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

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Community Healthcare MIC Group Seminar 3rd October 2019

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Outline

• 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

- ART for people with low CD4 counts or opportunistic infections

1. UNAIDS. Progress towards 90-90-90 2017
Universal Treatment for HIV

• 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?

1. UNAIDS. Progress towards 90-90-90 2017
Measuring the impact of universal treatment

- Audit of routine, anonymized clinic & lab data from 8 South African primary care clinics

Figure 1: Map of clinic locations

[Map showing clinic locations in KwaZulu-Natal]
Does the healthcare system have capacity?

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

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**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’

Problems with clinic-based HIV services

• 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)\(^5\)
- Over 1.2 million people receiving ART in CCMDD

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5. Roberts. CCMDD: A Public/Private Partnership to Increase Access to ART. 2018
Community ART delivery in South Africa

• Problems with CCMDD:

5. Roberts. CCMDD: A Public/Private Partnership to Increase Access to ART. 2018
Point-of-care (POC) viral load testing

- 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

- The Simplified TREATment and Monitoring (STREAM) Study
- Randomized trial of POC viral load testing in Durban, SA
  - 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

<table>
<thead>
<tr>
<th></th>
<th>Intervention Arm</th>
<th>Standard-of-care Arm</th>
<th>Absolute Risk Difference (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Viral suppression (&lt;200 copies/mL) and retention in care at 12 months</strong></td>
<td>89.7% (175/195)</td>
<td>75.9% (148/195)</td>
<td>13.9% (6.4-21.2)</td>
<td>&lt;0.001</td>
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</tbody>
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Point-of-care (POC) viral load testing and CCMDD

Acceptability of POC viral load testing

“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

<table>
<thead>
<tr>
<th>BOX 3: STAKEHOLDER MAP</th>
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<tbody>
<tr>
<td><strong>High Power</strong></td>
<td><strong>Satisfy</strong></td>
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<td>Provincial Department of Health</td>
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<td>Pharmacy Direct</td>
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<td>Community based pick-up point organisation</td>
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<td>CAPRISA management</td>
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<td>National Health Laboratory Service</td>
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<td>National Managers</td>
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<td><strong>Manage</strong></td>
<td>Municipality Health Unit</td>
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<td></td>
<td>Head of Primary Care</td>
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<td>Data manager</td>
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<td></td>
<td>PHC Clinic staff</td>
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<td></td>
<td>Nursing service manager</td>
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<td></td>
<td>CCMDD nurse</td>
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<td>Doctor</td>
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<td>Health Systems Trust</td>
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<td>Programme manager</td>
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<td>Programme manager</td>
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<td>Cepheid Inc</td>
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<td><strong>Low Power</strong></td>
<td><strong>Monitor</strong></td>
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<td>Abbott</td>
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<td>Molbio</td>
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<td>International AIDS Society Differentiated Care team</td>
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<td>ICAP Columbia – Southern Africa Differentiated Care team</td>
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<td><strong>Inform</strong></td>
<td>Clinic staff</td>
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<td></td>
<td>Phlebotomist</td>
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<td></td>
<td>Data capturers</td>
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<td>Receptionists and clerical staff</td>
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<td>National Health Laboratory Service</td>
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<td>Local Virology Laboratory</td>
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<td><strong>Low impact/stake-holding</strong></td>
<td><strong>High-impact/stake-holding</strong></td>
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</table>
Implementation Science techniques

Implementation Science techniques

Summary

• 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

• 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!)
Background: The Repair of Hernia

- Reduces the chance of recurrence
- Plastic netting (polypropylene)
- 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.
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++
How to Implement the Reverse Innovations?

- Compile more evidence - Especially long term and ventral hernias
- Streamline the process
- Approval process
- Plan for Implementation
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
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

- Evidence
- Regulations
- Cost
- Bad publicity of mesh
- Time / commitment
- Knowing who to contact
- Whole different skill set
Impact

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