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)[1]

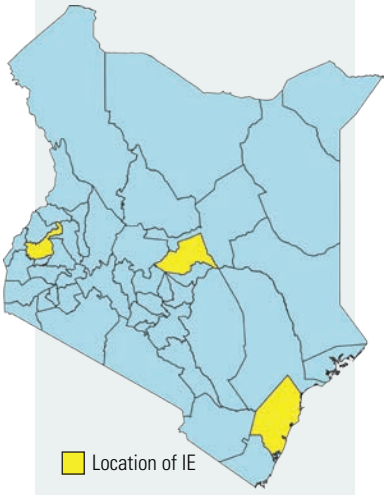
WBG Project Details

LOCATION:
National

WORLD BANK GROUP PROJECT:
Health in Africa (HiA) Initiative

PROJECT TYPE:
Advisory Services

IMPLEMENTING AGENCY:
Ministry of Health



Key Findings

- KePSIE is the largest randomized control trial on patient safety in any low- and middle-income setting, covering the census of 1,258 health facilities (private and public), serving 4.5 million individuals in three counties in Kenya.
- The trial demonstrates that a new inspection regime that includes clear rules for compliance, monitoring, and enforcement is feasible in this resource-constrained, low-compliance context, where only 3% of facilities complied with the government threshold for minimum safety at baseline.
- The intervention was effective at improving patient safety in all types of facilities. In the year after the intervention started, patient safety scores, as measured by the regulatory Joint Health Inspection Checklist, were 15% (0.49 standard deviations) higher in treatment facilities than control facilities. Private facilities recorded larger gains (19%) than public facilities (7%), and within private facilities, private "licensed" facilities recorded the largest gains (24%).
- These improvements moved 19% of treated facilities up from the lowest score category to higher categories of safety, and 4% above the government threshold for full compliance (>60% of maximum score). Based on these results, more than a year of sustained inspections would be required to move the system above the government threshold.
- The trial shows that unlicensed private facilities remain a source of concern. A large number of these poor-performing facilities continued operating after the enforcement of closures by the government, lowering the floor of patient safety in the system.

[1] This technical note is based on the forthcoming working paper "Randomized Regulation: The Impact of Inspections and Quality Standards on Health Markets" by Guadalupe Bedoya, Jishnu Das, and Amy Dolinger.

i2i DIME TRANSFORM DEVELOPMENT
WORLD BANK GROUP Health, Nutrition & Population
UKaid from the British people
KWPF KOREA-WORLD BANK PARTNERSHIP FACILITY

- Out-of-pocket payments did not increase for patients. Access to health care, both among richer and poorer patients, was not affected by government closures of unlicensed facilities as measured by outpatient visits. Most facility closures were in highly dense markets where patients had other alternatives. Overall, there was a reallocation of patients from the private to the public sector.
- The study demonstrates that improving regulatory-based accountability in health care can increase safety scores without any ancillary support such as private supervision services. The operational cost of the pilot is between US$95–US$165 per visit and was purposely designed to be viable at scale.
- The government is scaling up the intervention in all 47 counties in Kenya with the support of the World Bank.

> "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) —

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. The National Academy of Sciences estimates that 134 million adverse events and 2.6 million deaths occur annually as a result of unsafe medical care in inpatient services alone in low- and middle-income countries (LMICs) (National Academy of Sciences, 2018). Universal health coverage (UHC) defined solely in terms of increased access to care is insufficient—increased access to quality health care, and at the minimum, guaranteeing a high degree of patient safety, is key to improving outcomes, and it becomes indispensable during a pandemic of a highly-infectious disease such as COVID-19. Strengthening patient safety systems—including Infection Prevention and Control—is essential for containment measures as health facilities can drastically speed up the spread of the virus as was the case in the Ebola epidemic.[2] The most affected countries in West Africa, largely unprepared for such an outbreak, reported rates of infection among health care workers between 21 and 32 times that of the general population (WHO, 2015).[3] These types of vulnerabilities could further overwhelm health care systems in the Africa region and similar contexts.

But how to improve patient safety in a cost-conscious and sustainable fashion remains unclear. Systems to report and diagnose the barriers to improved patient safety are underdeveloped, even in high-income countries. In Africa, only a handful of countries report national policies on safe health care practices and corresponding monitoring systems (WHO, 2014; Wachter et al., 2010; Longo et al., 2005). There are few trials that can guide policymaker efforts: the common recourse of calling for better government stewardship and greater regulation, for instance, is not backed by evidence (Flodgren et al., 2016; Flodgren et al., 2011; Campbell et al., 1998). Finally, many health systems in LMICs are mixed systems with patients seeking care from a diverse set of public and private providers. Researchers and policymakers have only just started thinking about the policies that can improve quality of care in such mixed health systems; in most countries, even the data on the number and types of providers in a geographical area are unavailable. The lack of available data and evidence, and the complexity of health delivery on the ground, makes improving patient safety one of the most challenging—and pressing—concerns that we face today as a global health community.

The Kenya Patient Safety Impact Evaluation or KePSIE study, carried out between 2013 and 2020, is the largest trial around patient safety in LMICs and the first randomized controlled study to look at the impact of regulations and inspections in health facilities.

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

[2] As Peter Piot, the co-discoverer of Ebola points out, it is almost certain that a lack of patient safety and infection prevention and control practices in hospitals contributed to the spread of the epidemic in Sub-Saharan countries.

[3] In the current pandemic, this could further overwhelm the health care systems in regions such as Africa, reporting the lowest health care worker density worldwide at 2.3 per 1000 people, or one-ninth of those available in Europe, as per WHO estimates.

The design of the study, which we detail below, responds to three major questions in global health today.

- Can increased government regulation and inspections lead to improvements in patient safety in a fiscally sustainable manner, even without any ancillary support such as private supervision services?
- Does increased regulation—which may lead to closing down facilities that do not meet minimum regulatory standards—disproportionately hurt the poor?
- Can regulation and inspections improve care when *all* facilities—public and private—are held to the same regulatory standard, thus providing a much-needed policy for mixed health systems around the world?

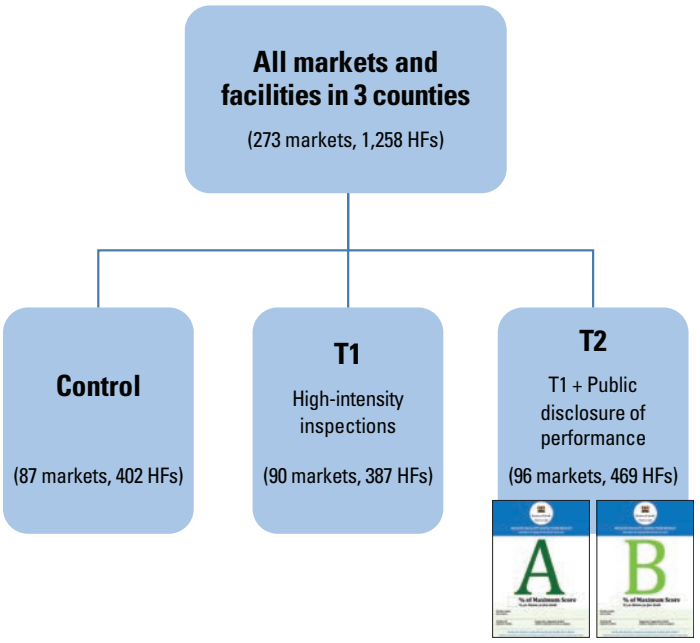
KePSIE: Randomized Regulation

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 Kenya's Health in Africa program. It seeks to evaluate the impact of government regulation and inspections on patient safety in public and private facilities using the gold-standard method of a randomized controlled trial. As ancillary inputs into the trial, it also provides support for the reform of the regulatory framework of inspections to improve patient safety in Kenya and develops a set of tools and instruments to measure and monitor patient safety that can be deployed across diverse settings.

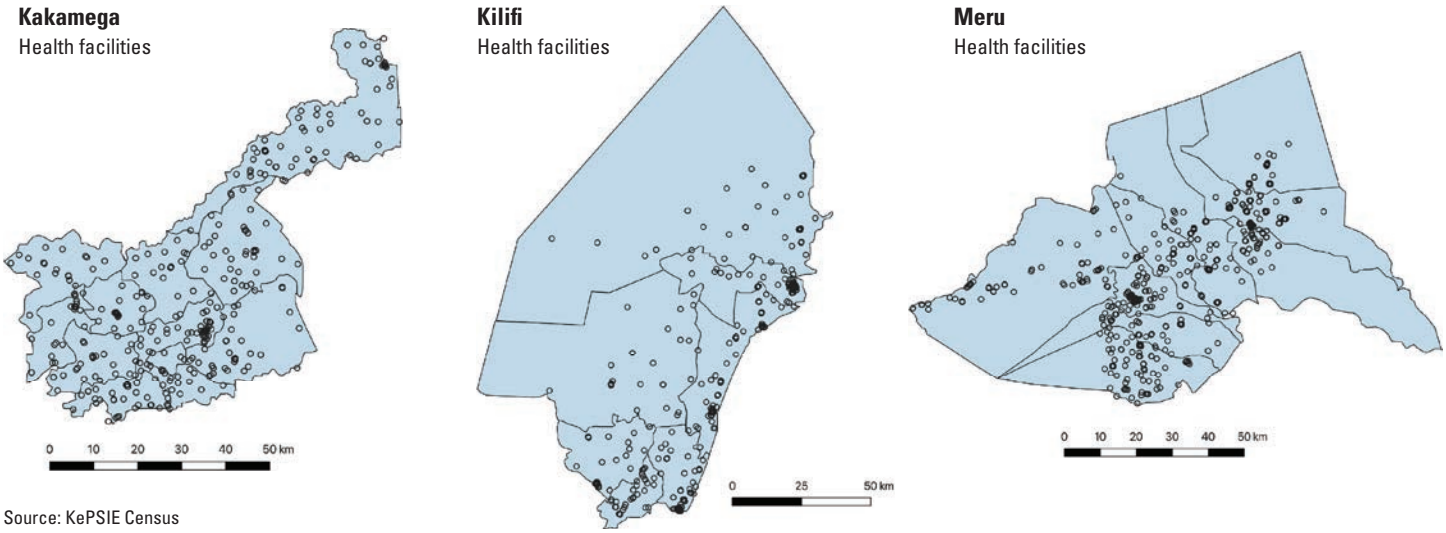
The KePSIE trial's unique design followed from the particular features of mixed health systems. Specifically, the trial followed all 1,258 private and public health facilities in three diverse Kenyan counties—Kakamega, Kilifi, and Meru—over 4 years. Every facility was allocated to a cluster of co-located health facilities, which we call a "health market."[4] The 1,258 health facilities span 273 health markets; the smallest health markets have only 1 health facility while the largest have 30-47 facilities.[5] The health facilities included in KePSIE serve more than 4.5 million people and provide 7 million health visits in a year.

[4] A health market is defined as a cluster of health facilities where no facility is more than four kilometers from the geometric center of the cluster.
[5] The number of health facilities varies throughout the study due to high turnover of facilities; 1,258 health facilities were randomized but baseline and endline numbers vary due to high turnover rates.

KePSIE Markets and Health Facilities by Arm



Counties have diverse health markets



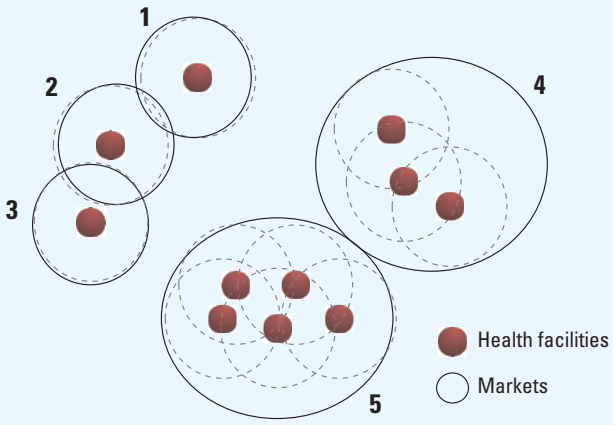
Source: KePSIE Census

BOX 1. How were clusters constructed and why are they necessary?

In the study areas, all facilities are grouped in health "markets", defined as geographical clusters where no facility is more than 4 kilometers from the center of the market. This market clustering allows us to conduct a market-level randomization, which is needed to understand how market conditions mediate the policy as well as patient reallocation across sectors and facilities.

The markets are defined by geographic delimitations. In the baseline, we found that around 70% of surveyed patients live within 4 kilometers of the health facility they visited. Using this distance, we apply a z-center clustering algorithm to the facilities. First, a randomly chosen facility is defined as a "cluster center." Next, every facility is matched to the market defined by the nearest cluster center. If any facility is more than 4 kilometers from its corresponding cluster center, the facility farthest from its cluster center becomes a new cluster center. Then the process is repeated. The algorithm therefore stops creating new clusters when all facilities are within the predefined distance (4 kilometers) from the cluster center that defines their market. The cluster size is the market size, or number of health facilities per cluster.

KePSIE Market Clustering Algorithm



The unit of treatment is always the health market. The design stems from the nature of the intervention and the relevance of capturing the effects at the market level. In particular, the treatment applied to one health facility may have spillovers on geographically proximate health facilities through consumer demand or other network effects. For instance, patients may choose to leave a less safe facility and visit a safer facility instead. The clustered design allows us to fully capture such spillovers at the market level and directly answers the question of how a scaled-up policy will affect patient safety—both through changes at the facilities, and changes in how patients choose facilities to visit.

The trial randomized all 273 markets to one of three groups: (1) high-intensity inspections with enforcement of warnings and sanctions for non-compliant facilities (T1); (2) high-intensity inspections with enforcement of warnings and sanctions for non-compliant facilities coupled with public disclosure of inspection results using scorecards (T2); and (3) "business-as-usual" low-probability inspections (the control group). At baseline we find no significant differences between treatment and control groups across the main outcomes of interest and other key variables, confirming the quality of the randomization. The impact of the interventions was assessed by comparing outcomes across the treatment and control groups at endline, after one year of intervention.

BOX 2. What is a randomized controlled trial, and why is it the "Gold Standard" for evaluating policy impact?

- A randomized controlled trial (RCT) is a method of impact evaluation in which all eligible units in a sample are randomly assigned to treatment and control groups. The treatment groups receive the intervention being tested, while the control group does not.
- RCTs are considered the gold standard in all clinical trials as randomization ensures that these two groups are statistically equivalent in the absence of a program. In ensuring statistical equivalence between groups, randomization rules out confounding variables that otherwise bias measurements. **That is why RCTs are considered the "Gold Standard" for impact evaluation.**
- In an RCT, because the control and treatment group are statistically identical in all aspects other than their participation in the program, any differences in outcomes must be attributed to the program itself.

Adjusted from Development Impact Evaluation (DIME) Wiki

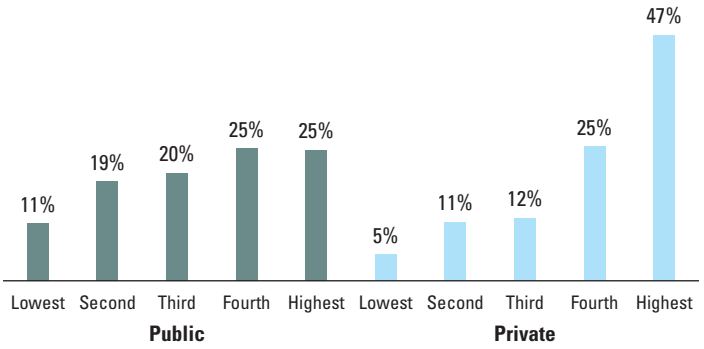
KePSIE: The situation prior to the trial

A national survey on patient safety showed that in 2012 in Kenya, only two percent of health facilities were compliant with minimum protocols and systems to assure patient safety (IFC and WHO, 2012). The KePSIE trial started with a large baseline survey of all facilities in the 3 study counties of Kilifi, Meru and Kakamega. In this section, we highlight select findings from the baseline survey to understand the context of the intervention.

> We highlight that Kenya is one of the few low- and middle-income countries to have a national survey on patient safety. The lack of data suggests that compliance with basic safety measures may also be poor in similar contexts.

FINDING 1: ***Patients seek care from both public and private facilities, although there are important differences across counties.*** KePSIE included all private and public facilities, or **the entire population** of health facilities in the 3 intervention counties. Across these counties, 64% of facilities were private, and the remaining 36% were public. Nevertheless, 71% of all patient visits were to public facilities, which saw an average of 1,159 patients per month. Private facilities saw an average of 260 patients per month, or less than 10 a day. As expected, private facilities overwhelmingly see patients from richer households, while public facilities cater to patients equally across the national wealth distribution.[6] There were some differences across counties, with Kakamega characterized by a larger proportion of more established public health facilities and Meru by the largest number of small, private facilities (73% of total). Consistent with greater private presence, 25% of patients in Meru reported not having paid for any of the services or medicines they received versus 75% in Kakamega.

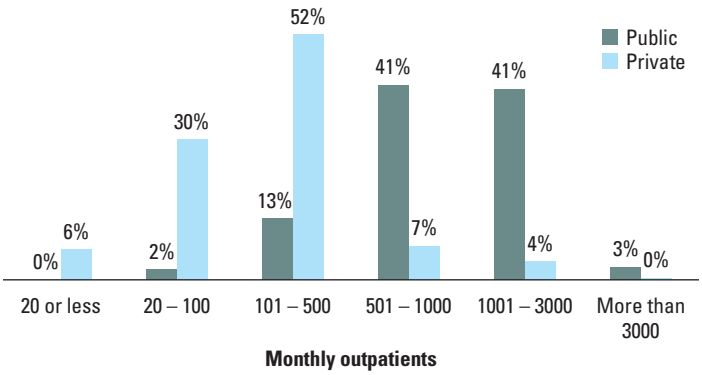
Private facilities see more patients from richer households, while public facilities cater to patients across the wealth distribution
% of patients in wealth quintile



FINDING 2: ***The fraction of private facilities misses a key fact, which is that most patients seek care in areas where there are multiple providers, public and private.*** Only 11% of patients in Kilifi, Meru and Kakamega seek care in an area where there is only 1 facility within a 4-kilometer radius. Again, there are some differences across the counties with larger market sizes in Meru, where 18% of markets have 11 or more facilities, compared to 4% in Kakamega and Kilifi. The fact that most patients seek care in areas where there is considerable choice underscores the importance of intervening at the level of the "market" rather than the facility.

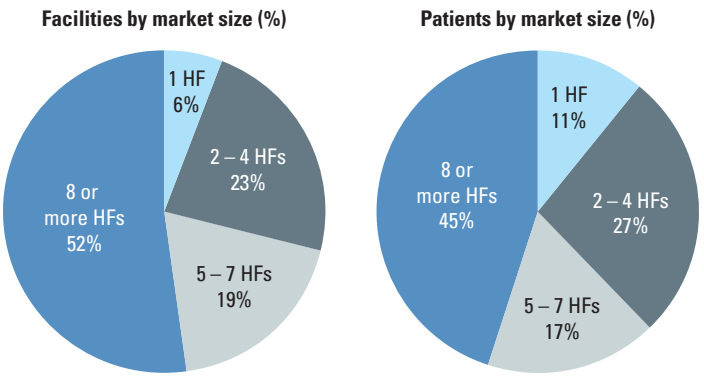
[6] Socioeconomic quintiles are constructed with a wealth index using exit surveys with patients and asset ownership in the same way as the Demographic and Health (DHS) Survey in Kenya. We mapped our sample to the national wealth quintiles, based on the 2014 DHS nationally representative survey.

Public facilities see many more outpatients than private facilities per month
% of facilities



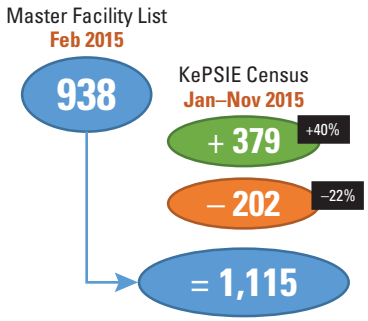
Only 6% of health facilities are singletons!

...and 11% of patients seek care in singleton markets



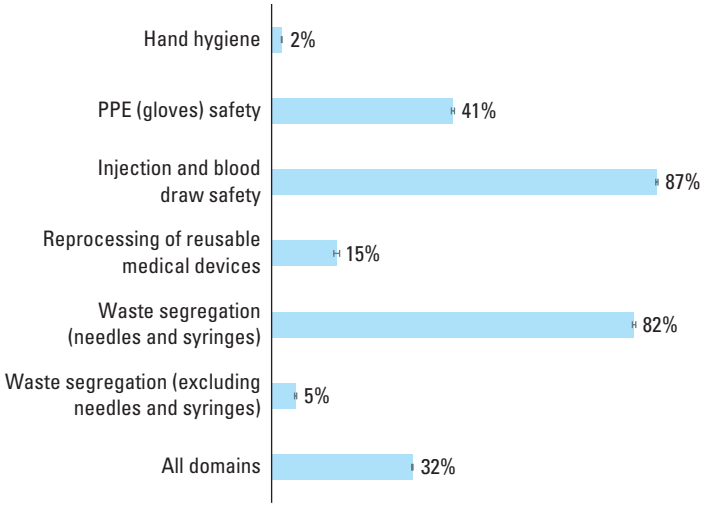
FINDING 3: ***Markets are not stable: Facilities close down and open frequently.*** The KePSIE census registered 379 new facilities (or 40%) that were not included in the government's Master Facility List (MFL), while 202 (or 22%) were no longer operating. Over the space of 4 years from the baseline to the endline, in the control areas where there were no inspections, 39 (or 11%) of all facilities closed down and 129 (or 37%) new facilities opened.

Facilities close down and open frequently



Compliance across Infection Prevention and Control Practices was low at 32%

Safety actions performed/Total indications triggering a safety action



Source: Bedoya et al. (2017)

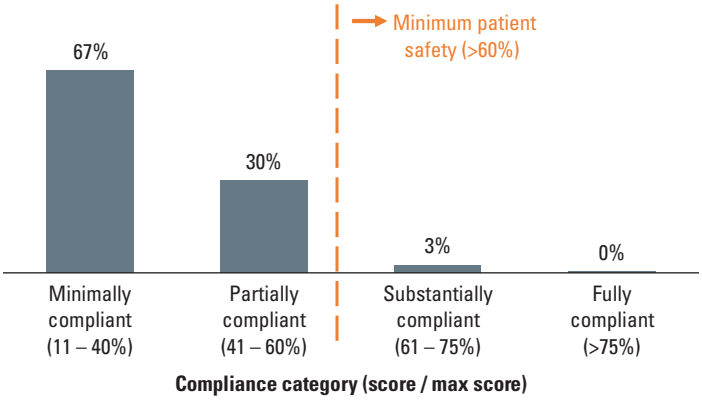
FINDING 4: ***Performance on patient safety measures was poor.*** **97%** of facilities did not comply with minimum standards, scoring below 60% of the Joint Health Inspection Checklist (JHIC) maximum score. This score measures the facility's compliance with the regulatory JHIC. The regulation assigns each item in the JHIC a score. The performance of each facility and the resulting compliance category is determined by the total points obtained over the maximum points possible, resulting in a percentage ranging between 0% and 100%. It is worth noting that facilities only comply with minimum standards if they fall into the two highest categories–substantially and fully compliant. Facilities are below the minimum standards and face warnings and sanctions if they are in the two lowest categories or if they do not have a valid license, in which case the inspection does not happen and a report for closure is issued.

Performance on patient safety measures not included in the JHIC was also poor. Average compliance across all domains of infection, prevention and control (IPC) practices in 19,000 observations of health care workers (HCWs) and patients was 32%. In an average visit, outpatients faced 3.7 violations of IPC safety practices, in great part due to poor hand hygiene. The best performing domains were all related to injections and blood draws, with 100% compliance with the use of new (rather than reused) needles and syringes! The worst performance was on hand hygiene, the cornerstone of IPC, and a critical practice for COVID-19 containment efforts.

FINDING 5: ***Public facilities perform better than private facilities.*** At baseline, public facilities scored 24% higher than private facilities in the JHIC.

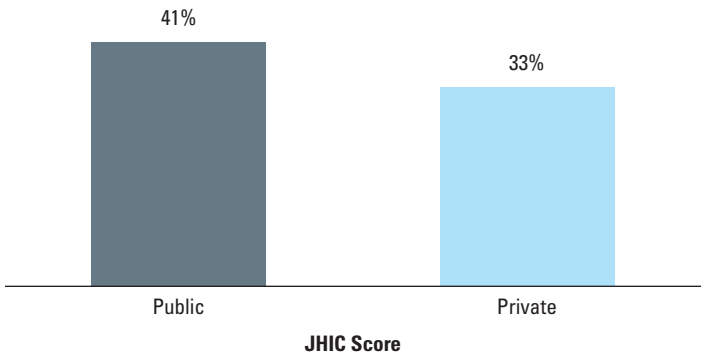
Performance was poor: Most facilities did not comply with minimum patient safety standards

% of facilities by category



Public facilities perform better than private facilities

% of JHIC max score



How can we think of the relationship between these patient safety measures and health outcomes?

The patient safety indicators as per the regulation are the minimum standards required for health care facilities as determined by Kenya's regulatory medical boards and councils. These items are **necessary (although not sufficient) inputs** to deliver quality care, and the fact that the majority of facilities (97%) did not comply with minimum standards to keep patients safe at baseline is a risky starting point. Take the example of infection prevention and control items, including availability of soap at hand-washing areas, availability of personal protective equipment (masks, gloves and gowns), and protocols for sterilization of equipment, or items in the medical consultation section including access to essential medicines such as glucose, adrenaline, sodium bicarbonate, diazepam, and phenobarbitone that should be available in the emergency tray in case of an emergency. Absence of these inputs at the designated areas puts patients and health care workers at risk, particularly during the COVID-19 pandemic. Currently, there is not enough evidence in the mapping of health interventions of this type to health outcomes. Recent evidence suggests that the relationship between practices and health outcomes may follow a threshold effect. Studies in Namibia and India find that high levels of compliance with a bundle of evidence-based practices rather than one or a few targeted practices in childbirth is associated to lower perinatal mortality (Semrau et al., 2020; Semrau et al., 2017; Kumar et al., 2016). More research is needed on the link of practices and bundle of practices to health outcomes, which is a critical area for future research and policy.

The KePSIE Intervention

The KePSIE intervention consists of three distinct phases.

Phase 1

Phase 1 (from 2013 to 2016) was the development of a new regulatory framework by Kenya's regulatory boards and councils under the Ministry of Health: the Medical Practitioners and Dentists Board, Clinical Officers Council, Nursing Council of Kenya, Radiation Protection Board, Pharmacy and Poisons Board, Kenya Nutritionists and Dieticians Institute, Kenya Medical Laboratory Technicians and Technologists Board, and the Public Health Officers and Technicians Council. The regulation was published in the Kenya Gazette 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. The enhanced regulatory framework includes: (A) the refined and easily deployable Joint Health Inspections Checklist (JHIC) 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. The regulation also includes inspections of all health facilities, both public and private (previously inspections were only conducted in private facilities). 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.[7] Immediate closure is indicated if the facility did not have a license or if the score is lower than 10% of the maximum score. According to the implementation guidelines for the regulation, these facilities are *"deemed to pose an immediate danger to the public. Facilities that fall in this category MUST not be allowed to continue operating, and MUST be closed immediately. Where requisite licenses are absent, prosecution should be recommended as outlined in the laws . . . [F]acilities in this category . . . have failed to show any meaningful effort towards compliance to minimum patient safety"* (MOH, 2015).

JHIC Scores, 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).

[7] This new regulatory framework builds on previous reform efforts that led to the first JHIC in 2012 (see Box 4). 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.

Phase 2

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, which can be broadly deployed in diverse settings. This set of instruments measures adherence to multiple dimensions of patient safety, including:

- Structural measures of patient safety developed by the regulators in the JHIC. This includes indicators related to protocols, infrastructure, equipment, and supplies with more than 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 health care worker knowledge, availability of supplies, and safety actions by health care workers for five IPC domains: (i) hand hygiene, (ii) protective gloves, (iii) injections and blood samples, (iv) disinfection of reusable devices, and (v) waste segregation. This is the first IPC tool combining multiple dimensions of patient safety in low- and middle-income countries (Bedoya et al., 2017).
- 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).[8] This allows multiple measures of patient safety and quality of care, including diagnostic accuracy, correct treatment, use of unnecessary or harmful medications, use of unnecessary antibiotics, and prevalence of substandard medicines. We used 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 (Daniels et al., 2017).

This phase also included the preparation for the implementation (2015–2016): 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.

Phase 3 (Implementation)

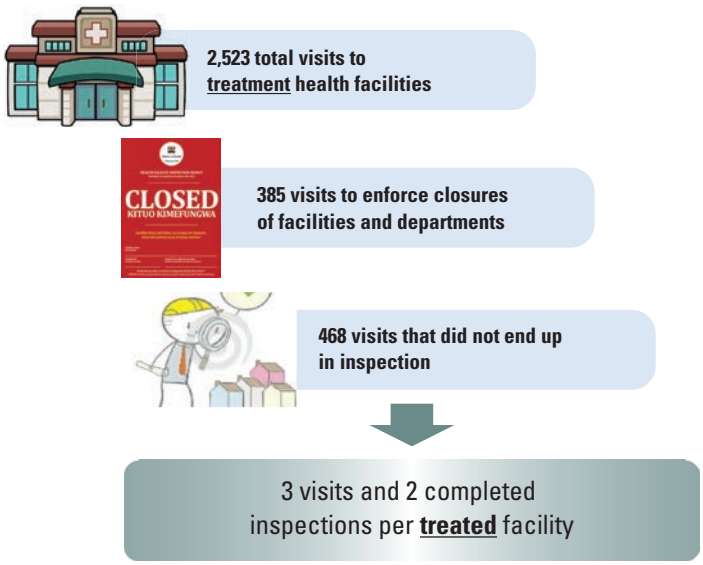
During the implementation, 2,523 visits to health facilities were delivered (November 2016 to December 2017). These visits included all the successful inspections, as well as some visits that did not lead to an inspection (for instance, if the facility was closed at the time of the first visit, triggering the need for additional visits) and visits by the MOH to enforce the closure of facilities and departments reported by inspectors, mostly due to lack of licenses. The operational costs for the implementation, once the system is set up, is between US$95–US$165 per visit.[9,10]

[8] 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.

[9] Estimates depend on elements particular to how the pilot was structured which highly affected the cost including the fact that inspectors were seconded from different government institutions, and most transferred from other regions; facility closure visits required staff from the central government to travel to the regions, and additional external support was required for implementation and monitoring of the operation. A forthcoming study by Bedoya et al. (2020) details key elements of the system that can be optimized using the learning from this pilot and its process evaluation.

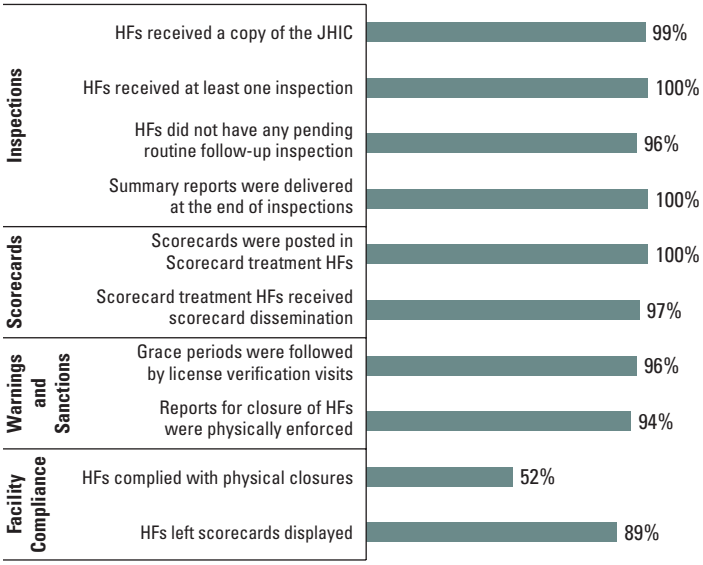
[10] Operation costs do not include the investment in setting up the system, for instance, the development of the regulatory framework, the implementation protocols, training materials, the electronic inspection tool, and the monitoring system. These costs are detailed in a forthcoming study by Chege et al. (2020) and may be useful for setting up similar systems in other countries.

Large operation to deliver the intervention



Overall, there was high adherence to the intervention across multiple components indicating that the implementation was a success in terms of delivering all its components: all or most treatment facilities received an inspection, received a copy of the JHIC, an inspection report, and a scorecard (if applicable). 94% of facilities and departments due for closure (nearly all unlicensed private facilities) were visited for enforcement of physical closure by the MOH and county teams. Minimal problems were reported during the physical closures even in the middle of two presidential elections and an extended nurses' strike. Based on quality checks, 89% of scorecards were found still displayed around 3 months after the inspection, and half of the facilities were found operational within weeks after the closure visit, when the quality teams were verifying compliance with implementation.

KePSIE had high fidelity to treatment components



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

Results

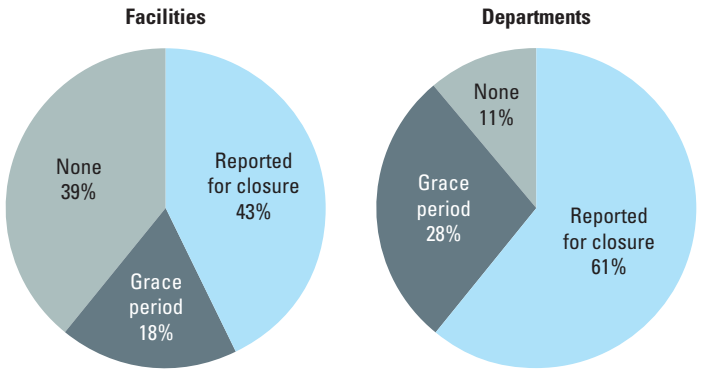
KePSIE impacts are estimated by comparing facilities in treatment and control markets using the endline data collected in 2018. With high facility participation—97% of the census of private and public facilities consented to the endline survey—and high compliance with treatment status—99% of randomized facilities received treatment[11]—the impact evaluation results are representative of the whole population in the study areas. We present high-level highlights of the impact evaluation results.

The regulation and inspections improved facility performance

1. Did the intervention lead to more closures of health facilities?

There were widespread licensing issues in the private sector: 61% of private facilities and 89% of departments within the facility (for instance, laboratories and pharmacies) were found with at least one licensing issue (lack of licenses or expired licenses) during the implementation. An important number of facilities solved the licensing issues during the implementation: 29% of facilities that did not have a license at the moment of the inspection visit obtained licenses after receiving a closure report and 61% of the facilities with an expired license—given a grace period—also solved their licensing issues. However, many facilities were closed down in spite of considerable time to solve these issues: facilities had on average 70 days to obtain licenses (or to demonstrate that the process was ongoing) because closures were not implemented immediately as planned.[12] Given the large number of facilities and departments reported for closure, a substantial operation was put in place to enforce the physical closures, which required 4 rounds of visits over the year, coordinated with multiple stakeholders and regulating groups.

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



Source: KePSIE MIS
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.

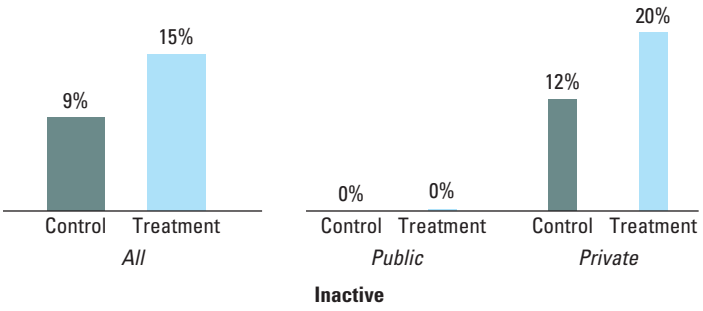
[11] This excludes facilities that went out of business during the implementation, or new facilities that were not in the randomization list. Only 3% in control facilities received treatment.
[12] Additional time was provided if the facility could provide paperwork or receipts as evidence of the application process. Guidance and information on requirements and processes for obtaining licenses were provided during the closure visits by the government team.

Constraints to Formalization

Due to the high level of informality in this setting and the considerable number of facilities that do not obtain licenses when they are provided with information and time, a question arises on the constraints to formalization that providers may face in this context. Constraints to formalization can include financial costs, transactional costs, and high regulatory burden and bureaucracy both at entry and in ongoing compliance (Bruhn and McKenzie, 2013). Although facility licensing has been streamlined with greater use of technology in recent years, qualitative evidence suggests some of these constraints may still be at play in the health sector in Kenya. Three boards and councils are responsible for the licensing of different types of facilities: the Medical Practitioners and Dentists Board, Clinical Officers Council, and Nursing Council of Kenya. Once a facility has all the requirements, the application for annual license renewal is immediate via online platforms. For the first-time license, or a one-time registration, application times can range between 1 and 4 weeks for the Medical Practitioners and Dentists Board and the Nursing Council of Kenya (representing 83% of facilities in the study sample), and up to 3 months for the Clinical Officers Council (17% of facilities in the study sample).[13] Overall, requirements to open a facility include business, building and health care professional certifications, an inspection by the county health team, and specific requirements depending on the level or services of the facility (e.g., inpatient facilities require a defined method of waste disposal). The annual licensing fees range between $50 and $250 for 95% of the facilities (levels 2-3) and up to $3,000 for larger facilities. The one-time registration required by some boards ranges between $50 and $400. Considering that the unlicensed facilities that did not obtain licenses are both smaller and have lower safety (40% fewer patients and 15% lower JHIC score) than unlicensed facilities that did obtain the license, constraints may include cost (versus revenues from patients) and having the minimum safety requirements to operate a health facility. More rigorous evidence is required on the binding constraints in this context.

Facilities in treatment markets were more likely to become inactive than in the control group

% of facilities



Despite the large number of licensing issues and associated closures, the number of inactive facilities one year later was not dramatically higher. Facilities in treatment markets were 6 percentage points more likely to become inactive (go out of business) compared to 9% in the control group, or a 68% increase by endline. The increase in inactivity was mostly concentrated in the (unlicensed) private sector. By the end of the intervention, 27% of private facilities had a closure enforced by the government due to licensing issues pending at the time of the closure visit. But half of these physically closed facilities were found active a few weeks after the closure visits based on independent implementation adherence checks conducted on average 2 months after the physical closure. By endline, 65% of facilities closed for licensing issues were found active (~7 months after the closure visit). This is important for quality because facilities effectively closed had a JHIC score at baseline 31% lower than those not reported for closure (27% versus 39%).[14]

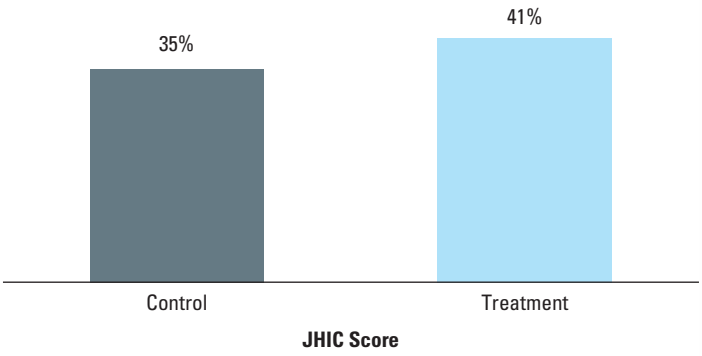
2. Did the intervention improve performance in patient safety scores?

The intervention improved patient safety as measured by the JHIC score, proving the role of inspections as a viable policy lever that can affect service provision. The JHIC score increased by 15% in treatment facilities compared to control facilities. Treatment facilities scored on average 41% of the maximum score compared to 35% in control facilities. This implies that the system as a whole moved from the lowest category of compliance (minimally compliant) to the next compliance category (partially compliant), still below the government threshold for full compliance (>60% score): 4% of facilities moved above this threshold for a total of 6% in treatment markets versus 2% in the control group. Around a year of sustained inspections were required to achieve these results.

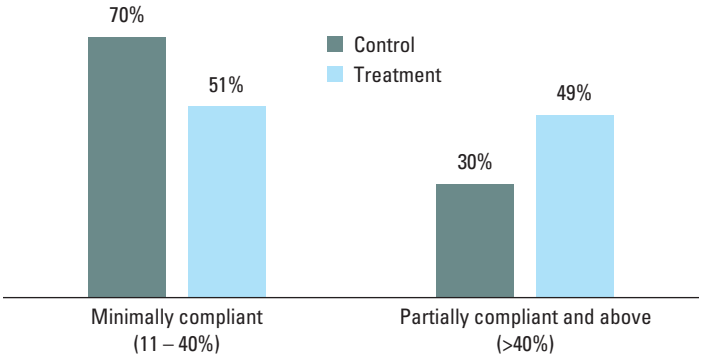
[13] Further details available on the websites of the regulatory boards and councils: Medical Practitioners and Dentists Board (https://kmpdc.go.ke), Clinical Officers Council (https://clinicalofficerscouncil.org), and Nursing Council of Kenya (https://nckenya.com).

[14] This figure is estimated over the treatment group for which we know the report for closure outcome.

The intervention improved the patient safety JHIC score
% of JHIC max score



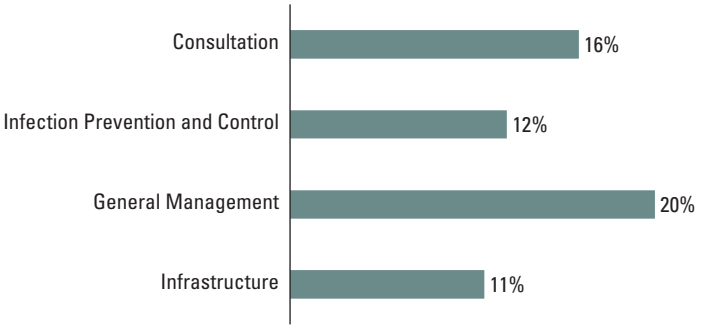
19% of all facilities moved from the minimally compliance category to higher compliance categories (compared to control)
% of facilities



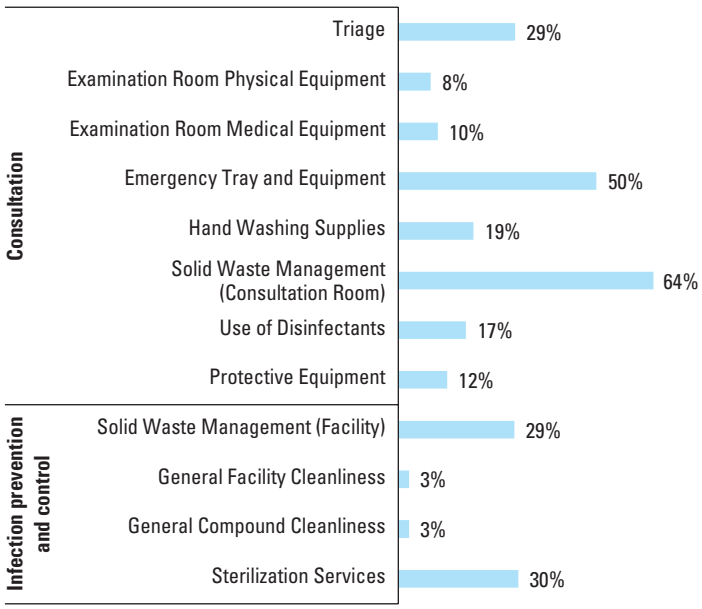
The impacts vary across different departments within facilities. Comparisons across departments—for the four departments that apply for all facilities regardless of their size—show, for instance, that the greatest improvements were in general management, and the lowest improvements were in infrastructure and infection prevention and control.

To illustrate further the type of items included in the JHIC and variation on impacts across different items, we present the results for two sections: consultation services and infection prevention and control. For instance, the impact on consultation services was 16% versus the control group, with solid waste management reporting the highest impact (64%) and with the physical and medical equipment impacts among the lowest at 8% and 10% respectively. In infection prevention and control, the highest impacts are in sterilization services and solid waste management at 30% and 29%, while the facility and compound cleanliness are lowest at 3%.

Impacts vary across departments in the health facilities
Score impacts as percent of control (%)



Impacts across subcategories in two sections of the JHIC
Score impacts as percent control (%)



Notes. The infection prevention and control (IPC) section of the JHIC includes general elements required at the facility level. Within each department section (e.g., pharmacy, laboratory, or consultation services), select IPC elements are included such as the availability of hand washing supplies and protective equipment and are required for each department.

3. Does the impact of inspections remain or fade out after 1 year?

Patient safety increased more in markets inspected in the first months and completing more of the full cycle: increases were much larger for markets where we started inspecting earlier. These were also the markets where more of the process could be implemented, highlighting the importance of continuous supervision and completing the regulatory schedule for continuous improvement.

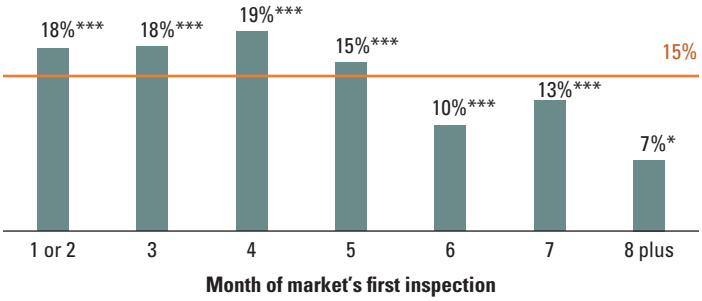
Markets inspected earlier (months 1 and 2) increased their JHIC score by 18% compared to control. This is nearly three times the impact on markets that received their first inspection in the latest months (8 plus), where JHIC score increased by 7% compared to control. This suggests little "fade-out" and potentially much larger effects as the model scales up.

4. Did unlicensed facilities operating in the market improve?

Unlicensed facilities–those with an expired license or no license at randomization–improved their patient safety but they lowered the floor of patient safety due to their lower performance. Unlicensed facilities still active at endline improved their JHIC score by 5.5 percentage points over 32% in the control

Patient safety increased more in markets completing more of the full inspection cycle

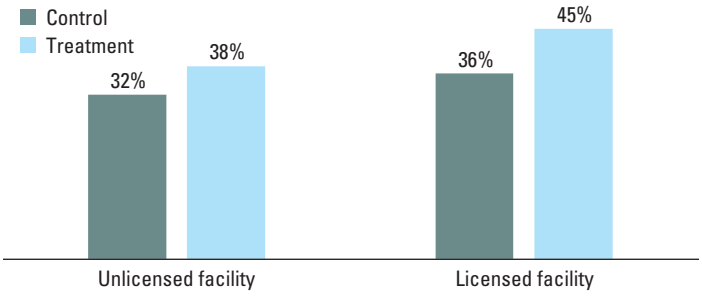
Impact (% of control)



Notes. Coefficients from regressions of JHIC Score on month of first market inspection using strata and health facility level controls. *** (**) (*) denotes significance at 1% (5%) (10%) level.

Unlicensed facilities improved their patient safety but they lowered the systems' overall patient safety

Randomized facilities active at baseline and endline (% of max score)



Notes. Unlicensed facilities are facilities with either no license or expired license, while licensed facilities are facilities with a valid license. License status in the control group was estimated using administrative data from the boards providing licenses in Kenya.

BOX 3. Improvements in Facilities versus Improvements for Patients

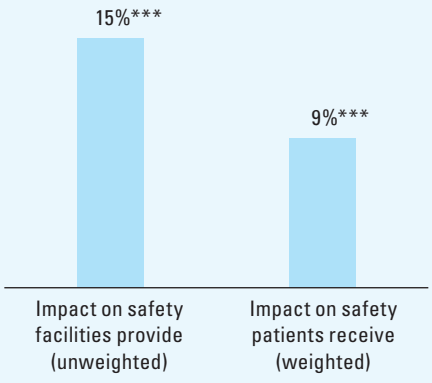
Small facilities improved much more than larger facilities. The average safety that facilities provide increased by 15%, compared to the control (as described before), while the average safety that patients receive increased by 9%.

Here, the average safety that facilities provide is measured as the unweighted impact on the JHIC score, while the average safety that patients receive is measured by the impact on the weighted JHIC score, where each facility is weighted by its outpatient caseload. An example of a market with two facilities can help illustrate the difference: One small facility attends 10% of the patients and improves its JHIC by 20%, while a large facility attends 90% of the market and improves its JHIC score only by 5%. The unweighted improvement across both facilities is 12.5% [=(20%+5%)/2]. This reflects the average quality that facilities offer. However, the large facility serves many more patients. We can estimate the average safety that patients receive by weighing each facility's improvement by the proportion of patients it attends. In this case, the safety that patients received improved by 6.5% [=(20%*10%) + (5%*90%)].

These differences highlight the importance of changing the behavior of decision-makers in larger facilities and their significance in health care delivery.

Impact on JHIC score: facility vs. patient

% of control



Notes. Weights are based on facility outpatients. *** (**) (*) denotes significance at 1% (5%) (10%) level.

group, **while licensed facilities improved by 8.7 percentage points over 36% in the control group, or 24%, which is the largest improvement across all types of facilities.**

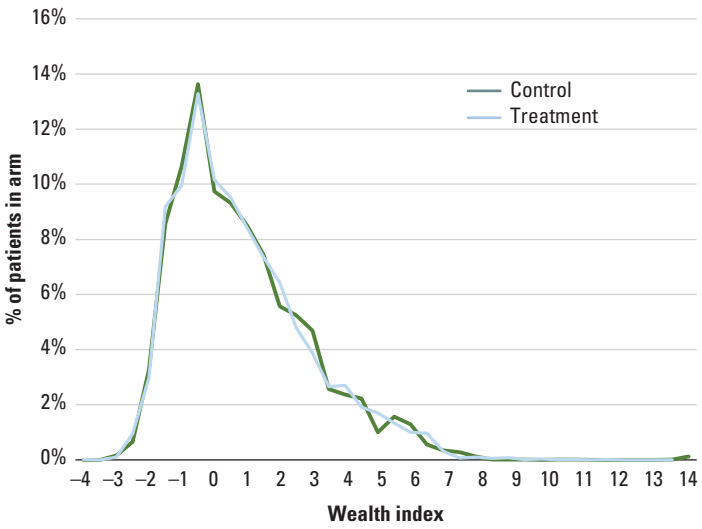
5. Did health facility closures affect the ability of patients—particularly the poor—to seek care?

Due to the market-level randomization and intervention, as well as the fact that most patients visit facilities within the radius of the market boundaries, we are able to assess whether patients were affected by closures through the impact on demand.

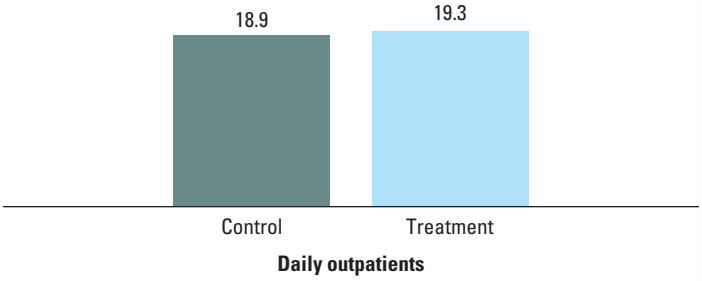
Facility inactivity did not affect facility use, or result in poorer patients being less likely to seek care. There was no significant impact on demand measured by outpatients, and the distribution of patients by socioeconomic status remained the same in treatment and control markets. Patients did not pay significantly more out-of-pocket expenses in treatment versus control markets.

Closures were mostly concentrated in highly dense markets where patients have other private and public alternatives. The government also established protocols so that public health concerns that may arise by closing a facility were addressed based on the estimated catchment area, the number of health facilities in the market, the level (size) of the health facilities in the market, and, if the closure is due to score (which accounts for <1% of closures), 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 (World Bank, 2016). These protocols were to ensure that no catchment areas would be without the provision of health care as a consequence of the intervention.

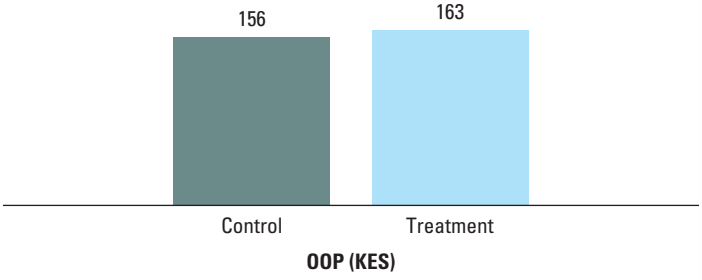
The distribution of patients by socioeconomic status remained the same in treatment and control



Facility use was not affected…



Patients did not end up paying significantly more out-of-pocket expenses (OOP)



Notes. Estimates are weighted using facility outpatients.

Potential Ethical Issues

The study was approved by the Ethics and Scientific Review Board at the African Medical and Research Foundation (Approval no. AMREF- ESRC P94/2013), the Kenyan Ministry of Health and authorities at participating facilities. We took care to ensure that our research satisfied the 3 basic principles advanced in the Belmont Declaration (1979) of Respect for Persons, Beneficence and Justice. We sought consent from every facility and patient who participated in the study and by working with every facility in the 3 counties (which were themselves chosen to represent the diversity of counties in the country) we ensured that the principle of justice was fulfilled. The question of whether facilities who do not have a license to practice and/or do not meet minimum patient safety requirements should be closed down, as required by the regulators, satisfied the principle of equipoise, with uncertain potential for harm or benefit. Although there is a strong belief in the global health community and among policymakers that unlicensed practitioners (who are therefore practicing illegally) should not be allowed to function, there is no prior evidence on the costs and benefits of actually doing so. If such clinics are the only option for local populations, shutting them down could decrease health care provision. Prior to the intervention, we used the full census data to plot each market and found that in Kenya, clinics that are stand-alone (that is, do not have any other clinics within 4Km) were predominantly public. This meant that were unlicensed clinics, which are all private, to be shutdown, it would still allow for multiple other options in the vicinity. In our data, 97% of unlicensed facilities have at least another facility in the market and 93% have 2 or more. In cases where clinics were closed by federal regulators, the closures were conducted with the full cooperation of the county authorities and the local community.

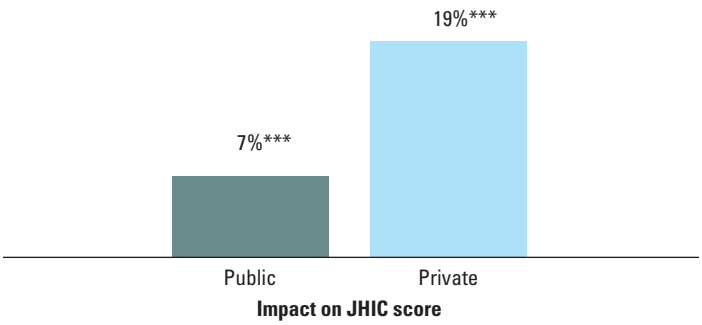
6. Were private and public facilities impacted differently?

What happens when public and private facilities are put on the same regulatory footing?

- Private facilities improved their safety twice as much as public facilities. This can be explained in part by the greater room for improvement in private facilities, which started with lower average scores. However, it may also be explained by higher autonomy of private facilities in comparison to the required processes, approvals, and budget allocations that may affect the ability to make changes in public facilities.
- Patients moved from the private sector to the public sector. Public facilities were performing *better* than private facilities. With the inspections leading to the closure of private facilities and the additional information provided in the markets, there was movement *away* from the private towards the public sector.

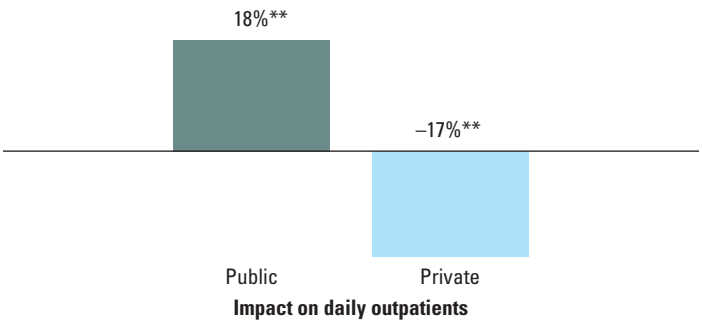
Inactivity was mostly concentrated in unlicensed facilities. For unlicensed facilities, the intervention increased inactivity by 12 percentage points in the treatment group (versus 21% in the control group), while inactivity decreased in the licensed group.

Private facilities improved more than public facilities
Impact (% of control)



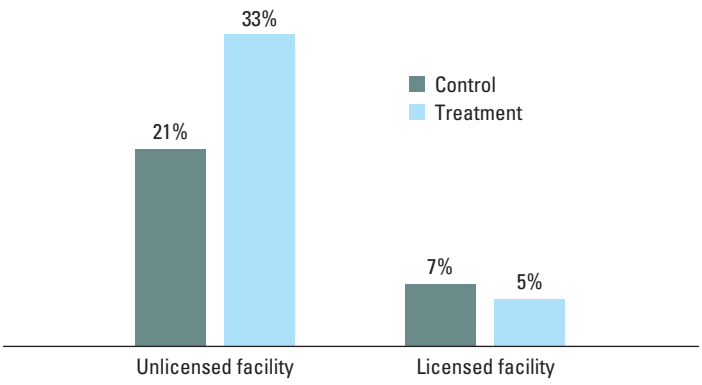
Notes. *** (**) (*) denotes significance at 1% (5%) (10%) level.

Patients moved *away* from the private towards the public sector
Impact (% of control)

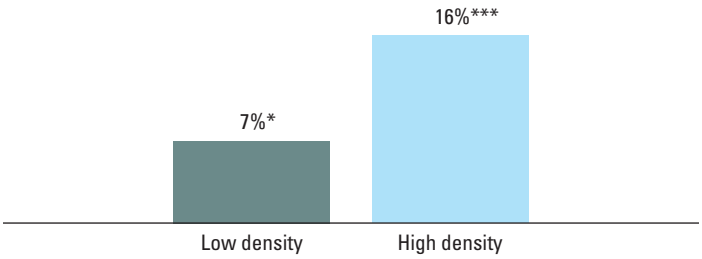


Notes. *** (**) (*) denotes significance at 1% (5%) (10%) level.

Inactivity was mostly concentrated on inlicensed facilities
Randomized private facilities (%)

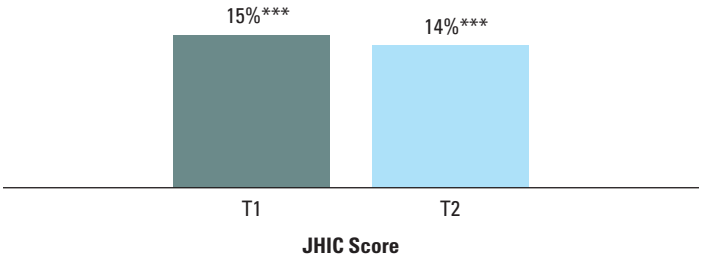


Safety improved more in markets with competition
Impact on JHIC score by market density (% of control)



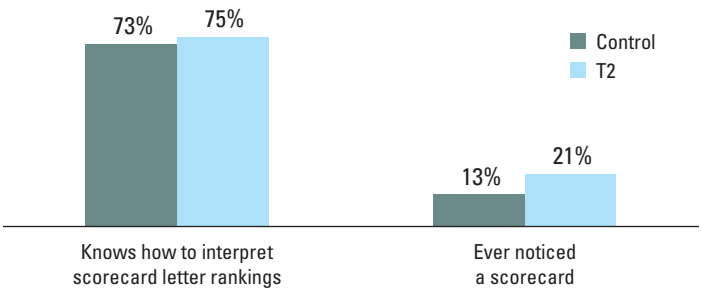
Notes. *** (**) (*) denotes significance at 1% (5%) (10%) level.

The scorecard information treatment had similar impacts to the inspection-only arm
Impact on JHIC score by arm (% of control)



Notes. *** (**) (*) denotes significance at 1% (5%) (10%) level.

Patients understood the scorecards but did not notice the scorecards
% of patients



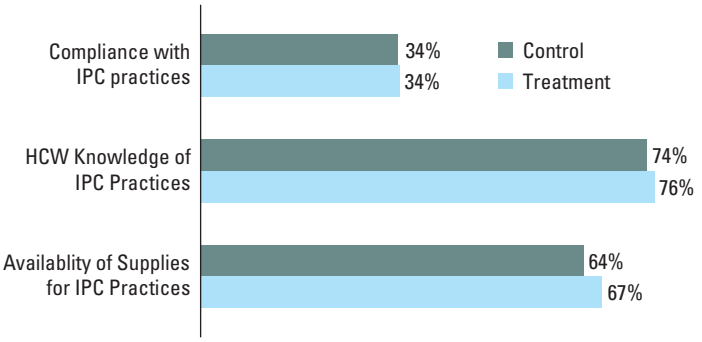
Notes. Estimates use patient sampling weights.

7. Did competition or the scorecards mediate the impacts?

Markets with more competition improved more. Markets with three or more facilities improved their JHIC score by 16% compared to control, while markets with one or two facilities improved their safety score by 7%. This highlights the importance of close monitoring of small markets without competition.

The scorecard information treatment had similar impacts to the inspection-only arm. Patients understood the scorecard ranking system but did not notice the scorecards. The scorecards ranking system was easy to understand, but most patients did not notice the scorecards, indicating more needs to be done in dissemination to inform patients.

Measures of patient safety that were not inspected did not change: Compliance with IPC practices, HCW knowledge, and availability of supplies
% of practices, HCWs, and supplies



8. Did measures of patient safety not included in the JHIC improve?

One concern of any intervention focused on improving patient safety and quality is whether it can lead to substitution of (non-inspected) inputs that go in the other direction of quality. When looking at the practices of infection prevention and control (IPC) based on observations of health care workers and 19,180 patient-provider interactions, we find small overall increases in practices (1%), knowledge (2%), and availability of supplies (4%), compared to the control group. There is considerable heterogeneity across IPC domains. In IPC practices, for instance, we find important impacts on disinfection of reusable devices (56% of control) and waste segregation excluding needles and syringes (14%), which are accompanied by increases in supplies available such as those for disinfection of reusable devices (19% of control) and waste segregation (14%). These results seem to indicate that supplies are important constraints to disinfection and waste segregation practices. They also suggest that facilities do not reduce inputs or

quality indicators in these dimensions, and if anything, they improve. How to engender behavior change—particularly in hand hygiene—remains the single biggest challenge for patient safety and IPC, and of paramount importance in the pandemic.

9. Is there evidence of leakage or rent-seeking?

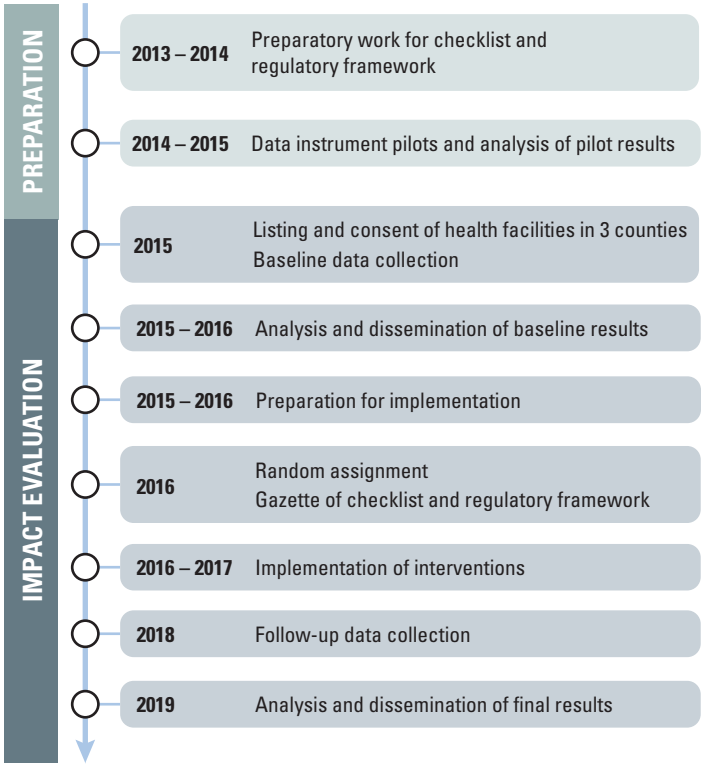
An important part of the pilot focused on how to guarantee quality of the inspections and minimize potential leakage due, for instance, to rent-seeking or lack of effort. For this, we included a combination of data quality checks and in-the-field monitoring through return visits to health facilities by independent quality officers. Overall there were no large discrepancies between quality checks and the inspections, leading to similar health facility compliance rates across inspectors within counties.[15] We find that 2% of facilities that were inspected reported any issues related to rent-seeking in endline data collection. Although we cannot rule out issues related with leakage or corruption, these figures suggest the quality checks and monitoring may have kept their incidence low.

[15] The quality of the inspections data collected in KePSIE forms is one of the most significant factors in ensuring that the results of the study are valid and leakage is limited. In order to discourage (and measure) manipulation of inspection results, quality controls included: (i) random visits to facilities by independent quality officers to conduct audits of inspections records; (ii) random visits accompanying inspectors on their visits; (iii) protocols to assign different inspectors for follow-up inspections to limit multiple inspections by a single inspector; and (iv) a system for feedback from facilities to report complaints, issues, or any other reports regarding inspectors or the inspections process.

These results present the first highlight of the regulatory reform: a significant increase in patient safety with no significant changes in fees or demand for the average patient.

- The intervention led to an increase in inactive facilities in a market characterized by a high turnover of small lower-quality facilities.
- All types of facilities improved—private facilities improved more than public.
- Some private facilities closed down, but reopened later on.
  - These closures did not hurt patients, as patient load and health seeking by poor and rich were very similar across intervention and control groups.
- Patients moved away from the private sector to the public sector.

KePSIE Timeline and Milestones



Box 4. Evidence-Based Reform of the Regulatory Framework for Health Inspections in Kenya

The reform that led to the current system of inspections did not happen overnight; rather, the enhanced regulatory regime was the outcome of a series of small steps accomplished over a period of six 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 with 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 finetune the JHIC, develop an implementation manual to facilitate operationalizing the inspection process, establish 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 JHIC and implementation guidelines in 2016.

PHASE 3: To Be Continued

Several 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, setting the basis for continuous improvement. The second generation JHIC was used in the KePSIE pilot and is now the basis for the national scale-up.

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 the 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, surveys and field pilots followed by data analysis to guide future choices, and implementation support to test the pilots.

(box continues on next page)

Box 4. (continued)

3. **Changing the regulatory environment is an incremental and detailed process:** The first generation of the JHIC was gazetted in 2012. The enhanced version was field-tested by the KePSIE team in 2014, and the stakeholders validated a revised version of the JHIC along with an implementation manual, scoring system, and warnings and sanctions system, which were gazetted in March 2016. The implementation of the pilots was also highly adaptive. Many scenarios arose in the implementation of the inspections that were not anticipated or clearly defined in the regulation. These scenarios led to different paths of actions for which protocols were developed for KePSIE's implementation led by the regulators. For instance, the electronic inspection tool in the tablets underwent more than 40 rounds of revision due to this learning-by-doing. The system was adapted based on continuous learning by all actors.

Appendix. The KePSIE Collaboration

KePSIE assesses the impact of inspections as designed and conducted through a fully scaled government-led program, rather than a "gold standard" research effort. Care was taken to develop the intervention tested within a government budget. The study has two critical elements related to the institutional framework and the potential scalability of the results: (1) 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) deciding on the specific parameters of the interventions to be evaluated as well as the operational guidelines; and (2) key involvement from the central government, which is responsible for the regulatory function, as well as the county health management teams responsible for providing health services.

An important feature of this intervention is that most of the components of the inspection system evaluated needed to be developed. Never before was this scale and type of inspections (high intensity and enforcement) conducted in Kenya. An operations manual was developed and signed by all stakeholders to document the governance and implementation arrangements for the pilot regime including: inspection and enforcement protocols; nomination, selection and training of inspectors; and governance arrangements, including roles and responsibilities for main actors in the system. The resulting package and lessons can be widely used to improve further patient safety and quality of care in countries around the world.

A multi-stakeholder effort

The interventions that were evaluated through this collaboration were designed through a participatory approach over a five-year process. This was a concerted effort by the government to build the conditions to test a new system.

- The three counties where the study took 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 MOH and regulatory boards and councils seconded the inspectors, who became the first cadre of full-time inspectors, gazetted under section 153 (1) of the Public Health Act, Cap. 242, after being trained as part of the pilot.
- The Medical Practitioners and Dentists Board, the national regulatory agency within the MOH that provides licenses to medical practitioners and private health facilities, conducted the logistics for the daily operations of the implementation.
- The county governments were a focal point in communication with health facilities and the implementation teams, and dedicated resources and space in the county hospitals and offices for inspectors.

- The MOH and the county teams conducted the enforcement of closures of health facilities and departments tied to inspection results.
- The World Bank Group provided technical assistance and facilitation throughout the process, including testing of the checklist, supporting the development of standardized training material for inspectors and protocols for the implementation of inspections (none were available before); developing an electronic JHIC and management monitoring and information system to manage and monitor the operation and reports; and supporting the implementation and quality of the pilots.

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Datasets

IFC-WHO Kenya Minimum Patient Safety Standards Compliance Survey (2012)

Kenya Patient Safety Impact Evaluation Team and Funding

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Funding was provided by the DIME Impact Evaluation to Development Impact (i2i) fund, the Korea World Bank Group Partnership Facility (KWPF), the Strategic Impact Evaluation Fund (SIEF), the Competitiveness Policy Evaluation Lab (ComPEL), the Health in Africa Initiative (HIA), the Knowledge for Change Program (KCP), and the Development Research Group (DECRG) at The World Bank.