Pragmatic Trials and their place in the Health Systems Research Toolkit

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The problem: Too many patients, not enough ART prescribers

2004/5:
4570 patients followed > 1 year
- 53% died
- 87% of these before ART

Phutadijhaba, Free State

Phutadijhaba’s funeral home

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Practical Approach to Lung Health and HIV & AIDS in South Africa

Symptom and sign based guideline: HIV/AIDS, STIs, TB, respiratory

Educational outreach: Clinic-based, short, repeated, interactive training by a trusted outsider

Equip nurse middle managers as outreach trainers through specialised training and support

Support materials highlighting key messages

Fairall L et al. BMJ 2005; 331:750-754
Zwarenstein M et al. BMJ 2011; 342:d2022
STRETCH
Streamlining Tasks and Roles to Expand Treatment and Care for HIV

Educational outreach training using PALSA PLUS model

Change facilitator: STRETCH provincial co-ordinator

Participatory action approach to re-organisation of care:
- Local facility management teams
- STRETCH toolkit
- Phased introduction

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Uebel K et al. Implementation Science 2011;6(1) 86
## STRETCH Trial Design

Cluster (clinic) trial with outcomes measured on 15,573 patients

<table>
<thead>
<tr>
<th>QUESTION</th>
<th>PARTICIPANTS</th>
<th>PRIMARY OUTCOME</th>
<th>DESIGN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nurse-led service as effective as a doctor-led one for patients on ART?</td>
<td>On ART ≥ 6 months</td>
<td>Viral load suppression</td>
<td>Equivalence</td>
</tr>
<tr>
<td>Improve on status quo, expanding access and reducing “waiting list” mortality?</td>
<td>CD4 ≤350 not yet on ART</td>
<td>Time to death</td>
<td>Superiority</td>
</tr>
</tbody>
</table>

The context of the STRETCH trial
Variability in implementation

Phase 1: Preparation
Phase 2: Re-prescribing
Phase 3: Initiation
Pragmatic Trials

“The pragmatic attitude favours design choices that maximize applicability of the trial’s results to usual care settings, rely on unarguably important outcomes such as mortality and severe morbidity, and are tested in a wide range of settings.”

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Zwarenstein M et al. *BMJ* 2008;337:a2390
PRECIS: Pragmatic-explanatory continuum indicator summary tool

- Practitioner Expertise (Comparison)
- Flexibility of the Comparison intervention
- Follow-up intensity
- Outcomes
- Participant Compliance
- Practitioner Adherence
- Practitioner Expertise (Experimental)
- Flexibility of the Experimental intervention
- Eligibility criteria
- Primary Analysis

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STRETCH


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STRETCH

CIPRA

Eligibility criteria
Follow-up intensity
Outcomes
Participant Compliance
Practitioner Adherence
Primary Analysis
Practitioner Expertise (Experimental)
Flexibility of the Experimental intervention
Practitioner Expertise (Comparison)
Flexibility of the Comparison intervention


The Research Strategy

“...good quality Health Policy and Systems Research (HPSR) demands an understanding of what strategy is appropriate to the question of focus.

The strategy is neither primarily a study design nor a method, but instead represents an overarching approach to conducting the research...”


Hope is the pillar of the universe: Health-care providers’ experiences of delivering anti-retroviral therapy in primary health-care clinics in the Free State province of South Africa. *Soc Sci Med* 2007; 64:954-964

The Mixed Methods Approach in the STRETCH trial


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Task shifting and integration of HIV care into primary care in South Africa – the development and content of the streamlining tasks and roles to expand treatment and care for HIV (STRETCH) intervention. *Implementation Science* 2011; 6(1):86

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Expanding access to ART in South Africa: The role of nurse-initiated treatment. *S Afr Med J* 2010: 100(4)

Implementing Nurse Initiated and Managed Antiretroviral Treatment (NIMART) in South Africa: a qualitative process evaluation of the STRETCH Trial. *Implementation Science* 2012; 7:66

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Effectiveness of task-shifting antiretroviral treatment from doctors to primary care nurses in South Africa (STRETCH): pragmatic parallel cluster randomized trial. Lancet 2012; 380:889-98

Expanding access to ART in South Africa: The role of nurse-initiated treatment. S Afr Med J 2010: 100(4)

Implementing Nurse Initiated and Managed Antiretroviral Treatment (NIMART) in South Africa: a qualitative process evaluation of the STRETCH Trial. Implementation Science 2012; 7:66

Cost-effectiveness of nurse-led versus doctor-led antiretroviral treatment in South Africa: Pragmatic cluster randomised trial. Submitted AIDS.
From Generalisability to Applicability in Context
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From Advocacy through Uncertainty to Ethics of Health Policy and Systems Development

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When Relevance of the intervention meets Feasibility of the evaluation
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