Application of Implementation Science to TB Evaluation: A Case Study from Uganda

Adithya Cattamanchi, MD, MAS
acattamanchi@medsfgh.ucsf.edu
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Implementation Science

- The **study of methods or strategies** to promote uptake of research findings into routine clinical practice

- NOT simply the validation of evidence-based practices or interventions in “real world” settings

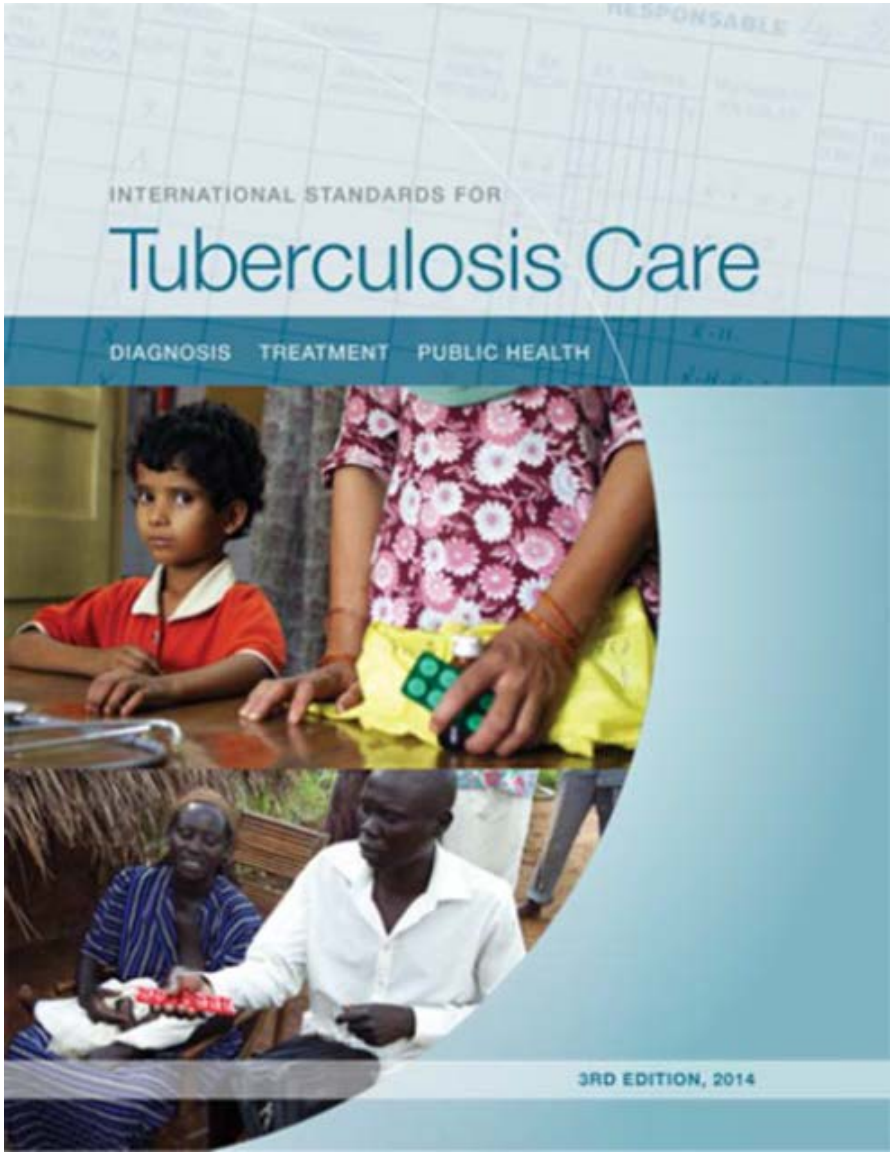
- Implementation depends on behavior of key stakeholders
  - Improving uptake requires changing behavior
  - To change behavior, it helps to understand determinants of current behavior and how behavior changes.

Reasons for Low TB Case Detection

- Cases are being diagnosed but not reported
- Cases are not presenting to TB diagnostic centers
- Cases seek care but are not diagnosed
  - Low sensitivity of microscopy (30-70%)
  - Poor quality of TB evaluation

TB Evaluation Guidelines

- **Standard 2**: All persons with unexplained cough of at least 2 weeks' duration should be evaluated for TB
- **Standard 3**: All persons who require TB evaluation should be referred for sputum-based microbiologic testing
- **Standard 3:** All persons referred for sputum microscopy should have at least 2 smears examined
- **Standard 8:** Smear-positive patients should be prescribed anti-TB therapy



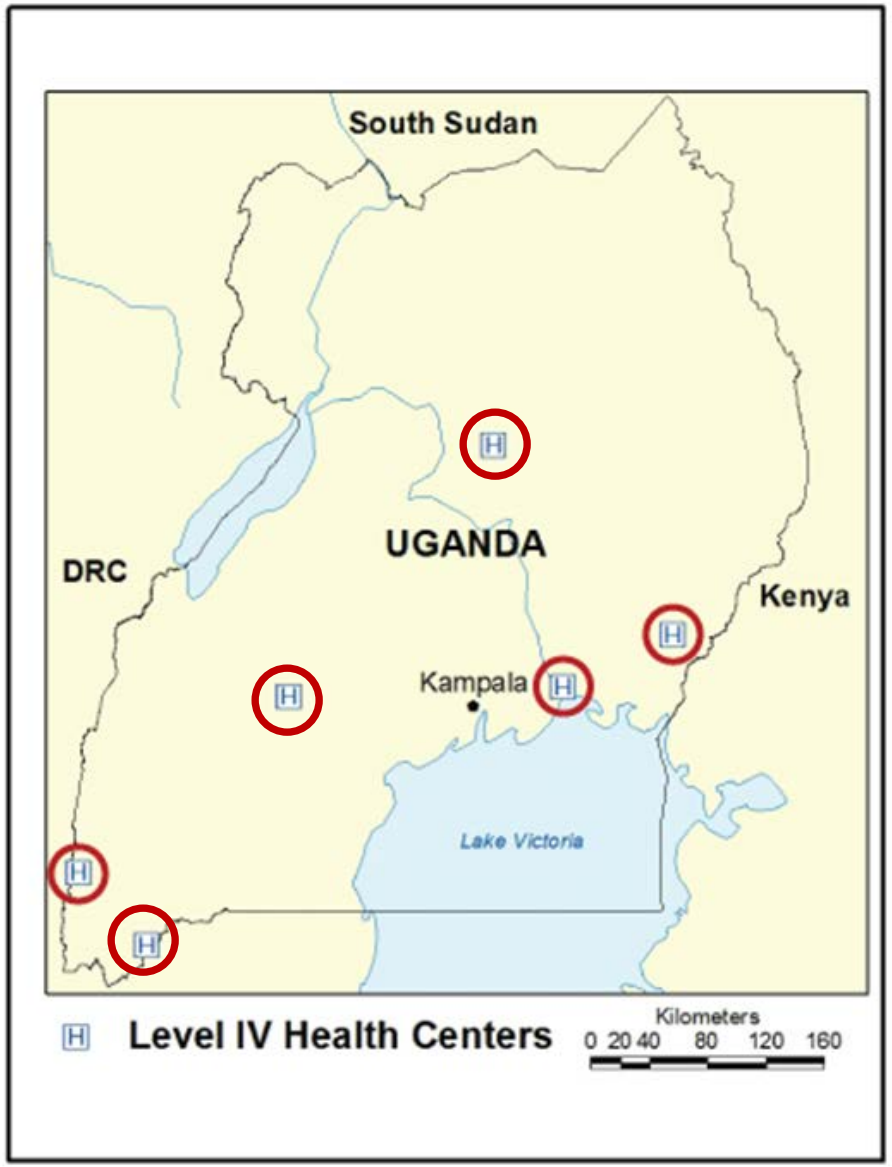
TB GOAL study

TB Guideline Observation and Adherence in Low-income countries

Study Objectives

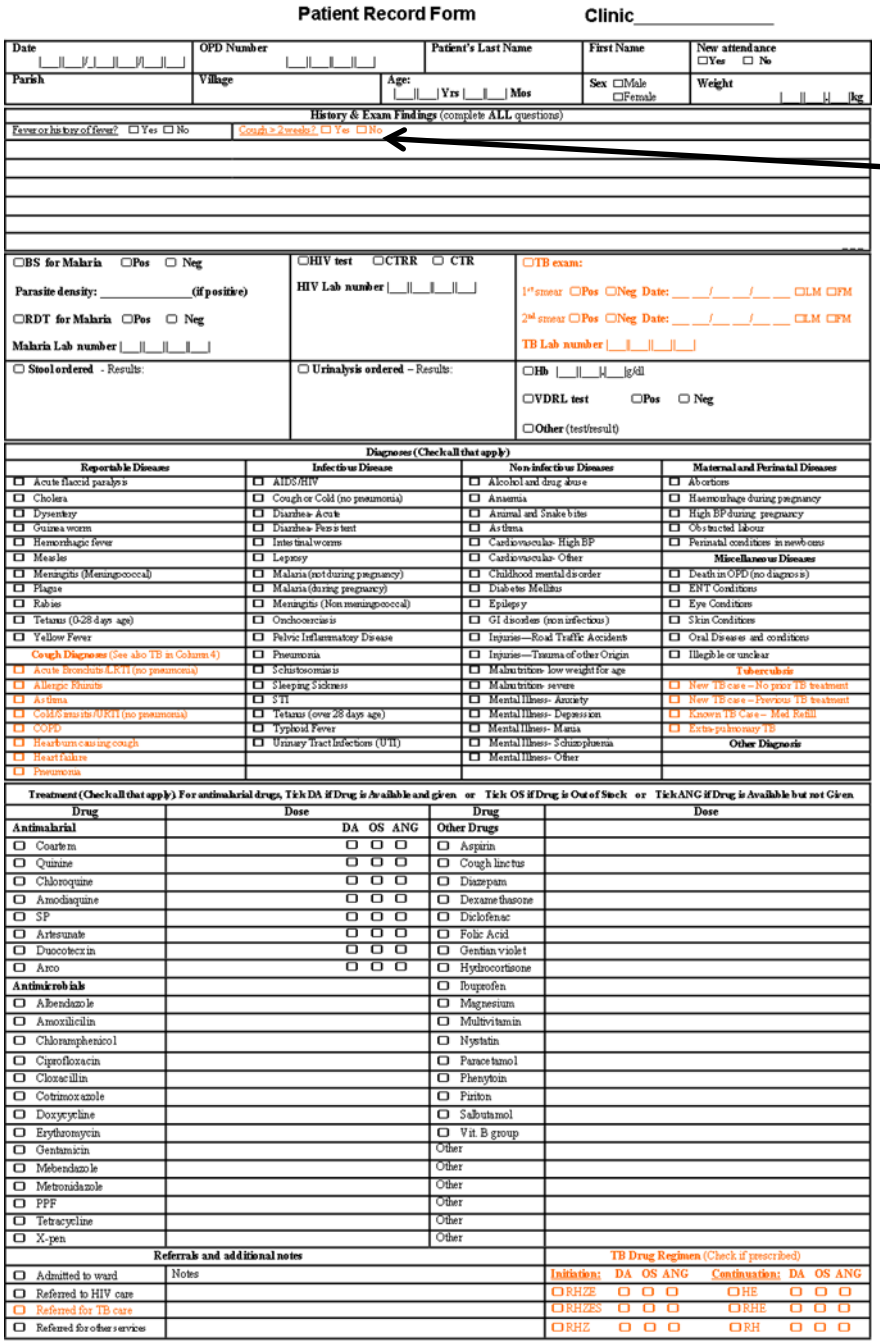
- To assess the quality of TB evaluation
- To identify modifiable barriers to TB evaluation
- To develop and test a theory-driven intervention to improve TB evaluation

Study setting



- Network of 6 government health centers
- Partners
  - Uganda Ministry of Health
  - Makerere University
  - UCSF
- Electronic data collection (>100,000 patients/year)


OUT PATIENTS DEPT



Patient Record Form

Clinic_____

Date |__|__|/|__|__|/|__|__|	OPD Number |__|__|__|__|__|	Patient's Last Name	First Name	New attendance ☐Yes ☐ No
Parish	Village	Age: |__|__| Yrs |__|__| Mos	Sex ☐Male ☐Female	Weight |__|__|.|__|kg

History & Exam Findings (complete **ALL** questions)

Fever or history of fever? ☐Yes ☐No	Cough > 2 weeks? ☐ Yes ☐ No

☐BS for Malaria ☐Pos ☐ Neg Parasite density: _____(if positive) ☐RDT for Malaria ☐Pos ☐ Neg Malaria Lab number |__|__|__|__|	☐HIV test ☐CTRR ☐ CTR HIV Lab number |__|__|__|__|	☐TB exam: 1st smear ☐Pos ☐Neg Date: __ __/__ __/__ __ ☐LM ☐FM 2nd smear ☐Pos ☐Neg Date: __ __/__ __/__ __ ☐LM ☐FM TB Lab number |__|__|__|__|
☐ **Stool ordered** - Results:	☐ **Urinalysis ordered** – Results:	☐Hb |__|__.|__|g/dl ☐VDRL test ☐Pos ☐ Neg ☐Other (test/result)

Diagnoses (Check all that apply)

Reportable Diseases	Infectious Disease	Non-infectious Diseases	Maternal and Perinatal Diseases
☐ Acute flaccid paralysis	☐ AIDS/HIV	☐ Alcohol and drug abuse	☐ Abortions
☐ Cholera	☐ Cough or Cold (no pneumonia)	☐ Anaemia	☐ Haemorrhage during pregnancy
☐ Dysentery	☐ Diarrhea- Acute	☐ Animal and Snake bites	☐ High BP during pregnancy
☐ Guinea worm	☐ Diarrhea- Persistent	☐ Asthma	☐ Obstructed labour
☐ Hemorrhagic fever	☐ Intestinal worms	☐ Cardiovascular- High BP	☐ Perinatal conditions in newborns
☐ Measles	☐ Leprosy	☐ Cardiovascular- Other	**Miscellaneous Diseases**
☐ Meningitis (Meningococcal)	☐ Malaria (not during pregnancy)	☐ Childhood mental disorder	☐ Death in OPD (no diagnosis)
☐ Plague	☐ Malaria (during pregnancy)	☐ Diabetes Mellitus	☐ ENT Conditions
☐ Rabies	☐ Meningitis (Non meningococcal)	☐ Epilepsy	☐ Eye Conditions
☐ Tetanus (0-28 days age)	☐ Onchocerciasis	☐ GI disorders (non infectious)	☐ Skin Conditions
☐ Yellow Fever	☐ Pelvic Inflammatory Disease	☐ Injuries—Road Traffic Accidents	☐ Oral Diseases and conditions
Cough Diagnoses (See also TB in Column 4)	☐ Pneumonia	☐ Injuries—Trauma of other Origin	☐ Illegible or unclear
☐ Acute Bronchitis/LRTI (no pneumonia)	☐ Schistosomiasis	☐ Malnutrition- low weight for age	**Tuberculosis**
☐ Allergic Rhinitis	☐ Sleeping Sickness	☐ Malnutrition- severe	☐ New TB care – No prior TB treatment
☐ Asthma	☐ STI	☐ Mental Illness- Anxiety	☐ New TB care – Previous TB treatment
☐ Cold/Sinusitis/URTI (no pneumonia)	☐ Tetanus (over 28 days age)	☐ Mental Illness- Depression	☐ Known TB Care – Med Refill
☐ COPD	☐ Typhoid Fever	☐ Mental Illness- Mania	☐ Extra-pulmonary TB
☐ Heartburn causing cough	☐ Urinary Tract Infections (UTI)	☐ Mental Illness- Schizophrenia	**Other Diagnosis**
☐ Heart failure		☐ Mental Illness- Other	
☐ Pneumonia			

Treatment (Check all that apply) For antimalarial drugs, Tick DA if Drug is Available and given or Tick OS if Drug is Out of Stock or Tick ANG if Drug is Available but not Given

Drug	Dose	DA	OS	ANG	Drug	Dose
Antimalarial					**Other Drugs**	
☐ Coartem		☐	☐	☐	☐ Aspirin	
☐ Quinine		☐	☐	☐	☐ Cough linctus	
☐ Chloroquine		☐	☐	☐	☐ Diazepam	
☐ Amodiaquine		☐	☐	☐	☐ Dexamethasone	
☐ SP		☐	☐	☐	☐ Diclofenac	
☐ Artesunate		☐	☐	☐	☐ Folic Acid	
☐ Duocotecrin		☐	☐	☐	☐ Gentian violet	
☐ Arco		☐	☐	☐	☐ Hydrocortisone	
Antimicrobials					☐ Ibuprofen	
☐ Albendazole					☐ Magnesium	
☐ Amoxilicilin					☐ Multivitamin	
☐ Chloramphenicol					☐ Nystatin	
☐ Ciprofloxacin					☐ Paracetamol	
☐ Cloxacillin					☐ Phenytoin	
☐ Cotrimoxazole					☐ Piriton	
☐ Doxycycline					☐ Salbutamol	
☐ Erythromycin					☐ Vit. B group	
☐ Gentamicin					Other	
☐ Mebendazole					Other	
☐ Metronidazole					Other	
☐ PPF					Other	
☐ Tetracycline					Other	
☐ X-pen					Other	

Referrals and additional notes		TB Drug Regimen (Check if prescribed)						
☐ Admitted to ward	Notes	Initiation:	DA	OS	ANG	Continuation:	DA	OS	ANG
☐ Referred to HIV care		☐ RHZE	☐	☐	☐	☐ HE	☐	☐	☐
☐ Referred for TB care		☐ RHZES	☐	☐	☐	☐ RHE	☐	☐	☐
☐ Referred for other services		☐ RHZ	☐	☐	☐	☐ RH	☐	☐	☐

Full Name Signature

← Patient demographics

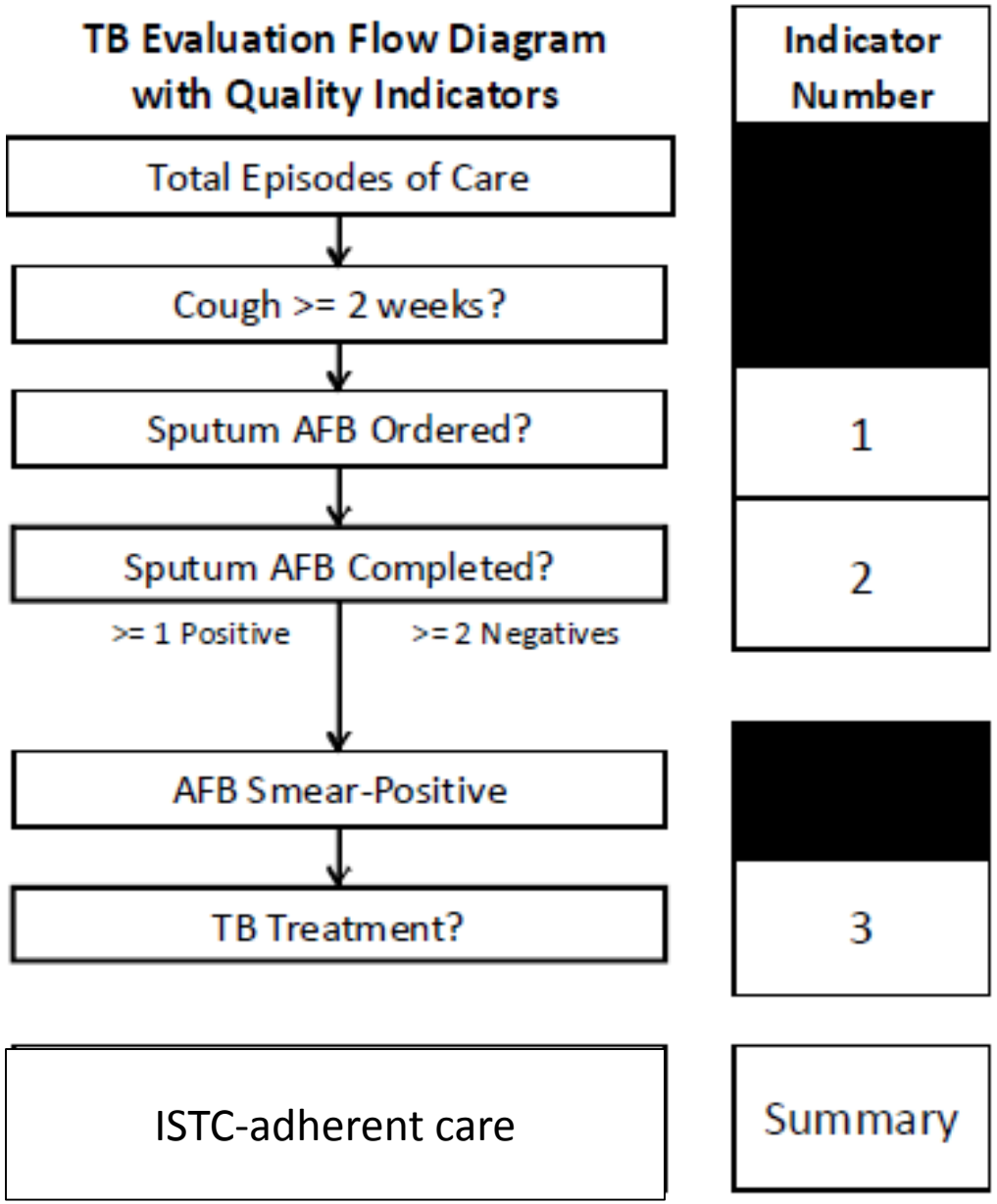
← Cough history

← TB exams

← TB diagnoses

← TB medications

ISTC Quality Indicators



Objective 1: “Define quality gap”

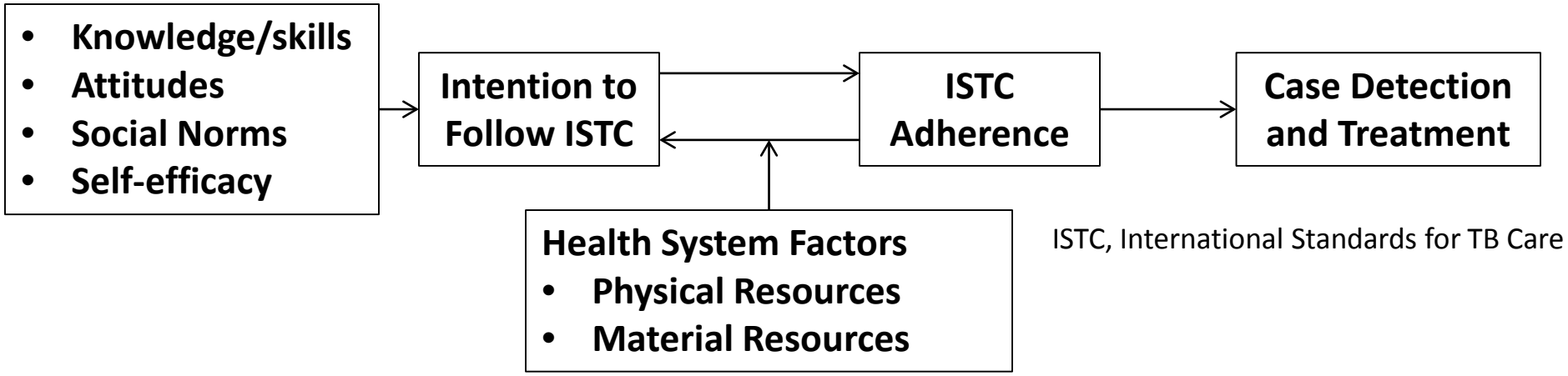
Q1 2009 (14,852 patients → 365 with cough >2 weeks)	
Standard 1: Referred for TB testing	21%
Standard 2: Completed TB testing (if referred)	71%
Standard 3: Treated for TB (if smear-positive)	73%
ISTC-adherent care	11%

ISTC, International Standards for TB Care

Davis JL, AJRCCM 2011

Objective 2: “Understand quality gap”

- Conceptual Model: Theory of Planned Behavior



ISTC, International Standards for TB Care

- Data collection
  - Key informant interviews
  - Field Observation
- Analysis
  - Transcribe interviews and field notes
  - Apply standard coding scheme to identify recurring themes

Health system barriers to TB evaluation

Clinic-level

- Poor infection control
- Limited private space
- Variable leadership

NTP-level

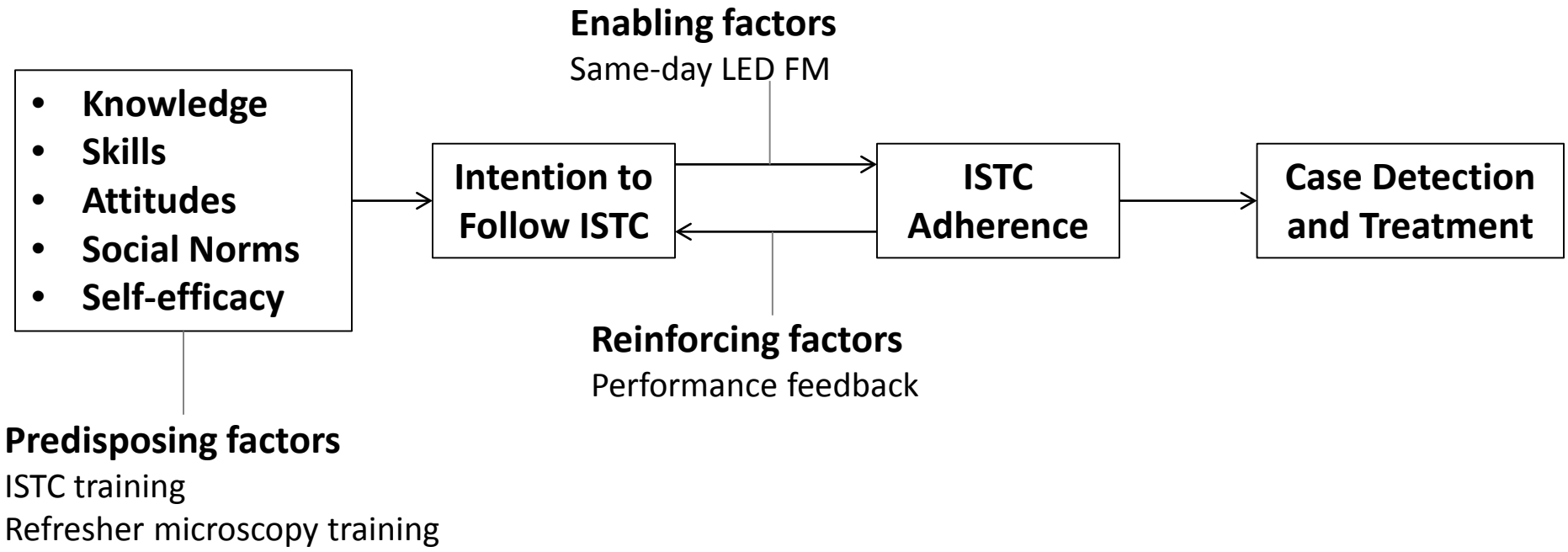
- Inconsistent oversight
- Stock-outs of reagents and drugs

Provider-level barriers to TB evaluation

PRECEDE framework	Recurring themes
Predisposing factors (Knowledge, attitudes, beliefs, intention)	• Low motivation of staff • Inconsistent training of staff *"Some of us are trained, but some new staff are not trained."*
Enabling Factors (Factors that if addressed make it easier to initiate the desired behavior)	• Workload faced by lab staff • Multi-day sputum collection and evaluation *"When they have a cough for more than 2 weeks they are sent to the lab. But the problem is they get the first sample and sometimes, actually most times they don't bring the second sample."*
Reinforcing Factors (Factors that if addressed make it easier to continue the desired behavior)	• Limited capacity for patient follow-up • Lack of communication and coordination between staff *"…actually at times we have met but we don't meet [regularly], only when we realize there is a problem that's when we communicate and say why is this happening, then we try to rectify."*

Objective 3: “Improve quality gap”: Theory-informed intervention

- Evidence review
- Stakeholder consultation
- Feasibility



Intervention details: Performance feedback

- Goals
  - Facilitate training/continuous quality improvement

- Report card provided to each site monthly
  - PLAN: Identify plans to improve performance
  - DO: Implement plans
  - STUDY: Review updated report card
  - ACT: Refine or change performance improvement plans

Intervention details: Same-day LED FM

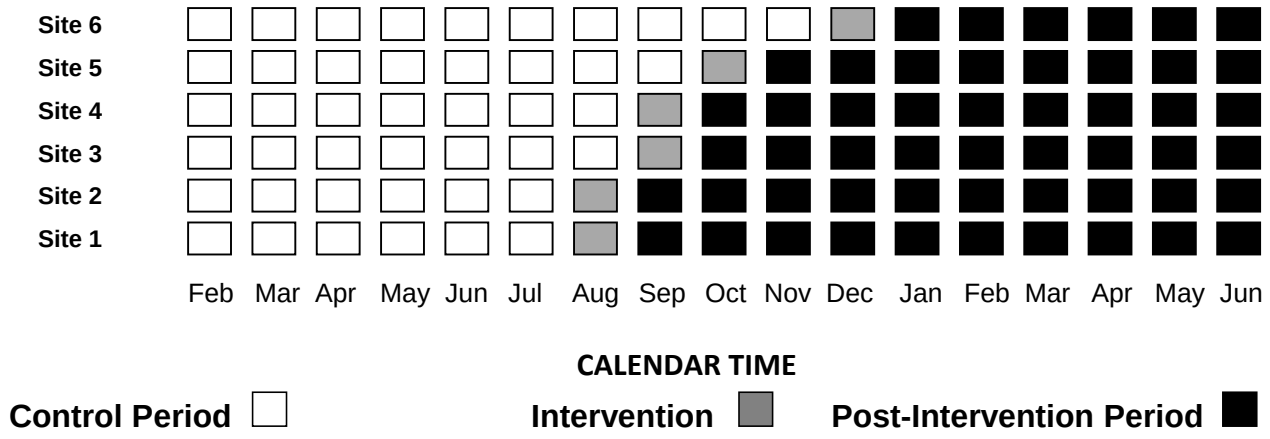
- Goals
  - Facilitate same-day TB evaluation and treatment
  - Reduce laboratory workload/patient waiting time

- 5-day training at each health center
  - FM staining
  - Use of LED fluorescence microscope (PrimoStar iLED)
  - Identification of AFB: practice and proficiency testing
  - Re-organization of work flow

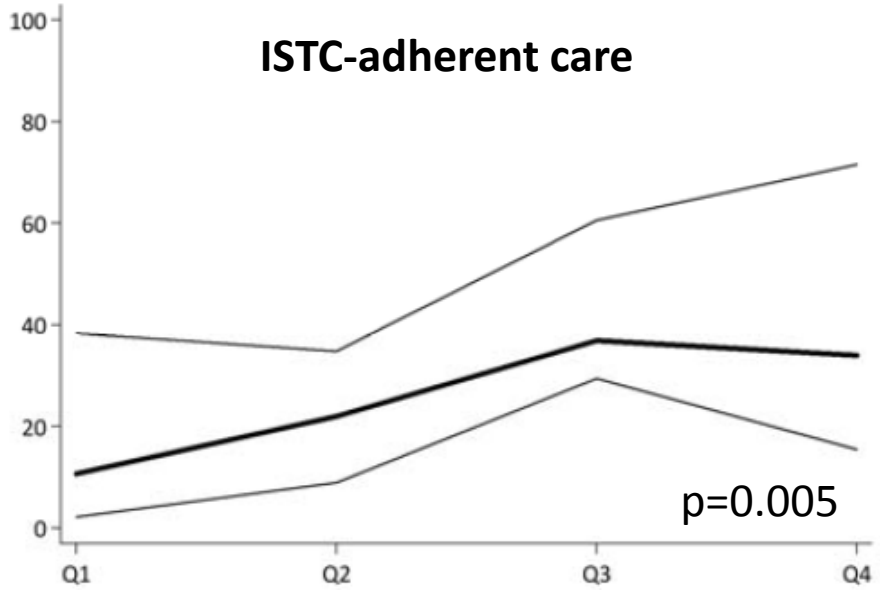
Evaluation of intervention components

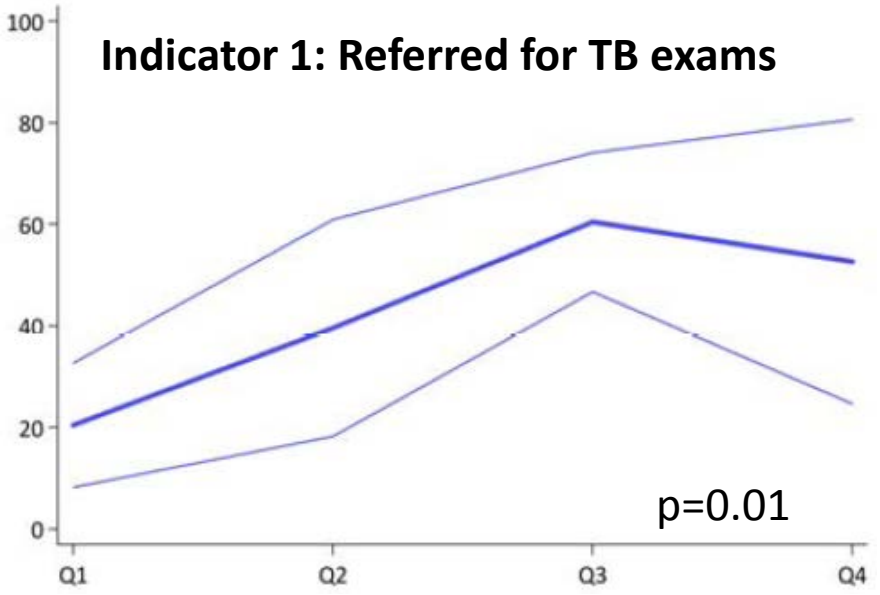
- ISTC/Refresher Microscopy training
  - Before-and-after study assessing trend over time

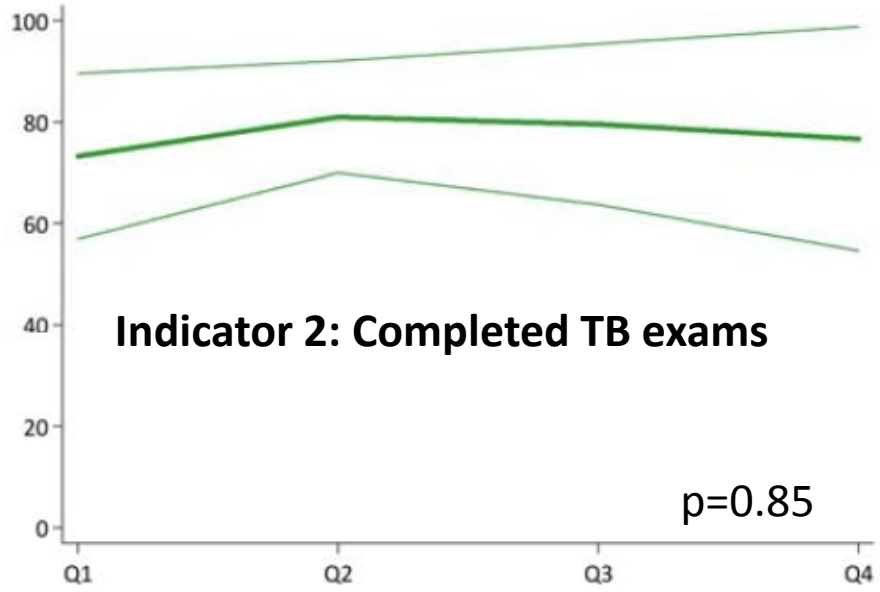
- Same-day LED FM and Performance feedback
  - Interrupted time series study

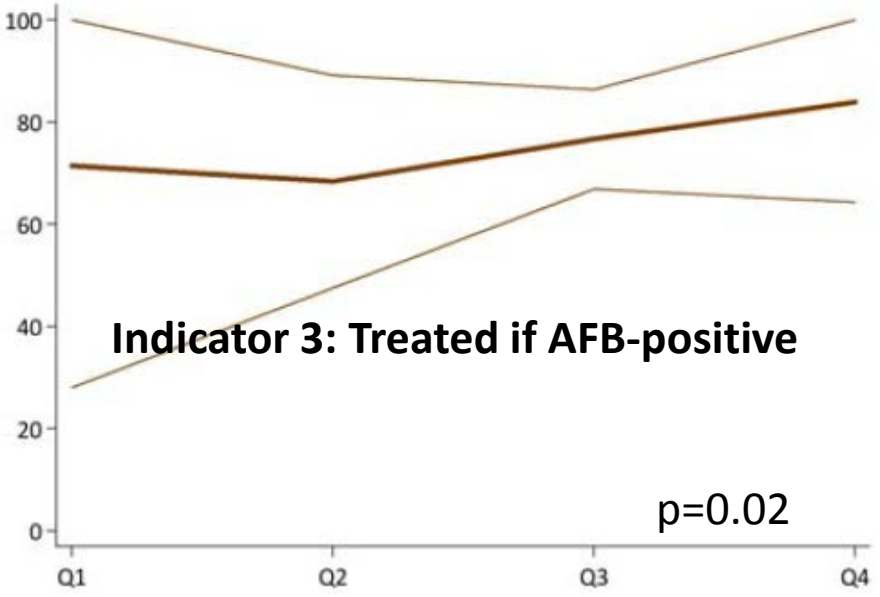


Impact of ISTC/Microscopy training - 1







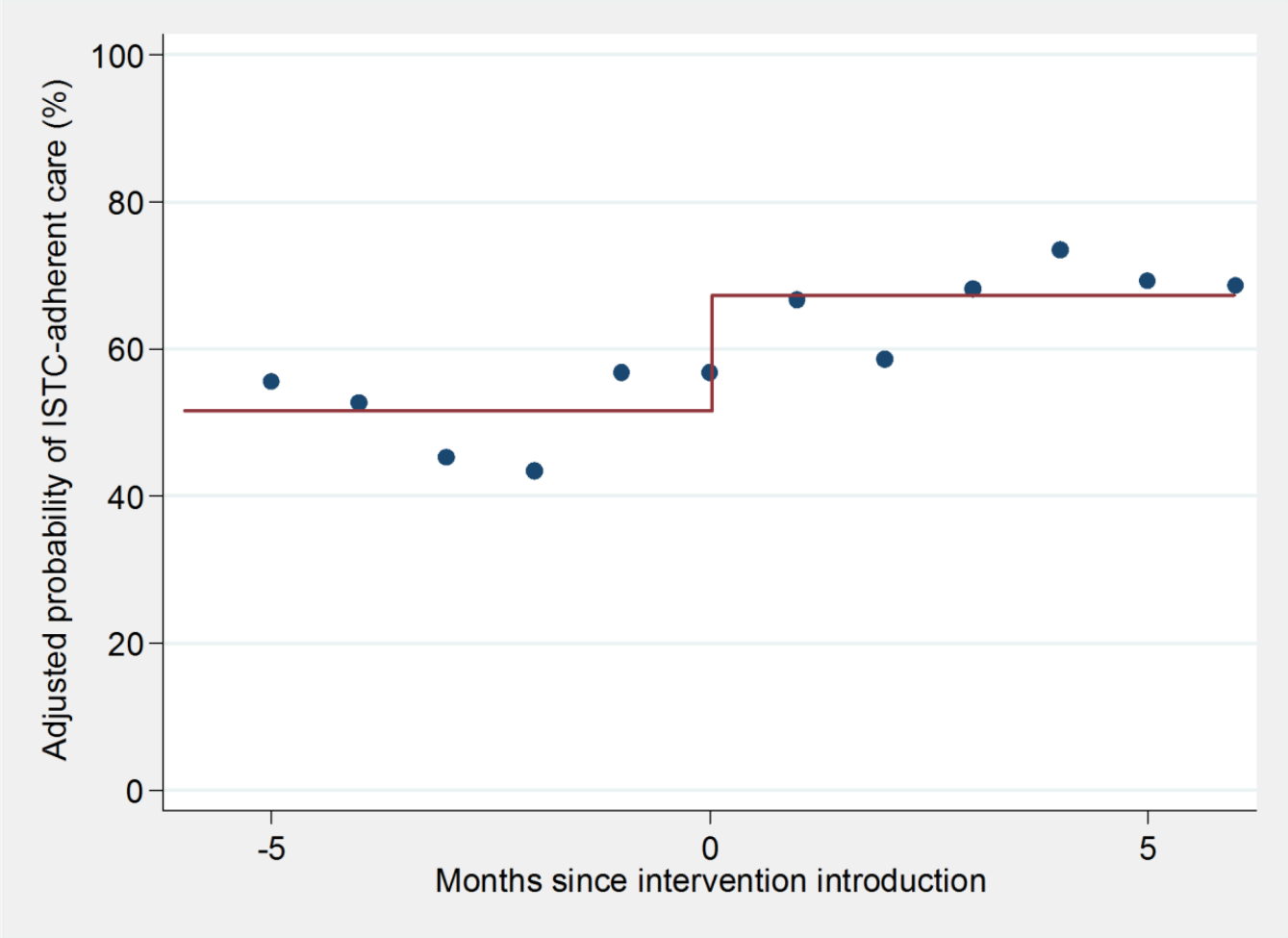


Impact of ISTC/Microscopy training - 2

- High yield of smear examination (13-21%)
- Modest improvements → 3.5-fold increase in TB case detection (7 to 25 cases/quarter)

Impact of performance feedback - 1

Proportion receiving ISTC-adherent care



Impact of performance feedback - 2

Outcome	Performance Feedback		
	Pre N=838	Post N=608	Difference
Received ISTC-adherent care	52%	67%	+16% (+8 to +23)
Referred for sputum examination	72%	82%	+10% (-7 to +27)
Completed sputum examination	74%	84%	+10% (-8 to +27)
Initiated treatment if smear-positive	72%	85%	+13% (-3 to +30)

Impact of same-day LED FM

Outcome	Same-day LED FM		
	Pre N=907	Post N=1043	Difference
Received ISTC-adherent care	58%	75%	+17% (+1 to +33)
Referred for sputum examination	78%	78%	+0.3% (-1 to +7)
Completed sputum examination	75%	96%	+21% (+4 to +38%)
Initiated treatment if smear-positive	86%	98%	+12% (-2 to +28%)

Summary

- Guideline implementation requires changing provider behavior
- A behavioral perspective may be helpful to inform barrier assessment and intervention choice
- Same-day microscopy and performance feedback are feasible and complement ISTC training
- Improving the quality of TB evaluation has a large impact on case detection

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