How to write a case study

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The Doha Declaration in Action: An Examination of Patent Law Flexibilities in the South African Acquired Immunodeficiency Syndrome Epidemic

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Global Health Case Studies

A Compilation from PPHS 511
Fundamentals of Global Health

McGill | GLOBAL HEALTH PROGRAMS | PROGRAMMES DE SANTÉ MONDIALE

McGill **PPHS 511 Case Study Template**

Title

Ensure the title is informative and implies the research question

Abstract

200-word summary of the case study and a visual abstract

Tips:
• Write this part last

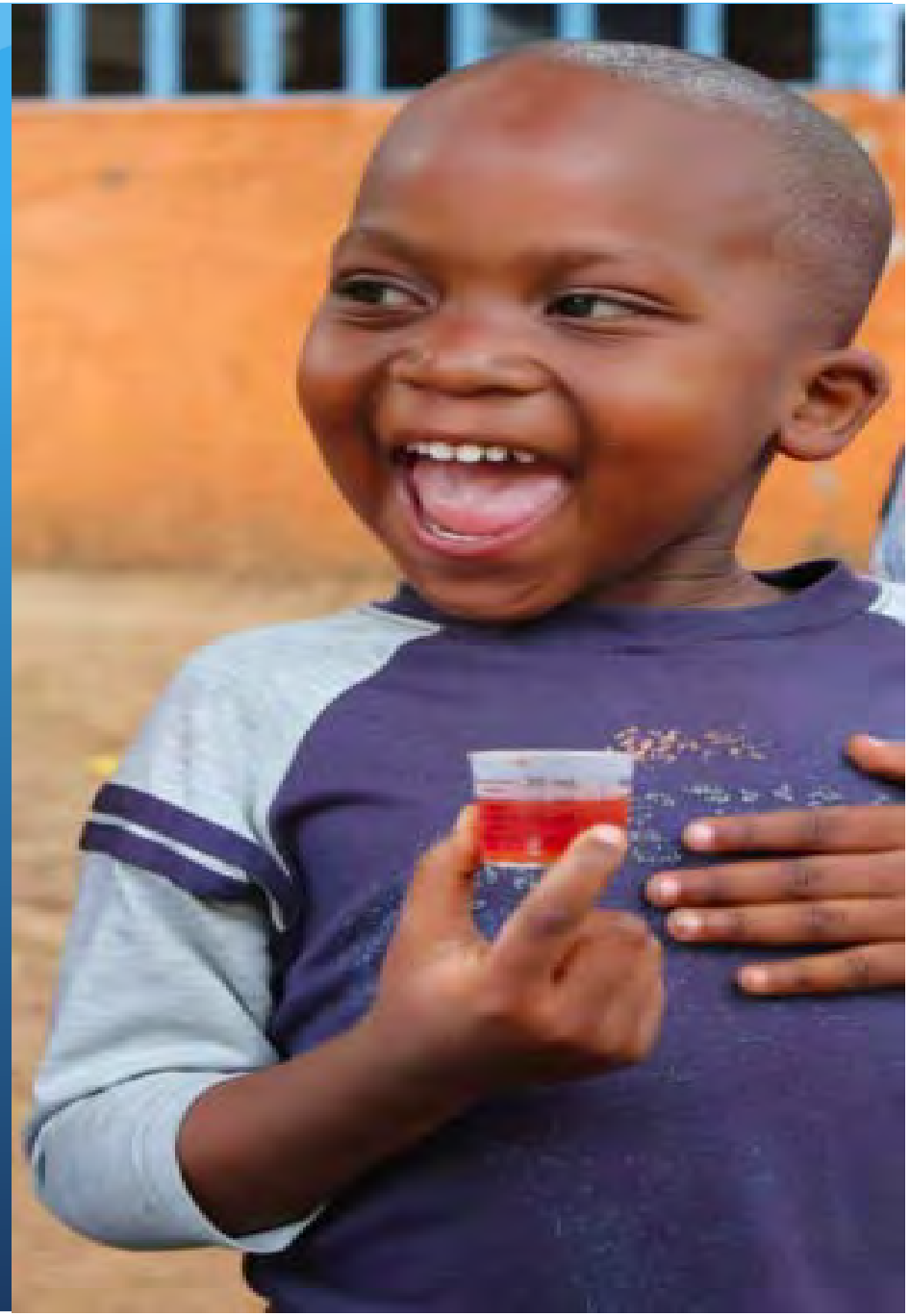
Brief background and motivation for intervention

What is the context of the intervention? Who are the key players? What motivated the intervention?
Are there any previous or similar efforts that informed this intervention?

Tips:
• Start this section broadly and then become more specific
• Establish the problem the intervention is addressing
• The term intervention is used loosely here, you can do a case study on a program, a product, a law, a new organization, etc.
• Should provide the information necessary for the reader to understand the case study question (next section)

The Roll-Out of Child-Friendly Fixed-Dose Combination TB Formulations in High-TB-Burden Countries: A Case Study of STEP-TB

Lena Faust, Kawsar Abdi, Kristin Davis, Chen He, Caitlin Mehrotra, and Emilie Stibolt



Visual abstract

STEP-TB Child-friendly FDCs

- ✓ No more crushing of adult pills
- ✓ Better taste
- ✓ Reliable dosing
- ✓ **Better results**

Achieving near-universal availability and utilization of child-friendly FDCs in Kenya would lead to **2,660 lives saved** over the next five years in the country

15 USD
per treatment course

Introduction

Population: Children (0-14 years) in high TB burden countries

Intervention: first-line child-friendly TB drugs

Comparator: First year post-launch vs. present, or previous FDCs vs. new FDCs (depending on outcome)

Outcome: Market incentivization and coverage of new drugs

Time: post-2016 roll-out of TB Alliance pediatric TB drugs

Background

- 87% of the global TB burden is in 30 high-burden countries
- 10% of TB patients are children (0-14 years old)
- Childhood TB neglected
- In 2010, the WHO revised its guidelines for dosing for treatment of childhood TB

Goals of STEP-TB

"Improved access to correctly dosed, properly formulated, affordable, high quality TB medicines for children."

UNITAID

- Development of appropriately-dosed medicines for children
- Affordability
- Eliminate or reduce market barriers
- Increased commitment to adopt new FDCs
- Delineate clear pathway for introduction

Intervention Timeline

- **2010** - WHO revises pediatric TB dosage guidelines
- **Dec 2012** - UNITAID commits to 16.7 million USD for the development of new pediatric TB formulae
- **2013** - STEP-TB program is officially launched
- **Dec 2015** - Two new FDCs are launched
  - developed by MacLeods
- **Jan 2016** - New FDCs are available from the GDF
- **Oct 2016** - Kenya becomes first country to nationally roll out new pediatric TB medicines

Key Features of Intervention

2 new FDC pills: RHZ 75/50/150 mg (intensive) & RH 75/50 mg (continuous)

- $15.54 USD for six month treatment
- ⅓ companies made it to market - MacLeods

Key Features of Intervention

Marketing

Kenyan Rollout - Oct 2016

- Public launch with international media coverage
- Sustained outreach campaign supported by TB Alliance
- Template for future rollouts

Louder than TB Campaign

- Raised awareness of pediatric TB as a critical issue

High Volume Countries

- Concentrated effort in high volume countries ie. India, the Philippines
- Imperative in creating adequate market size

Impact:

Reminder: Key Outcomes:

- The STEP-TB project made available two first-line child-friendly FDCs: RH 75/50 mg and RHZ 75/50/150 mg (1)

- WHO Endorsement in March 2017: WHO and UNICEF joint statement urging *"All national TB programmes to discontinue and replace the previously used medicines for children weighing less than 25 kg with the child-friendly dispersible TB FDCs as soon as possible."* (2)

Impact: Framework for Evaluation

Summary of Self-Articulated Goals of STEP-TB:

⇒ Considerations for Impact Evaluation

1. Development of child-friendly, appropriately formulated medicines for the first-line treatment of TB (drug-susceptible)

   ⇒ Quality

1. Making these formulations available and affordable to children globally
   - Requires reducing market barriers to introduction
   - Increasing the commitment of countries to implement the new formulations

   ⇒ Availability, Affordability

Impact: Metrics of Evaluation

Areas of Focus for Impact Evaluation:

1. Availability of the new FDCs in high-burden countries (and globally)
1. Quality of new FDCs, as evidenced by endorsement by official bodies
2. Affordability
3. Lives Saved in Kenya: An impact projection using the MAP-IT Model

Could not assess:

- ✗ Improved Adherence
- ✗ Improved Treatment Outcomes

(no patient-level data on these outcomes with the new compared to old FDCs) (1)

Impact: 1) Availability

Status of orders and deliveries of the new FDCs in HBCs:

- 13 of the 22 project countries had ordered the new FDCs by the time of final project evaluation (May 2017)
  - As well as 23 non-project countries

Treatment Initiation: Kenya:

- More than 1,300 children initiated on the new formulations since roll-out in Oct 2016 (as of May 2017)
  - This represents 21% of pediatric cases of TB in Kenya in 2016 (1)

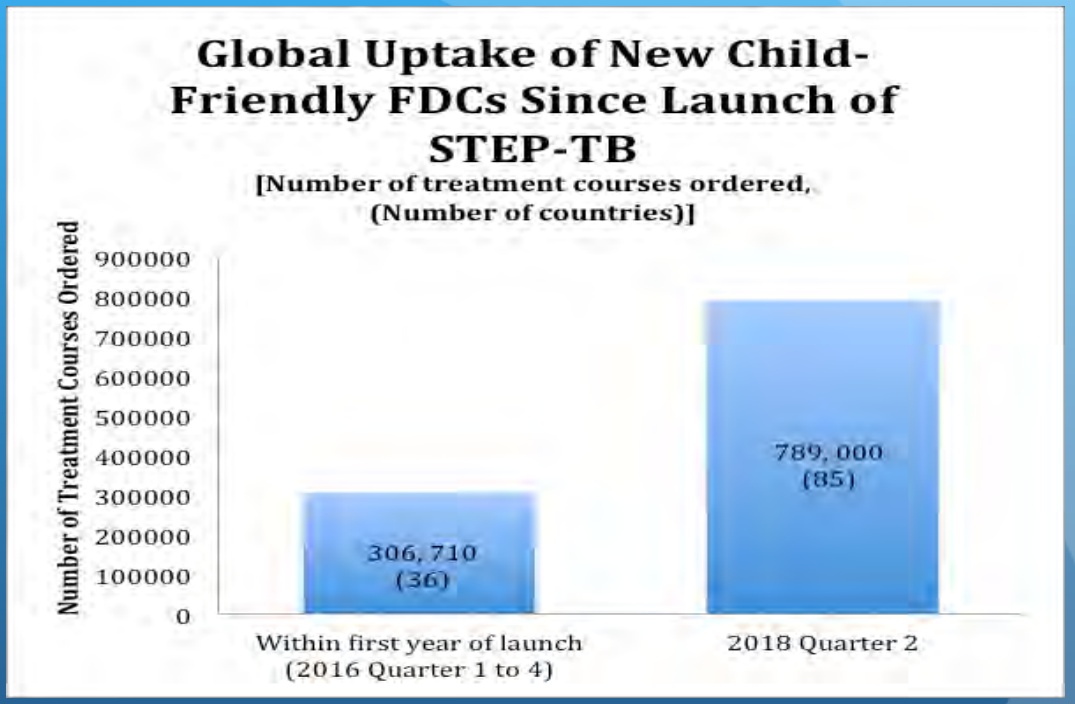


Figure 2. Global uptake of new child-friendly FDCs within the first year of the launch of STEP-TB (end-2016) compared to most recent estimates (mid-2018), by number of treatment courses ordered and number of countries ordering. (2, 5)

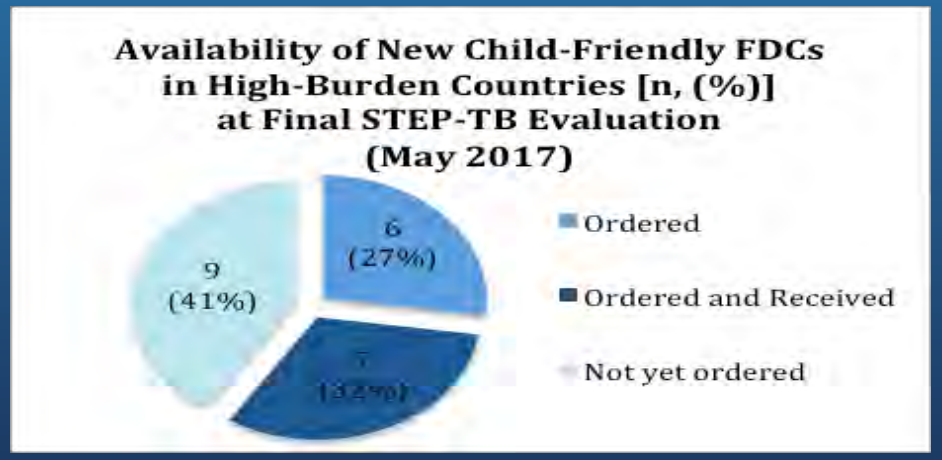


Figure 1. Availability of new pediatric first-line FDCs (RH 75/50 mg and RHZ 75/50/150 mg) in the 22 high-burden countries [n (%)], as of May 2017 Final STEP-TB Evaluation (1)

Impact:

2) Quality:

- The new child-friendly FDCs are endorsed by the WHO and UNICEF
- Are on the most recent iteration of the WHO Model List of Essential Medicines for Children (March 2017), whilst previous FDCs were not. (1, 3)

3) Affordability:

- One full course of treatment: USD 15 (Previous FDCs priced between USD 13 - 22. (1, 5)

Impact: 4) Lives Saved in Kenya: An Impact Projection Using the MAP-IT Model

- The MAP-IT Model was developed as part of STEP-TB (6)
- Allows estimation of lives saved through modification of different screening, diagnostic, or treatment parameters, compared to baseline values estimated from national data.
- We used this model to estimate lives saved if availability and correct use of the new FDCs was scaled up to near-universal levels (98%) in Kenya.

Impact: 4) Lives Saved in Kenya: An Impact Projection Using the MAP-IT Model

Model Assumptions / Parameters:

- Timeframe & Setting: 5-year period, 2019-2024, Kenya
- Estimates for likelihood of progression to active disease, mortality, based on WHO TB database
- “Moderate” estimate mode used (6)
- Baseline conditions reflect standard screening, immunization, diagnostic and treatment practices in Kenya
- The only parameters modified were: Availability and correct use of:
  - Presumptive treatment for drug susceptible TB
  - Clinical treatment for confirmed drug susceptible TB
    - (in the public and private sectors)

Presumptive treatment

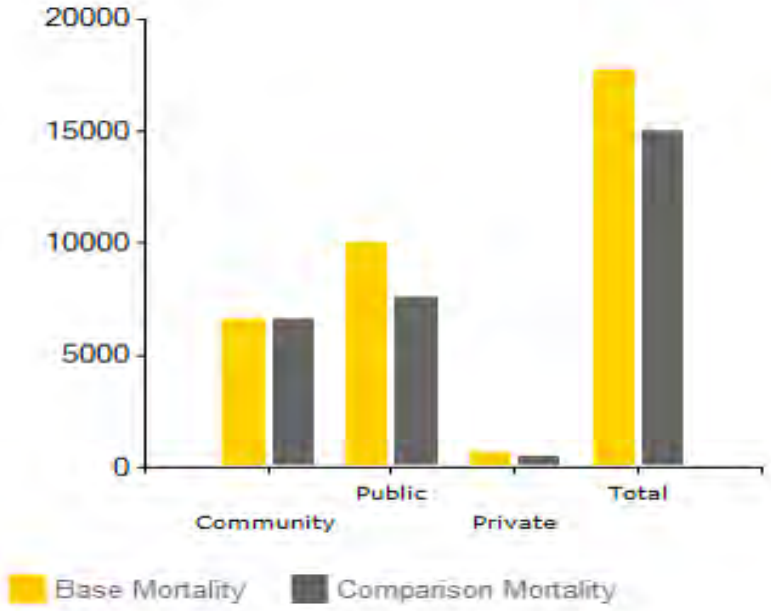
	Public: BASE	Public: NEW	Private: BASE	Private: NEW
Penetration (Availability) (%):	90	98	90	98
Utilization (%):	40	98	40	98
Efficacy (%):	95	95	95	95

Clinical treatment for confirmed TB

	Public: BASE	Public: NEW	Private: BASE	Private: NEW
Penetration (Availability) (%):	90	98	90	98
Utilization (%):	65	98	65	98
Efficacy (%):	95	95	95	95

Impact: 4) Lives Saved in Kenya: An Impact Projection Using the MAP-IT Model

Figure 3. Estimated reductions in TB-associated mortality among children (0-14 years) in Kenya under near-universal availability and utilization of new child-friendly FDCs (assuming standard Kenyan screening, immunization and diagnostic conditions).



Total Mortality Table	Base	Comparison	Lives Saved *
COMMUNITY			
Moderate	6,796	6,796	0
PUBLIC			
Moderate	10,203	7,750	2,453
PRIVATE			
Moderate	852	646	207
TOTAL	17,852	15,192	2,660

Treatment Conditions: Base mortality = 90% availability, 40% and 65% utilization (for suspected and confirmed TB, respectively) of new child-friendly FDCs in public and private settings. Comparison mortality = near universal (98%) availability and utilization of new FDCs in public and private settings.

Estimates generated using the MAP-IT Model Version 1.0.2, Data version 3.0.0 (6)

Impact Summary and Comparators:

Impact Area	Metric/Criteria	Comparator Condition	Intervention Condition
		Within the first year following launch of STEP-TB (End of 2016)	**Mid-2018**
Availability	Number of countries ordering the new child-friendly FDCs	36	85
	Number of treatment courses ordered	306,710	789,000
		Previous pediatric FDCs	**New pediatric FDCs**
Quality	Inclusion on the WHO Model List of Essential Medicines for Children	No	Yes
Affordability	Price of a full course of treatment (USD)	13-22	15
		Post-launch baseline availability and use of new FDCs	**Near-universal use of new FDCs**
Lives Saved	Number of additional lives saved	Baseline (0)	2,660

2019 update:
93
1,000,000

(1-3, 5, 6)

Impact: Limitations

Lack of Data: Limitations of Impact Evaluation:

- Limited estimates of the burden of childhood TB due to difficulties of diagnosis in children, historical lack of prioritization of pediatric TB (Onyango et al 2018)
  ⇒ Limitations of projections and impact predictions

- Although information on order volumes is available, availability does not guarantee high coverage or appropriate use. (availability at NTP-level does not necessarily reflect access at patient-level). (1)

- no data on:
  - Improved adherence with new FDCs
  - Treatment outcomes with new FDCs (vs. custom titration)
    ⇒ Cannot assess public health impact

Impact: Limitations

Systems-level barriers: Limitations of Impact

- Barriers to use among healthcare providers:
  - Challenges of accurate TB diagnosis in children, a lack of knowledge of how to use the new formulations, lack of awareness of their availability. (1)

- Despite their inclusion on the WHO EML and their availability through the Global Drug Facility (GDF), regulatory barriers hinder the adoption of the new FDCs, particularly in low-burden countries
  - e.g. in the EU, child-friendly FDCs are not registered with the necessary agency the (European Medicines Agency) due to low market incentives in this region. (2)
  - Significant implications for high-risk populations in low-burden countries ...TB in Canadian Indigenous communities

Lessons Learned: Reasons for Success

- Understanding the burden
- Creating a market incentive
- Generation of a broad and valuable partner landscape
- Improved palatability and taste of new formulations

- Optimized pediatric dosages
- Ease of administration
- Affordability

Financing

- **August 2013** - Unitaid invested **US$ 17$ million** in the STEP-TB project
  - Collaboration between TB Alliance and the WHO
- Additional support from:
  - WHO, the Global Fund, USAID, MSH
  - National TB Programs (NTPs)
- **Price set** ⟶ **US$ 15.45** for full 6-month treatment course

- (Funding challenges for pediatric TB: represents 10% of the total TB burden, receives only 3% of TB research funding)

Facilitating scale-up

1. Suppliers → need a predictable market
2. Countries need to have technical assistance in order to properly support new product transition, introduction and use
3. High burden countries need to enter and stay in the market
4. Coordination with NTPs

Future Implications

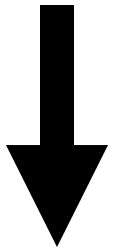
Challenges

- Maintaining sustained interest from partners
- Sustainable market incentivisation
  - What about high-risk populations in low-incidence countries?
- Data transparency / program evaluation
- Ethics of conducting TB studies in children
- No child-friendly formulations to treat drug-resistant forms of TB

Would you fund it?

- Are you convinced?
  - If so, what convinced you?
- Are you left with other questions?

What was the main question?



Think PICO(T)

PICO(T) Questions

Population

Intervention

Comparator

Outcome

(Time)

Did Farm Radio improve mental health literacy?

Did Farm Radio improve mental health literacy?

Did Farm Radio’s depression education segments increase the likelihood of Malawi adolescents recommending peers seek care for depression symptoms compared to before hearing the program?

Did Farm Radio's depression education segments increase the likelihood of Malawi adolescents recommending peers seek care for depression symptoms compared to before hearing the program?

So, what was the main question?

Types of assessment

Feasibility 

 mpact/efficacy

Cost Effectiveness 

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Case study in PICOT format

Clearly identify the population, intervention, comparator, outcome(s) of interest and time period (optional) of your case study.

Tips:

- Focus not only on feasibility of an intervention, but its impact and/or cost-effectiveness.
- The comparator could be a similar population that did not receive the intervention or a historical control (i.e. compare the situation after the intervention to the situation before the intervention)

Goal of intervention

What, specifically, was the intervention trying to achieve? How was it anticipated to impact the outcome of interest?

Strategy (methods)

What is the intervention? How/where/when was it implemented? What was the scale?

Tips:

- Give a clear description of the mechanics of the intervention but don't get bogged down in the details

Impact

Did the intervention impact the outcomes of interest in your research question?
Were there any unexpected or unintended consequences?

Tips:

- Seek concrete (preferably numerical) evidence for the success or failure of the intervention (for some interventions, there may be published impact evaluations already available)
- If you are only able to show association and not cause, that's okay but be clear about this in the paper
- Incorporate 2-3 figures or tables that summarize your evidence

Why it worked or why it didn't

What factors lead to the success/failure of this intervention? E.g.,

- Was it culturally appropriate?
- Made use of local knowledge?
- Was sufficiently funded?
- Had government support?
- Engaged key stakeholders (e.g. patient advocates)?
- Integrated into existing programs?
- Engaged new donors?

…

Tips:

- This is where you really tell a story. What should other people learn from this case study?

Financing

How much did the intervention cost? Which actors contributed funds and how much? Who will pay for the intervention in the future?

Tips:
- Some intervention may have cost-effectiveness evaluations published which should be discussed
- You may need to contact involved actors or granting agencies to establish the amount of funding

Future implications

What is the future fate of the program? If it was effective, does it appear sustainable? What are the key takeaway lessons for members of the global health community? Are there next steps you would recommend?