



**A Cross-Sectional Cluster Randomised
Stepped Wedge Trial to Assess the
Effectiveness of Audit**

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Outline

- **Background & Standards Based Audits**
- **Objective**
- **Design Considerations**
- **Proposed Study Design**
- **Questions for discussion**

Background

- **MDGs – improved antenatal coverage & facility births in many countries**
- **Quality of care provided often falls short of best practice**
- **Standards for provision of ANC and PNC in LMIC have been developed and agreed**



Example Standards and Indicators

- 1 All women attending for ANC are screened for hypertension and proteinuria (pre-eclampsia) at the booking visit**
 - Proportion of new ANC attenders who had BP measured & urine checked for protein**

- 2 All babies receive immunisations as per national protocol**
 - Proportion of newborns who received vaccinations according to schedule**

Standards-Based Audits

Clinical audit of agreed standards / full audit cycle – a quality improvement (QI) method

- **Month 1 – assess current quality of care** **Before**
- **Month 2 – take action to address issues identified in month 1**
- **Month 3 – re-assess quality of care** **After**

Objective

Assess effectiveness of standards-based audit to improve compliance of HCFs with agreed standards for ANC and PNC

- **Need a scientifically rigorous evaluation methodology**

Design Considerations

- **Multiple standards to be assessed**
- **Standards can be assessed in successive quarters within a health care facility (HCF)**
- **Limited number of times each standard should be assessed within a HCF**
- **Study duration should not exceed two years**
- **20 clusters (HCFs)**

Proposed Study Design 1/2

- **Six standards assessed sequentially (audit cycle periods: 3-months each) at each HCF**
- **Incomplete cross-sectional SW-CRT for each of six standards**
- **For each standard ‘action month’ of the audit cycle to follow an SW design, with steps in months 4 to 21**

Proposed Study Design 2/2


- **Baseline assessment (month 1) for all six standards**
- **Workshop introducing standards based audits after baseline**
- **Three strata for month in which the first audit cycle begins (months 3, 4 and 5)**

Overview of design for all 6 standards


Stratum	Cluster	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22
1	1	0		0	A	1	0	A	1	0	A	1	0	A	1	0	A	1	0	A	1		
	2	0		0	A	1	0	A	1	0	A	1	0	A	1	0	A	1	0	A	1		
	:																						
2	8	0			0	A	1	0	A	1	0	A	1	0	A	1	0	A	1	0	A	1	
	9	0			0	A	1	0	A	1	0	A	1	0	A	1	0	A	1	0	A	1	
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3	15	0				0	A	1	0	A	1	0	A	1	0	A	1	0	A	1	0	A	1
	16	0				0	A	1	0	A	1	0	A	1	0	A	1	0	A	1	0	A	1
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Audit cycle for each of the 6 standards

 All 6 standards


 Workshop conducted

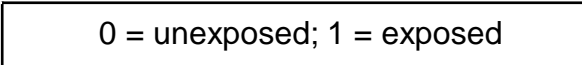
 0 = unexposed; A = action; 1 = exposed

Overview of design for all 6 standards

Stratum	Cluster	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22
1	1	0	0	0		1	0		1	0		1	0		1	0		1	0		1		
	2	0	0	0		1	0		1	0		1	0		1	0		1	0		1		
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2	8	0		0		1	0		1	0		1	0		1	0		1	0		1		1
	9	0		0		1	0		1	0		1	0		1	0		1	0		1		1
	:																						
3	15	0		0		1	0		1	0		1	0		1	0		1	0		1		1
	16	0		0		1	0		1	0		1	0		1	0		1	0		1		1
	:																						


 Standard 1

 Workshop conducted

 0 = unexposed; 1 = exposed

Standard 1 to be Assessed:

Stratum	Cluster	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22
1	1	0		0		1															1		
	2	0					0		1												1		
	:																						
2	8	0			0		1															1	
	9	0						0		1												1	
	:																						
3	15	0				0		1															1
	16	0							0		1												1
	:																						

 Standard 1

18 Step Design for Standard 1

Stratum	Clusters	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22
1	1 & 7	0		0		1															1		
2	8 & 14	0			0		1															1	
3	15	0				0		1															1
1	2	0					0		1												1		
2	9	0						0		1												1	
3	16	0							0		1												1
:	:	:																	:	:	:	:	:
2	19	0																		0		1	
3	20	0																			0		1

Data Collection for Each Standard

At each HCF data to determine percentage compliance will be collected for 25 cases at:

- 1. Month 1 (baseline)**
- 2. The month immediately prior to the action month**
- 3. The month immediately after the action month**
- 4. Month 20, 21 or 22 (month following the action month of the last standard at the HCF)**

Sample Size & Data Analysis

Outcome for each standard: increase in proportion of respondents with satisfactory standard of care

Analysis: mixed effects linear regression model
dependent variable: percentage satisfactory
fixed effects: intervention and month
random effects: cluster

Difference detectable with 80% (90%) power: 19% (21%) if ICC=0.10

Summary

An incomplete SW-CRT to assess the effectiveness of standards-based audit to improve compliance of HCFs with each of six standards for ANC and PNC

Questions for Discussion

- **How to estimate an aggregated score (across all 6 standards)?**
- **Is the 4th assessment useful?**
- **Is the design too incomplete?**

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