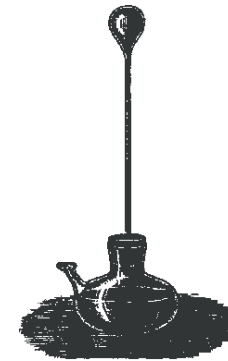


What are we trying to achieve?

- A fundamental CHANGE intended or unintended in a system or society



Hogben test

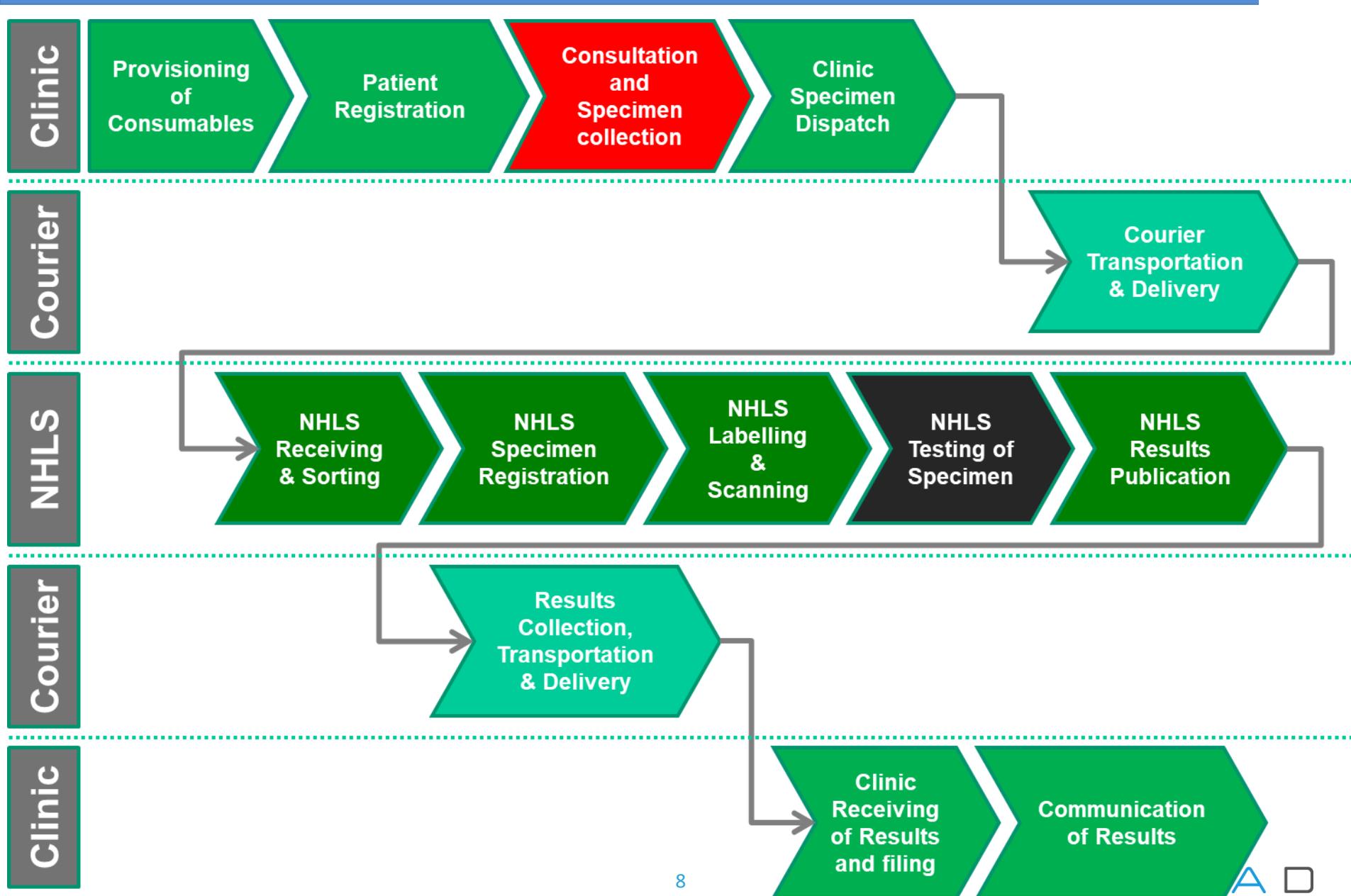


Typical development of POCTs

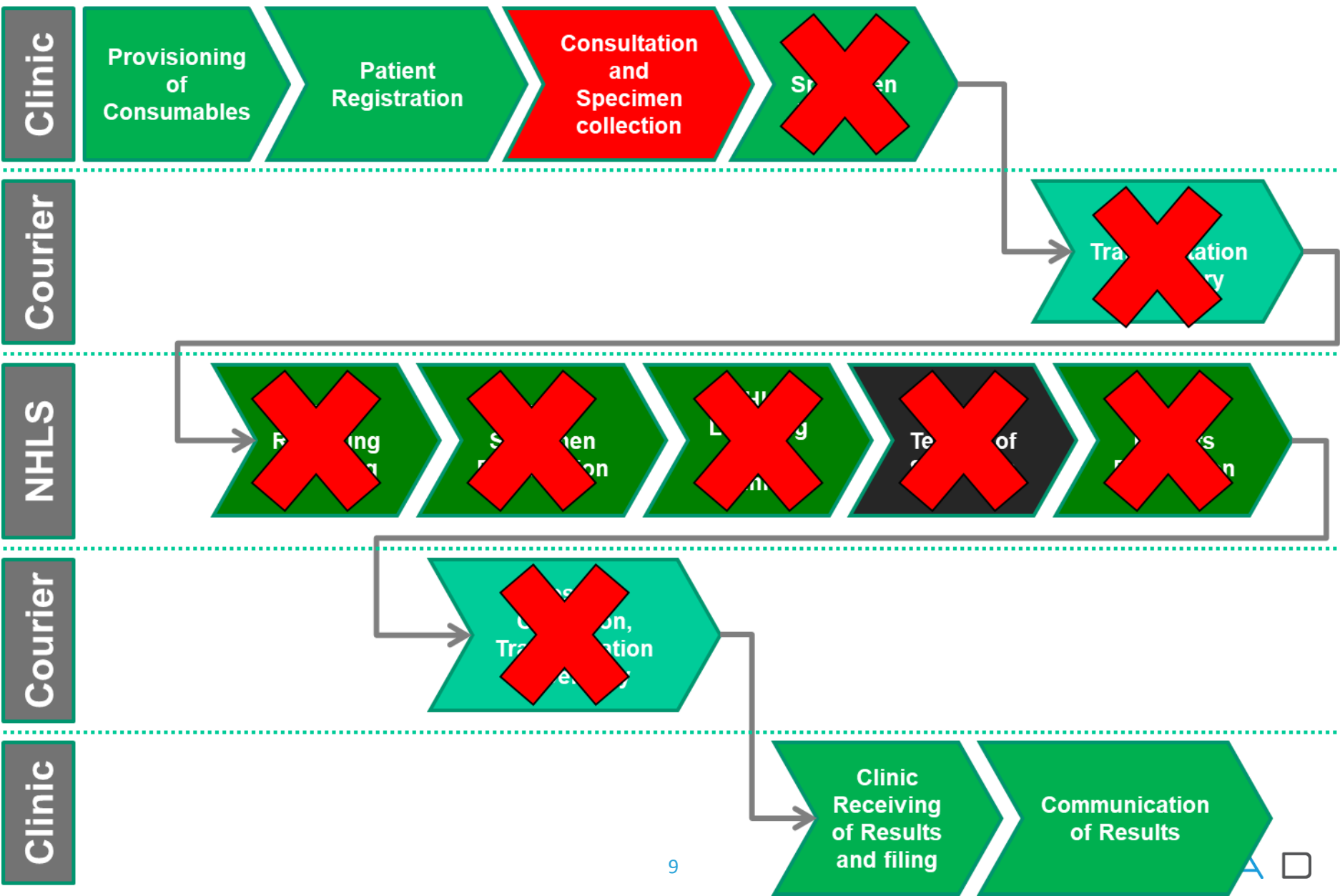
- A fundamental CHANGE intended or unintended in a system or society



Where do POCTs fit?



Where do POCTs fit?



Where do POCTs fit?



Clinic

Provisioning
of
Consumables

Patient
Registration

Consultation
and
Specimen
collection

Clinic Specimen
Testing -
Pre-Analytic
Phase

Clinic

Clinic
Testing of
Specimen

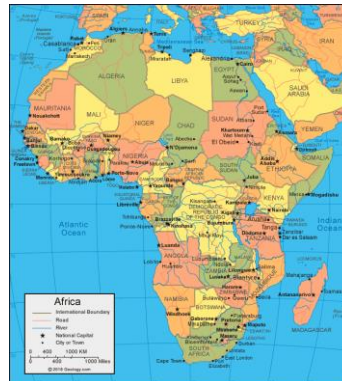
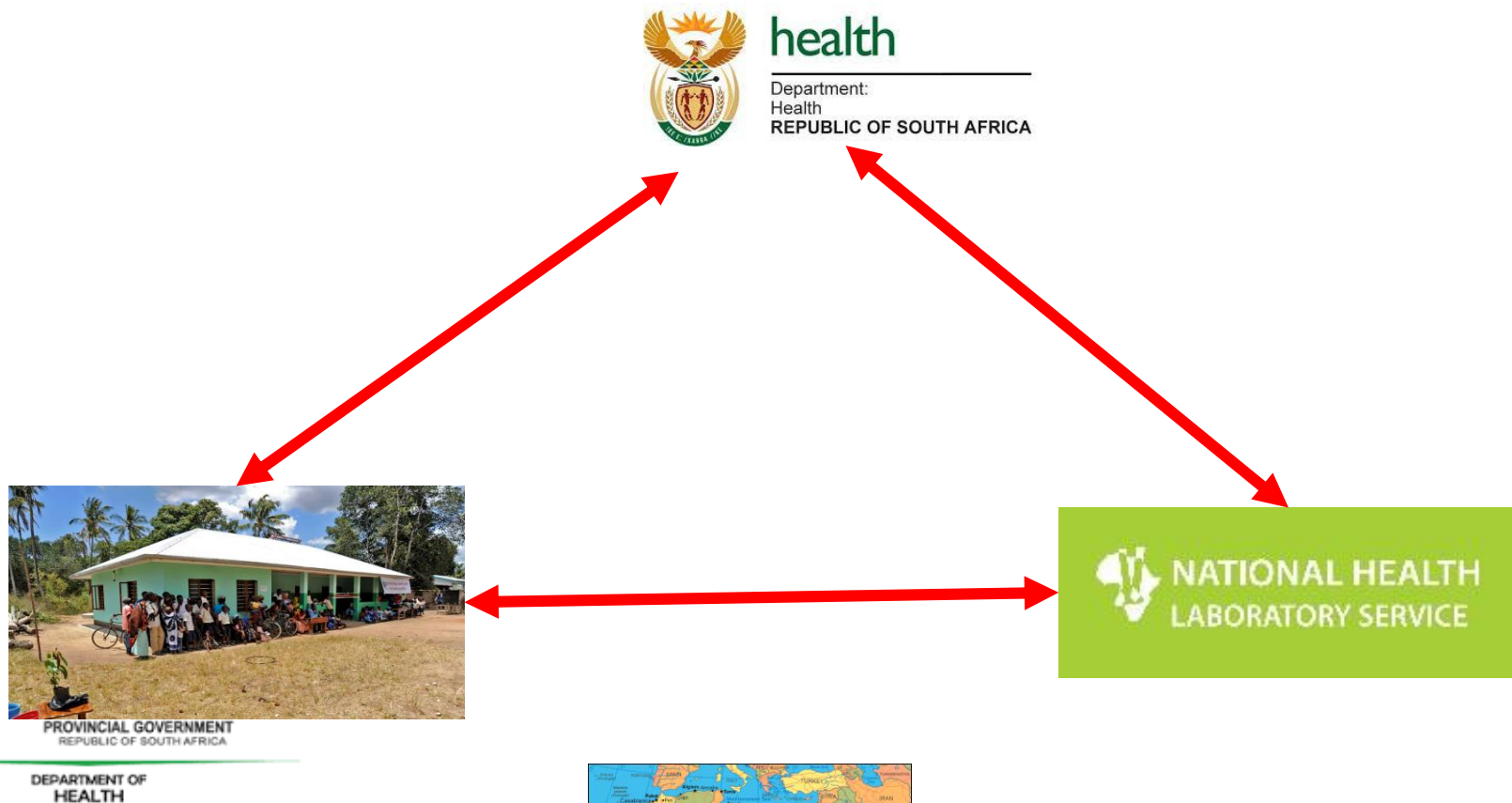
Clinic Specimen
Testing –
Post-Analytic
Phase

Clinic
Receiving
of Results
and filing

Communication
of Results



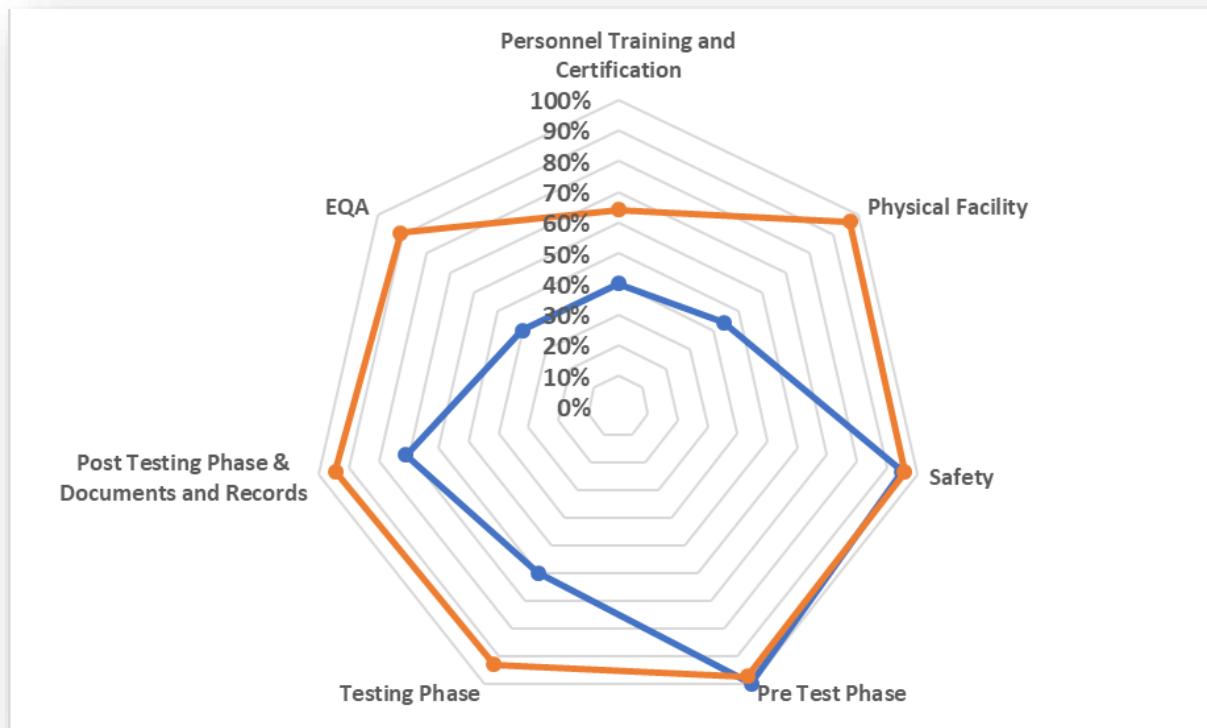
COMPLEX RELATIONSHIP TO NATIONAL MODEL



POCT quality falls within a system



- **POCT's are a lab test**
 - In the hands of non-lab people
- **Same QA principles**
 - Continuous quality improvement



- **Accuracy**
 - Sensitivity
 - Specificity
- **Improve the patient experience**
 - Take less time off
 - No need to come back again for result
 - Home-based



- **Antibody POCT**

- Relatively simple and robust

The accuracy of HIV rapid testing in integrated bio-behavioral surveys of men who have sex with men across 5 Provinces in South Africa
Tendesayi Kufa, MBChB, PhD, ^{a,b,} Tim Lane, PhD, MPH, ^c Albert Manyuchi, DPhil, ^d Beverley Singh, Nat. Dip. Med, Tech, ^a Zachary Isdahl, MBA, ^c Thomas Osmand, MPH, ^c Mike Grasso, MPH, ^e Helen Struthers, PhD, ^{d,f} James McIntyre, MBChB, FCROG, ^{d,g} Zawadi Chipeta, PhD, ^h and Adrian Puren, MBChB, PhD^{a,i}*

- **Molecular POCT - Greatest systemic complexity**

- Specimen issues
- Specialized human capital
- Infrastructure

- **Significant opportunity**



Do they work in the field?



AMERICAN
SOCIETY FOR
MICROBIOLOGY

Journal of
Clinical Microbiology®

Field Evaluation of Performance of Alere and Cepheid Qualitative HIV Assays for Pediatric Point-of-Care Testing in an Academic Hospital in Soweto, South Africa

Tanya Y. Murray,^a Gayle G. Sherman,^{a,b,c} Firdose Nakwa,^b William B. MacLeod,^{d,e} Nosisa Sipambo,^b Sithembiso Velaphi,^b Sergio Carmona^{f,g}

RESEARCH ARTICLE

Peripheral clinic versus centralized laboratory-based Xpert MTB/RIF performance: Experience gained from a pragmatic, stepped-wedge trial in Botswana

Tefera Agizew^{1*}, Rosanna Boyd^{1,2}, Ndwapi Ndwapi³, Andrew Auld⁴, Joyce Basotli¹, Sambayawo Nyirenda¹, Zegabriel Tedla¹, Anikie Mathoma¹, Unami Mathebula¹, Chawangwa Lesedi¹, Sherri Pals⁴, Anand Date⁴, Heather Alexander⁴, Thomas Kuebrich¹, Alyssa Finlay^{1,2}

POCT vs. near-to-care test

- Where to place?

- Ex

- Im

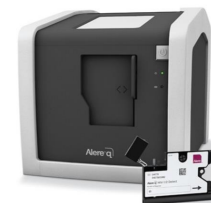


Implement immediately across the board?



Operational requirements:

- Uninterrupted power supply
- Ambient temperature no higher than 30°C
- Biosafety equivalent to smear microscopy
- Adequate storage for test kits (or cartridges) at temperatures no higher than 28°C

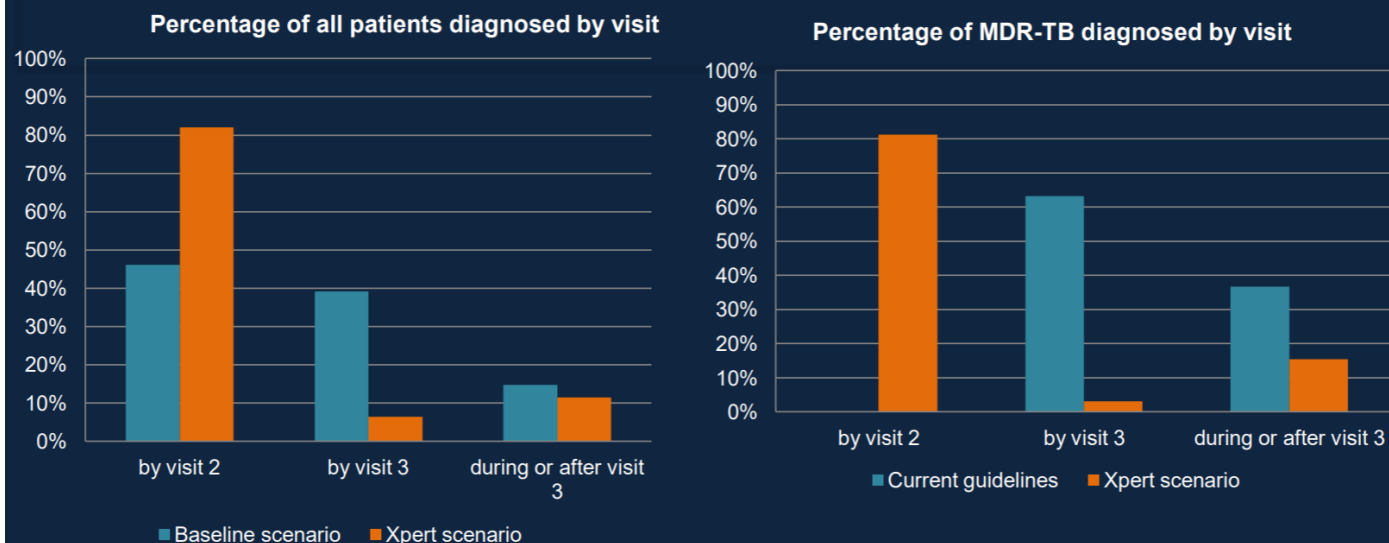


POCT falls within a system



- Should we presume that NTC will have

At full placement
Predicted Time to diagnosis



- Currently 46% of cases are diagnosed by visit 2 and a further 40% by visit 3
- Xpert scenario prediction at full coverage: 83% by visit 2 and 89% by visit 3
- By full placement: 87% diagnoses to be made by GeneXpert

W. Stevens

Boehme study, 2011. Time to detection: 1 day for Xpert/smear, 20 days for LPA, 106 days for DST

NATIONAL HEALTH
LABORATORY SERVICE
NATIONAL INSTITUTE FOR COMMUNICABLE DISEASES



Special purpose rapid tests



- **Incidence testing**

- Differentiates between

- Recent
 - Established

- Possible p

- Annual A

- Incidence



Asanté™ HIV-1 Rapid Recency® Assay for Identification of Recent HIV-1 Infections



Figure 1. Point-of-Care Recency Test (Asante HIV-1 Rapid Recency Assay) Illustration

- **Home-based**

- Significant
 - Partner testing
 - QA issues
 - What does positive mean



POCT and connectivity – the importance of data



health

Department:
Health
REPUBLIC OF SOUTH AFRICA



PROVINCIAL GOVERNMENT
REPUBLIC OF SOUTH AFRICA

DEPARTMENT OF
HEALTH



NATIONAL HEALTH
LABORATORY SERVICE



YES!

- Define need – impact
- Monitor
- Robust policy base
- QA
- Overload existing staff

N



26 OCTOBER 2018

- **Already a game changer**
- **New age – molecular POCT**
- **Works within a system**
 - Cannot presume impact
- **Importance of data linkage**
- **Cost implications**
- **Need to find ways of expanding in region**



SEAD

HEALTH STRATEGY INSIGHT IMPLEMENTATION

MANY THANKS

