

A Global Model for Improved Patient Safety

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Common Perceptions

There is a consensus that universal health coverage defined solely in terms of increased access to care is insufficient. Quality health care is certainly key to improving outcomes; however, systems to report and diagnose the barriers to improving patient safety are underdeveloped, even in high-income countries. In Africa, only a handful of countries report national policies on safe healthcare practices and corresponding monitoring systems (World Health Organization 2014). There is little research that can guide policy maker's efforts: for instance, the common recourse of calling for better government stewardship and greater regulation is not backed by evidence (Flodgren et al. 2016).

Estimates suggest that 134 million adverse events from unsafe medical care occur in inpatient services globally every year in low- and middle-income countries (National Academy of Sciences 2018). However, there is scarce data on patient safety and quality of care in low- and middle-income countries, which constrains our ability to assess problems and design appropriate policies.

Therefore, interventions that illuminate the extent of the problem, and identify how resource-constrained governments can address this development challenge sustainably, are a global health priority.

Questions We Should Be Asking

The Kenya Patient Safety Impact Evaluation (KePSIE) team started working with the Kenyan government in 2013 to assess whether their

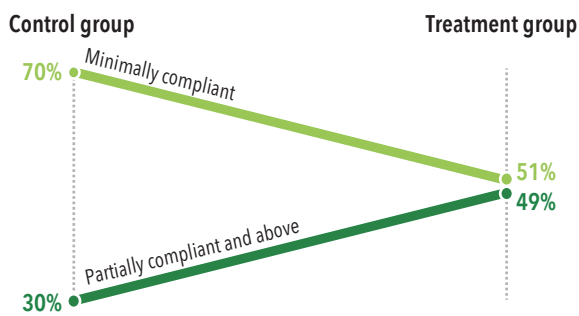
recently reformed health inspection system was improving patient safety. The KePSIE team found that the existing system lacked basic elements that, in theory, could improve patient safety, including clear and well-known guidelines, adequate capacity to monitor health facilities' performance, and consequences for underperforming facilities. After this assessment, and agreement with stakeholders, the government decided to embark on system reform. Prior to the intervention, only 3 percent of facilities complied with minimum patient safety standards according to KePSIE's baseline for the three study counties (Kakamega, Kilifi, and Meru).

As part of KePSIE, a new regulatory framework on health inspections was published in the Kenya Gazette Supplement in 2016, consisting of a standardized checklist, warnings and sanctions, a risk-based score system, a timeframe for facilities to improve, and the inclusion of both public and private facilities to be inspected (previously, only private facilities were inspected).¹

KePSIE was (and remains) the largest trial on patient safety in low- and middle-income countries—and the first randomized controlled study to look at the impact of regulations and inspections in health facilities. The overarching question the impact evaluation aimed to answer was whether regulation and inspections improve the quality of care when all facilities—public and private—are held to the same regulatory standard.

¹ The regulation provides licensed facilities time to improve, with lower performing facilities inspected more intensely and facing the risk of closure if they do not improve within a given timeframe.

Figure 4.10 Improved Facility Compliance in Treatment Versus Control Groups



Note: “Minimally compliant” health facilities score between 11 and 40 percent on the patient safety assessment, while facilities deemed “partially compliant and above” score above 40 percent.

The answer can provide much-needed policy for mixed health systems worldwide.

An electronic inspection system was piloted to assess the impact of the new reform in all health facilities (1,258 private and public) in Kakamega, Kilifi, and Meru counties. These facilities serve over 4.5 million people representing 7 million health visits annually.

The facilities were randomized into three groups:

1. High-intensity inspections with enforcement of warnings and sanctions for non-compliance;²
2. Same intervention as above, coupled with public disclosure of inspection results using scorecards; and
3. “Business-as-usual” with low-probability of inspection (the control group).

The impact of the interventions was assessed by comparing outcomes across the treatment and

² In practice, this means that facilities in the markets assigned to this treatment group will all be inspected by teams of dedicated inspectors using the new, enhanced regulatory framework. Boards and councils will use their legal authority to enforce any sanctions resulting from the inspection.

control groups one year after the start of the intervention (see figure 4.10).

At the outset, there was no job description for inspectors, no training materials or protocols, no monitoring or management system, and limited institutional links. The team worked to strengthen monitoring, evaluation, and delivery functions. Protocols and institutional arrangements were established with the government; as was a pilot Management and Information System designed to manage implementation, and monitor progress and challenges in real-time for adaptive learning and mid-course corrections.

Our Findings

Government regulation and enforcement of health inspections improved patient safety in public and private facilities in Kenya. In the year following the intervention, patient safety scores were 15 percent higher on average in treatment facilities compared to the control group, driven by private facilities (with a 19 percent improvement) and especially formal private facilities (24 percent). Public facility scores increased by a smaller, but still significant, 7 percent. In addition, the entire system moved from “minimally compliant” to “partially compliant” as a result of one-fifth of facilities in the treatment groups moving from the minimally compliant category to higher compliance categories.

The program’s operation cost (US\$95–165 per inspection visit, three visits per treated facility on average) qualifies this as a low-cost, scalable intervention. The study demonstrates that improving regulatory-based accountability in health care can increase safety scores without ancillary support such as private supervision services.

Policy Implications

The operational success of the inspections pilot proved that such a system can work in Kenya. The KePSIE pilot was designed to be cost-effective and illuminate how inspection systems operate when implemented “at scale.” As a result, the government is scaling up this intervention at the national level through a new World Bank operation, making Kenya one of the leaders in patient safety policy in Sub-Saharan Africa.

KePSIE is a country-led initiative, with all stakeholders deeply committed to the process. The team’s technical expertise and assistance strengthened the reform process’s outcome through data collection, field pilots, implementation monitoring, and data analysis to guide future choices.

The project is being scaled up at the national level. We are going to train inspectors in the remaining 44 counties and they will be doing inspections on a daily basis, just like KePSIE. And we will adopt almost everything from KePSIE, to improve both the quality and legality of services.

—IMPACT EVALUATION CLIENT

The institutional capacity, operational guidelines, and systems to carry out such an innovative system at scale did not exist prior to this intervention, and were developed and tested as part of KePSIE. The resulting package can be used to further improve patient safety and quality of care in countries around the world.



This case study is based on an impact evaluation conducted within DIME’s Gender, Economic Opportunity and Fragility research program. See: “Safety First: Improving Access to Quality Health Services in Kenya, Expanding Global Knowledge on Disease Prevention.” (November 2020) This technical note is based on the forthcoming working paper “Regulation as a Policy Lever to Improve Patient Safety and Quality of Care: A Process Evaluation of the Health Inspection Pilots of the Kenya Patient Safety Impact Evaluation” by Guadalupe Bedoya, Jishnu Das, Amy Dolinger, Rebecca de Guttry, Yoon Sun Hur, and Ju Young Lee.*

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