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Fostering HIV Program Quality to Achieve Epidemic Impact

Guest Editors:

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The role of quality improvement in achieving effective large-scale prevention of mother-to-child transmission of HIV in South Africa

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Introduction: After a late start and poor initial performance, the South African Prevention of Mother-To-Child Transmission (PMTCT) programme achieved rapid progress in achieving effective national-scale implementation of a complex intervention across a large number of different geographic and socioeconomic contexts. This study shows how quality-improvement methods played a significant part in PMTCT improvements.

Methods: The South African rollout of the PMTCT programme underwent significant evolution, from a largely ineffective, context-insensitive, top-down cascaded training approach to a sophisticated bottom-up health systems' intervention that used modern adaptive designs. Several demonstration projects used quality-improvement methods to improve the performance of the PMTCT programme. These results prompted a national redesign of key elements of the PMTCT programme which were rapidly scaled up across the country using a unified, simplified data-driven approach.

Results: The scale up of the quality-improvement approach contributed to a dramatic fall in the nationally reported transmission rate for mother to child transmission of HIV. By 2012, measured infection rate of HIV-exposed infants at around 6 weeks after birth was 2.6%, close to the reported transmission rates under clinical trial conditions.

Conclusion: Quality-improvement methods can be used to improve reliability of complex treatment programmes delivered at primary-care level. Rapid scale up and effective population coverage can be accomplished through a sequence of demonstration, testing and rapid spread of locally tested implementation strategies supported by real-time feedback of a simplified indicator dataset and multilevel leadership support.

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Introduction

Despite a slow start to its antiretroviral therapy (ART) programme, South Africa has shown a decade of significant progress in managing the HIV epidemic. It has by far the largest numbers of people infected with HIV of any country with an estimated 6.4 million people living with HIV [1] and ongoing high prevalence of HIV (29.5%) in pregnant women attending public sector facilities [2]. Approximately, 270 000–300 000 unborn and newly born infants require protection from HIV each

year through the Prevention of Mother-To-Child Transmission (PMTCT) programme.

The provision of ART over the last decade to an estimated 2.7 million adults and children [3] and near universal coverage of PMTCT has turned the tide in the fight against the HIV epidemic in South Africa. These achievements in large-scale ART are credited with the observed increase in life expectancy from 52 years in 2006 to 61 years in 2012 [4], and significant declines in maternal, child and infant mortality [5,6]. Adult mortality

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has declined by more than 50% since its peak in 2003 and 2004. For children 2–14 years, the downward trend in HIV prevalence (5.6% in 2002 to 2.4% in 2012) reflects the success of the scale up of South Africa's PMTCT programme [7].

A number of structural and policy changes, promoted by enthusiastic and visionary leadership were key elements of the programme's remarkable turnaround in the past 5 years. This brief study focuses on the role of quality-improvement interventions in the rapid progress of South Africa's national PMTCT programme.

Methods

When the South African government introduced its PMTCT programme in 2002, the rollout followed a conventional format for a large scale clinical programme, relying on the introduction of locally adapted protocols and accompanying clinical training. In designing the national implementation plan, the South Africa National Department of Health (DoH) drew from early global experience with use of antiretroviral drugs in pregnancy as well as its own study of PMTCT services at 18 pilot sites across the country [8], as well as earlier isolated programmes that had been initiated in the Western Cape province by Medecins Sans Frontieres. The DoH assembled guidelines, a training programme for nurses to administer the programme, a supply chain system to ensure provision of antiretrovirals at all health facilities in the country and adaptations to the District Health Information System (DHIS) to ensure that programme performance could be tracked and reported.

Within 3 years of introduction of the South Africa PMTCT programme across the health system, it was clear that efforts to ensure reliable delivery of nevirapine for PMTCT were largely ineffective. Rollins et al. [9] estimated that the vertical transmission rate in one of the country's largest provinces in 2004-2005 was 20.1%, showing minimal impact of the PMTCT programme that had been widely implemented by that time. In response, external nongovernmental organizations (NGO) partnered with academic units and provincial departments of health to explore better ways to deliver the programme. Quality improvement was one of the methods that was introduced. All the quality-improvement approaches described in this study followed the model for improvement [10] (identification of an outcome goal based on best-available evidence, a set of measures to track progress towards that goal and a systematic way to test local ideas to close performance gaps).

Using methods that had been pioneered globally by the Institute for Healthcare Improvement (IHI) and University Research Co (URC), PMTCT demonstration

projects were established in a number of health districts (the district being the lowest level of administrative delegation in the public health system) from 2005 onwards. Within some districts, hospitals and their referring clinics formed learning networks that followed a format of joint meetings and site-based activities – using the IHI "Breakthrough Series" (BTS) model [11] - to improve PMTCT performance. Quality-improvement teams from these facilities came together to learn the principles of quality improvement, design new approaches to overcoming barriers to reliable PMTCT care and to learn from each other's experiences. Between these meetings facility teams and district managers were provided coaching on data-driven approaches to performance improvement. These approaches were systemized and scaled up throughout South Africa through implementation of the Accelerated Plan (so called A-Plan). This was achieved by engaging technical partners to use and scale up quality-improvement methodology in all districts [12].

The quality-improvement approach was simplified as the implementation became standardized during the scale up. Whereas the demonstration and early tests of scale up used a structured, time-bound learning network (BTS) structure, the final scale up of PMTCT throughout the country was driven by introduction of standard work that had been developed and tested in the earlier phases. The learnings from the demonstration projects were assembled into a 'how to' guide [13] that gave specific examples about how to successfully design improved practices for each step of the PMTCT pathway.

Results

The contribution of quality-improvement methods to the success of the South African PMTCT programme can be tracked through a series of activities that fall into three broad phases: a demonstration phase that provided proof of principle of the value of the quality-improvement approach; a test of scale up phase that built confidence and capability around quality-improvement approaches to rapid improvement in performance; and a national scale up phase which used the lessons from the first two phases.

Demonstration phase

In 2005, when the first demonstrations of using quality improvement to improve PMTCT programmes were introduced, the quality-improvement method had not previously been tried in South Africa. As such there was neither institutional knowledge nor understanding of how this approach might work or its value in the South African HIV environment. Three demonstration projects contributed significantly to the understanding of how quality-improvement methods could be applied in the South African context.

Urban subdistrict Western Cape

The project included all primary-care facilities and specialized birthing centres in a low-income health subdistrict of the city of Cape Town, South Africa. Between 2006 and 2009, changes in PMTCT practice and clinic flow design were developed in the prototypeinnovation phase (seven primary-care clinics and two birthing units) and were then rapidly spread to the hospital and 17 facilities in the scale up phase [14]. Frontline healthcare workers used the model for improvement to identify and improve performance gaps at each step of the PMTCT pathway. Improvement was facilitated and spread through the use of a Breakthrough Series Collaborative. The external technical advisors worked closely with provincial and municipal government health managers who introduced protocol changes and additional resources to support performance improvement. During the period of study, the proportion of HIV-exposed infants testing positive declined from 7.6 to 5%. Compared with baseline, key intermediate PMTCT processes improved significantly: antenatal antiretroviral increased from 74 to 86%, intrapartum antiretroviral increased from 43 to 84% and postnatal HIV testing increased from 79 to 95%. The project concluded that key elements of the project success included a clear design, leadership buy-in, building local capacity to use systems improvement methods and a reliable data system that provided real-time system performance data to both managers and frontline staff. The demonstration project has provided ongoing key inputs into the design and scale up of other HIV programming in the region.

Rural district-wide intervention in KwaZulu-Natal The project included all three hospitals and 18 comprehensive primary-care facilities in the rural, lowincome district [15]. The project used a data-driven process improvement approach that included an initial assessment undertaken by a team of district supervisors, followed by workshops to assess results, identify weaknesses and set improvement targets. The external project facilitator then visited the facilities monthly and used realtime data reports to engage clinic staff in planning local improvements. Although using the basic data-reflective approach to improvement, this project contrasted with the Western Cape project in that the initial assessment and redesign of the programme were undertaken by district and unit managers and not by frontline providers. One year following the intervention coverage of CD4 testing increased from 40 to 97%; uptake of maternal nevirapine from 57 to 96%; uptake of infant nevirapine from 15 to 68%; and 6-week PCR testing from 24 to 68%.

Three district rural and urban demonstration KwaZulu-Natal province

This was an intervention in three large districts in KwaZulu-Natal province, including 14 hospitals and over 200 primary-care clinics [16]. The project was the first large-scale demonstration of the use of quality-

improvement methods to rapidly improve PMTCT performance in South Africa. It was designed in response to the report that the South Africa PMTCT programme had been largely ineffective [9]. The intervention was operationalized at district and facility levels through working closely with the provincial and district management teams. At the district level, district management staff, information officers and medical officers met with the local technical support partner (an NGO, named 20000+) on a monthly basis to review PMTCT process data, analyze systems successes and failures and support improvements in the facilities. At the facility level, the quality-improvement implementation was undertaken by improvement teams, including clinic-based PMTCT professional nurses, HIV-testing counsellors, data clerks and the facility operational manager. Quality-improvement mentors from the support NGO visited facilities every other week to train and mentor these teams to use data-driven quality-improvement methods (systems analysis and rapid cycle testing of local ideas) to close performance gaps for each step of the pathway. Although each district pursued the same common objective (to decrease mother to child transmission to 5%) each used a different, context-sensitive implementation and scale up strategy to achieve the objective [17]. The project resulted in numerous innovations for PMTCT that were collated and rapidly scaled across the province. The qualityimprovement approach provided a template for a rapid national scale up that required minimal further modification as it had already been tested in multiple contexts.

Test of scale up

As the experience of the initial successful quality-improvement demonstration projects became more widely known to provincial and national PMTCT programme managers, the knowledge that was generated in the demonstration projects was incorporated, in 2008, into a national initiative – the 'A-Plan' – to dramatically improve performance of the national PMTCT programme. The Plan included both demand creation as well as system improvement activities.

District management teams from one district each from five provinces, together with their technical support partners, were assembled by the DoH to form a learning community to rapidly test the application of a data-driven approach to PMTCT care, based on the learnings from the 3-district project described above and the experiences to-date of the assembled partners. This was the first phase of expansion of a rapid national scale up plan to achieve a new national goal to reduce mother to child transmission to less than 5% by 2011. Using local knowledge gleaned from demonstration projects and a phased rapid scale up design that had been successfully deployed with other global quality-improvement large-scale programmes [18], the A-Plan was able to show that, with minimal additional training, the core elements of quality improvement could be successfully deployed in a range of settings with support from a group of partners who had not used the methods previously [17]. The tested 'package' of implementation strategies and local data focus that the quality-improvement approach introduced was successfully tied to other significant improvements that were being introduced by the DoH: improvements in PMTCT protocols and changes that allowed nurse-led prescribing of antiretroviral [19].

National scale up

Although the A-Plan proposed a three-phase design for scale up, the lessons from the initial five district intervention were rapidly distilled into the national strategy. Improvements were then rapidly introduced across the country, together with more effective drug regimen protocols and an updated set of PMTCT indictors that were tracked on the routine data collection system across the country. A new set of data dashboards were subsequently introduced to track and report progress quarterly with key indicators at all levels (national, provincial and district) of the health system [20]. In this way, key performance successes and challenges were highlighted in close to real time and supported prioritization of actions. Using the national DHIS data monitoring system that is updated each month, the South African PMTCT programme showed remarkable improvement in performance of key processes of care that were being tracked by the DHIS across the country (Fig. 1). This progress in processes of care, supported by a high level of political commitment, and a number of policy and practice changes [21] translated into a marked reduction in reported mother to child transmission rates for HIV-exposed exposed infants tested at 6 weeks after birth. For infants tested in 2008 and 2009, mother to child transmission rates were reported for KwaZulu-Natal province at 7.1% [22]. Annual national population-based surveys from 2010 onwards showed steady declines to an average of 2.6% in 2012 (Gaga AE, personal communication, South Africa, November, 2014) [23]. These results were mirrored by the standard PCR results analyzed by the National health Laboratory Services which showed a decline in early mother to child transmission of HIV from 20.9% in 2004 to 2.4% in 2012 [24] (Fig. 2).

Between June and November 2011, the DoH developed a national action framework, 'No child born with HIV by 2015 and improving the health and well being of mothers, partners and babies in South Africa'. This framework supports integrated maternal, newborn and child health and PMTCT programmes in the country. The framework ensures evidence-based, accelerated programme scale up and delivery of quality services with further innovations to overcome remaining barriers. The framework proposed that data-driven action plans be developed for all the districts and provinces. In 2012–2014, decentralized data-driven plans were developed with ongoing monitoring of results and progress.

A summary of the main quality-improvement and programmatic interventions is shown in Figure 3.

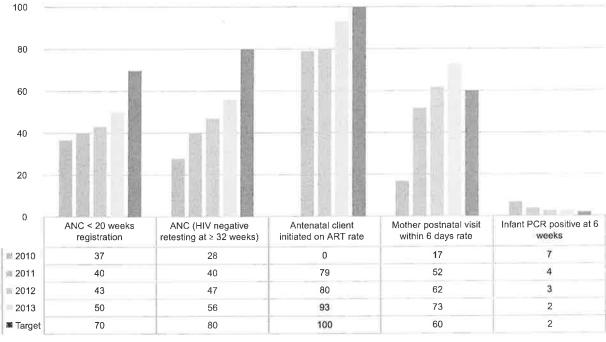


Fig. 1. Key processes of care and HIV transmission rates across the South African public clinic and hospitals between 2010 and 2013. ANC, antenatal care; AZT, zidovudine; HAART, highly active antiretroviral therapy; PCR, polymerase chain reaction. *All HIV-positive exposed babies.

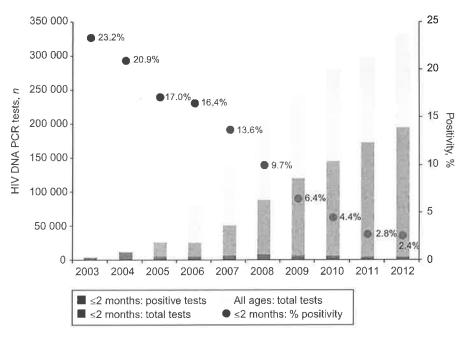


Fig. 2. Progress in number of babies tested for HIV (HIV DNA PCR tests) and early vertical transmission (positivity %) in infants \leq 2 months of age in South Africa. Reproduced with permission from Sherman [24].

Advances in the knowledge base for protection of infants exposed to HIV through breast feeding has offered opportunities to expand to the postnatal period the lessons learned during the last few years of remarkable progress in perinatal transmission. South Africa has adopted newer protocols that provide antiretroviral protection to the mother—infant unit during

breastfeeding. Efforts are now underway to apply a systems improvement approach to ensure that all HIV-exposed infants are as effectively protected in the postnatal period as they have been in the prenatal and intrapartum periods. This aim was assisted by recent policy changes. In April 2013, South Africa revised the PMTCT regimen to triple ART (ART regimen, fixed dose combination) for

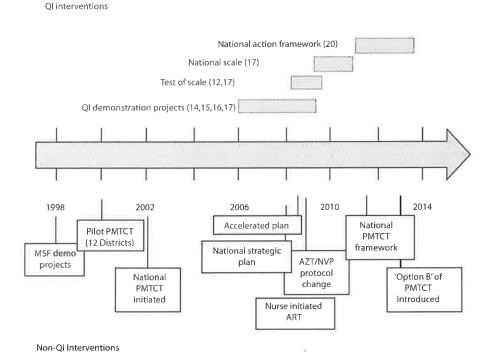


Fig. 3. Timeline of QI and non-QI activities that contributed to reduction of MTCT in South Africa.

all HIV-infected pregnant women and lactating mothers. More recently, the DoH announced a further policy change from January 2015 to provide ART for life for all HIV-infected pregnant and breastfeeding mothers and also to introduce PCR testing at birth for HIV-exposed infants.

Discussion

There are many determinants that have been ascribed to the remarkable success of the South African PMTCT programme. A review of the programme by Barron et al. [21] lists a number of factors that were important in the successful scale up of PMTCT in South Africa. After an indecisive and delayed start, the South African Department of Health in 2002 introduced a national PMTCT programme, available in theory to all pregnant mothers. Although a number of technical improvements to the programme were introduced over the next 5 years, it was not till 2008 that the DoH focused its efforts on a systems approach to overcome the initial poor performance of the programme. A series of successful quality-improvementbased demonstration projects were the springboard for the national accelerated scale up which has used a datafocused systems approach ever since [20,21].

In addition to its focus on data-driven decision making, the quality-improvement efforts promoted the four elements of the systems improvement framework proposed by Deming [25]; an integrated systems approach, elimination of data variation, a learning system to accelerate change, and change management strategies that addressed the psychology of change. In terms of the change management strategy, the phased demonstration/ test of scale/national scale up sequence provided opportunity for introducing a novel approach from the ground up, with increasing participation that started at facility level but quickly engaged leadership at district, regional and national level. Increasing appreciation of the value of the quality-improvement approach across the health system was driven by advocacy for the method that came from the frontline staff and managers who found it an increasingly effective way to achieve their goals, and transmitted their enthusiasm to DoH leadership. Another factor that drove improvement was the switch from incremental goal setting to bold 5-year national strategic plans that set aggressive, time-bound targets for reduction of national mother to child transmission rates, based on evidence for what was possible and supported by leaders who promoted a simplified, locally proven change strategy.

The relentless focus on real-time data that showed rapid improvement was a key factor in driving increasing levels of belief that the quality-improvement approach had something to offer that was better than the status quo. Significant policy support for improvements in national clinic-based data collection and reporting (including

addition of data reporting elements to the DHIS and new multilevel data dashboards) were key elements that facilitated the quality-improvement approach. Evaluation of the change in data performance over time suggested that the quality-improvement process itself could be a significant factor in improving the reliability of the data that were being collected and reported from the DHIS. Initial analysis showed that the PMTCT process data being reported on DHIS was highly unreliable. However, within 12 months of engagement in a quality-improvement initiative, these reported indicators showed major improvements in completeness and accuracy [26]. This was a crucial development since the quality-improvement approach relies so heavily on feedback of reliable data, and all PMTCT improvement projects described in this study used data from the DHIS.

Additional turning points for the acceptance of quality-improvement as a primary method for effecting rapid change was the design of the A-Plan for PMTCT that was conceived by the DoH in 2008. This policy change and leadership support provided legitimacy for the quality-improvement methods at a time when there was increasing interest in a rapid simple solution to the overwhelming burden of HIV infection that affected nearly a third of all pregnant women in South Africa. The A-Plan mandated a single methodology across the entire country that was based on local evidence of its successful effect [12]. The Plan engaged all nongovernmental and governmental implementing partners to use the same approach and the same small set of indicators to monitor improvements in the programme.

The quality-improvement methods and scale up design described in this study contributed to rapid improvement in outcomes for a population faced with a deadly disease, indicating that this approach can and should be used to rapidly implement complex multistep programmes on a national scale. The results achieved through national public health system programming were similar to those achieved under clinical trial conditions, a rare accomplishment. The perinatal PMTCT programme, implemented over the months-long course of each pregnancy, was facilitated by the preexisting schedule of antenatal visits and high rates of skilled delivery in South Africa. A system of PMTCT interventions was able to be grafted fairly easily onto this preexisting routine without much disruption or added burden. It remains to be seen whether the same result can be achieved for postnatal PMTCT in which the frequency and reliability of visits for infants declines significantly after the first few months of life.

Acknowledgements

Conflicts of interest

There are no conflicts of interest.

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