Evaluation Designs for QI Interventions in Complex Settings

Pierre M Barker MD
Senior Vice President: IHI
Clinical Professor: Gillings School of Global Public Health
The Current State

“4 million women, newborns and children in sub-Saharan Africa could be saved every year if well-established, currently available, affordable health care interventions could be implemented across the region”

African Academies of Science, Accra, 2010
Where is the problem?

- Basic science
- Efficacy studies
- Effectiveness Studies

Context-sensitive “real-life” implementation

Scale-up to populations

Implementation science
Quality Improvement: Bringing Together Two Types of Knowledge

Evidence Based Subject Matter
Knowledge Protocols/Guidelines Clinical Training

the “what”

Implementation Knowledge
Motivation/Leadership Efficient Systems Accurate Reflective Data Context-sensitive learning

the “how”
Improvement: Bringing Together Two Types of Knowledge

- Evidence-based Subject Matter Knowledge
- Implementation Knowledge
Case Example: PMTCT Scale-up in South Africa
Implementation and Scale-up of Effective Perinatal PMTCT in 3 Districts (S. Africa)

3 Districts,
• pop 5.5 million,
• 202 clinics,
• 18 hospitals

Project Aim:
Decrease MTCT to <5% between 2008 and 2011
Local leadership

Context-sensitive learning systems to accelerate local solutions to close performance gaps:

Generating and testing local solutions to close performance gaps
Implementing and Scaling up PMTCT in 3 Districts of KZN Province South Africa

Cluster randomized design

Randomization Unit: Nurse supervisor plus 6 – 10 clinics

Research Questions:

1. Could a QI intervention lead to district-wide improvements in PMTCT care and outcomes?
2. Was there added value associated with clinic participation in a Collaborative Learning Networks?
Cluster Randomization with Step Wedge design

- 48 Clusters
- 24 Intervention
- 24 Control
- Wave 1: 9 intervention; 9 Control
- Wave 2: 8 intervention; 8 Control
- Wave 3: 7 intervention; 7 Control
Cluster Randomized Design

Intervention 1
QI alone

Intervention 2
QI plus collaborative learning network
1st issue: Can you believe the data?

Rates of HIV testing of Pregnant Women in Three Districts

Performance Target: 90-110%
2nd issue: Integrity of fixed protocol

- Lack of design flexibility to take account of variation in district leadership abilities
- Design ignored natural referral linkages (usually within sub-district, but often across district borders)
- Unable to adapt design to changing realities (e.g. elimination of nurse supervisor position in one district)
- Randomization forced participation of the “unwilling” and denied participation of the “willing”
- Major impact on study staff morale
Other Issues

- Focus of intervention on clinics vs District Management team
- Contamination everywhere (district-wide supports were being improved)
- Multiple external improvements driving change (not just QI)
DSMB Review - Project Reset

- RCT abandoned – replaced with adaptive design (different for 3 districts).
- Re-designed “change unit” to account for natural referral patterns
- Pace and design of scale-up adapted to district capabilities
- Closer working relationship with District Managers
- Improved data Feedback system
Project Reset: adaptable design

**District 1**

All subdistricts had hospital and facilities learning network

**District 2**

Sequential hospital and facilities subdistrict learning network

**District 3**

Focus on only one hospital/facilities learning network
Adaptive design – 3 districts, 3 designs

Rates of HIV testing of Pregnant Women in Three Districts

- Ugu
- Umgungundlovu
- eThekwini

Performance Target 90-110%

- Project launch
- Umgungundlovu redesign
- eThekwini redesign
- Active project support ends
Using Counterfactuals (whole district comparisons)

Ngidi et al. J Acquir Immune Defic Syndr 2013;63:e133–e139
Eliminating MTCT: HIV positive rates for infants tested at 6 wks

Policy: New protocol introduced: HAART if CD4<350

Health System/QI: HIV testing >95% pregnant women in all 3 Districts

Health System/QI: QI approach spread to 3 Districts

Health Systems/QI: Starting mothers on HAART reaches 90% in 3 Districts

Training/decentralization: Nurses at PC clinics trained in providing ARVs
Conclusions/Questions

- Are cluster randomized designs appropriate for QI studies in complex settings?
- Can/should CRDs be applied within districts?
- Are counterfactuals needed in QI?
- Are time-series plus step wedge designs sufficient for QI research in complex settings?
- Was this CRD attempted too early - would it have succeeded with a mature implementation change package?
A case report of evaluating a large-scale health systems improvement project in an uncontrolled setting: a quality improvement initiative in KwaZulu-Natal, South Africa

Kedar S Mate,1,2 Wilbroda Hlolisele Ngidi,3 Jennifer Reddy,3 Wendy Mphatswe,3 Nigel Rollins3,4 Pierre Barker1,5

Conventional evaluations of improvement interventions: more trials or just more tribulations?

Kaveh G Shojania

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Thank You!
Implementation and Scale-up Framework

Best Practice exists
New Scale-up Idea

Set-up
Build Prototype
Test Scale-Up
Go to Full-Scale & Sustain

Foster Adoption
Leadership
Learning Systems
Infrastructure for Scale-up
Human Capacity for Scale up

Phases of Scale-up
Adoption Mechanisms
Support Systems