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Assessing Health Care Quality Using Routine Data: Evaluating the Performance of the National Tuberculosis Program in South Africa

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Abstract

Objective: To assess the performance of health care facilities by means of indicators based on guidelines for clinical care of TB, which is likely a good measure of overall facility quality.

Methods: We assessed quality of care in all public health facilities in South Africa using graphical, correlation and locally weighted kernel regression analysis of routine TB test data.

Results: Facility performance falls short of national standards of care. Only 74% of TB patients provided a second specimen for testing, 18% received follow-up testing, and 14% received drug resistance testing. Only resistance testing rates improved over time, tripling between 2004-2011. National awareness campaigns and changes in clinical guidelines had only a transient impact on testing rates. The poorest performing facilities remained at the bottom of the rankings over the period of study.

Conclusion: The optimal policy strategy requires both broad-based policies and targeted resources to poor performers. This approach to assessing facility quality of care can be adapted to other contexts and also provides a low-cost method for evaluating the effectiveness of proposed interventions. Devising targeted policies based on routine data is a cost-effective way to improve the quality of public health care provided.

Keywords: Quality of care, quality measurement, health care delivery, health policy, tuberculosis, antibiotic resistance, South Africa

Introduction

Measuring the quality of care delivered in the public health facilities of low- and middle-income countries (LMICs) is an important first step in the process of improving population health because it enables the targeting of government interventions and the evaluation of their impact (Chassin et al. 2010; Rowe et al.

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2005). Though government, management and donor motivation is required to drive improvements in quality of care, better knowledge is an important first step (Batalden and Davidoff 2007). The experience of high-income countries demonstrates that robust performance measures with tight links to patient outcomes can lead to performance improvements (Chassin et al. 2010). Methods that use routinely collected data sources to assess overall quality of care on a large scale provide an attractive alternative to traditional, costly data collection methods such as one-off surveys, observational studies, and focus groups. Assessing the quality of care provided at health facilities compared to national clinical standards of care may be used to identify poorly performing facilities that require intervention or additional resources such as training, staff, supplies, or funding.

In this study, we develop a low-cost method to assess quality of care provided in health facilities using routinely collected nationally representative health facility data. There are many goals for performance such as efficiency, equity or coverage; however, here we focus on delivery of specific services that improve health (Arah et al. 2006). This evaluation strategy allows policy makers and health care managers to determine (1) how poor performance is distributed geographically, (2) how quality of care responds to policy changes and program implementation, and (3) whether quality rankings of facilities change over time (i.e. "quality mobility"). The results of these types of evaluations can inform national public health strategy and guide the design of focused interventions. Ultimately, the data-driven targeting of public health resources can efficiently improve the quality of care provided at health facilities.

This study applies the method to the public health emergency of tuberculosis (TB) in South Africa using electronic laboratory data from the national TB program. TB is the leading infectious disease killer in the world, despite being a curable disease. In 2014, 9.6 million worldwide contracted the disease and 1.5 million people died from it (WHO 2015). National TB programs in countries like South Africa, which has one of the highest TB incidence rates in the world, play a critical role as the first line of defense against a growing epidemic of drug-resistant TB that is a salient risk to high-income countries. Prompt and effective TB diagnosis, follow-up testing to ensure treatment is effective and drug-resistance testing are all necessary to reduce the risk of spreading TB and propagating drug-resistant forms of TB.

We focus on process performance measures rather than outcome measures because they better fulfill the criteria for validating accountability measures: that the care process (1) leads to improved outcomes, (2) accurately captures whether the care has been provided (Dilraj et al. 2013), (3) addresses a process that has few "intervening" care processes required, and (4) has little or no chance of inducing unintended adverse consequences (Chassin et al. 2010). In South Africa, clear national clinical guidelines disseminated to health facilities specify protocols for TB diagnostic testing and virtually all instances of diagnostic testing in public health facilities are captured in electronic laboratory data. We use routinely collected data from all public health facilities in South Africa to identify facilities where only a low proportion of TB-positive patients are receiving the diagnostic and monitoring tests required by national guidelines. These TB-specific indicators are hypothesized to be good measures of overall quality of care because all facilities are

equipped to perform TB testing and are aware of the public health threat of the disease, including the risk of nosocomial transmission.

Methods

Data were extracted from the South African National Health Laboratory Service (NHLS) database for all TB tests performed in public health facilities between January 2004 and December 2011. We included tests in the period prior to the national rollout of the Xpert MTB/RIF assay (Cepheid, USA) beginning March 2011, to capture longer time trends and to ensure generalizability to the many LMICs with high TB rates and do not yet have widespread access to Xpert technology. Tests by polymerase chain reaction (PCR, LPA, Xpert), comprising no more than 3.93% of tests per year, were dropped to ensure that changes in testing practices associated with the Xpert rollout do not skew our results. The sample included all patients aged 16-64 years for a total of 26,245,412 tests from 3,939 health clinics and 429 hospitals. We extracted unique patient identifiers, patient age and sex, type of test performed, date of test, health facility type and location, and calculated facility testing rates. A TB-positive test result was coded as at least one positive result from smear microscopy or culture.

We created facility-level indicators for clinical testing rates based on guidelines from the South African National Department of Health's tuberculosis management protocols that follow standards set by the World Health Organization (South Africa Dept. of Health 2004, South Africa Dept. of Health 2009). We analyzed three metrics: diagnosis based on two patient specimens, the adherence to guideline-defined treatment monitoring, and the identification of drug-resistant TB (DR-TB) among patients experiencing treatment failure. These metrics were chosen because they are routinely documented within the TB program and represent clinical behaviors of critical importance to the control of TB: diagnosis, treatment monitoring, and identification of DR-TB.

Per the clinical guidelines prior to 2011, all patients receiving a diagnostic test should provide a second specimen for smear microscopy testing within one day of the initial test (South Africa Dept. of Health 2004, 2009). Second specimen testing rates were calculated as the proportion of patients who provided a second specimen within two or seven days before or after the first TB-positive test result. The guidelines indicate that patients should provide sputum for smear microscopy both at the end of the two-month intensive phase (7 weeks for new cases, 11 weeks for retreatment) and at the end of treatment (5 months for new cases, 7 months for retreatment) to monitor treatment response. Monitoring test rates were calculated as the proportion of patients receiving a second TB test within 90, 120, 180, 270, or 365 days of an initial TB-positive test result, excluding the first 30 days. Drug sensitivity testing (DST) was recommended for patients that remain smear- or culture-positive at the end of the intensive phase of treatment, those with smear-negative pulmonary or extrapulmonary TB, patients with previous TB, or high risk patients. DST rates were therefore calculated as the proportion of patients with a second positive TB test more than 60 days after the initial TB positive result (i.e. evidence of potential treatment failure) who received DST within 90 or 120

days after an initial positive test result.

We used these three broad measures (second specimen, monitoring tests, and DST) analyzed at varying time windows following the initial diagnostic test to create a set of 15 facility-level indicators of performance. Correlations between facility performance rates were measured by Pearson's paired correlation coefficients. Differences in testing rates by province and location type were determined using ordinary least squares regression analysis robust to heteroskedasticity. Curves of the distributions of testing rates were produced using locally weighted kernel regression smoothing (i.e. lowess). Extrapulmonary TB and smear or culture-negative cases were excluded from this analysis (South Africa Dept. of Health 2009). Facilities from KwaZulu-Natal were excluded from this analysis due to limited data availability. All analyses were performed using Stata 14 (Stata Corp, College Station, TX, USA). Ethics approval was obtained from the University of Michigan Institutional Review Board, Ann Arbor, MI, USA, and the University of Cape Town Faculty Ethics in Research Committee, Cape Town, South Africa.

Results

Trends in national testing rates

The facility-level second specimen rate observed in the data remained stable at a mean of 76% from 2004-2007 (Fig. 1). The rate reached a maximum in 2008 then dropped steadily to 60% at the end of 2011. The rate of 90-day monitoring testing remained level between 2004-2007 at around 25%. Similar to the second specimen rate, the monitoring testing rate rose to 29% in 2008, but declined to 15% from 2009 onwards. The DST rate rose to 16% in mid-2007 then dropped to a minimum of 9% in late 2008, in parallel with the spike in second specimen and monitoring testing rates in that same time period, and rose steadily after 2009 to a maximum of 30%.

Similar trends were observed when testing rates were stratified by patient sex and facility type (clinic versus hospital), although second specimen and monitoring testing rates were higher in clinics than in hospitals and DST rates were considerably higher in hospitals than in clinics (Fig. 2; $p < 0.001$ for all three comparisons). Patients diagnosed with TB in hospitals are typically discharged to clinics for ongoing treatment. These patients are also more severely ill and symptomatic, leading to higher rates of empirical therapy (i.e. treatment initiation without positive TB test) and lower second specimen rates. Additionally, symptomatic patients receiving TB care in hospitals may be treated with a high index of suspicion for treatment failure and thus receive higher rates of DST than do patients seen in clinics.

We found that testing rates are responsive to some, although not all, changes in clinical guidelines and national awareness campaigns. We saw increases in testing rates around January 2007, when the first South African National Strategic Plan was released with the aims of improving drug resistant TB case finding and treatment and strengthening DOTS (South Africa Dept. of Health 2007). Testing rates also increased in July 2008 when the first annual South Africa TB conference took place and the WHO endorsed the Geno-Type MTBDRplus line probe assay (Hain Lifesciences, Germany), and in December 2009 when the World

Cup Kick TB campaign began. There was a decrease in second specimen and monitoring testing rates in early 2009 when the national guidelines were amended to require one, rather than three, negative smear tests for a smear-negative diagnosis (South Africa Dept. of Health 2009), which may have led to a perception that diagnostic technology was becoming more sensitive. By contrast, DST rates increased throughout the data to approximately triple from 2004-2011. The rate of DST increased in 2006 around the extensively drug-resistant TB (XDR-TB) outbreak in rural KwaZulu-Natal, likely due to greater awareness of DR-TB (Gandhi et al. 2006). Since facilities in KwaZulu-Natal are excluded from this analysis, the true increase may be more pronounced than observed in this data.

Correlation of testing rates within facilities

Measures of second specimen rates at all time windows were highly correlated with one another ($r > 0.90$), so we considered the second specimen rate during the first 7 days after a first TB-positive test as a summary measure in our analyses (Table 1). We used monitoring testing within 90 days of first TB-positive test and DST within 120 days as summary measures thereafter.

We observed weak correlations between second specimen and DST rates (correlation coefficient = 0.008) and between second specimen and monitoring testing rates (correlation coefficient = 0.270). The finding that indicators are not all correlated indicates that testing rates based on a single guideline do not provide an accurate measure of overall facility quality of care. The weak positive correlation between second specimen and monitoring testing is unsurprising given that the facility and patient characteristics that increase testing at one time period are likely the same for a different time period. Since not all patients were supposed to undergo DST, this indicator is not correlated with the others. Treatment failure and the emergence of drug resistance develop with some stochasticity, which may lower the correlation with monitoring testing rates.

Distribution of facility testing rates

We plot smoothed curves (kernel densities) of facility rates of second specimen, monitoring testing, and DST (Fig. 3). The compressed distributions of the facility-level indicators reveal many facilities with similarly low second specimen and monitoring testing rates and few outlier facilities with higher testing rates. The clinical guidelines indicate that all patients should receive a monitoring test within the first 90 days of treatment. Although the mean facility testing rates observed in the dataset are underestimates due to patient record linking, we found that they are well below target: only 73.6% (SD 13.6) of patients provide a second specimen and 18.1% (SD 9.7) receive monitoring testing ($p < 0.001$). The DST rate among patients with treatment failure is very low (13.5%, SD 15.5) and much lower than the observed treatment failure rate of 20% ($p < 0.001$). The distribution of facility DST rate reveals that some facilities test at rates near 50%; however, the observed rate in our data is considerably lower than guideline recommendations. It is clear that many patients who likely have drug-resistant TB are not tested for it.

Mobility in rankings over time

Table 2 shows the fraction of facilities that fell into each quartile of testing rates in 2007 (rows) and transitioned to each quartile in 2010 (columns). The ranking of the majority of facilities remained constant over the time period in the dataset. Of the facilities in the top and bottom quartiles for second specimen rates in 2007, 50% and 43% remained in the same quartiles in 2010, respectively. Similarly, 45% and 50% of the bottom and top facilities in monitoring testing rates remained in the same quartile in 2010 as in 2007. Although a subset of facilities in the bottom quartile in 2007 increased to the top quartile by 2010 for second specimen (11%) and monitoring (13%) testing rates, an approximately equal proportion dropped from the top quartile to the bottom quartile.

Variations in testing rates by province

Table 3 shows the province rates for second specimen, monitoring testing, and DST; stars indicate which provinces have rates that were statistically significantly different from the Western Cape. The facility second specimen rates were highest in the Northern Cape and lowest in Gauteng. By contrast, the highest rates of monitoring testing were in Free State and the lowest in Eastern Cape. Facility rates of DST were highest in Eastern Cape and lowest in North West, however the rates in North West province were not statistically significantly different from the Western Cape. The Eastern Cape had particularly poor indicators overall: one-third of facilities in the bottom quartile of second specimen rates were in Eastern Cape, as were 46% of the facilities in the bottom quartile of monitoring testing rates.

Discussion

This study makes a significant contribution to the literature by developing a cost-effective, easy-to-implement method of assessing health facility quality of care. This method can be adapted to different diseases and countries provided that accurate laboratory data is available and there are clear protocols for providing health care. This cost effective method may also be attractive in high-income countries. Our method provides national-level analysis, time trends and standardized inter-facility comparisons – all metrics that are difficult to measure in traditional observational studies, which are typically small in scope, resource-intensive, and focused on short time periods (Scholz et al. 2015, Juma et al. 2014). Previous studies that examined facility quality have used costly direct assessments, workshops, and continuous monitoring, as well as more cost-effective methods such as national surveys, national registries, and routine data from a subset of facilities (Govender et al. 2000, Mabaera et al. 2008, Curado et al. 2009, Doherty et al. 2009, Backus et al. 2010, Scott et al. 2012, Zurovac et al. 2014, Falisse et al. 2015). Routine data are generally accessible worldwide because many low-income and most middle- and high-income countries already have electronic data collection systems established in their health systems. In contrast to prospective designs, routine data can be used retrospectively, provide results quickly, and have minimal ethical concerns (Powell

et al. 2003). This study also contributes to a small body of literature on developing new metrics of quality of care from facility data (Nesbitt et al. 2013, Tripathi et al. 2015).

Our findings are consistent with other studies in LMICs that find low testing rates vis-à-vis national clinical guidelines for TB diagnosis and treatment, frequent prescribing of incorrect drug regimens, and widespread lack of knowledge of international guidelines (Suleiman et al. 2003, Hussain et al. 2005, Yadav et al. 2012, Achanta et al. 2013, Wang et al. 2014). Poor performance has been shown to be driven by several health system factors including weak infrastructure and limited resources, insufficient training, accountability, or supervision of healthcare personnel, poor patient-provider relationships, poor record keeping, inadequate awareness of guidelines, and high patient volumes (South Africa Dept. of Health 2009, Bell et al. 2011, Achanta et al. 2013, Mala et al. 2014). Additionally, South African health departments have significant human resource shortages that may inhibit facilities' ability to comply to national guidelines (Narasimhan et al. 2004, Haines et al. 2005). The provision of the recommended series of diagnostic and monitoring tests depends on several factors at the facility level: healthcare providers must decide to test patients, testing resources must be available, the facility must afford the higher cost for culture tests, and providers must understand the importance of DST.

Low testing rates are influenced not only by provider behavior, but also by patient factors. Patients must be physically present in healthcare facilities for second specimen and ongoing testing, and studies in South Africa have found loss to follow-up rates between 16-50% (Edginton et al. 2005, Botha et al. 2008). Further, very ill patients or those co-infected with HIV may experience difficulty producing a sufficient sputum sample for a TB test. Finally, there are high rates of empirical TB treatment in South Africa, in which patients are initiated on TB treatment based solely on clinical symptoms and chest X-rays but without a positive bacteriological test result.

There are several limitations to our findings. The full implementation of these measures requires an investigation of the contributions of patient demographics, socio-economic factors and co-morbidities to the distribution of performance indicators. These measures are unfortunately not available in the laboratory data used for this study. Data quality issues related to poor patient record linking lead us to underestimate true testing rates, but our estimates nevertheless allow us to observe trends over time and compare facilities throughout the country. Since the distributions of second specimen and monitoring testing rates are somewhat compressed, overall mobility is likely overstated since small changes in facility testing rates can produce sizable increases in overall ranking. The apparent poor performance vis-à-vis to DST recommendations may be driven by the high rates of HIV/TB co-infection in South Africa, which hinders patients' ability to produce sputum samples.

Overall, TB testing rates did not change considerably over the study period and there was little mobility of facilities in the ranking of testing rates. Increases in testing rates around certain important national events were only of short duration. It is likely that the introduction of new testing technologies such as the Xpert MTB/RIF test will produce only a transitory increase in testing rates, and facilities with low testing

rates between 2004-2011 are likely to continue to lag in performance and quality of care. Our results are important even as testing technologies change since it is unlikely that the rollout of new technology will address the underlying factors that contribute to poor adherence to guidelines. Additionally, although Xpert is more sensitive than smear microscopy, the national guidelines continue to require two sputum samples at diagnosis and monitoring time points. Any rollout will likely require additional investments in training and monitoring if it is to successfully improve quality of care. In the case of South Africa, we find that the distribution of facility testing rates is narrow, suggesting that broad-based policies designed to raise testing rates nationally may be more appropriate than are interventions targeting a small subset of poorly performing facilities. However, our analysis does find that facilities in provinces with low testing rates, such as the Eastern Cape, could benefit from additional resources to raise testing rates.

The distributions of performance indicators in this study suggest that the optimal national strategy to improve quality of care is a combination of broad-based policies to raise overall testing rates combined with targeted resources to areas with a concentration of poor performing facilities. Since facilities identified as poor performers in one domain, such as TB care, are likely to face challenges with other types of care, these deficiencies could simultaneously be targeted for intervention. Further work is needed to assess the relative contribution of facility compliance relative to patient access factors in order to identify specific interventions with greatest promise. The performance evaluation using routine data outlined here could be adapted to other diseases with clear clinical protocols in countries with electronic medical records systems and reliable data entry, and the use of routine data also allows for low cost, real-time feedback for use in evaluating the effectiveness of interventions. Ultimately, devising targeted policies based on readily-available routine data is a cost-effective way to improve the quality of care provided in the public health sector and increase the returns to government health care spending.

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Figure legends

Figure 1. Facility-level testing rates from 2004-2011. Second specimen indicates a second specimen was analyzed within 7 days before or after a first TB-positive test, monitoring indicates a test within 90 days of the first TB-positive test (excluding tests within the first 30 days), and DST indicates a drug resistance test within 120 days of first TB-positive test for patients with evidence of treatment failure (a second positive test result within 60-90 days of first positive test). Policy changes are indicated with dashed lines: (A) XDR-TB outbreak in KwaZulu-Natal, (B) South African National Strategic Plan & Tuberculosis Strategic Plan, (C) first annual South Africa TB conference and the WHO endorsed the GenoType MTBDRplus line probe assay, (D) national guidelines for diagnosis smear-negative amended to require one, not three, tests, (E) World Cup Kick TB campaign.

Figure 2. Facility-level rates of (A) second specimen, (B) monitoring, and (C) DST testing 2004-2011, by facility type. Policy changes are indicated with dashed lines: (A) XDR-TB outbreak in KwaZulu-Natal, (B) South African National Strategic Plan & Tuberculosis Strategic Plan, (C) first annual South Africa TB conference and the WHO endorsed the GenoType MTBDRplus line probe assay, (D) national guidelines for diagnosis smear-negative amended to require one, not three, tests, (E) World Cup Kick TB campaign.

Figure 3. Smoothed distributions of facility-level testing rates of (A) second specimen within 7 days of a first TB-positive test result, (B) monitoring tests between 30-90 days of first TB-positive test result, and (C) DST rate within 120 days of first TB-positive test result in patients with evidence of treatment failure after 60 days. Vertical lines indicate 10th, 50th, and 90th percentile of indicators.

Table 1. Pearson's pairwise correlation for monitoring and DST rates at differing time periods post first TB-positive test result. Monitoring indicates a test between 30-90 days of the first TB-positive test and DST indicates a drug resistance test within 90 days of first TB-positive test for patients with evidence of treatment failure.

	1	2	3	4	5	6
1 - 90 day Follow-up	1.000					
2 - 120 day Follow-up	0.982	1.000				
3 - 180 day Follow-up	0.964	0.989	1.000			
4 - 270 day Follow-up	0.950	0.978	0.992	1.0000		
5 - 365 day Follow-up	0.945	0.973	0.989	0.997	1.0000	
6 - 730 day Follow-up	0.930	0.962	0.980	0.990	0.995	1.0000

	1	2
1 - Sensitivity testing - 90 days	1.000	
2 - Sensitivity testing - 120 days	0.821	1.000

Table 2. Transition matrices of testing rate quartiles (0-24th, 25-49th, 50-74th, and 75-99th percentile of distributions) between 2007 and 2010. Only facilities with testing data in both 2007 and 2010 included.

Second specimen	2010				
2007	Bottom quartile	2nd quartile	3rd quartile	Top quartile	Total
Bottom	50.51	23.48	15.03	10.98	100.00
2nd quartile	23.48	32.17	25.29	19.07	100.00
3rd quartile	11.98	26.04	35.51	27.47	100.00
Top quartile	13.26	18.37	25.67	42.70	100.00

	2010				
Monitoring tests	Bottom quartile	2nd quartile	3rd quartile	Top quartile	Total
2007	Bottom quartile	2nd quartile	3rd quartile	Top quartile	Total
Bottom	45.42	24.94	17.35	12.29	100.00
2nd quartile	25.85	39.76	22.18	12.20	100.00
3rd quartile	14.08	25.07	33.94	26.90	100.00

Top quartile	13.18	11.53	25.53	49.76	<i>100.00</i>
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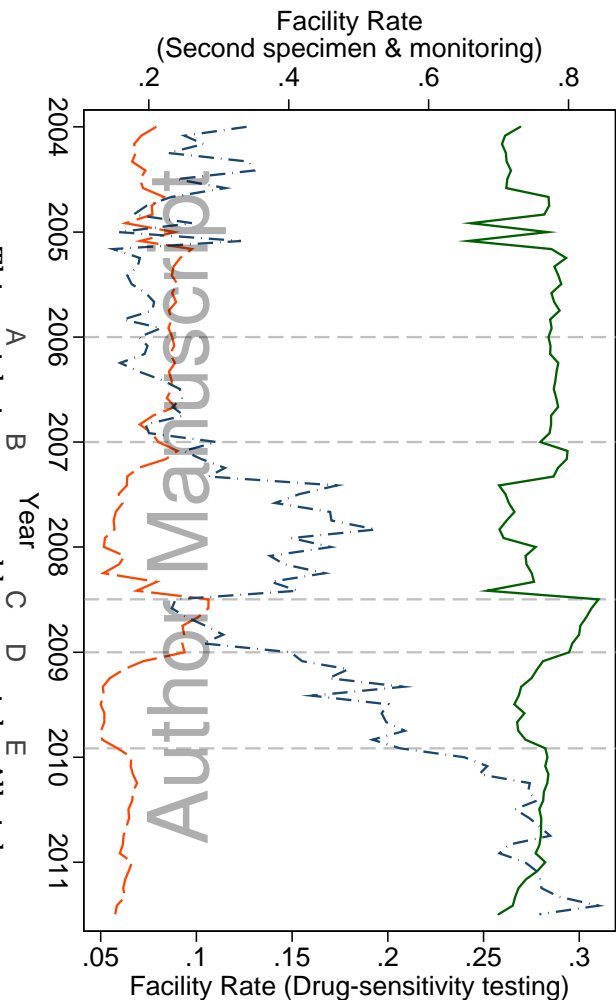
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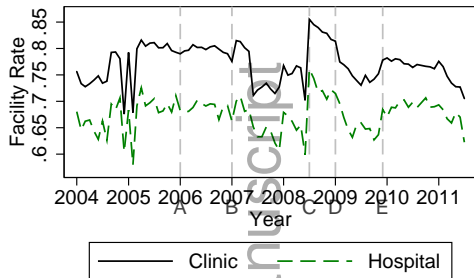
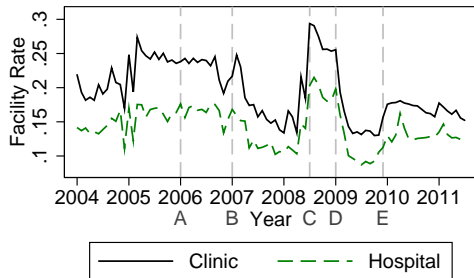
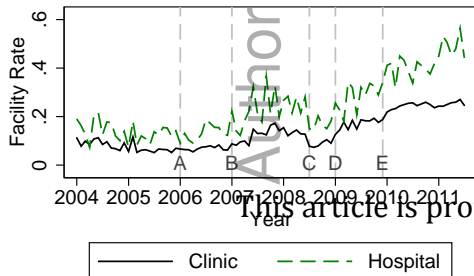
Table 3. Facility-level testing rates by province in 2010. Mean facility rates were standardized to the Western Cape and ranked. For second specimen and monitoring, bottom quartile facilities are those in the 0-24th percentile of the rate distribution. For DST rates, bottom tertile facilities are those in the bottom 0-32nd percentile of the testing rate distribution. Rates are relative to Western Cape reference. Facilities from Kwazulu-Natal are excluded.

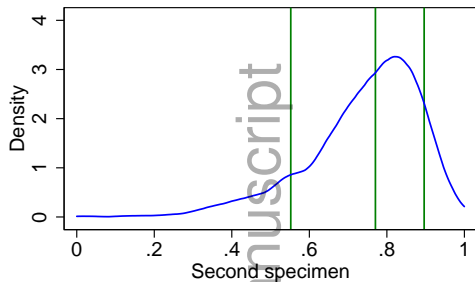
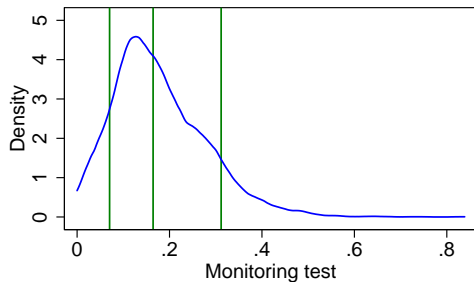
Province	Second specimen		Monitoring		DST	
	Rate (rank)	Bottom quartile facilities (%)	Rate (rank)	Bottom quartile facilities (%)	Rate (rank)	Bottom tertile facilities (%)
Western Cape (ref)	1.000 (3)	7.00	1.000 (2)	4.19	1.000 (4)	12.57
Eastern Cape	0.898 (7)**	32.77	0.507 (8)***	45.73	1.626 (1)*	12.58
Free State	0.932 (6)	10.38	1.022 (1)***	4.64	0.818 (6)**	11.44
Gauteng	0.889 (8)***	16.51	0.976 (3)***	7.95	1.087 (3)***	14.06
Limpopo	0.962 (5)***	14.00	0.691 (6)***	16.27	0.569 (7)	14.13
Mpumalanga	1.014 (2)***	6.16	0.862 (5)***	4.68	0.866 (5)***	13.39
North West	0.981 (4)***	9.66	0.959 (4)	7.57	0.459 (8)	18.12
Northern Cape	1.048 (1)***	3.52	0.682 (7)***	8.97	1.504 (2)*	3.70

Tests of statistically significant difference from Western Cape rates: *** $p < 0.01$, ** $p < 0.05$, * $p < 0.10$

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