

SAFETY FIRST:

Improving access to quality health services in Kenya, expanding global knowledge on disease prevention

A Look at the Kenya Patient Safety Impact Evaluation (KePSIE)

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. 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.¹

The lack of effective systems to regulate, measure, and improve patient safety severely limits evidence-based decision-making. Systems to report and diagnose constraints to patient safety are underdeveloped, even in high-income countries.^{2,3} Regions such as Africa lag further behind with only a few countries reporting national policies on safe healthcare practices and corresponding monitoring systems (WHO, 2014). Measuring patient safety remains a challenge, but the little data that does exist show that critical improvements are required. In Kenya (one of a few low-income countries with a national survey on patient safety), two percent of health facilities in 2012 were compliant with minimum protocols and systems to assure patient safety (IFC and WHO, 2012). Further, there are few trials that can guide policymakers to improve patient safety in such settings: frequent calls for more inspections and greater regulation, for instance, are not backed by evidence of the impact of such policies.

KePSIE AND ITS EXPECTED POLICY INFLUENCE

In this context, the Kenya Patient Safety Impact Evaluation (KePSIE) is a unique partnership between the Kenyan Government and the World Bank Group, building on long-term support for regulatory reform in the health sector through IFC's Health in Africa program. KePSIE is the largest trial aimed at improving patient safety in low and middle-income countries. It has three main objectives: (1) support the reform of the regulatory framework of inspections to improve patient safety in Kenya; (2) develop a



"Patient Safety refers to a set of practices—hand hygiene, use of sterile syringes, availability and use of health supplies—that reduce the probability of preventable harm to patients and healthcare workers during the process of healthcare and is therefore considered the foremost attribute of quality of care."

—WHO (2014)

A hospital with poor hygiene was responsible for the first Ebola outbreak in 1976:

"In their hospital, they regularly gave pregnant women vitamin injections using unsterilized needles. By doing so, they infected many young women in Yambuku (then Zaire, now DRC) with the virus."

"Clinics that failed to observe this and other rules of hygiene functioned as catalysts in all additional Ebola outbreaks." Their mistakes, "drastically sped up the spread of the virus, or made the spread possible in the first place. Even in the current Ebola outbreak in West Africa, hospitals unfortunately played this ignominious role in the beginning."

—Peter Piot, co-discoverer of Ebola

¹ Jha AK, Larizgoitia I, Audera-Lopez C, Prasopa-Plaizier N, Waters H, and Bates DW. The Global Burden of Unsafe Medical Care: Analytic Modelling of Observational Studies. *BMJ*. 2013; (10): 809-15.

² Wachter, Robert M. "Patient Safety at Ten: Unmistakable Progress, Troubling Gaps." *Health Affairs*, 2010; 29: 165-73.

³ Longo, Daniel R., Hewett, John E., Ge, Bin, and Schubert, Shari. "The Long Road to Patient Safety. A Status Report on Patient Safety Systems." *JAMA*, 2005; 294(22): 2858-2865.

set of tools and instruments to measure and monitor patient safety that can be deployed across diverse low-income settings; and (3) evaluate the impact of accountability mechanisms—through different models of health inspections—on patient safety and quality of care, quantity, and prices of health services in Kenya.

Using clusters of co-located health facilities as the unit of intervention (we call these “health markets;” technically they are defined as clusters of health facilities where no facility is more than four kilometers from the geometric center of the cluster), the trial will experimentally allocate all 1,100 private and public health facilities in three Kenyan counties—Kakamega, Kilifi, and Meru—to one of three groups: (1) high-intensity inspections with enforcement of warnings and sanctions for non-compliant facilities; (2) high-intensity inspections with enforcement of warnings and sanctions for non-compliant facilities coupled with public disclosure of inspection results; and (3) “business-as-usual” low-probability inspections (the control group). The impact of the interventions is assessed through differences in the follow-up and baseline surveys across the three groups.

The results from this study will help understand the extent to which governance and accountability mechanisms can improve service delivery in low-income countries, particularly patient safety and quality of care in the public and private sectors. They will also help us understand how inspection systems operate when implemented “at scale.” Patient safety is a global public health problem and the KePSIE project will expand global knowledge on at least two fronts. First, the production and dissemination of tools and instruments to measure patient safety and design inspection systems to be produced through the project that will have wide applicability across diverse low-income settings.

Second, the project will advance rigorously-tested policy levers that can improve safety through better stewardship.

KePSIE OUTPUTS

1. An Enhanced Regulatory Framework for Health Inspections Focused on Patient Safety (✓ completed)

KePSIE’s first output is a new regulatory framework launched by the government in 2015, and detailed in the Windsor Agreement, October 2013. These include: (A) the refined and easily deployable Joint Health Inspections Checklist (JHIC) that is focused on the fundamentals of patient safety; (B) a scoring system that allows facilities to be categorized according to the level of risk presented to patients; and (C) scores that trigger warnings and sanctions to be enforced according to a facility’s level of risk.

This new regulatory framework builds on previous reform efforts that led to the first JHIC in 2012 (see Box 1 in page 6). It constitutes one of the most comprehensive efforts to monitor patient safety in the region so far. To give some context, of 45 countries in the Africa region with de jure inspection regimes, only five (South Africa, Mauritius, Namibia, Equatorial New Guinea, and Seychelles) actually carry out any type of inspections, and mostly for private health facilities (IFC, 2011). Publicly available checklists in the five countries, where available, are not as detailed and standardized as the Kenyan JHIC.

2. A Toolkit of Instruments to Measure Patient Safety in Multiple Domains (✓ completed)

Patient safety and quality of care are inherently multi-dimensional. However, limited available measures also limit our understanding of which parameters to focus on. From 2014 to 2015, KePSIE developed and validated a set of tools and instruments in close collaboration with the Ministry of Health and the regulatory boards and councils that can be broadly deployed in diverse low-income settings. This set of instruments measures adherence to multiple dimensions of patient safety, including:

- Structural measures of patient safety developed by the regulators. This includes indicators related to protocols, infrastructure, equipment, and supplies of over 300 items across all units and all types of health facilities.
- Infection prevention and control (IPC) practices in outpatient settings, specifically in consultation, laboratory, and injection rooms. These instruments measure healthcare worker knowledge, availability of supplies, indications



that trigger a patient safety action, and safety actions by healthcare workers for five IPC groups: (i) hand hygiene, (ii) injection and blood draw practices, (iii) use of personal protective equipment, (iv) disinfection of reusable medical devices, and (v) waste segregation. This is the first IPC tool combining multiple dimensions of patient safety in low-income countries.

- Case-specific checklists of essential and recommended care for four medical cases (tuberculosis, unstable angina, asthma, and diarrhea with severe dehydration in infants sleeping at home).⁴ This allows multiple measures of patient safety and quality, including diagnostic accuracy, correct treatment, use of unnecessary or harmful medications, use of unnecessary antibiotics, and prevalence of substandard medicines. We use unannounced standardized patients (surveyors trained to present like real patients, but unknown to the doctor), which are considered a “gold standard,” to reduce multiple biases from commonly used measures. This is the first study using the standardized patient methodology in Sub-Saharan Africa.

3. Pilots of Inspections to Improve Patient Safety (*expected*)

KePSIE seeks to assess the impact of inspections and monitoring as designed and conducted through a fully scaled government-led program, rather than a “gold standard” research effort. The study has two critical elements related to the institutional framework and the potential scalability of the results: (1) a task force that includes representatives from multiple bodies, both public and private (Ministry of Health, multiple medical boards, health management teams, and the private sector in the three pilot

counties), that defines the specific parameters of the interventions to be evaluated as well as the operational guidelines; (2) key involvement from county health management teams responsible for providing health services as well as from the central government, which is responsible for the regulatory function.

Interventions that will be evaluated through this collaboration, as well as the instruments, and evaluation design, were decided through a participatory approach over a three-year process. The three counties where the study will take place, for instance, were selected by the health management representatives of the 47 Kenyan counties to represent different conditions and markets in the country. The inspection checklist to be tested has been designed, tested, and validated by the regulators.

Moving forward, the new inspection regime to be tested will add new operational arrangements including: (1) the use of a cadre of full-time inspectors, recruited and trained as part of the pilot; (2) inspection of all health facilities, both public and private (previously inspections were only conducted on private facilities); (3) the development of standardized training material for inspectors and quality assurance tools for inspections (none were available before); and (4) the development of an electronic JHIC and a monitoring and information system to report quantitative results and risk assessments of facilities. The resulting package can be widely used to improve further patient safety and quality of care in countries around the world.

⁴ The four specific cases were scripted to make the diagnosis as obvious and uncomplicated as possible, and were based on the guidelines from the Kenyan Ministry of Health with support from an advisory council.

SNEAK PEEK OF KePSIE EARLY FINDINGS

3%

health facilities that are substantially or fully compliant with patient safety standards

A census of 1,100 facilities in Kakamega, Kilifi, and Meru in 2015 found that facility performance on patient safety, measured through the new regulatory checklist, is poor: 65 percent of the facilities are minimally compliant, obtaining between 10 and 40 percent of the maximum score, 32 percent of facilities are partially compliant (41–60 percent), and three percent are substantially or fully compliant (60 percent and above) with minimum patient safety standards. Nevertheless, simple changes such as appropriate documentation and manuals can increase average compliance significantly from 40 percent to 60 percent of the maximum score.

During a validation study in 23 facilities in Nairobi, a low overall adherence to IPC practices (38 percent) was found. Outpatients faced 3.6 violations of IPC safety practices in great part due to poor hand hygiene. In contrast, observations with 605 patients did not detect a single case of syringes being used for more than one patient.

3%

number of cases where hand hygiene was complied

SNEAK PEEK OF KePSIE EARLY FINDINGS *(continued)*

Better performance in correct treatment when compared to counterparts in other countries

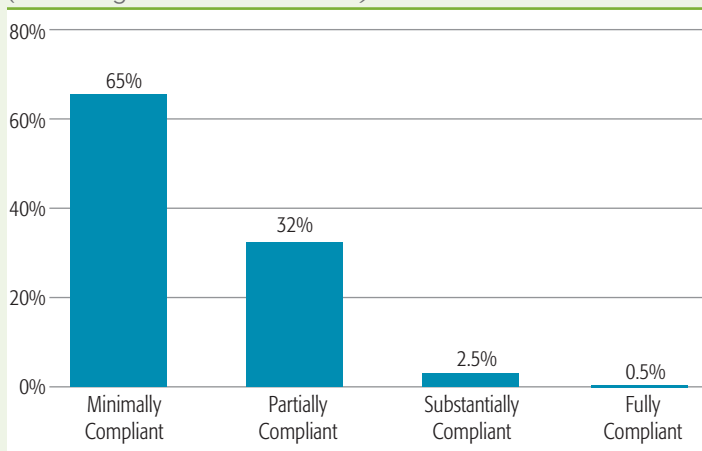
Standardized patients, validated in 42 facilities in Nairobi, showed that healthcare providers performed much better than counterparts in India and China in terms of correct treatment and time spent with the patients for three of four conditions, although the use of unnecessary medicines and antibiotics is very high, like in other countries. For instance, we found correct treatment of 50 percent for tuberculosis (vs. four percent in India), 73 percent for child diarrhea (vs. 18 percent in India), 81 percent for asthma (vs. 57 percent in India), and 10 percent for unstable angina (vs. 41 percent in India).

After analyzing all facilities in the country it was found that although private facilities are widespread throughout the country, public facilities remain the only choice in hard-to-reach, sparsely populated rural areas. Surprisingly, the lowest per capita coverage of health services (health facilities/10,000 inhabitants) in Kenya is in very low income, very dense populations: typically urban slums.

Kenya's urban slums have the lowest per capita coverage of health services

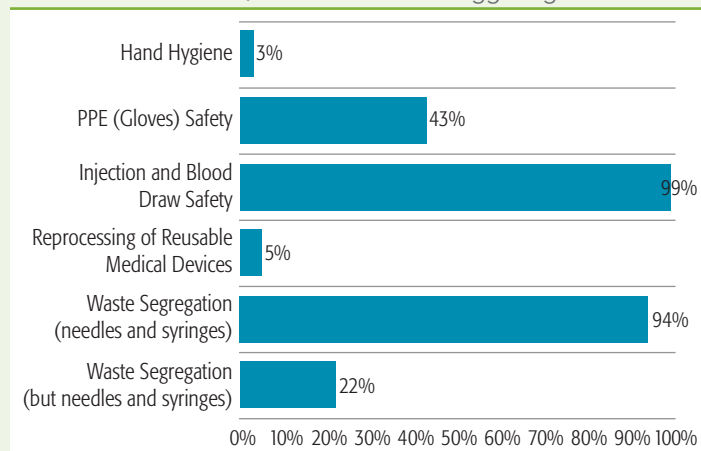
Facility Performance on Patient Safety

(Percentage of Maximum Score)

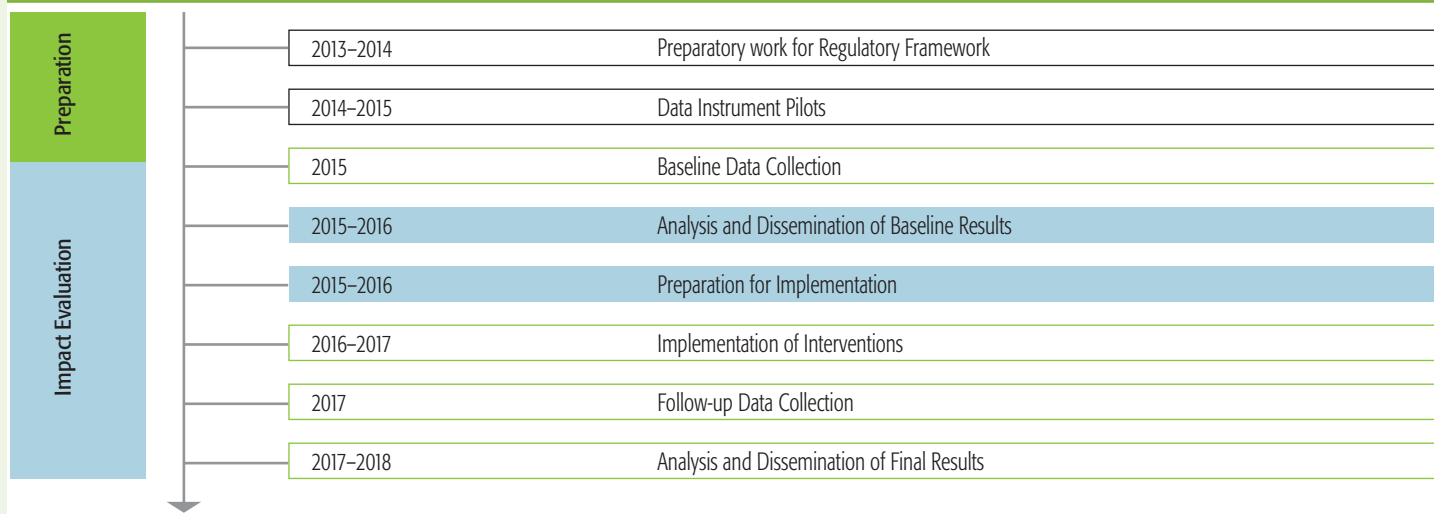


Adherence to IPC Practices

PS Actions Performed/Total Indications Triggering a PS Action



Progress and Next Steps



Evidence-Based Reform of the Regulatory Framework for Health Inspections in Kenya

The reform that ended with the current system of inspections did not happen overnight; rather the enhanced regulatory regime has been an outcome of a series of small steps accomplished over a period of five years that has balanced the needs of different stakeholders with the technical requirements and rigor necessary for such an inspection system.

Phase 1: First Generation Joint Health Inspection Checklist

In early 2010, as a product of multi-stakeholder dialogue, supported by the WBG through the Health in Africa Initiative, public, private and civil society stakeholders in the health sector agreed to partner in developing a health inspections regime that would be fair, transparent and have a focus on guaranteeing the safety of all Kenyans. The reform at that moment focused on tackling transparency and coordination issues such as: (i) inspections could be arbitrary and non-transparent as there was no publicly available information on what inspectors would evaluate and results of sanctions were applied at the discretion of the inspecting authorities; (ii) the different professional boards and councils conducted inspections at different times and with different requirements thus placing a significant burden on health facilities, especially small clinics, and (iii) inspections were based on a fuzzy notion of quality that did not allow monitoring the performance of facilities and was disconnected from any kind of patient-centered improvements. As a consequence, patient safety levels in public and private health facilities were unknown with high potential for adverse effects on health outcomes. After two years of robust discussions, stakeholders developed the foundations of the Joint Health Inspections regime. All professional boards and councils with a legal authority to inspect private health facilities agreed to conduct joint inspections based on an agreed set of minimum mandatory patient safety standards as reflected in the Joint Health Inspections Checklist (JHIC) published in the official gazette on June 30, 2012.

Phase 2: An Enhanced Regulatory Framework for Health Inspections

After the progress achieved with the JHIC, and a considerable time of field-testing by the boards and councils, a set of challenges was identified by the KePSIE team and the stakeholders including (i) discretionary grading in the inspections due to lack of definitions on specific items to be inspected; (ii) inadequate capacity by part of the boards and councils to inspect and monitor a significant number of facilities, and (iii) lack of incentives to improve patient safety at different levels of compliance with the standards due to unclear sanctions and weak enforcement.

In October 2013, KePSIE's Task Force including the MOH, the regulatory Boards and Councils, the private health sector and the

WBG signed an agreement, the "Windsor Agreement", to fine-tune the JHIC, develop an implementation manual to facilitate operationalizing the inspection process, develop a scoring criteria to generate a risk rating of facilities that would feed into transparent warnings and sanctions, and translate these scores into usable information for consumers. In addition, the agreement included a gold-standard evaluation by the KePSIE team of the new regulatory framework in selected counties. As part of the Windsor Agreement, a technical working group (TWG) was constituted and asked to further the reform of a regulatory framework and led to the new launch of the JHIC and implementation guidelines in 2015.

Phase 3: To be Continued

More than five years after the reforms were started, the Checklist continues to be fine-tuned based on the results and feedback from months of rigorous field-testing, and now a new phase will start to pilot different regimes to feed policymaking, setting the basis for continuous improvement. The second generation JHIC has been finalized and is in the process of being gazetted. At the same time, arrangements for the patient safety improvement trials in three counties are being finalized and implementation of pilot interventions in three counties will start later this year.

There are three key messages that emerge from this reform process:

- 1. Successful regulatory reforms require deep commitment from the national authorities and participation by all the stakeholders:** The administrative reform in Kenya has been entirely a country-led initiative, with all the stakeholders deeply committed to the process. In addition, the reform process has been participatory, and at every step, the focus has been on building consensus among all the relevant stakeholders, including private sector representatives.
- 2. Technical expertise and assistance by development agencies such as IFC and the World Bank can strengthen the final outcome of the reform process:** The WBG team has played an important role in facilitating the reform process, through technical expertise, and surveys and field pilots followed by data analysis to guide future choices.
- 3. Changing the regulatory environment is an incremental and a detailed process:** The first generation JHIC was gazetted two years after the first draft was agreed upon by the stakeholders. The enhanced version was field-tested by the KePSIE team in 2014, and the stakeholders validated a revised version Checklist along with an implementation manual, scoring system and warnings and sanctions system were launched in November 2015.

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