

# Implementing point-of-care viral load testing in community HIV programmes in South Africa

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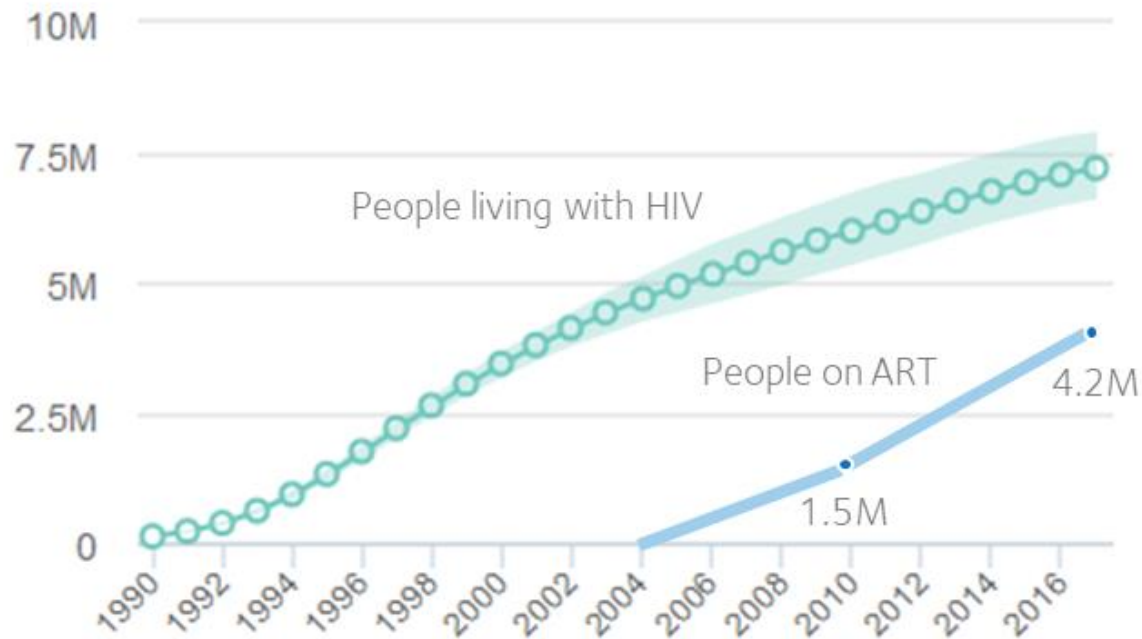
# Outline

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- The HIV epidemic in South Africa
- The public health response: Universal antiretroviral therapy (ART)
  - The impact of universal treatment in primary care
  - Re-organizing healthcare services: community antiretroviral programmes
- STREAM: a randomised trial of point-of-care viral load testing
- Innovation project:
  - Implementing point-of-care viral load testing in community antiretroviral therapy programmes

# The HIV epidemic in South Africa

People living with HIV & on ART in South Africa<sup>1</sup>



- ART for people with low CD4 counts or opportunistic infections

# Universal Treatment for HIV

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- WHO guidelines to provide antiretroviral therapy (ART) for all people with HIV since 2015
  - Reduces morbidity and mortality even in people with high CD4 count
  - Decreases onwards HIV transmission
  - Implemented in South Africa in 2016
- The challenges of Universal Treatment
  - Does the healthcare system have capacity?

# Measuring the impact of universal treatment

- Audit of routine, anonymized clinic & lab data from 8 South African primary care clinics
- Eligibility: Non-pregnant, aged >15 years, initiating ART between Jan 2015-Jun 2018.

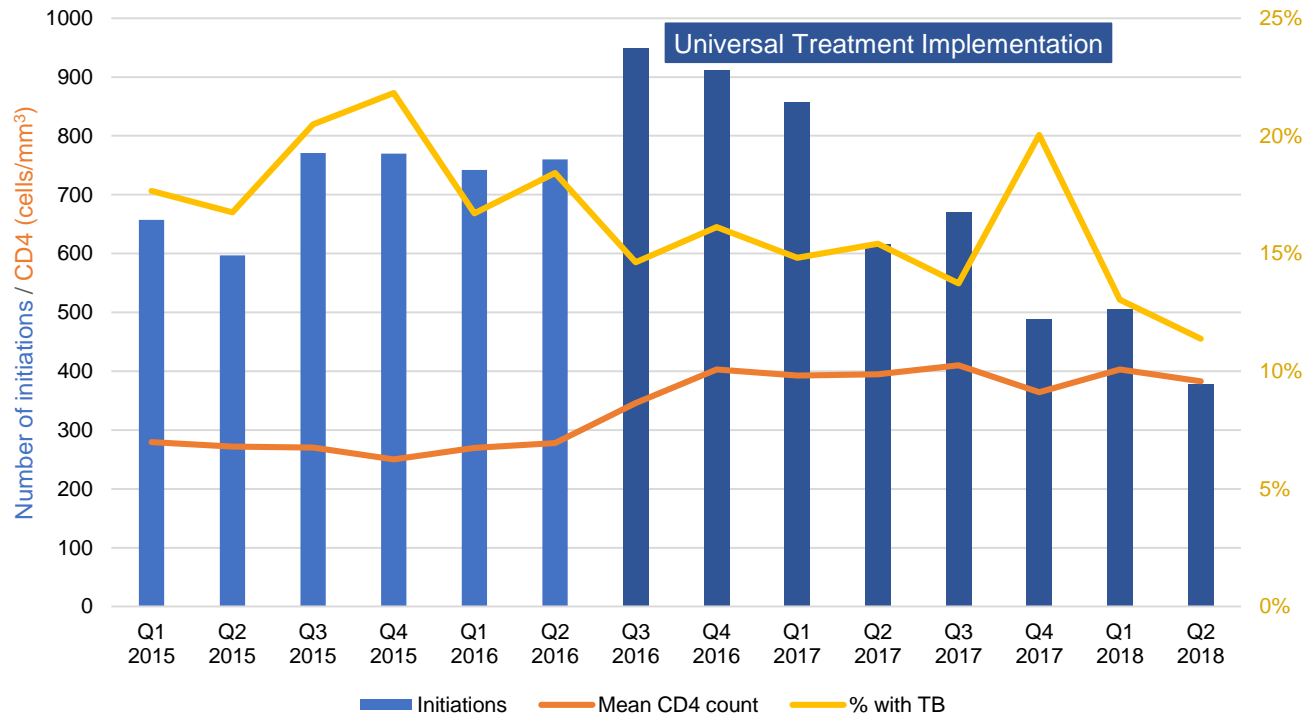
Figure 1: Map of clinic locations



# Does the healthcare system have capacity?

- Aim: describe trends in ART initiations between Jan 2015-Jun 2018, N = 9675

Figure 2: ART initiations, mean CD4 count and proportion of patients with tuberculosis between January 2015 to June 2018



# Providing services to healthier populations

- Starting more 'healthy' people on ART
- Need to adapt services
- Provide tailor made 'differentiated care' services rather than 'one size fits all'



**I feel healthy  
and need to  
be at work!**

John, the client



# Problems with clinic-based HIV services

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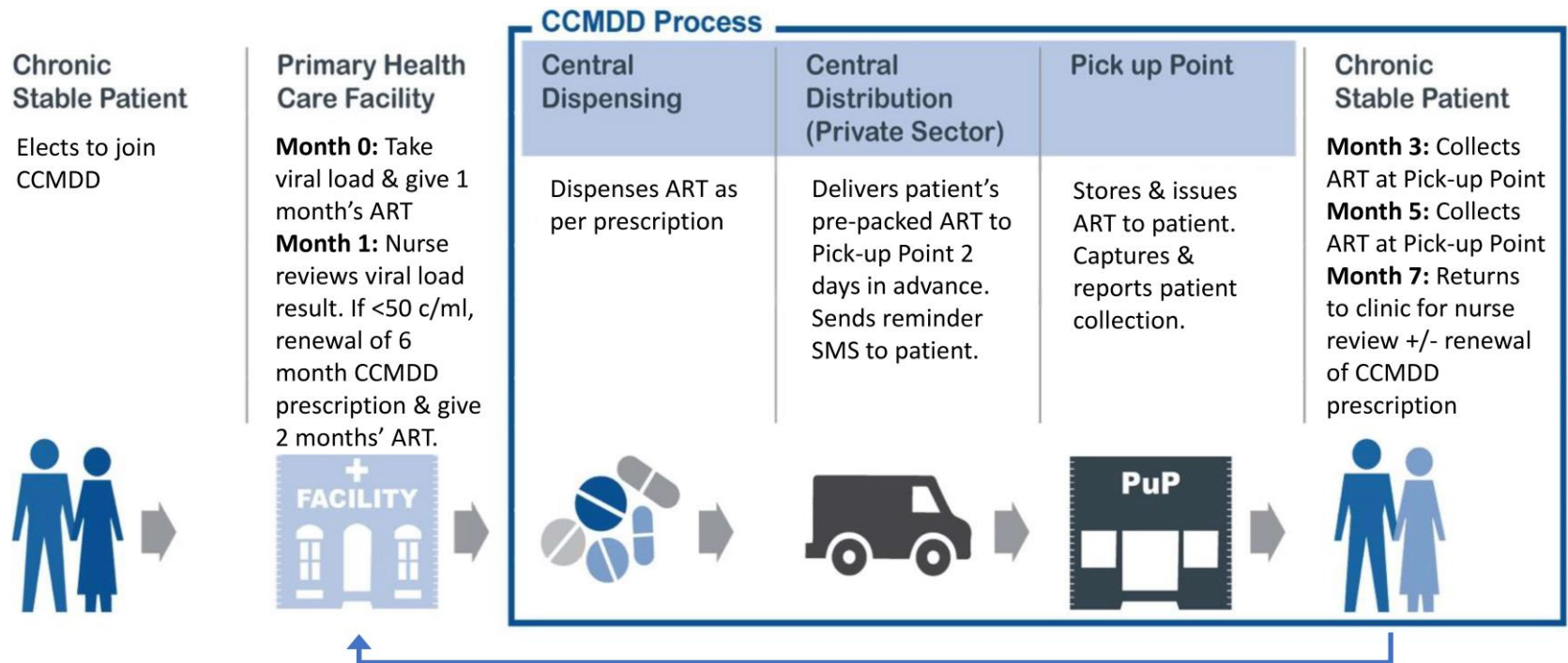
- Interviews and focus groups with 55 patients and 8 healthcare workers
- Need to adapt services
- Provide tailor made ‘differentiated care’ services rather than ‘one size fits all’





# Community ART delivery in South Africa

- Centralised Chronic Medication Dispensing & Distribution (CCMDD)<sup>5</sup>
- Over 1.2 million people receiving ART in CCMDD



# Community ART delivery in South Africa

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- Problems with CCMDD:

# Point-of-care (POC) viral load testing<sup>6</sup>

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- Xpert HIV-1 VL assay
- Fully automated molecular PCR assay
- Provide a viral load result in 90 minutes from 1ml of plasma
- Diagnostic accuracy approved by World Health Organization
- Could reduce clinic visits, save patient transport costs and speed up clinical decisions



# Point-of-care (POC) viral load testing<sup>6</sup>

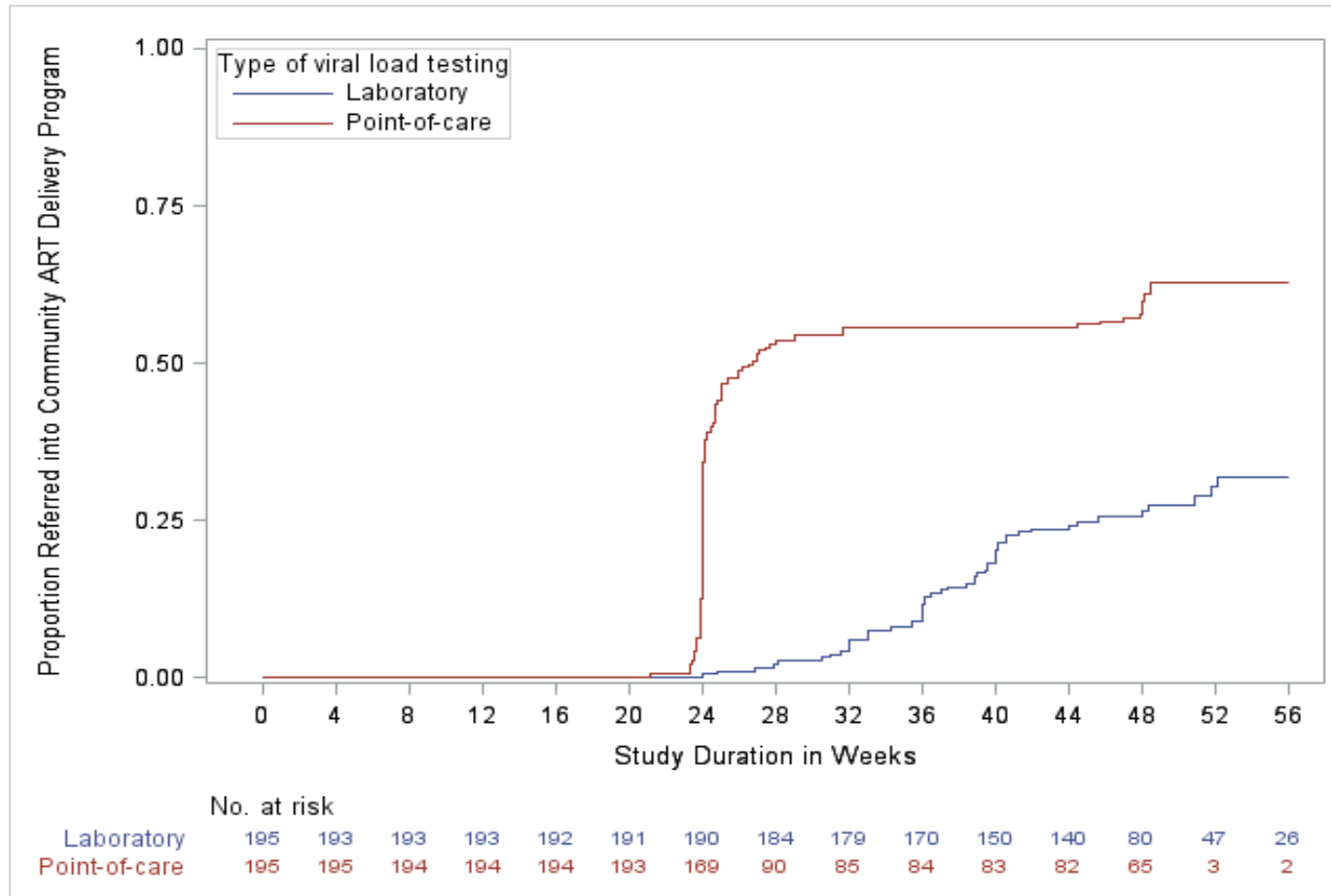
- The Simplified TREATment and Monitoring (STREAM) Study
- Randomized trial of POC viral load testing in Durban, SA<sup>7</sup>
  - 390 non-pregnant adults on ART for 6 months, follow up for 1 year
  - Intervention: POC viral load testing (Xpert HIV-1 VL)
    - Result within 2 hours
  - Standard care: laboratory viral load testing
  - After 6 months in the study, CCMDD referral if viral load suppressed



# Point-of-care (POC) viral load testing<sup>8</sup>

	Intervention Arm	Standard-of-care Arm	Absolute Risk Difference (95% CI)	P value
<b>Viral suppression (&lt;200 copies/mL) and retention in care at 12 months</b>	89.7% (175/195)	75.9% (148/195)	13.9% (6.4-21.2)	<0.001

# Point-of-care (POC) viral load testing and CCMDD<sup>8</sup>



# Acceptability of POC viral load testing

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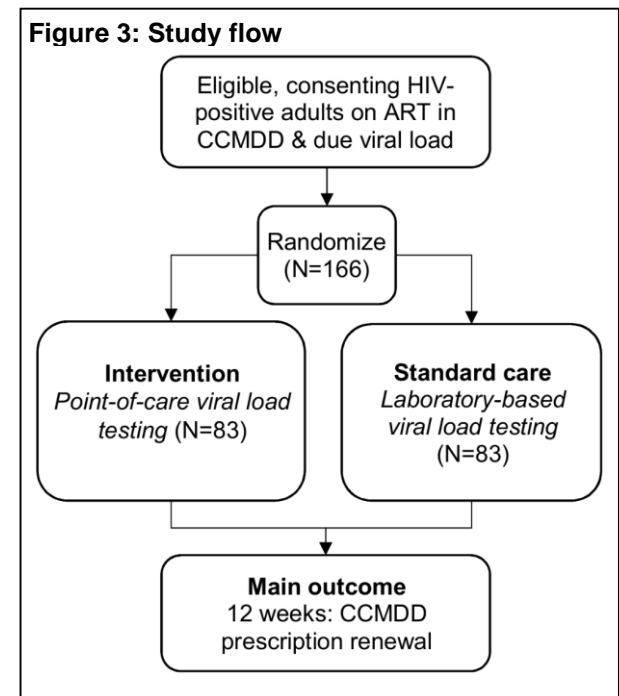
*“I even save money that I use for transport. If I take bloods today and they tell me I should come back after two weeks that means I have to pay another transport fare to come here [clinic]; Whereas I can wait two hours and get my results and leave afterwards.” (Client, female, 42 years)*

*“I don’t think it can work, because clinics get full and there will need to be space for people who are waiting [for POC results] and space for people who need to be attended. Where are all these people going to wait? there will be a lot of congestion .” (Client, male, 28 years)*



# Innovation project proposal

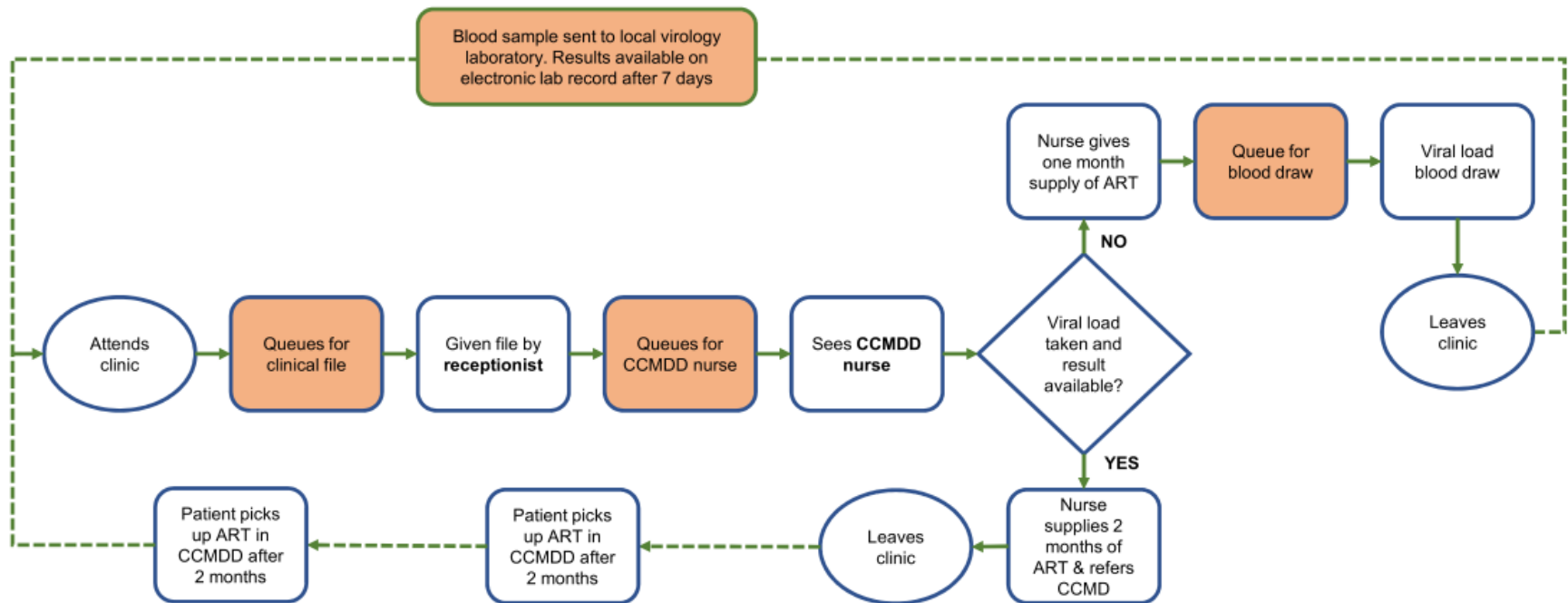
- Single-site, randomized pilot study of implementing point-of-care viral load testing in South Africa
- Aims:
  - To determine if implementing point-of-care viral load testing is feasible in a routine primary care clinic, and to estimate its effect size on CCMDD renewal.
- Evaluation
  - % in POC arm with same-day viral load result
  - % with CCMDD renewal at 12 weeks (i.e. not dormant) in POC arm
  - % with CCMDD renewal at 12 weeks (i.e. not dormant) in SOC arm
  - Focus groups discussions and interviews with clinic staff



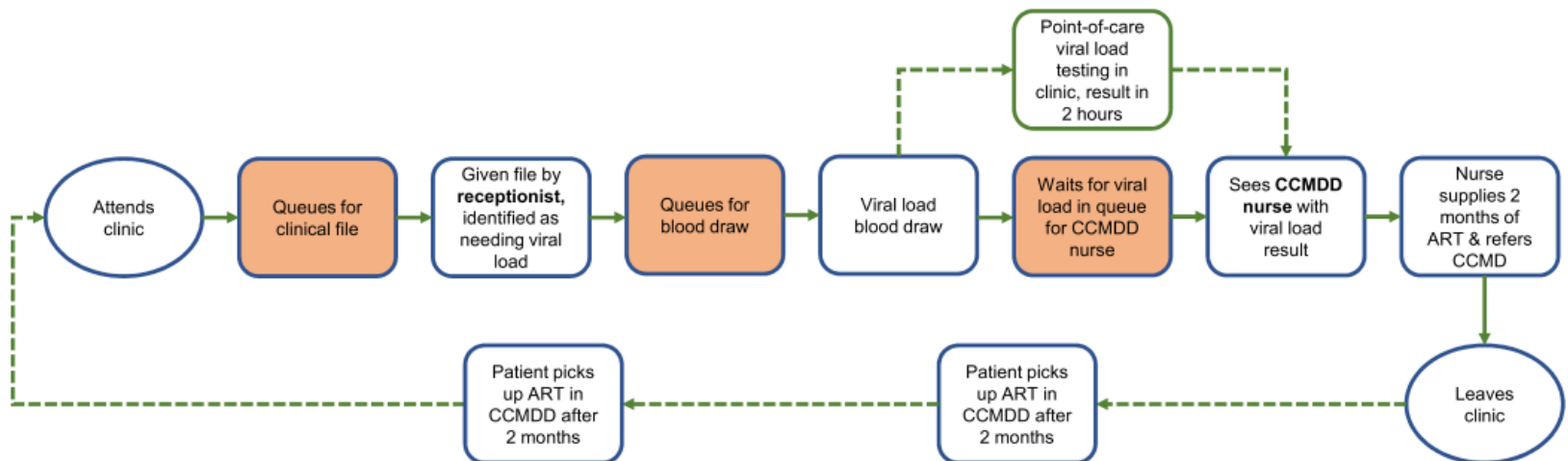
# Implementation Science techniques

<b>BOX 3: STAKEHOLDER MAP</b>		
<b>High Power</b>	<b>Satisfy</b> <ul style="list-style-type: none"> <li>• Provincial Department of Health</li> <li>• Pharmacy Direct</li> <li>• Community based pick-up point organisation</li> <li>• CAPRISA management</li> <li>• National Health Laboratory Service</li> <li>• National Managers</li> </ul>	<b>Manage</b> <ul style="list-style-type: none"> <li>• Municipality Health Unit</li> <li>• Head of Primary Care</li> <li>• Data manager</li> <li>• PHC Clinic staff</li> <li>• Nursing service manager</li> <li>• CCMDD nurse</li> <li>• Doctor</li> <li>• Health Systems Trust</li> <li>• Programme manager</li> <li>• Cepheid Inc</li> </ul>
<b>Low Power</b>	<b>Monitor</b> <ul style="list-style-type: none"> <li>• Abbott</li> <li>• Molbio</li> <li>• International AIDS Society Differentiated Care team</li> <li>• ICAP Columbia – Southern Africa Differentiated Care team</li> </ul>	<b>Inform</b> <ul style="list-style-type: none"> <li>• Clinic staff</li> <li>• Phlebotomist</li> <li>• Data capturers</li> <li>• Receptionists and clerical staff</li> <li>• National Health Laboratory Service</li> <li>• Local Virology Laboratory</li> </ul>
	<b>Low impact/stake-holding</b>	<b>High-impact/stake-holding</b>

# Implementation Science techniques



# Implementation Science techniques



# Summary

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- Universal Treatment of HIV will greatly increase the number of people on ART in South Africa
- New models of care are needed to efficiently provide universal ART in South African primary care clinics
- Novel point-of-care viral load testing technologies could increase efficiencies in community ART programmes
- More evidence around *implementation* of these assays is required

# Acknowledgements

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- Prof Chris Butler and Prof Gail Hayward (Supervisors)
- Dr Nigel Garrett & Dr Paul Drain (STREAM Principal Investigators)
- Funders and collaborating organisations
- THET Health Innovation Fellowships



# What do Innovations Look Like?

Ryan Ghita

NHS Specialist Surgical Registrar

Northumbria – Tanzania Partnership

THET Innovation Fellowship



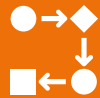
# What Is Innovation



Product



Treatment



Process



IT



# An Innovation (not ours!)



**Tropical Medicine & Surgery**

**Research Article**

**Open Access**

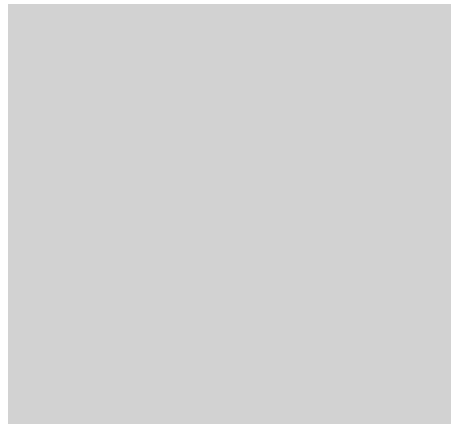
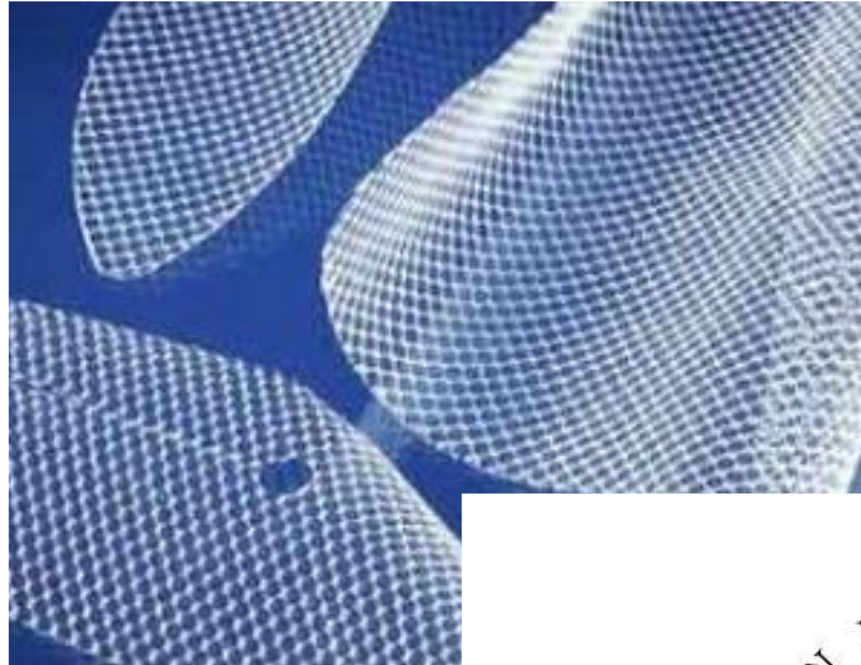
Ten-Year Personal Experience of Using Low Density Polyethylene (LDPE) Mesh for Inguinal Hernia Repair

Ravindranath R Tongaonkar<sup>1</sup>, David L Sanders<sup>2\*</sup> and Andrew N Kingsnorth<sup>3</sup>

<sup>1</sup>Dr. Tongaonkar Hospital, Dondaicha, Dist - Dhule (Maharashtra) 425 408, India

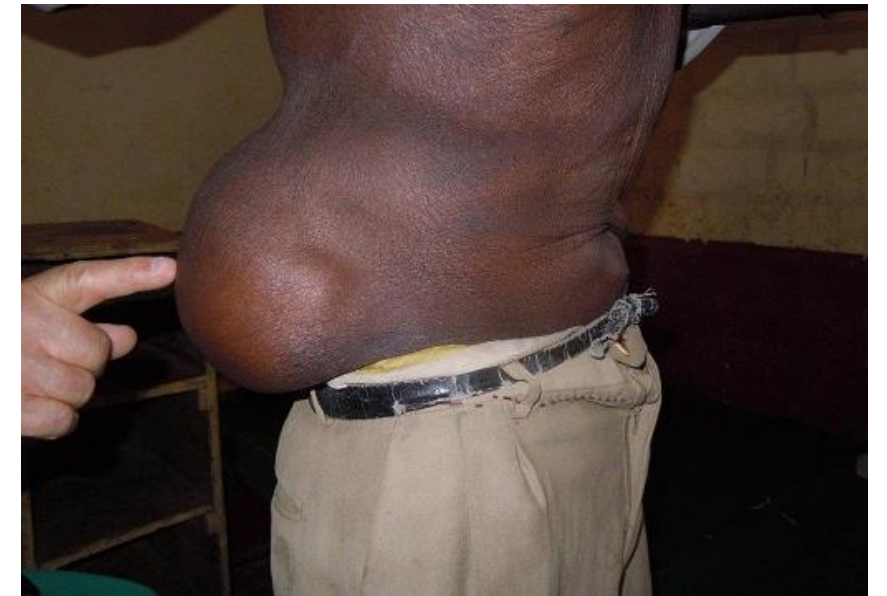
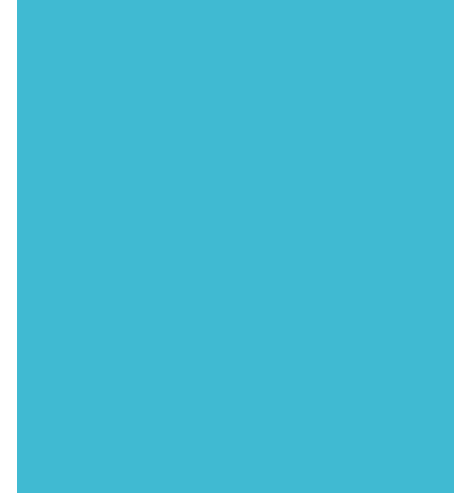
# Background: The Repair of Hernia

- Reduces the chance of recurrence
- Plastic netting (polypropelene)
- 30 + years
- ~~Pelvic floor mesh repair~~



## Background: Low and Middle Income Countries

- 27% life time risk in males
- Tanzania alone 4.4 million DALYS
- Significant economic impact due to disability and premature death
- North west Tanzania mortality rate of 9.7%
- Larger and more severe





# Applying the Innovation of Others

Strong partnership

Seen first hand the suboptimal hernia repair and effects of recurrence

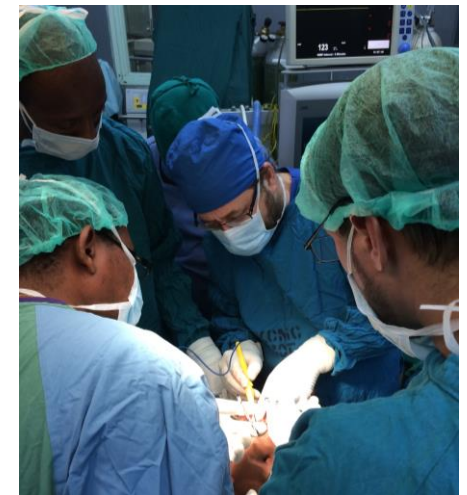
Mesh expensive

Low availability



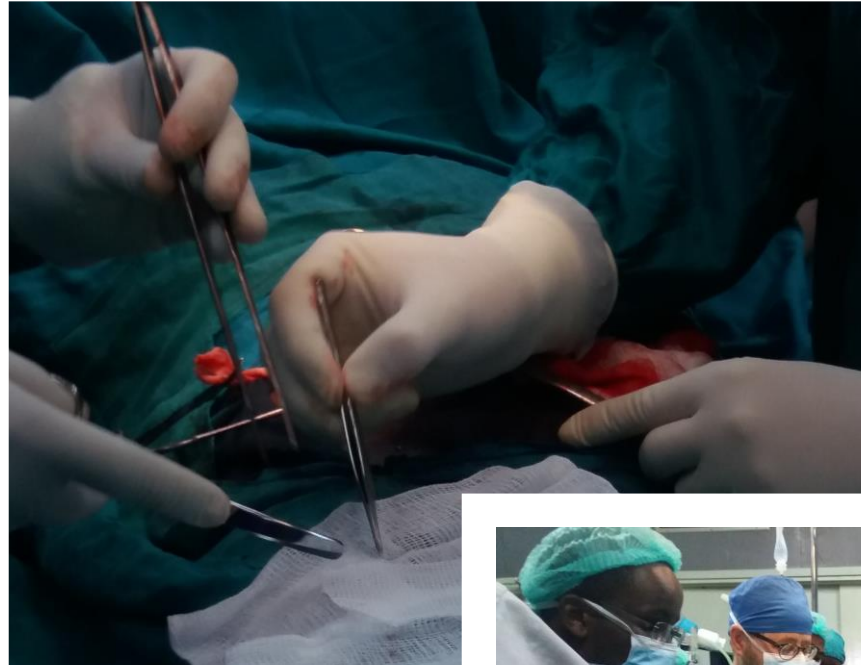
# Applying the Innovation of Others

- Sourced an undyed untreated mosquito netting
- Cut sterilized and packed in UK
- Delivered to Tanzanian surgeons
- Followed patient up for 2 years



# Applying the Innovation of Others

- Surgeons and patients happy
- Outcomes were good
- Room for improvement
- Sourced our own mesh to our specification





# Applying the Innovation of Others

- Used since 2013 making adjustments
- 220+ operations
- Retrospective data collection on all
- 64 patients up to 40 months

## Conclusions

The generic mesh has favourable outcomes in terms of recurrence in comparison to other low-cost meshes, and is vastly more cost effective. Larger studies are required to support this finding.



Masters by Research: 2016-17

The Long Term Clinical Outcomes of Hernia Repair Utilising Mesh, at Kilimanjaro Christian Medical Centre, Northern Tanzania

Kathryn Parker-Conway  
Word Count: 8462

Then we  
started asking  
the question...

Why can we not use this mesh here in the NHS?

120 000 hernia operations per year

£30 compared to < £2++





Compile more evidence  
- Especially long term  
and ventral hernias



Approval process



Streamline the process



Plan for  
Implementation

How to  
Implement the  
Reverse  
Innovations?

# How to Implement the Reverse Innovations: Compiling Evidence

## Unique position for data collection

- Previous experience
- Long-term follow up



## How to Implement the Reverse Innovations : Compiling Evidence

- With the support of a THET innovation fellowship
- Set up a study to collect data prospectively
  1. Meet with members of surgical team
  2. Delivered more mesh
  3. Dedicated member of staff for the data collection
  4. Recruited 5 patients

# How to Implement the Reverse Innovations : Approval Process

- CE marking route
  - Understand how to approach
  - Cost
  - Testing
  - Brexit
- Department of Medicines and Healthcare Products Regulatory Agency
  - Not require CE marking
  - Pelvic floor mesh publicity
- Supply Chain and Procurement

CE



Medicines & Healthcare products  
Regulatory Agency



# How to Implement the Reverse Innovations: Process Streamlining and Implementation

## Packaging



## Sterilizing



## Implementation

- Northumbria lead for innovation and clinical trial officer
- Account manager at NHS supply chain
- Northumbria Procurement Business Partner
- Forwarded for Bright ideas award

## Barriers & What We Have Learned

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Evidence

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Regulations

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Cost

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Bad publicity of mesh

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Time / commitment

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Knowing who to contact

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Whole different skill set

# Impact

- Huge potential cost savings
- Valuable data for KCMC
- Valuable data for generic mesh/mosquito netting
- Price drop?
- Knowledge

# Successes

- Happy with quality product and process
- Partners in KCMC using the mesh and having good outcomes
- Implemented the research
- Plan in place for approaching regulatory approval
- Have plan or road map for implementation
- THET fellowship , shortlisted for Bright Ideas award



Thank You

