Case Study: Improving Patient Safety in Kenya

Adapting learning through the lens of a regulatory reform and its impact evaluation

1. Background

What: A country-led effort to design, implement and evaluate an inspection system for public and private health facilities in Kenya with the overall aim of improving patient safety standards (practices that reduce the probability of preventable harm to patients and healthcare workers during the process of healthcare, such as availability of hand hygiene supplies and new syringes) and health outcomes in the country. The original regulatory framework brought together all professional boards and councils with a legal authority to inspect health facilities (around 8 at the time), and defined a unique agreed tool with a set of minimum mandatory patient safety standards gazetted in in 2012 in what is known as the Joint Health Inspections Checklist (JHIC). The Kenya Patient Safety Impact Evaluation (KePSIE) is participating in the piloting of a revised version of the program, informed through an adaptive learning process. This project will start the implementation of the inspection pilots in November 2016, therefore, the analysis of the adapting learning process so far only includes the pre-implementation phase: design, baseline, and preparation for implementation.

Why: Primum non nocere—first, do no harm. This most basic tenet of medical care is routinely violated in clinics and hospitals around the world today, and even more so in low- and middle-income countries. Evidence on this first tenet of medical care is scarce, and few low-income countries have effective systems to regulate, measure, and improve patient safety. Estimates suggest that approximately 42.7 million adverse events resulting from unsafe medical care occur in inpatient services globally every year, and two-thirds of them happen in low- and middle-income countries. Based on KePSIE’s baseline data collection, 97 percent of Kenyan health facilities were non-compliant with minimum patient safety standards in 2015, suggesting substantial room for improvement from the status quo.

Who: This project is a partnership between the Kenyan Government and the World Bank Group. There is a deep commitment from the national and local authorities and participation by all stakeholders: The administrative reform is entirely country-led, with all stakeholders strongly committed to the process. The implementation of the pilot is a joint effort between the government and the World Bank. From the government side, the Ministry of Health has contributed staff throughout the project. A multi-disciplinary team has been assembled, and the World Bank’s Development Impact Evaluation (DIME) is leading the monitoring and the impact evaluation of the project. Four staff with significant or full-time dedication have been part of the research team (two economists, one field coordinator, and one research assistant); five staff have contributed with their expertise according to the demand of the project. We are grateful for the support of the governments of the United Kingdom, the U.S., and Canada through generous contributions from the Strategic Impact Evaluation Fund, the T&C Impact Program, and the Impact Evaluation to Development Impact (i2i) Initiative. The KePSIE team includes Guadalupe Bedoya (Principal Investigator), Jorge Coarasa, Jishnu Das (Principal Investigator), Amy Dolinger, Ana Goicoechea, Njeri Mwaura, Khama Rogo, and Frank Wafula, supported by Benjamin Daniels, and Chex Yu from the World Bank Group. The team works together with the Kenya Ministry of Health, the regulatory boards, and councils.

project; and additional field support has been provided as part of the fieldwork activities (6 supervisors and survey firm support through pilot and data collection). Funding is provided mostly by donors.

2. Process for Learning and Adapting Through the Impact Evaluation Cycle

1. Reviewing the Theory of Change (ToC)

The original program design required a full conceptual review to ensure it had the best chance of reaching its intended objectives. At the outset of KePSIE, stakeholders recognized the progress achieved with the JHIC (lower transaction cost and improved transparency) but identified the following regulatory challenges: (i) unclear and discretionary rules of the game (e.g. rating in the inspections was not consistent due to lack of definitions on specific items to be inspected); (ii) inadequate government capacity to inspect and monitor a sufficiently large number of facilities (around 4% of facilities are inspected in a given year), and (iii) lack of incentives to improve patient safety at different levels of compliance with the standards (e.g. unclear (virtually inexistent) sanctions and weak enforcement, except for extreme cases of malpractice). Stakeholders judged this as a sufficient basis for action. The World Bank KePSIE team, the national and local government and the private sector thus agreed to form a Task Force and work on a stronger theory of change, a new regulatory framework, development and validation of a set of tools to measure and monitor patient safety, and a gold standard RCT to assess the impact of different models of health inspection. Figure 1 presents the revised ToC that resulted from this process and constitutes the basis for continuing the process.

Figure 1. KePSIE Theory of Change
Advantages

- A participatory approach to diagnose constraints and gaps and a process helps create ownership, and increases the chances that the theory of change is solid and contains the critical elements for the intervention to affect the ultimate goal.
- A participatory approach can contribute to the process formalizing how decisions will be made (a task force, and a technical working group) if special care is taken in building/enhancing the institutional framework for such participation.

Risks/Challenges

- Choosing an inadequate composition of the team that participates in the decisions may jeopardize the process. For instance, excluding relevant stakeholders will create political discomfort and lack of ownership; not having the right level of participants (e.g., decision makers in the task force, adequate technical expertise) can lead to sub-optimal decisions.

Lessons

- Understanding the local context and its political economy, and designing an adequate participatory framework is critical for making decisions at the ToC level, when evidence is usually scarce.

2. Design the inspection pilots

The next subsection refers to testing and adapting the inspection program as conceptualized through the ToC.

Question for the audience: What type of data would you ideally like to have to define the parameters of the new regulatory framework? How would you gather and use these data in this process?

Program Approach: The original design features (i.e. the JHIC) lacked evidence of their appropriateness and structured piloting was needed. Based on the revised ToC, a Technical Working Group (TWG) drafted a new JHIC with more than 300 standardized items that facilities should have to comply with safety standards. The KePSIE team piloted this new JHIC in a sample of facilities, and a range of scoring models (e.g. alternative weighting strategies) were simulated and presented to the TWG to select a scoring system, mapping of risk categories for facilities according to their performance, and warnings and sanctions. The pilot revealed that most facilities failed to comply with minimum safety standards. The government thus decided to design a regulatory framework that includes warnings and sanctions while providing sufficient time (6-12 months) and feedback to facilities to help them meet minimum standards (and resort to closure only when all else fails). This system design choice was an “adaptation” to conditions on the ground and included pre-piloting of the tool, data collection, discussion and analysis, and adaptation. Figure 2 shows a sample of the materials included in the field test results and discussion.
Advantages

- The combination of local technical expertise and a high-skilled research team provided a strong structure for the design and adaptation, and what type of data could be informative in the process
- Field-testing provided important inputs for a more informed discussion and decision on the parameters of the new regulatory framework (type of scoring system, the risk matrix, warnings and sanctions).
- The participatory approach including all stakeholders at this stage increased ownership and enriched the discussions throughout the process

Risks/Challenges

- A significant risk stems from choosing the wrong elements to pre-test or discuss. This risk can be mitigated by having the right set of skills in the team: the technical expertise to define what to test given local conditions; a research team that can help in the structure and data choice; and facilitation favorable for discussions with the relevant stakeholders, who can point to potential issues missed.
• Another risk stems from collecting data that can be misleading of the broader population. This risk is reduced if the sample selection and methods for testing follow rigorous technical standards. As we confirmed in our comprehensive data collection a year later, the qualitative results from our pre-pilots hold in the larger population.

Lessons

• Adapting learning requires significant and multi-disciplinary expertise to come together at critical points in time.
• High-quality data and analytical skills can considerably improve the decisions to adapt the programs. They will increase the chances to be successful as the new data help making assumptions closer to real conditions.
• Even having all the elements in place, challenges remain to identify which components within the regulatory framework matter the most to improve patient safety and health outcomes. Rigorous experimentation and impact evaluation would be needed to go beyond a descriptive understanding and unpack causal mechanisms.

3. Choosing an experimental framework

Impact evaluation: The experimental arms are an essential component to inform selection of inspection modalities. Despite having a stronger design foundation on which to improve chances of program success, some of the mechanisms through which impact would be greatest during scale-up were still unclear and could only be answered through causal inference, based on a rigorous impact evaluation. KePSIE experimentally allocates the 1,100 private and public health facilities (which represent the full population of facilities in the counties of Kakamega, Kilifi and Meru, and about 10% of facilities in Kenya)—to one of three intervention arms: (1) high-intensity inspections with enforcement of warnings and sanctions for non-compliant facilities (top-down accountability); (2) high-intensity inspections with enforcement of warnings and sanctions for non-compliant facilities, and public disclosure of inspection results (top-down and bottom-up accountability), and (3) “business-as-usual” low-probability inspections (the control group). Comparing results of the three arms will be the basis for selecting scale-up modalities.

The experimental framework was discussed and agreed by the KePSIE Task Force. It was also defined such that the implementation of the intervention arms had to mimic possible at-scale conditions. To this end the regulatory boards, the Ministry of Health and the governments of the pilot counties held discussion-design-reassessment-design sessions, including on the process of building local capacity to ensure feasible scale-up. The first full-time cadre of inspectors was selected after a performance-based process with government staff.

The result of the ToC review, design pilots and evaluation design was an Enhanced Regulatory Framework for Health Inspections for Patient Safety, which was gazetted in March 2016 (Legal Notice No. 46), and an Operations Manual ratified by the Task Force that defines all the elements and protocols for the intervention pilots and the impact evaluation. These outputs incorporate lessons from the conceptual phase, including well-defined and less discretionary rules of the game, and the strengthening of incentives for facilities to improve patient safety as well as details on the
implementation and its institutional framework. Even though the evidence backing these decisions was limited, basic economic theory would predict that improving accountability structures might result in long-lasting impacts.

4. Developing a real-time implementation monitoring framework and system

**Question for the audience:** How might a monitoring system contribute to adapting learning for this project? What do you think the role of ICT may be in monitoring and evaluation systems that support adapting learning? What data should be monitored? How should decisions be made when monitoring reports are released?

The **M&E system is an essential component of adaptive learning.** At the outset, there was no job description of inspectors, no training materials or protocols, no monitoring system, and no institutional arrangement to link the MOH, the regulatory bodies participating, the three county governments and the inspectors for an intervention such as the one we were designing. The extended team developed all these materials, standards and protocols as the basis for the implementation and the monitoring functions. In addition, a low-cost system was put in place to conduct inspections in tablets and manage progress and monitoring through a web-based monitoring system that reports progress, performance and challenges in real time. The monitoring system includes: (i) data on planning and progress of the inspection pilots (e.g., are inspections taking place?); (ii) inspection results at the facility and aggregate levels for each pilot (e.g., how are facilities performing in each intervention?), and (iii) third-party monitoring indicators to assess quality of intervention and protocol adherence (e.g., what is the quality of the inspection delivered?). This customized solution then leads to the availability of timely and actionable information to identify challenges in the implementation, and enhance accountability to make mid-course corrections, without the intensive use of resources, expertise or equipment commonly absent in poor-resource contexts. An example of the visualization is presented below. The two screenshots highlight a few functionalities to plan for inspections and follow up progress (Figure 1), and to monitor the performance of facilities that have been inspected (Figure 2).

**Figure 3. KePSIE Monitoring System (Demo) - Inspector Visit Plan/Maps**

![Tool for planning and tracking progress, with geo-referenced information on all facilities in Kakamega county with the status of incomplete/complete inspection, and basic information at the facility level. Filters to select information for other regions, by inspector or period are available at the top](image-url)
The system was developed and piloted with inspectors and other officials that will be using it but it will remain flexible during the first months of implementation. Protocols have been devised to govern the monitoring function, including access to information by all relevant actors, and user authorization levels and decision functions according to the implementation protocols. It also aims to guarantee transparency becoming an accountability enhancer as the information is reported almost in real time to all actors. Quality control mechanisms as well as escalation instances are also included. The implementation of the inspection pilots will start at the end of September.

Advantages

- Designing extensive protocols and standards previous to the design of a monitoring system improves the quality of the indicators followed and potentially the quality of the inputs and analysis for decision-making
- ICT can substantively enhance the possibilities for monitoring progress (and adaptive learning) in settings with low-capacity and where no systems are in place (as opposed to developing expensive/risky solutions)
- Once again, a participatory approach with local expertise, involvement of key stakeholders, and a strong research team are critical to build a comprehensive measurement framework of indicators to monitor for timely and actionable information.

Risks/Challenges

- A challenge for designing such a system is the detailed and extensive thinking of what should be measured, how it should be measured and what the governing principles and protocols of the monitoring function should be. This is a process that takes time, and rushing into it is usually costly down the line.
• An additional risk stems from the fact that after designing the system stakeholders may not use it or the system may become outdated. In order to address these risks, ICT solutions offer significant opportunities to automatize most steps to minimize the risk of the system falling apart for the inaction of a specific actor or due to technical constraints. It becomes essential to assess the potential in each case as well as to test all the pieces to make sure that the final users are comfortable and can use it seamlessly. Extensive testing and flexibility are essential to address these risks.

Lessons

• A participatory approach and building institutional arrangements may seem to be a cause of delays in the process, however, most adaptive programs would require a monitoring system that builds extensive inputs from experts and institutions that may not be familiar with this type of interaction. A careful process is invaluable in the long term.

• In our experience, the contribution of a highly skilled research team that imposes structure on the design, implementation process, measurement system and rigorous testing is critical to potentiate adaptive learning.