**Title: Strengthening Regulation for Patient Safety: Front line staffs’ perceptions of Kenya’s regulatory reforms**

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Background

Health systems in low and middle-income countries (LMIC) are increasingly pluralistic, involving a wide mix of public, not-for-profit and for-profit providers. Regulation should be a key foundation of the Government’s stewardship role of these heterogeneous facilities, but performance of this function is generally weak, with serious consequence for patient safety and quality of care. In an effort to improve regulation of health facilities, Kenya introduced a set of innovative regulatory interventions in public and private facilities in 3 Kenyan counties. These comprised the use of the Joint Health Inspections Checklist (JHIC), which synthesises the areas covered by all the regulatory Boards and Councils; increased inspection frequency; risk-based inspections where warnings, sanctions and time to re-inspection depend on inspection scores; and display of regulatory results outside facilities. We aimed to examine the views and perceptions of facility owners on these regulatory reforms.

Methods

The study was conducted in 3 counties using qualitative methods. We conducted 51 in-depth interviews with health facility owners/managers to explore their perceptions and experiences of the implementation of the regulatory reforms. We specifically sought to find out how the inspections were perceived in terms of fairness and legitimacy. We also sought to identify facilitating and impeding factors to implementation and ways in which implementation could be improved. Finally, we explored the differences between the new inspections and the previous regime of inspections in terms of efficiency and incentives & opportunities for corruption. Data was managed using Nvivo software and analysed using a framework approach.

Results

The inspections were generally seen as fair, legitimate, transparent and supportive, and different from previous inspections which were characterised as intimidating and punitive. Facilities had implemented some patient safety measures as a result of the inspections and they felt the quality of services had improved. However, smaller facilities felt that some of the content of the inspections was only relevant to bigger facilities and that it was inappropriate to assess them on these requirements. Most facilities felt that there was need for mechanisms of supporting them to address gaps identified during inspections, especially public facilities that have very little control over their own resources and processes. The display of inspection scores at facilities was supported by better performing facilities but opposed by poor performers. While the scorecards were generally not thought to be well understood by patients, there was evidence that their display motivated health workers to improve. The use of an electronic inspection checklist was perceived to reduce opportunities for bribery but there were still a few unsuccessful cases of bribe solicitation by inspectors.

Conclusion

These new inspections have been received positively by health facilities and should be scaled countrywide. There is need to have a mechanism in place that supports health facilities to implement inspection recommendations to improve quality and patient safety. The general public needs to be educated on the scorecards so that they can understand them better and make informed choices.

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