Regulation for Safety and Quality of Care

A Process Evaluation of the Health Inspection Pilots of the Kenya Patient Safety Impact Evaluation[1]

Key Findings

- The largest randomized control trial on patient safety standards in any low- and middle-income country, conducted in Kenya, shows that regulation on minimum patient safety standards for all types of facilities improved the regulatory safety score by 15% (0.49 standard deviations) in treated facilities relative to control facilities, without increasing patients' out-of-pocket payments or decreasing facility use.
- The process evaluation shows that the "at-scale" pilot was successful with high compliance across most intervention components. This is remarkable, considering that nearly the entire system was developed from the ground up, including a new regulatory framework and a system for monitoring and enforcement.
- Facilities report positive perceptions and experiences with the new regulation, in contrast with the previous system that was perceived as less transparent, and more discretionary and punitive.
- External factors such as presidential elections and health workers' strikes did not seriously affect operations and outcomes due to a strong institutional setting and high-level commitment to the pilot.
- Several critical mechanisms are at work: (i) a strong authorizing environment and institutional arrangements; (ii) strong leadership from the Ministry of Health (MOH) and the counties, with contributions from multiple stakeholders; (iii) an innovative, adaptive learning process which led to data- and evidence-informed mid-course corrections; (iv) a remarkable effort to enforce warnings and sanctions beyond the provision of information and feedback to facilities; and (v) important external support, capacity-building, and facilitation.
- The cost of routine inspections (once the system is set up) for the pilot was between US$95–US$165 per visit, much lower than the cost of private supervision services.
- Critical risk factors for sustainability of the operation at a larger scale without external support require attention, such as: inadequate governance arrangements and institutional coordination at all levels; insufficient capacity to meet conditions on the ground; failure to enforce warnings and sanctions on time; and exclusion of unlicensed facilities from government systems.
- The study demonstrates how a strong accountability system can improve patient safety in contexts with underdeveloped systems, if the key elements of accountability are aligned in the design of the regulation as well as during its implementation. It also highlights the investment required for such systems and the capacity-building efforts required for effective regulation.
- The intervention has influenced policymaking in multiple areas including the scale-up of the implementation of the regulatory framework to all 47 counties in Kenya.

[1] 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.

i2i DIME TRANSFORM DEVELOPMENT
KIEP
UKaid from the British people
KWPF KOREA-WORLD BANK PARTNERSHIP FACILITY

Context

As the global community works to achieve universal health coverage (UHC), there is growing consensus regarding the importance of *quality health care services* to achieve this goal. Nonetheless, there is limited knowledge on how to assess and monitor quality, beginning with patient safety. The first tenet of medical care is preventing adverse effects to patients and health care workers during health care provision. Estimates suggest that 4 out of 10 patients are harmed in ambulatory care and that 2.6 million deaths occur in inpatient services alone in low- and middle-income countries (LMICs) due to unsafe care (WHO, 2020). Most of the global disease burden caused by adverse events (82%) is estimated to fall on LMICs with the cost of safety violations exceeding by far the cost of prevention (WHO, 2018; IHME, 2015). However, robust evidence is lacking to inform policymakers looking to strengthen their accountability systems through external inspections (Flodgren et al., 2016; Flodgren et al., 2011; Campbell et al., 1998) or even through health service accreditation and certification systems (Brubakk et al., 2015; Hinchcliff et al., 2012; Greenfield et al., 2012). Closing this knowledge gap is particularly consequential in Africa, where only a few countries have established national policies on safe health care practices and corresponding monitoring systems (WHO, 2014).

> "Patient safety is the absence of preventable harm to a patient during the process of health care and reduction of risk of unnecessary harm associated with health care to an acceptable minimum."
>
> — WHO (2020) —

In this context, the Kenyan Ministry of Health and the World Bank Group started a partnership, the Kenya Patient Safety Impact Evaluation (KePSIE), to strengthen the regulatory framework for inspections and evaluate its impact at scale. As part of this effort, in 2016, Kenya gazetted a new high-stakes regulatory framework on minimum patient safety standards including a scoring system with warnings and sanctions for all public and private health facilities. In 2017, a pilot to implement this framework at scale was conducted in three Kenyan regions to evaluate the impact of the new regulation. KePSIE is the largest randomized control trial on patient safety conducted in any low- and middle-income country, and the first experiment to assess the impact of regulatory health inspections, and the focus of this analysis.

At least four elements make this case a unique learning opportunity. First, KePSIE's high-quality impact assessment indicates the intervention significantly improved patient safety, improving the regulatory safety score by 15% (0.49 standard deviations) and moving the average treated facility up a compliance category from "minimally compliant" to "partially compliant." This is significant given the low starting point of only 3% of facilities complying with minimum patient safety standards prior to the trial. Overall, the average facility before the trial was in the lowest category of "minimally compliant," well below the benchmark established by the government for full compliance (scoring above 60% of the maximum score). The intervention improved patient safety for all types of facilities without increasing patients' out-of-pocket payments or reducing demand for health care, both among richer and poorer patients, demonstrating the potential of regulatory-based accountability at a reasonable cost (Bedoya et al., 2020). Second, KePSIE covered the entire universe of public and private facilities (formal and informal) in the study counties, or 10% of all facilities and population in the country (4.5 million catchment population). Third, the intervention was a country-led initiative, with all stakeholders deeply committed to the process and using an adaptive learning process. Conceptually, stronger regulation and implementation were developed and adopted by the government for this trial after an assessment of the limitations of the system at the time. Close consideration and adaptation to local conditions took place and, by and large, the intervention operated under government rules and constraints. Finally, the impact evaluation was designed with a comprehensive monitoring system, including process indicators, outputs and intermediate outcomes to monitor fidelity to the intervention design and potential mechanisms at play. All in all, these elements make this intervention a rare opportunity to shed light on the process of high-stakes inspections, as they would work at scale, and help us identify the next critical elements for advancing the agenda on how government regulation systems can support quality improvements in health care provision.

Process Evaluation Objectives and Dimensions

This process evaluation assesses the implementation of the health inspections system piloted in KePSIE. It aims to inform policymakers and practitioners looking to implement similar systems at scale and particularly in contexts with underdeveloped systems to measure, monitor, and improve quality standards of health service providers. The study describes the main decisions and activities undertaken in developing such a system, assesses the extent to which the pilots were implemented as planned, sheds light on potential mechanisms at work, and identifies the contextual factors that acted as barriers or facilitators in the implementation of such systems.

Process evaluation dimensions and questions

Implementation
- What is implemented and how?

Mechanisms of Impact
- How does the delivered intervention produce change?

Context
- How does context affect implementation and outcomes?

Governance and Institutional Arrangements
- What is the authorizing environment for the inspections pilots?
- To what extent are the institutional and governance arrangements designed for the intervention effectively used, and how may they affect the implementation and results?

Resources and Efficiency
- What are the resources allocated by the different stakeholders?
- What are the fundamental factors affecting implementation efficiency?

Sustainability and Risks
- What are the critical elements for the sustainability and scalability of the inspection system and threats to implementation fidelity?

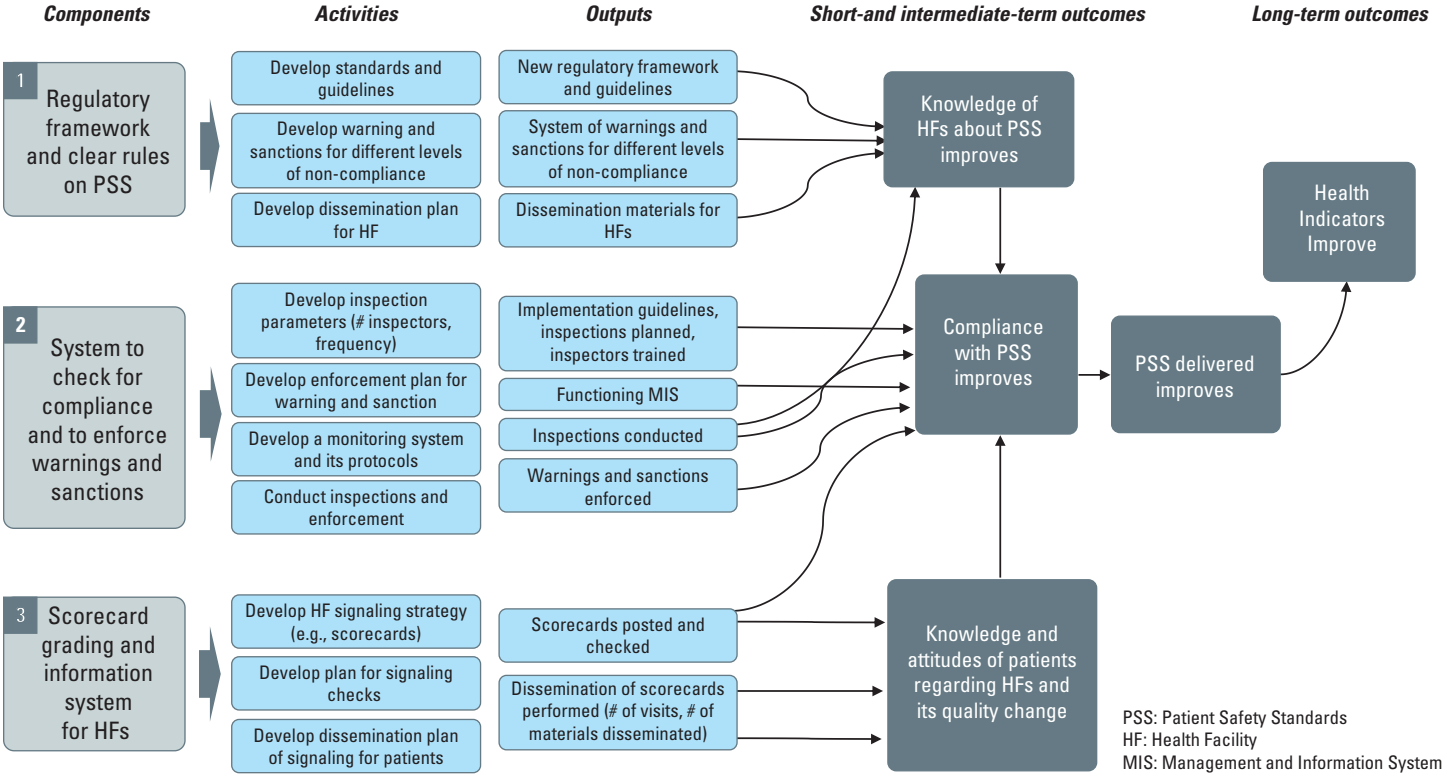
Six dimensions are assessed in this study: 1) implementation including fidelity, dose (the quantity of the intervention delivered and received), coverage and adaptations; 2) mechanisms of impact such as participant responses and potential mediator processes explaining subsequent changes; 3) contextual factors potentially acting as barriers to or facilitators of the intended effects; 4) governance and institutional arrangements influencing the implementation; 5) critical resources and efficiency determinants, and 6) sustainability and risk factors for replicability and scalability. These dimensions are assessed across KePSIE's intervention components, the intervention's theory of change, and the hypothesized links between the intervention components and outcomes.

KePSIE Inspection Pilots and Theory of Change

The KePSIE health inspections were expected to improve patient safety by strengthening accountability in the health system to align incentives for compliance with minimum patient safety standards. There are three broad components across this intervention: (1) a regulatory framework accompanied by clear guidelines on the minimum patient safety standards that facilities are expected to comply with; (2) a monitoring system to track compliance with minimum quality of care and patient safety standards, and enforce warnings and sanctions over time; and (3) a scoring and information scorecard system to publicize health facilities' compliance with minimum patient safety standards. The figure below presents a simplified theory of change behind the intervention, including its main components/inputs, activities, outputs, and the hypothesized causal chain to select outcomes of interest.

The main assumptions behind the theory of change of this intervention is that the combination of two or more of these components leads to an inspection system that provides incentives

KePSIE Theory of Change



Source: KePSIE project documents

for health facilities to comply with patient safety standards. For instance, activities and outputs from component (1) are expected to affect the knowledge of minimum patient safety standards by facility in-charges, which is a necessary (although not sufficient) condition to improve compliance. Activities and outputs in component (2) are expected to directly affect compliance by creating incentives (and costs for noncompliance) through feedback and enforcement. These two components aim to create top-down accountability. Finally, the third component is expected to affect consumer demand, through the provision of information to patients (bottom-up accountability), causing a reallocation of demand to facilities with higher patient safety scores, which in turn may induce changes in provider behavior. In the long-term, better compliance with minimum patient safety standards among treated health facilities contributes to improvements in the health outcomes of the population they serve.

The intervention required a new regulatory framework with warnings and sanctions that are enforced (weak sanctions and enforcement, except for extreme cases of malpractice, were previously the norm), a new system to check for compliance and to enforce warnings and sanctions at scale (around 4% of facilities were inspected in a given year previous to the intervention), and the development of a scorecard system to inform patients of the performance of the facility. This intervention, therefore, falls within the definition of complex interventions by the UK Medical Research Council (Craig et al., 2008). It involves multiple interacting components, spanning from a regulatory reform to the development of a system to manage, monitor and enforce it. Its implementation relies on the interaction of several organizational levels, including the Ministry of Health and regulatory boards and councils at the national level, and the county health teams and health facilities at the local level.

The target population of the intervention is all public and private facilities in three counties of Kenya—Kakamega, Kilifi, and Meru—ranging from Level 2 primary clinics to Level 5 hospitals.[2] KePSIE uses a randomized design to assess impact and, therefore, the census of health facilities in these counties is randomly divided into three groups. One treatment group (T1) receives components (1) and (2) to test the impact of top-down accountability. A second group (T2) receives components (1) and (3) to test the additional impact of bottom-up accountability. A third group only receives the regulatory framework in (1), which applies to all facilities at the national level, but no high-intensity inspections except for cases of malpractice.

[2] According to Kenya's Essential Package for Health (KEPH) classification. The intervention does not include stand-alone laboratories, pharmacies, or other facilities providing only specialized services.

Process Evaluation Data Sources

Data Source	Analysis	Examples of Indicators	Sample / Respondents
Project Documents	Qualitative	Regulation gazette published; inspection protocols established; scorecards validated; dissemination plans developed	NA
Administrative Data	Quantitative	Licensing status of facilities and departments; facility inclusion in government records	All treated and not treated facilities
Management and Information Systems	Quantitative	Proportion of HFs inspected; proportion of warnings and sanctions enforced, proportion of closed facilities found non-operational during quality checks	All treated facilities
Survey Data	Quantitative	Proportion of in-charges that are aware of the regulation; proportion of patients that have been affected by closures; proportion of HFs that report receiving full JHIC report	All treated and not treated facilities
Semi-structured Interviews	Qualitative	Actors' roles and responsibilities; perceived obstacles to implementation; overall assessment of the intervention components and their long-term sustainability; recommendations for improvement	Implementation Coordinator (WBG); Logistics Firm (Medical Board); Inspectors; County authorities
Focus Group Discussions	Qualitative		Inspector Training Expert Group (ITEG); World Bank Quality Team

Methods

This process evaluation uses a mixed-method assessment that combines quantitative and qualitative instruments and methods. The overarching framework closely follows the UK Medical Research Council (MRC) Process Evaluation of Complex Interventions Guidance and is complemented by other sources including Wholey, Hatry, and Newcomer (2004) and Rossi, Freeman, and Lipsey (2013). Quantitative sources include survey data from KePSIE's baseline and endline, and implementation data on all treated facilities from KePSIE's management and information system (MIS). We use a combination of observational analyses and take advantage of KePSIE's experimental design to assess impact on relevant intermediate outcomes, when possible. In addition, we complement these with qualitative analyses of project documents, administrative data, semi-structured interviews and focus group discussions with the main implementation actors.

Results

Implementation: What was implemented and how?

The implementation of the pilots was a multi-year effort because it required setting up an entire system. The implementation can be divided into two phases: the preparation (2013–2016) and the implementation of the one-year inspections pilot (November 2016–December 2017). Preparation included the reform to the regulatory framework of the inspection system for minimum patient safety standards, and the development of the institutional framework, systems, parameters, nomination and training of inspectors and overall capacity building required to operate the pilot inspections at scale. The enhanced regulatory framework was gazetted in Kenya Supplement No. 31 (Legislative Supplement No. 25) as part of Legal Notice No. 46 in the Public Health Act (Cap. 242) on March 21, 2016 to be applied at the national level. The elements of the framework included (a) a refined Joint Inspection Health Checklist with itemized minimum patient safety indicators to make it leaner and less discretionary, easier to deploy and further 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; (c) warnings and sanctions to be enforced according to a facility's level of risk. Additionally, the new regulatory framework

Large operation to deliver the intervention

2,523 total visits to treatment health facilities

385 visits to enforce closures of facilities and departments

468 visits that did not end up in inspection

3 visits and 2 completed inspections per **treated** facility

The study counties were selected by the health management representatives of the 47 Kenyan counties.

The MOH and regulatory boards and councils seconded the inspectors, who became the first cadre of full-time joint inspectors.

The Medical Practitioners and Dentists Board conducted the logistics for the daily operations of the implementation.

The World Bank Group provided technical assistance and facilitation throughout the process, developed the MIS system and monitored the implementation.

The MOH led the enforcement of closures of health facilities and departments.

The county governments were a focal point in communication with health facilities and the implementation teams, and dedicated resources for inspectors.

was extended to public facilities (only private facilities were covered by the previous legislation).

A large and complex operation took place in the study counties. The implementation of the pilot in the 3 counties included 2,523 visits to health facilities in the treatment arms. These visits included all successful inspections, as well as some visits that did not lead to inspections (for instance, if the facility was closed at the time of the first visit, triggering the need for additional visits) and a large number of visits by the MOH and the county team to enforce the closure of facilities and departments due to the widespread licensing issues.

Multiple stakeholders cooperated to develop and deliver the intervention. All elements of the intervention were designed and implemented through a participatory approach over a five-year process.

The various components of the KePSIE intervention were delivered successfully overall, including the development of a regulatory framework with clear rules of the game, a strong system to check for compliance, and a scorecard system to disclose facilities' performance, reflecting high fidelity to elements of the intervention related to plans, rules, and the development of systems.

KePSIE plans, rules, and systems developed as planned

1. Regulatory framework and clear rules of the game
2. System to check for compliance

Top-down accountability

- ✓ Standards and guidelines on patients safety (JHIC)
- ✓ Scoring system
- ✓ Warnings and sanctions for different levels of non-compliance
- ✓ Dissemination plan on standards for facilities

- ✓ Operational guidelines, plans, and Management and Information System (MIS) for carrying out electronic inspections, tracking progress, and assessing and ensuring quality
- ✓ Protocols for informing facilities about the new regulation
- ✓ Protocols for enforcing closures
- ✓ Inspectors with standardized training

3. Scorecard system to disclose HF performance

Bottom-up accountability

- ✓ Scorecards
- ✓ Dissemination plan on scorecards for facilities
- ✓ Dissemination activities
- ✓ Texting system for verification of scores by patients

Regulatory Compliance Categories, and Follow-Up Actions

Checklist Score	Compliance Category	Follow-up Action
≤ 10% or no license	Non-compliant	Immediate closure
11% – 40%	Minimally compliant	Re-inspection in 3 months. Facility will be closed if it does not score over 40% of the maximum score in the 3rd inspection.
41% – 60%	Partially compliant	Re-inspection in 6 months. Facility will be closed if it does not score over 60% of the maximum score in the 3rd inspection.
61% – 75%	Substantially compliant	Re-inspection in 12 months
> 75%	Fully compliant	Re-inspection in 24 months

Source: Kenya Gazette Supplement No. 31. 21st March, 2016 (Legislative Supplement No. 25). Legal Notice No. 46. The Public Health Act (Cap. 242).

The new regulation has strong "sticks" but under a supportive principle. The government 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).

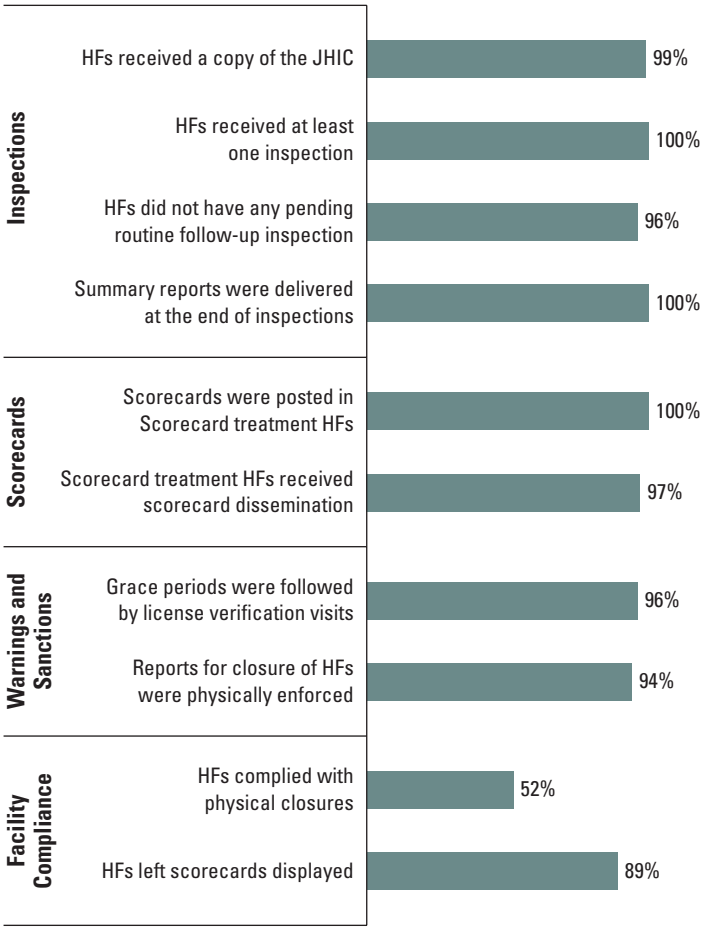
Under the new regime, facilities that score less than 60% of the maximum score are visited frequently (the lower the score, the more frequent the visits). They have 3 visits to improve to the next category or face closure. Once they are above 60%, they are inspected every 12 months or 24 months (if they score above 75%) without facing risk of closure. Only facilities with no license or scores below 10% face immediate closure. In practice, closures were mostly due to lack of licenses.

A high level of delivery of the inspection components is reflected across multiple indicators. Almost all (99%) of the treatment facilities reported receiving a copy of the JHIC before or during the first inspection. All (100%) were inspected at least once, and received a summary report outlining the inspection results, findings, and recommendations. At the end of the implementation, almost all (96%) follow-up inspections that were due (as determined by the regulation based on the results of previous inspections) had taken place. In all scorecard treatment facilities, a scorecard was posted at the end of each inspection (100%) and dissemination visits were conducted to raise awareness among patients about their meaning (97%). Finally, the majority of warnings and sanctions were executed: grace periods given to facilities and departments to comply with licensing requirements were followed by license verification visits in 96% of the cases and, as of the end of the implementation, closure of facilities and departments was physically enforced by the MOH and the county authorities in 94% of the facilities reported for closure and that had not solved their license issues by the time of the closure visits.

Facilities' compliance with the implementation varied. Compliance with scorecards was high: during quality checks, scorecards were still found displayed in 89% of treatment facilities (on average 3 months after the inspection). Compliance with closure was much lower: 52% of facilities where closure was physically enforced were found inactive (on average 2 months after the physical closure), while the remaining 48% had reopened.

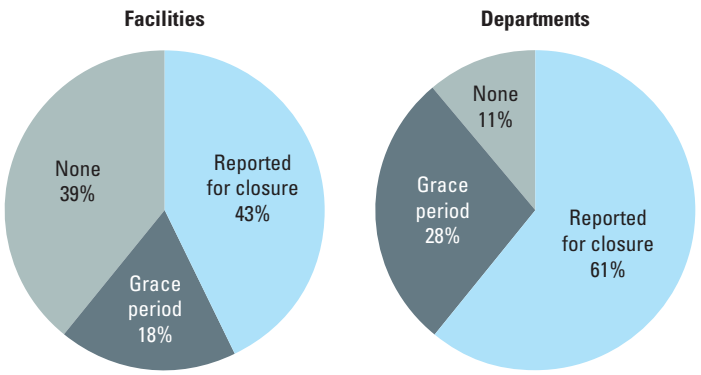
Widespread licensing issues and enforcement of closures imposed a significant cost to the system, while signaling to facilities that enforcement was a credible threat. Across the three counties, 64% of facilities were private. A majority of them (61%) and the departments within these facilities (89%) reported at least one licensing issue. This ranged from having an expired license, which implied a 90-day grace period and a re-visit to verify, to having no license available, which resulted in a report for immediate

KePSIE inspections had high fidelity to intervention components



Source: KePSIE Management Information System (MIS)
Facility compliance with physical closures is based on quality checks on average 3 months after the inspection. Facility compliance with scorecards displayed is based on quality checks on average 2 months after closure.

61% of private facilities and 89% of private departments were found with at least one licensing issue during the implementation



Source: KePSIE MIS
Notes. Indicates most severe license-related sanction ever applied for all private facilities that received an inspection. Excludes 6 facility closure reports that were not due to licenses.

closure.[3] Given the extent of these issues, new protocols were developed so that inspectors provided facilities with information about how to renew their licenses. Detailed license information for facilities and departments, including contact information and GPS coordinates for facilities, was captured in the MIS and shared with the boards and councils to facilitate the licensing process. Overall, the operation required 385 visits to facilities for the enforcement of closures. The majority of these physical closures were due to licensing issues.[4] With delays in the rollout of the implementation, most facilities were not inspected more than twice and, therefore, closures for reasons related to JHIC performance, such as scoring less than 60% and not improving to the next highest compliance category by the third inspection, were rare.

A team from the MOH and the county offices conducted closure visits in four waves during the year of implementation. The process involved posting of a closure scorecard and notifying the in-charge of the decision and process to obtain a license. The closure visits happened on average 70 days after the closure report (vs. a 1-day protocol). Therefore, a large number of facilities (around one third of those that received closure reports in the inspection) were able to obtain the licenses before the closure visit, and avoid physical closure.

The closure visits were visible events, in many occasions involving the participation of the community. The participation from the MOH was particularly important as the team and MOH coordinator explained in detail the reasons for the closures and implications for the patients of receiving care from unlicensed providers.

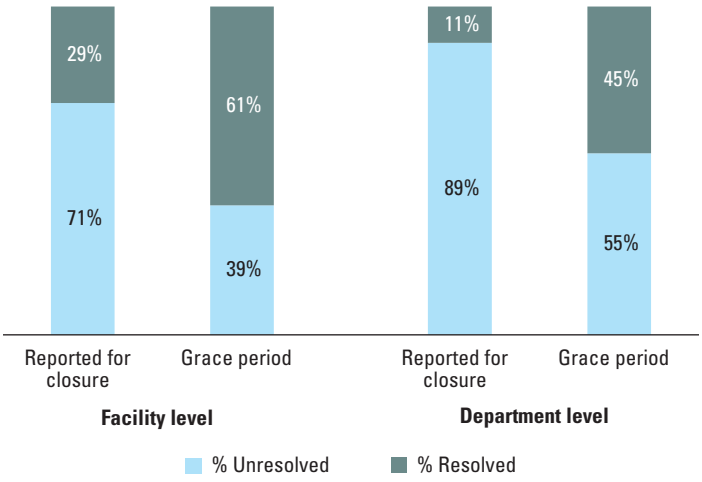
[3] As per protocols for the implementation, inspectors did not enforce closures in the pilot system. To separate the role of inspections and closures, inspectors administered closure reports after an inspection and the county government and MOH were responsible to enforce closures of facilities and departments based on the inspection reports.
[4] A few closures were due to performance on the JHIC, such as scoring below 10% of the maximum score (the non-compliant category) or scoring less than 60% of the maximum score and not improving to the next highest compliance category by the third inspection visit.

The county government did not perform closure visits without the leadership of the MOH. The closure visits took place only when the MOH team travelled to the counties to carry out the enforcement in closure rounds. In focus group discussions and interviews with stakeholders, it was mentioned several times that because of the county permanent presence in the areas and the familiarity of the county officials with the communities, the closure visits were problematic and county officers may be conflicted. Therefore, the presence of an "external" government body, such as the MOH, allowed the closures to take place, although at a much lower frequency than considered previously. Given the importance of enforcement, this is an area for consideration in the scale-up of inspections.

By the end of the implementation (December 2017), a large proportion of licensing issues related to grace periods had been resolved, and a lower—but nonetheless—important share of the lack-of-license issues had also been resolved. 61% of facilities with grace periods had obtained a license verified by an inspection, and 45% of the departments with grace periods had done so as well by December 2017. This is an important achievement and mobilization by the facilities and boards and councils. Of the facilities and departments reported for closure due to lack of license, 29% and 11% respectively had obtained a license that had been verified by the end of the implementation.

The year after the intervention, during KePSIE's endline data collection, 65% of the facilities that were physically closed due to licensing issues, and had not resolved their issues by December 2017, were found operational and offering their services. A large majority of these facilities did not have a license by the end of 2018 as per administrative records from the regulatory boards and councils (B&Cs). Furthermore, the majority of all operating facilities (97%), including the unlicensed facilities, consented to the

Licensing issues status by the end of the implementation pilots
% of cases unresolved/resolved



survey. Therefore, the impact evaluation reports that these facilities, while also improving their score, have much lower patient safety, which lowers the floor of patient safety.

The number of inspections to facilities was smaller than originally envisioned, due to delays in the implementation of inspections.

- It took over 7 months to complete the first inspection in 90% of facilities, which led to facilities receiving less visits than the one-year schedule based on the regulation.
- One third of follow-up inspections were conducted with an average delay of 81 days.
- Licenses (for grace periods) were verified after 120 days (vs. a 90-day protocol).
- Physical closures were executed 70 days after the report for closure (vs. a 1-day protocol).

The implementation of the intervention was modified considerably to adapt to the conditions on the ground. Adaptations included increased participation of the government in the delivery and logistical management of inspections, customization of warnings and sanctions to address widespread informality in the private sector, centralization of their enforcement, and a larger operational role of the management and information system managed by the WBG. Overall, most adaptations contributed to the pilots closely resembling what the government would face in a scale-up. The table below presents the elements that help fit the intervention to the context and the ones that threaten the fidelity of the intervention.

Overall, an adaptive learning process embedded throughout the process seems to contribute to the success of the intervention and the results. Some illustrations from the project are as follows:

- The enhanced regulatory framework was developed by a Technical Working Group (TWG) based on the assessment by all stakeholders. The draft regulatory tool was tested in 42 facilities in Nairobi and results were used to simulate different scoring systems and helped show that most facilities would not comply with the new regulation. Based on these findings, the new regulatory framework was developed to give facilities time to improve. Significant adaptation also took place during implementation. Many scenarios arose in the implementation of the inspections that were not anticipated or clearly defined in the regulation or its guidelines. These scenarios led to different paths of actions for which protocols were developed for KePSIE's implementation. For instance, given the significance of the licensing issues in the private sector, 3-month grace periods for facilities and departments with expired licenses were implemented to give them time to renew their licenses. This required a new protocol and an additional visit to verify they had obtained the new licenses after 90 days.
- A large number of visits did not result in an inspection because the in-charges were absent or had left when the inspector arrived (likely due to the lack of a license). The government, therefore, decided to establish a new protocol that would lead to closure reports for multiple unsuccessful visits. The protocol includes a notice letter which states that an inspector has visited the premise to conduct an inspection, waited up to 30 minutes, and was unable to carry out the inspection. The letter provides contact information and notifies the facility staff that a second inspection will be attempted in the next weeks and, should the staff not be available at the next attempt, the facility will be reported for closure.

Adaptations and elements that helped or threatened intervention fidelity

Adaptation	Elements helping the intervention fit the context	Elements threating fidelity
Medical Board assigned by the MOH as the logistics organization (vs. private provision planned)	■ The logistics benefited from greater knowledge of reality on the ground and more authority/credibility	■ Confusion in line of command led to inefficiencies and delays
Inspectors were selected among government staff nominated by the B&Cs (vs. call for government and private sector candidates)	■ Government inspectors lent inspections more authority and credibility	■ B&C's capacity led to 6 available inspectors on average (vs. 12 planned) ■ Misaligned incentives and accountability contributing to absences and other HR issues
Grace periods (90 days) were introduced for HFs and departments with expired licenses	■ Better fit to widespread informality and sudden demand to B&Cs to manage license applications ■ Differential treatment of informal (unregistered) versus expired license	■ Weakened enforcement or sanctions ■ Additional inspectors' workload (due to the license verification visits required after the grace periods)
Closures enforcement changed from immediate physical closure executed by the counties to a few closure waves executed by MOH and county	■ Enabled physical enforcement as closures by county officials as per the original protocols were not being executed at all	■ Weakened enforcement of sanctions
Management and information system scope increased substantially	■ Facilitated standardization, management and monitoring in a constrained environment ■ Facilitated accountability through transparency and sharing of data	■ Dependence on external team

BOX 1. How Did KePSIE's MIS Support the Implementation?

The KePSIE management and information system (MIS) was a pilot system consisting of an application to conduct inspections electronically and a platform to manage inspections planning and monitor progress on inspections. This customized solution made available timely and actionable information for all stakeholders, including the facilities, inspectors, MOH, B&Cs and counties for planning, monitoring, adaptation, and accountability.

Illustration: KePSIE MIS Summary Figures

Illustration: KePSIE Facility Inspection Report

Section 2:Health Facility Infrastructure	Max Score	Observed Score	Percentage Score
A. Building	35.00	26.07	74.48%
1. Signage and accessibility	15.00	11.77	78.46%
Does the facility display legible signage?	3.00	2.83	94.39%
Does the facility display signage that is accurate (relevant)?	3.00	2.37	83.72%
Does the signage include the facility name?	3.00	2.81	99.22%
Does the signage include department namesand direction?	3.00	1.87	66.20%
Does the facility have an accessibility ramp for disabled/wheelchair patients?	3.00	1.88	62.78%
2. Ventilation	10.00	7.20	72.03%
Adequate ventilation is defined as at least 5% of the overall wall size of the room, or artificial ventilation. Check across different sections of the facility and score according to the overall performance.	10.00	7.20	72.03%
3. Lighting	10.00	7.10	70.95%
Adequate lighting is at least 10% of the overal size of the room. How well does this facility satisfy this criterion? Check across different sections of the facility and score according to the overallperformance.	10.00	7.10	70.95%

To illustrate how the system worked, it is useful to follow the journey of different actors as they interact with the system. First, an inspector conducted the inspection in a facility with the eJHIC in a tablet, using a software that calculates the facility's score, compliance category, and related follow-up actions in real time. The records were uploaded to a web-based system, where they were available to officials from the Ministry of Health, the Boards and Councils, the counties, and the implementation team. Facility in-charges would also receive a system-automated email (if an email was provided) with a full report of compliance with each JHIC standard. Within two weeks, the inspector would print and deliver copies of the full inspection reports to the local government health office. Next, the inspector planned for upcoming inspections over the next days and weeks, and for which the system provided a list of assigned facilities, precise locations on maps, and due dates for follow-up inspections based on each facility's inspection history with daily updates. When the government closure teams were ready to enforce closures of facilities and departments (e.g., pharmacies and laboratories within a facility), the system automatically produced a list based on inspector closure reports including the history of previous actions and inspection reports for each facility and department. Finally, when the Ministry of Health coordinators, the Boards and Councils, and the counties wanted to use data for planning and policy, the system provided easy-to-read, nearly live reports on the progress and results of inspections.

The system underwent extensive development and testing. Before the implementation of inspections, field-testing and fine-tuning activities were carried out for more than six months to verify measurability and relevance of the standards included in the JHIC, and the eJHIC was extensively tested in the KePSIE baseline. For the pilot, the MIS was designed to be highly adaptive as it reflected an entirely new inspection system being implemented for the first time at scale in Kenya. During the pilot, many scenarios arose that were not anticipated or clearly defined in the regulation. These scenarios led to different actions that inspectors may take in the field, for which protocols were developed with the MOH based on the current regulations for KePSIE's implementation. The electronic inspection tool in the tablets underwent more than 40 rounds of revision due to this learning-by-doing process, and the web-based system expanded in scope to include many additional elements for the management of inspections. Over 4 years, including before and during the pilot, the standardization of the inspections and detailed protocols were fine-tuned by a multidisciplinary team. Continuous learning with the MOH, B&Cs, and counties led to a comprehensive measurement framework of indicators for timely and actionable information for managing inspections across counties. The MIS package, including the electronic JHIC (eJHIC), web-based system source codes, and other implementation support tools, were shared with the MOH and B&Cs along with training sessions and workshops to support the transfer of knowledge for the national scale-up.

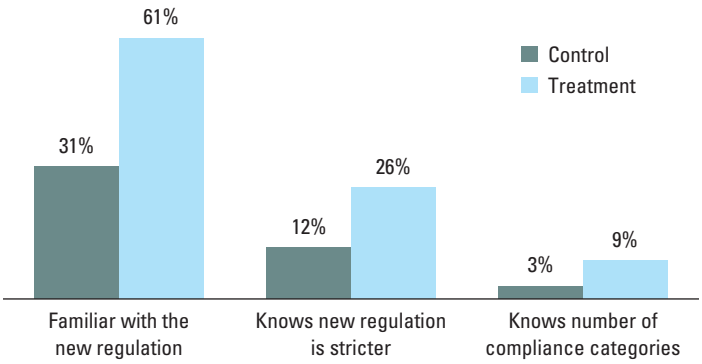
- The electronic inspections and management systems helped this process by reporting progress, performance, and challenges in real time. The system included: (i) data on planning and progress of the inspection pilots (*e.g., are inspections taking place?*); (ii) inspection results at the facility and aggregate levels for each pilot (*e.g., how are facilities performing in each intervention?*); (iii) up-to-date history at the facility and department level of previous actions and due dates to support enforcement, and (iv) third-party monitoring indicators to assess intervention quality and protocol adherence (*e.g., what is the quality of the inspection delivered?)*. As Box 1 describes, the system was critical to integrate multiple stakeholders and assess the progress and issues with the system, and for mid-course corrections.

Mechanisms of Impact: How might the delivered intervention produce change?

Knowledge, feedback and enforcement are key intermediate outcomes that the intervention aimed to affect to improve compliance. Merging survey and monitoring data helps shed light on what mechanisms may be stronger for the intervention to produce impact.

Knowledge of the regulation improved significantly. At endline, the percentage of in-charges in treatment facilities who report being familiar with the regulation doubled with respect to control. However, many still do not recognize important features of the new regulation: 26% of in-charges know the new regulation is stricter, and only 9% know the number of compliance categories.

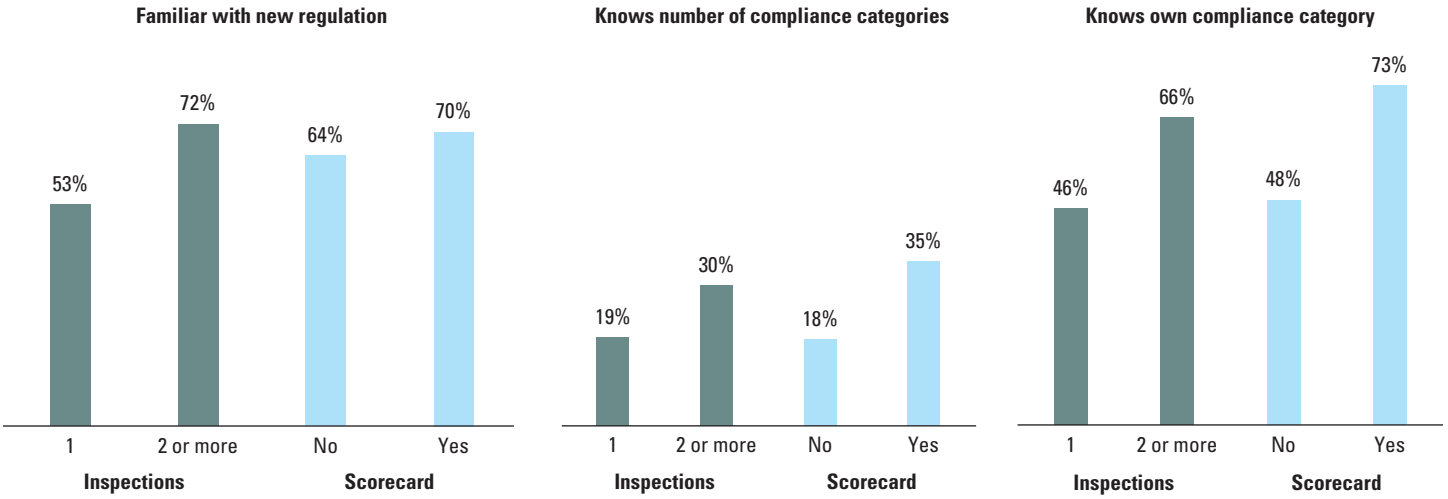
Facility in-charge knowledge of regulation
% of health facility in-charges



Having more inspections and being in the scorecard treatment arm correlates with better knowledge of the regulation and of the facility's performance. In-charges of facilities with 2 or more inspections are significantly more likely to be aware of the regulation than those with one inspection (72% vs. 53%), and to know the number of possible compliance categories (30% vs. 19%) and their own compliance category (66% vs. 46%). Similarly, in-charges in the scorecard arm are more familiar with the new regulation (70% vs. 64%), are more likely to know the number of compliance categories (35% vs. 18%), and are more likely to know the compliance category they belong to as per the last inspection (73% vs. 48%), than facilities in the inspections-only arm.

Enforcement seems to be a stronger mechanism than information or feedback working to produce impact. Facilities with a higher number of inspections reported a higher impact, and

In-charge familiarity with regulation (treatment facilities)
% of health facility in-charges - Endline reports and MIS data

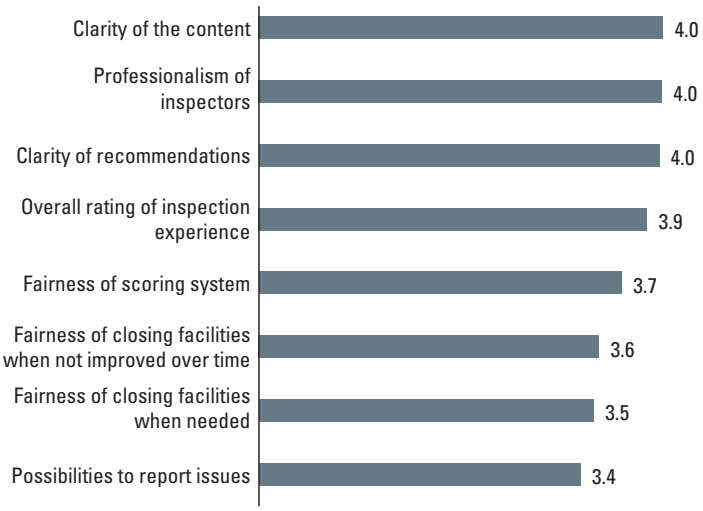


the scorecards and no scorecard arms had similar impacts. These results, together with higher knowledge due to more inspections and scorecards suggest that enforcement (larger number of visits to enforce warnings and sanctions) is a stronger channel than knowledge or information/feedback alone (scorecards acted as an additional feedback/information loop affecting knowledge further with no additional impact).

In-charges of facilities that were inspected rated favorably the Joint Health Inspections system across multiple dimensions. Elements such as clarity of content, professionalism of inspectors, and clarity of recommendations were rated at 4 points out 5, while considerations of fairness with the scoring and closures were rated lower at between 3.5 and 3.7. The lowest element was the possibility to report issues (3.4), which suggests a limited response for questions or queries from the facilities. These results are in contrast to the previous perception of a punitive and harassment system reported by the private sector and stakeholders.[5]

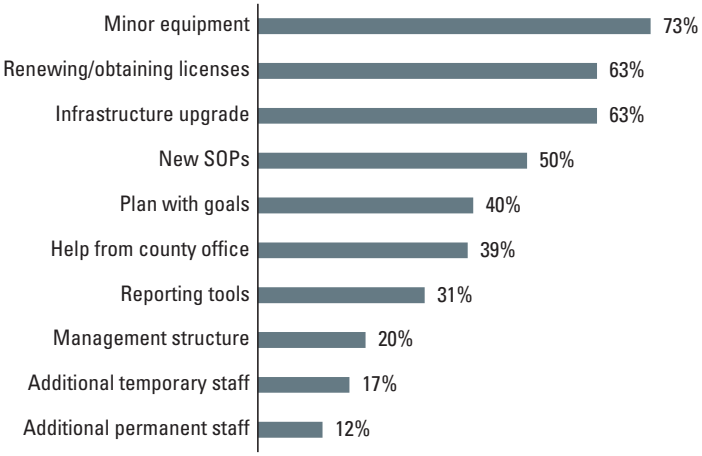
Positive perceptions and experiences of in-charges with the new system may contribute to the success of the system
% of health facility in-charges

In-charge rating of Joint Health Inspections (if inspected)
On scale from 1 to 5, 1 being "very bad" and 5 being "very good"



[5] See further work: "What lies behind successful regulation? A qualitative evaluation of Kenya's health facility inspection reforms," by Eric Tama, Irene Khayoni, Catherine Goodman, Dosila Ogira, Timothy Chege, Njeri Gitau, and Francis Wafula, *forthcoming*.

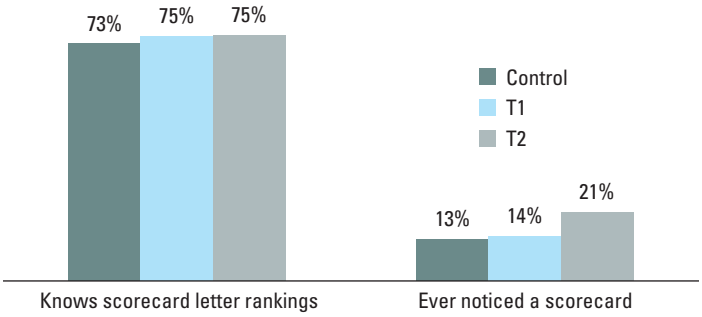
Changes Implemented
Facilities that report implementing changes—% of health facilities



In-charges and decision-making bodies at treated facilities reported multiple elements of focus for compliance, including acquiring minor equipment (73%), followed by addressing licensing issues (63%) and upgrading their infrastructure (63%). Therefore, the intervention had differential responses by type of item in the regulation. The largest costs were reported in infrastructure.

The ranking system was easy for patients to understand, but most of them did not notice the scorecards; therefore, the bottom-up accountability could not be tested properly. A better dissemination campaign would be necessary to further understand the potential of informing patients about facility performance.

Patient Intermediate Outcomes by Arm
(% patients)



Patients are not significantly affected by the inactivity or closure of facilities. A patient exit survey with 11,100 patients shows that when issues are reported, they are mostly related to the need to travel farther to receive health care. This may explain why the government did not face important challenges in closing facilities. Most facilities that were closed were also located in highly dense markets where patients had other alternatives. Protocols were also established by the government to ensure

Patient has been affected by facility closure(s)
% of patients

that catchment areas would not be without the provision of health care as a consequence of the intervention. These included: (i) assessing markets following government closures based on the number of health facilities in the market; (ii) the level (size) of the health facilities in the market; and (iii) problems that may be out of the control of the health facility to fix in the proposed time frame and the number of points that these represent in the overall JHIC score (only in cases where a closure was due to score, which accounts for <1% of closures) (World Bank, 2016).

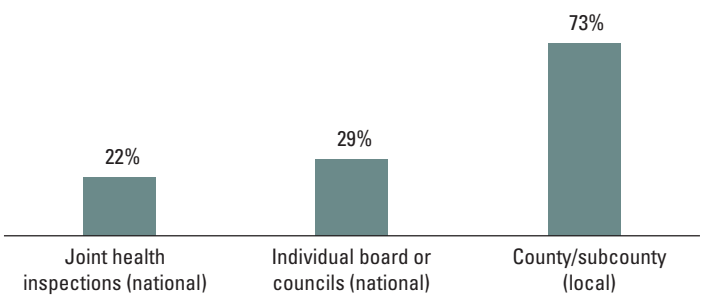
Context: How does context affect implementation and outcomes?

The regulation had a significant impact on patient safety in spite of multiple unfavorable contextual factors, including low level awareness of the regulation, multiple actors visiting the facilities, and other negative external shocks.

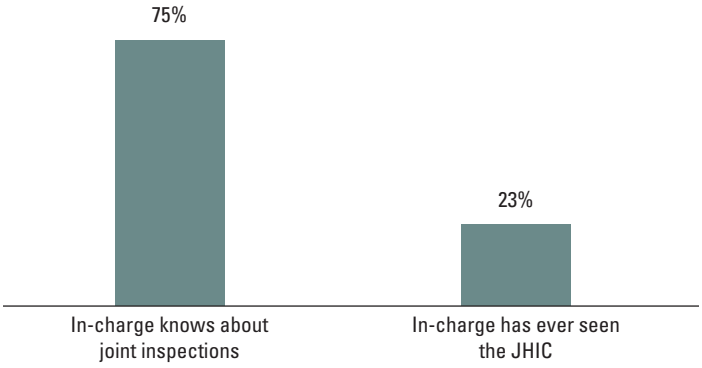
At baseline, facilities reported low awareness of the regulation. 75% of the facility in-charges reported knowing about the previous joint inspections that had been operating for 2 years by the time of the survey. Only 23% reported having seen the Joint Health Inspection Checklist.

Facilities also reported multiple groups visiting them for diverse types of supervision. Facilities reported a high number of actors visiting them in the previous year, including the national and local governments and private organizations. The county and subcounty officials were the most present (73% of facilities reported visits), followed by individual boards and councils (29%), and the joint

Government supervision visits in last 12 months
% of facilities at baseline



In-charge HF Awareness of regulation
% of facilities at baseline



health inspection teams (22%). Some private facilities reported belonging to franchises (17%) or undergoing some accreditation process (9%). Visits varied in frequency, duration and enquiries. There is some suggestive evidence that these multiple actors and visits created confusion. For instance, the JHIC teams at that moment had not conducted 22% of inspections in these 3 counties. Therefore, these visits may include other government officials different from the joint inspections team, which indicates confusion about the teams that are visiting the facility.

In addition, the implementation of the inspection pilots interacted with three important external factors: (i) turnover of high-level government officials at the national and local level; (ii) two presidential election rounds; and (iii) nurses' and doctors' strikes.

The nurses' strike lasted for 5 months and created some delays in inspections in public facilities. 13% of public facilities could only be inspected for the first time in the last quarter of the year of implementation. No major delays occurred in the private sector where the implementation was focused. Overall, private and public facilities received on average the same number of inspections. Against predictions from all stakeholders, minimal problems were reported during physical closures even in the middle of two presidential elections and with government turnover

at the national and county levels. The resilience of the pilots to these factors seems to be in part explained by the high-level commitment to the project, the institutional arrangements, and the fact that most closures happened in highly dense markets, so patient choice was not affected (see mechanisms section).

Governance and Institutional Arrangements: What is the basis of the authorizing environment for the inspection pilots? To what extent are the institutional and governance arrangements designed for the intervention effectively used and how may they affect the implementation and results?

The nature of the intervention required participation of multiple institutions and layers of government, and new arrangements and procedures.

The high-level commitment and decisions taken by the MOH and the county health offices created the authorizing environment for public and private actors alike. The government facilitated a series of agreements and appointments that became the institutional framework for the different components of the intervention. The outputs of these groups were then enacted as regulation (including the gazettement of new regulation and the first gazettement of authorized sole joint inspectors under the Public Health Act), as well as process documents that defined how the interventions would be implemented (protocols for how to apply the new regulation). This is a critical factor to consider when developing similar initiatives in comparable contexts.

Multiple organizations committed their staff and expertise, with strong leadership from the MOH to make the operations work under government conditions, while building their capacity.

The teams and organization operated under structures that were designed for the pilot and required substantial support from the MIS developed by the research team to manage and monitor the inspections, an area in which government capacity was low. The facilitation of a multidisciplinary team from the World Bank Group supported the implementation and monitoring of intervention fidelity.

Elements that worked well include the partnership and responsibility from each stakeholder, especially at the high level. There was a foundational commitment of stakeholders and general guidelines defined at the Windsor Agreement in October 2013. In

Examples of government actions: high level

- ✓ Agreement and commitment of stakeholders (Windsor Agreement)
- ✓ Appointment of KePSIE Task Force (KTF) bringing together national and county levels, and public and private sectors
- ✓ Appointment of technical working group to draft new regulatory framework
- ✓ Nomination of Inspector Expert Training Group (ITEG) to train inspectors and provide technical oversight of implementation

Examples of government actions: operational level

- ✓ Appointment of MOH Coordinator to manage inspectors and oversee implementation
- ✓ Secondment and gazettement of first cadre of full-time inspectors from regulatory boards and councils
- ✓ Nomination of county-level focal points to facilitate implementation with health facilities
- ✓ Nomination of Kenya Medical Practitioners and Dentists Board to oversee logistics of implementation

the development of the institutional framework, the mandates and responsibilities of each stakeholder were clearly defined in detail at the oversight and technical levels.

Government capacity building, planning, and communications have room for improvement. Due to the large scale of inspections and follow-up actions and, in particular, the high proportion of licensing issues, the government lagged behind in capacity to deal with the high level of requests. Issues in logistics and communications were reported most by inspectors in surveys conducted during the year of the implementation, in spite of the additional support from the World Bank.

> *"There are substantial delays in B&Cs issuing licenses. There should be regular updates of the staff list from various boards and councils to minimize calls during inspections."*
>
> **— Feedback survey of Inspectors at Feb 2018**

Some select responsibilities and roles of key institutional groups, such as the county governments, were not performed as planned. This is an area requiring better assessment to address the risks of participation and feasibility when multiple actors and potential conflicts of interest are involved. In particular, the main responsibility of the county government for enforcement of closures was not conducted as originally planned, but was led by the national MOH team.

> *"The counties should have a clearer role both at high level and technical level (e.g. logistics, closures)."*
>
> **— Interview of County Director of Health**

> *"On closures, the County Public Officers might have a conflict of interest and/or it was not clearly understood their role in closures."*
>
> **— FGD of Inspectors**

In summary, the institutional and governance arrangements designed for the inspection pilots at the national and local level were, overall, conducted as planned. However, the government had limited capacity to address the scale of issues reported, the number and wide range of actions required by the regulation schedule, and the level of informality of the private sector. These areas require special attention when developing similar systems as they affected the implementation and are likely to have affected the results (e.g., decreasing the potential impact of the intervention).

Resources and efficiency: What are the resources allocated by the different stakeholders? What are the fundamental factors affecting implementation efficiency?

KePSIE inspections were possible due to the effort and resources from multiple stakeholders. The Ministry of Health, the county governments, and the World Bank Group joined efforts to fund this intervention in a unique partnership. There are two important components of the cost of the intervention. First, the investment to set up the system. Second, once the system is in place, the cost of conducting routine operations. We focus on the cost of routine operation activities in this section, which helps us assess the average cost per visit to make the system work as intended by the regulation.

The pilot followed a particular model of inspections where all inspectors were located in the county headquarters and used vehicles provided by central and regional governments to visit health facilities. Inspectors were seconded by different government institutions, and most transferred from other regions. Facility closure visits required staff from the central government to travel to the regions. Additional external support was required for implementation and monitoring of the operation. This is a poor model for costs in a fully scaled-up version, where the number and location of inspectors can be flexibly determined and external support is minimized. Nevertheless, the routine pilot costs help provide a benchmark that can be improved upon using standard tools from operational research. On average, a visit to a health facility during the pilot cost around $165 in operational costs. Of this, $54 (33%) were inspector costs, including salaries, allowances and compensations for being outside of their duty station; $17 (10%) were transportation costs to visit each facility; and $13 (8%) included other costs related to office, supplies and technology. The remaining $81 (49%) of the total, included government management ($22 per visit) and external World Bank support for implementation, MIS management and inspection quality assurance ($59 per visit). However, several factors complicate the interpretation of this cost. First, for 28% of visits the inspector could not start the inspection and the facility required multiple visits.[6] Second, there were days when vehicles were used for other government activities or were not functioning. Third, there were days when vehicles were available, but inspectors were

[6] Visits did not result in an inspection because the in-charges were absent or had left when the inspector arrived (likely due to lack of a license). Due to vehicle constraints, inspectors in these cases were required to wait for a shared vehicle to come back after taking other inspectors to separate (sometimes distant) facilities, before proceeding to the next facility. Waiting times could be up to several hours.

Implementation Resources

Resources contributed by stakeholders for the implementation of the pilots

Ministry of Health		County Governments	World Bank Group
Department of Health Standards, Quality Assurance, and Regulation (DHSQAR)	Regulatory Boards and Councils (B&Cs)		
■ MOH coordinator of inspections ■ MOH high-level staff to lead and support the process ■ Staff to support development of regulation	■ Secondment of inspectors ■ ITEG member time in training and technical support ■ In-kind resources to support workshops and training ■ Staff to support development of regulation	■ Secondment of inspectors ■ Inspection offices ■ Inspection vehicles ■ County focal points ■ Public health officers to support closures	■ Stipends, top-ups, and per diems for inspectors ■ Transportation (fuel, drivers) ■ Inspection materials and equipment ■ Implementation and management support ■ Staff to support development of regulation, tools, protocols, MIS, and quality monitoring

absent. Therefore, we view this cost per visit as an upper-bound, since at least three of these problems–unsuccessful visits, non-functioning vehicles and inspector absence (during which we paid for the vehicles)–can be sharply reduced in subsequent years with more experience.[7] For instance, at best, a team of two inspectors could complete 6 inspection visits in a day (versus 3.5 during the pilot) with variation across regions based on market structures. Additionally, the World Bank support management valued at local government costs would be reduced considerably. These two actions would imply a per-facility cost of $95 per visit. Further, alternate models where (for instance) inspectors are either located in multiple cities in the county or have multiple bases within which they travel will further decrease transport costs, and a larger scale of inspections will also decrease costs per visit related to office, supplies, technology and management.[8] Next we discuss details on select items where efficiency gains can be produced and costs could be reduced.

There are opportunities identified for efficiency improvements. As we expect when building a complex system at scale, there was a diverse set of challenges. A first type of constraint was the efficient use of inspectors. Due to the dynamic nature of the intervention, the requirements for follow-up actions and visits depended on the performance of facilities according to the inspection cycle. In combination with a lower number of inspectors seconded (with respect to what was planned), this limited the completion of the cycle in the year of inspections. Inspectors were also not available 100% of their time (22% of the time they were out of duty or in other activities, not including standard leave and an 18-day election period), which also affected the flow of inspections. Therefore, how the inspections are planned and the time availability of inspectors are flagged as risk elements for the efficiency and sustainability of the system.

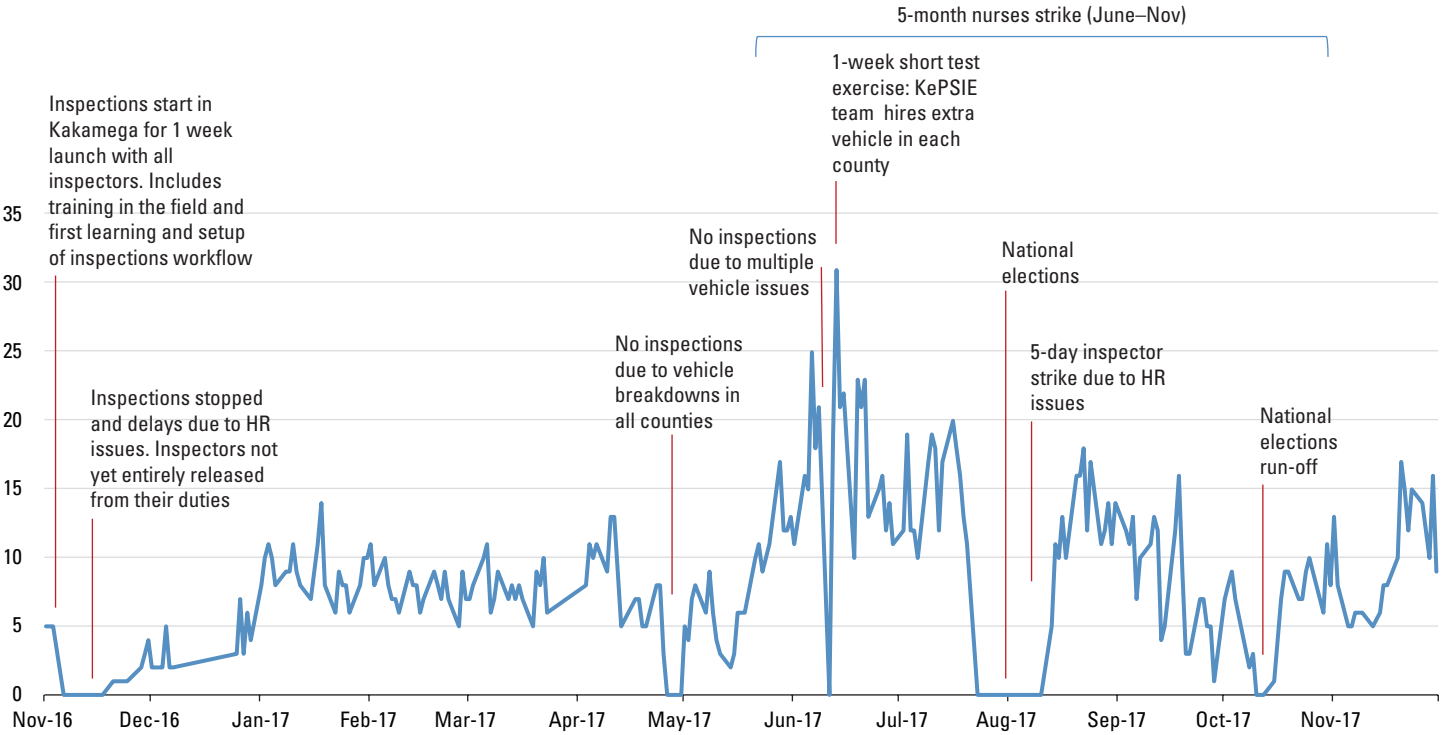
A second type of constraint includes transportation and logistics-related issues that were identified as important factors for determining efficiency. Given the number of vehicles, inspectors reported spending 50% or more of their time either waiting for a car to pick them up or in transit. In addition, 11% of the time on average (and around 35% in some months) vehicles had problems causing delays, including breakdowns, maintenance, fuel not being available due to payment delays, and, in some cases, because the vehicles were being used for other duties. In a short 1-week exercise, the research team found that an additional vehicle and improvements in the logistics planning could double the number of visits and completed inspections. This suggests that greater efficiency could result from different combinations of resources. However, this depends on the inspection load, number of unlicensed providers, vehicle costs, and inspector salaries. Therefore, this was identified as a constraint that needs to be analyzed according to the local conditions and inspection cycle.

Building a system with inspectors based in the region and strategic areas within the counties (versus inspectors transferred from other regions) will improve the cost-efficiency of the operation, by reducing extra stipends and allowances due to working outside of the duty station, and minimizing commuting time and transportation costs, helping address the two constraints described above.

[7] For example, the government established a new protocol that would lead to closure reports for multiple unsuccessful visits. These visits are expected to decrease further as the system matures.

[8] We exclude from these costs the fixed costs of building the inspection system, which included the development of the enhanced regulatory framework, implementation protocols, training materials, and the electronic inspection system. These costs are detailed in a forthcoming study by Chege et al. (2020) and may be useful for setting up similar systems in other countries.

Inspection visits by day and select events



Notes. Vehicle issues include breakdowns/maintenance, no fuel due to payment delays, and vehicles being used by county government.

"Inspectors in Meru spent half of the time in a given day, waiting for a vehicle to pick them up, when they only have one vehicle at their disposal."

— Bi-weekly Monitoring Report

In general, rolling out such a large and complex operation implied limited capacity. Inspectors rated logistics and communication the lowest in surveys on the implementation.

"There were delays on responses from [MOH and logistics coordinators] due to their excessive work."

— Interview with Inspectors in March 2018

Sustainability and risks: What are the critical elements for the sustainability of the inspection system and threats to implementation fidelity?

A critical element for the sustainability of the implementation of such an inspection system at scale is the necessary infrastructure and institutions to support the components of the intervention consistently and reliably in the long term. Planning would benefit from data systems and continuous analyses of the data that take into consideration the health market conditions in each county. Inadequate capacity remains a risk for the system to work or to work at the lowest cost possible. In Kenya, the scale-up of this model is being implemented through the county governments and a new institution at the national level is taking leadership in inspections, the Kenya Health Professions Oversight Authority. Given the high-level government commitment and county government teams that are established and experienced with inspections, the country has great leverage for the organizational structure necessary for the scale-up. However, the decentralization also imposes some risks. Inadequate governance and communication systems across the multiple agencies and levels of institutions required for making the inspection system work is a high risk. The World Bank Group facilitated the governance and coordination of these elements in the pilot, and considerably supported the communication across different actors and the implementation of the pilot interventions. Appropriate support and capacity-building to meet the adequate levels of institutional coordination, governance, and communication is critical.

There are a few additional areas where risks are identified based on the lessons from the pilot. These risks stem from threats to implementation fidelity, that is, that the intervention is implemented in the way that is intended by the regulation. A few areas are flagged including threats to sufficient tracking or monitoring due to the complexity of the intervention and its dynamic nature

(multiple potential outcomes of the inspections and follow-up visits). Multiple threats to service delivery are flagged including the risk of failure to comply with warnings and sanctions on time, and to include remote, distant facilities or an important number of facilities that are not in the government records, which have on average the lowest patient safety in the system. Failure to monitor enforcement with closures, and limited capacity of the boards and councils to provide required licenses are also identified as key areas to consider as risks.

Finally, due to the role of the MIS, the complexity of the intervention, and the reliance on an external team for this function, the risks related to quality should be assessed and addressed when implementing the intervention at large scales. Building the pilot MIS took a multi-disciplinary team beyond ICT to leverage technology while making sure the system responded to the needs of the different actors and activities. Substantial efforts were dedicated to verifying and improving the adherence to inspection protocols and quality of implementation. Quality officers conducted back-check visits in which they administered a subset of the JHIC to check the quality of the inspections data. All inspection reports were monitored with automated data flags, and some were also manually checked either visually or through double entry to ensure that they reflected the correct results of the inspections. Quality officers also conducted return visits to more than half of the facilities reported for closure to verify whether they complied with the closure report. What conditions and capacity building is required to take advantage of the returns to digital development, is an important question for scale-up and replication.

Despite the expected challenges when developing a new system at scale, the inspections were successful and the lessons from this

Threats to implementation fidelity

Threats to intervention design

- ☐ Complexity of the intervention
- ☐ Lack of standardization of implementation guidelines for inspectors
- ☐ Inadequate governance, institutional coordination, and communication strategies

Threats to intervention training, supervision and support

- ☐ Insufficient tracking or monitoring of service delivery/dosage
- ☐ Inconsistent supervision and/or inadequate communication

Threats to the service delivery

- ☐ Inspector motivation, competing activities
- ☐ Failure to comply with the warnings and sanctions on time
- ☐ Failure to respond to facilities' requests
- ☐ Failure to plan logistics adequately
- ☐ Inspector caseload too low (or too high)
- ☐ Failure to visit faraway facilities
- ☐ Failure to include facilities that are not in the government records

Threats to service take-up or compliance

- ☐ Failure to monitor and enforce compliance with sanctions
- ☐ Failure of boards and councils to provide necessary licenses
- ☐ Failure to provide support for compliance (e.g., counties to public facilities)

endeavor are expected to shed light on critical elements to build inspections systems at scale. KePSIE's inspections proved that building and successfully operating strong accountability systems is possible in Kenya and similar contexts.

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