Using Quality Improvement to Address Healthcare Challenges in Developing Countries

By

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A Master’s Paper submitted to the faculty of the University of North Carolina at Chapel Hill in partial fulfillment of the requirements for the degree of Master of Public Health in the Public Health Leadership Program.

Chapel Hill

2008

Advisor:

Second Reader:

Date
Abstract

In recent years, the need for improved quality in healthcare has become increasingly clear. This paper demonstrates the specific need for improvement in developing countries and the applicability of quality improvement (QI) to this unique context. Developing countries are still searching for sustainable solutions to a variety of health crises. Inefficiencies in systems still diminish health outcomes and result in needless loss of life. In order to close the gap in performance and bring improved care to patients in the developing world, organizations must increasingly look to QI. QI has been applied in the United States to healthcare and public health settings as a means of identifying areas for improvement and establishing the infrastructure to implement changes. The same methodologies can be applied in developing countries as a sensible means of addressing their healthcare challenges, which are often attributed to system failures rather than lack of available treatments.

This paper clarifies how the Model for Improvement, developed by the Associates in Process Improvement, can be simply understood and utilized by QI teams in any context. The Model helps organizations identify what they wish to accomplish, how to identify when a change has resulted in improvement, and what changes can be made. A Plan, Do, Study, Act (PDSA) cycle allows organizations to decide how changes will be implemented and measured; implement the change; analyze the change and its effects; and determine how to move forward based on the results.

Project 20,000+ in KwaZulu-Natal (KZN), South Africa, offers a clear example of the applicability of QI and the Model for Improvement to healthcare systems in developing countries and can serve as a model for other organizations. This partnership between the KZN Department of Health, the University of KZN, and the Institute for Healthcare Improvement seeks to improve
the program for prevention of mother-to-child transmission (PMTCT) of HIV in the province. With prevalence estimated around 40% and MTCT rates of over 20%, the need for effective change is clear. The project relies on QI teams, guided by trained quality mentors and comprised of local administrators and providers, to identify and implement changes. Thus far, these teams have already seen improvements in delivery of care as well as collection and reporting of data. Though the impact of this partnership on rates of MTCT has yet to be measured, the improvement of intermediate measures warrants the modeling of other QI efforts after this project.

Developing countries present unique challenges, but this paper shows that the principles of QI are applicable in this setting. Project 20,000+ has shown that QI can empower providers and administrators and revitalize their commitment to creating positive change. In addition to the work in South Africa, examples from Ghana, Malawi, and Latin America demonstrate the value of QI for addressing a variety of healthcare challenges. Learning from these few examples, other organizations can better understand how QI methods provide the opportunity to generate sustainable improvement and reduce the burden of high morbidity and mortality in the developing world.
Introduction

In recent years, the need for improved quality in healthcare has become increasingly clear. In the United States and around the world, public health and healthcare professionals are recognizing the importance of raising the bar to ensure that patients are receiving care that is safe, effective, patient-centered, timely, efficient, and equitable.\(^1\) While medical technologies continue to bring new hope to those in need, healthcare systems still demonstrate considerable gaps in performance that limit the impact of these treatments. In the United States and other developed nations, these gaps include long waiting times, poor continuum of care, and a staggering number of medical errors.\(^1,2\) As these performance gaps are brought to light because of rising costs, patient dissatisfaction, and poor health outcomes, the healthcare industry is increasingly looking to the field of quality improvement to provide a means of achieving higher levels of performance.

In developing countries, where healthcare is often disjointed and resource-constrained, the challenges are greater and the stakes are even higher. Much of the world’s population continues to face high morbidity and mortality due to inadequate resources and poor delivery of care. In particular, sub-Saharan Africa suffers from an HIV/AIDS epidemic that has overwhelmed the healthcare system and devastated the lives of many people. As we seek to lessen the burden of disease in developing countries, we can apply lessons learned in the developed world to meet the growing challenges of healthcare in developing countries. These same quality improvement methodologies that are gaining rising levels of support amongst healthcare organizations in the United States can be applied in the context of developing countries to avoid repeating the same mistakes and to address the problems that are unique to developing countries. A growing number of organizations are using quality improvement to
tackle the complex health challenges of the developing world and provide sustainable solutions
and improved health outcomes.

The Evolution of Quality Improvement

Quality improvement (QI) emerged in the United States in the manufacturing industry as
a means to reduce wasteful inefficiencies and improve customer satisfaction. Early contributors
to QI, including Walter Shewhart, W. Edwards Deming, Armand F. Feigenbaum, and Joseph
Juran, defined quality beyond the notion of cost to include customer satisfaction and
achievement of performance standards. They designed methods and tools to help managers
develop and meet standards of quality in their systems. These quality leaders, along with others,
laid the groundwork for the QI efforts that have now extended beyond manufacturing into the
field of healthcare. These methodologies have been adopted in healthcare and public health in
the United States and are slowly being embraced by healthcare organizations in the developing
world. An understanding of these methodologies and their history clarifies how they can be used
to address healthcare delivery in a variety of contexts.

There are obvious distinctions between manufacturing and healthcare that must be
understood to successfully employ QI methodologies in the healthcare setting. For one,
manufacturing involves repetitive cycles with standardized inputs enabling high analyzability
and low worker discretion. Healthcare, on the other hand, involves nonstandardized and variable
inputs, unpredictable demands, and high worker discretion.³ Though quality from an industrial
perspective in some ways differs from quality from the healthcare perspective of quality, Avedis
Donabedian argued in the 1980s that the industrial model could help the professional healthcare
model understand “the need for greater attention to consumer requirements, values, and
expectations.” Also, the industrial model demonstrates the need for improved “design of systems
and processes,” which is also needed in healthcare. By examining the history of QI in the United States, an attempt can be made to identify linkages to current issues facing healthcare providers in the developing world. The key question remains, “How much of what has been learned about QI in the developed world can apply to the very different context of healthcare in developing countries?”

QI was introduced in several healthcare settings in the mid-1980s by key physicians, such as Paul Batalden at Hospital Corporation of America, Donald Berwick at Harvard Community Health Center, and Brent James at Intermountain Health System. Despite the early influence from physicians, the profession has been generally slow to act in adopting QI practices. In 1986, the National Demonstration Project on Quality Improvement in Health Care (NDP) was launched to explore the applicability of QI in healthcare settings. Born from the increased awareness of QI in healthcare and a greater appreciation of and will for change, the Institute for Healthcare Improvement (IHI) was founded in 1991. IHI has been central in building capacity for change through its educational and networking programs. Additionally, they have led the way with improvement efforts throughout the world and emphasis on exchange of knowledge. In 2000, the Institute of Medicine (IOM) published To Err is Human, which reported on medical errors in the United States and set a national agenda for reducing medical errors and improving patient safety. One year later, IOM introduced a second book, Crossing the Quality Chasm, which identified practices that impede quality medical care and offered principles and systems approaches for create change. These widely publicized works have been “the focal point” for quality efforts in healthcare by providers, institutions, payers, government programs, regulatory agencies, and many others. While the quality movement in healthcare is really just beginning,
these key actors have been instrumental in demonstrating the effectiveness of QI methods and have led the charge to achieve dramatic improvements in healthcare around the world.

**Understanding the Basics of Quality Improvement Methodologies**

Quality improvement aims to tackle problems within a system by identifying components of that system that can be changed to provide better outcomes or a more efficient process. Though logic can often be used to identify problems and solutions, QI employs methodologies that seek to “increase the chance that a change will actually result in sustained improvement from the viewpoint of those affected by the change.”

Because QI emphasizes lasting changes to systems, rather than quick-fix interventions, it is a reasonable approach to consider in addressing the health problems of developing countries.

In healthcare, the primary stakeholders are the patients, but can also include anyone else who has expectations about a given process or output. Most successful organizations that use QI methods rely on a mission, values, and objectives to guide their improvement efforts. Goals are used to provide direction and, along with performance measurement, evaluate whether performance is favorable or unfavorable to the organization. Once a mission, values, and objectives have been identified, multidisciplinary QI teams work to plan and implement a series of changes that are intended to raise performance levels. Changes are best implemented on a small scale, where the effects of the change can be evaluated with the use of data, and those changes which are successful can be fully integrated into the system. QI utilizes methods that guide the implementation of changes to increase the likelihood that they are accepted and sustained. Though the introduction of changes can be met with both internal and external resistance, the QI methods described in this paper and elsewhere can help minimize the risk and enhance the results.
Involvement of Stakeholders

Understanding the expectations of key stakeholders is an important component of any QI project. Though many healthcare professionals are reluctant to use the term “customer,” it is an appropriate title for anyone who is affected by a particular process or outcome. Internal customers are those within the organization, such as healthcare providers or hospital administrators, while external customers are those people from outside the organization who receive services or products from the organization. The most obvious external customer is the patient. Other external customers may be the patient’s family, payers, and regulatory bodies. Though the health outcomes of the patient are generally the obvious focus, QI efforts often greatly impact healthcare providers, a group of internal customers, by providing a force for motivation and empowerment that can lead to reduced costs and increased efficiency in the long run. In the context of the developing world, where providers often feel overwhelmed by high volumes of patients and limited resources, this sense of motivation and empowerment is crucial to achieving long-term gains.

Once stakeholders have been identified, their expectations should guide the delivery of services and improvement of processes and outputs. The acceptability of any given performance indicator should be measured against these expectations. The requirements of customers and process design must be continually evaluated, and, if processes are not aligned with stakeholder requirements, the process must be improved. Though all stakeholder groups may not be directly involved in the improvement process, consideration of their expectations will increase the likelihood that changes will be accepted by these groups. In developing countries, where organizations sometimes act in silos with little coordination between key parties, this inclusion of
stakeholder interests can enable formation of partnerships which increase the likelihood of success and sustainability.

Quality Improvement Teams

Improvement teams are the primary agents of change who are responsible for identifying gaps in performance, analyzing the causes, implementing solutions, and evaluating the results. Teams must include individuals who understand the problem at hand and are familiar with the associated processes. For this reason, improvement teams in healthcare often include more staff than managers. When identifying and proposing solutions, it is crucial to include the people who will be responsible for implementing changes so that they understand the quality improvement strategy and can identify potential barriers to successful implementation of changes. Because it is not feasible to include all affected persons on the improvement team, the team must create a mechanism for obtaining input from others so that these perspectives and pieces of information can be considered. Inclusion of affected groups allows for greater consideration of concerns and interests and will foster enhanced cooperation and creativity in identifying solutions.

One of the best ways to engage these groups is to empower representative members to participate in the process of problem identification and problem solving. This empowerment through improvement teams generates a greater commitment to the organization and ownership of the proposed changes but can only be sustained if improvement team members have a clear understanding of their goals and authority. The degree of authority held by an improvement team varies widely between organizations and must be clarified at the onset of an improvement effort. Teams that think they have the authority to make changes but then discover that they can only make recommendations are likely to feel disheartened or disappointed if their efforts do not lead to actions.
Model for Improvement

Improvement team members must be committed to learning QI methodologies and applying them in their own organization. While there are numerous improvement methodologies, the Model for Improvement is a structure that is widely used in a number of contexts and can be easily learned and utilized. Developed in 1993 by Associates in Process Improvement, the Model consists of three fundamental questions as well as a rapid change or Plan, Do, Study, Act (PDSA) cycle.

The first question asks, “What are we trying to accomplish?” It is recommended that improvement efforts start with a project charter to outline the aim of the project and allow for review by stakeholders. The charter should offer a general explanation of what the project hopes to accomplish, why improvement is needed, suggestions for measures, aspects of the system where attention should be focused, and recommendations for possible changes. The people involved in the project should also create goals, often with numeral targets to outline expectations. These goals, along with measurement, are necessary to gauge performance, and should be clearly stated so that project members can evaluate whether they are being met. The creation of a project charter and clear goals communicates the importance of implementing changes that will alter the current system and result in improvements.

The second question in the Model for Improvement is, “How will we know that a change is an improvement?” In simple systems, it is sometimes clear through observation, but in complex systems, the use of measurement and data is almost always required to evaluate whether a change is an improvement. The selected measures should reflect the interests of the customers, both internal and external, and should be balanced to ensure that the whole system, not just some aspects, is improved. When available, data that measures performance prior to the change can
be compared with data after the change to determine if the change can be labeled an improvement.⁹

In some instances, it takes a long time to obtain the data needed to measure the impact of a change. For example, a clinic that seeks to reduce the occurrence of heart disease amongst their patients may not know for years which patients will develop the disease. When this happens, teams can select intermediate measures that are related to the global measure. In the heart disease case, intermediate measures might include percentage of patients with high cholesterol levels or percentage of patients who are smokers. Though it will take time to determine if the occurrence of heart disease is reduced, these intermediate measures can be obtained at the time of care. Improvement in intermediate measures indicates progress but is not sufficient to ensure that the project aim is accomplished. Additionally, process measures can be used to determine if a PDSA cycle was carried out as planned.⁵ For example, in the clinic, what percentage of smoking patients were given information about smoking cessation. Global, intermediate, and process measures are all needed to steer learning and action and are an essential component of an improvement project.

The next step in the Model is to ask, “What changes can we make that will result in improvement?” When identifying possible changes, it is important to consider what would be desirable to their stakeholders and to plan how the change will be executed.³ A list of change concepts, which are general approaches that can help generate ideas for changes, is available from the Institute for Healthcare Improvement (see Appendix).¹⁰ The Plan phase of the PDSA is critical to the success of the cycle. A good plan starts with a statement of the specific objective of the cycle which varies depending on the “degree of belief.” Possible objectives might be “to increase the degree of belief that the change will result in an improvement” or “to evaluate how
much improvement can be expected if the change is made.” The plan should also include details about how the change will be implemented (who, what, where), how the change will be measured, and predictions about the change. Though there will always be unforeseen challenges, investment of time and resources in planning enables greater learning from the cycle.

The next step, of course, is to implement the change or “Do.” This involves carrying out the plan that was already created and collecting data to keep track of the change. In most instances, it is best to implement the change on a small scale, learning from the test cycle and evaluating whether to introduce the change in a broader context. During this phase, it is important to document problems or unanticipated outcomes associated with the change. The unforeseen consequences of any change are important to consider when determining whether a change should be implemented on a larger scale. In this phase, teams can also begin to analyze their data.

The Study phase involves further analysis of collected data and building knowledge that will help teams predict whether a change will result in improvement when extended to a larger scale. By comparing test data to predictions made in the change plan and to data before the change was made, teams can begin to understand how they should move forward with a given change. A number of QI tools, such as control charts and run charts, can be helpful in conducting data analysis. Like the Plan phase, the Study phase is not one to rush through. It is imperative that teams study their data carefully before moving on to the Act phase. In the Act phase of the PDSA cycle, a change is adopted, adapted, or abandoned. Changes are not often adopted after one PDSA cycle. After testing on a small scale, a change can be run through additional PDSAs to sequentially build on existing knowledge. Multiple cycles can clarify whether a change should be increased in scope, altered, or tested under different conditions. In
some cases, changes may be abandoned, and teams will move on to test a new change through PDSAs. As teams gain more knowledge about a given change, they can be increasingly confident in increasing the scale and eventually implementing on a broader scale.

Implementing a change involves permanently altering the way work is done and incorporating the change into the day-to-day operations of the organization. Because many changes involve people, implementation on a larger scale is often accompanied by increased resistance. For simple changes within small systems, the “Just do it” approach can be used. When changes are more complex and systems are larger, the parallel approach, which implements a change while the old system is still in place, or the sequential approach, which gradually increases the completeness and coverage of the change, can reduce the negative impact of the change. Once improvements are implemented, organizations must take action to ensure that the gains are maintained. Standardization, which involves creation of specific policies and practices that guide a process, is one step to help sustain improvement. The established standards should be well documented, utilized by employees, included in employee training, and regularly updated and changed if new knowledge arises. Continued measurement also offers a means of maintenance after implementation and will help an organization determine whether the desired results are being achieved and can be expected in the future. Once a change is implemented, it can be spread to other areas of the organization or to areas outside the organization. Building on lessons learned during implementation, such as infrastructure issues and resistance from staff, other units can adopt the change. This often involves further PDSAs to adapt the change to the circumstances of the context but requires less development because of the lessons learned in previous PDSAs.
The Model for Improvement, while comprised of several important components, is a simple quality improvement methodology that can be easily understood and utilized by members of an improvement team. Its applicability in both clinical and administrative contexts enables its effective use in the healthcare setting and its transferability to the contexts of developing countries. Once an organization has identified its improvement aim, a set of balanced measures, and potential changes, the PDSA cycle guides teams through planning, testing, and implementing changes. The continual nature of the Model for Improvement provides a means for ongoing evaluation and adjustment to ensure that improvement is sustained and practices are relevant and beneficial to the organization. As the health challenges in developing countries continually evolve, this methodology provides a reasonable approach for implementing change and driving improvement in health.

Implementation of Quality Improvement in a Developing Country – Lessons Learned from South Africa

*QI in the Developing World*

The principles and methodologies of QI lay the groundwork for the larger paradigm shift that must drive improvement efforts. Before an organization can successfully implement changes and experience improved results, they must create a culture that is dedicated to such efforts. The context of the developing world is ripe for this type of work. The seriousness of the healthcare challenges in developing countries, coupled with growing local, national, and international support, provides a body of committed individuals to enact necessary changes and provide sustainable solutions. While a multitude of organizations seek to better the lives of people in developing countries through better access to needed treatments and higher standards of care, they often lack the tools needed to implement solutions that are cost-effective and sustainable.
Few organizations exist that are doing QI work in developing countries. There are alternative interventions that undoubtedly require less involvement from local providers and rely on outside funding sources rather than the limited coffers of local health departments. But the solutions generated from QI offer support from key stakeholders and equip local providers and administrators with skills that can be applied in a multitude of contexts. This approach leaves a sustainable impact on the healthcare systems that will ultimately result in improved health for these communities and greater leadership from within their own organizations. The work of Project 20,000+ in South Africa provides a unique example of how U.S.-based organizations can effectively partner with local bodies to provide QI training. This project demonstrates how QI can be applied successfully in a developing country and result in improved healthcare systems and patient outcomes.

Health Environment in South Africa

HIV has taken a devastating toll on the people of South Africa. Prevalence of HIV amongst adults is estimated to be 15-49%, and almost 6 million people in South Africa were living with HIV in 2007. According to 2008 estimates by the World Health Organization (WHO), about 60% of pregnant women living with HIV in South Africa received antiretrovirals for prevention of mother-to-child transmission (PMTCT).\textsuperscript{13} Despite the roll-out of PMTCT programs throughout the country, HIV/AIDS remains the leading cause of death among young children and accounts for 40-60% of all childhood mortality in South Africa.\textsuperscript{14} While Europe and the United States have reduced mother-to-child transmission rates to less than 2%, through active screening and identification of HIV-positive women in antenatal clinics, early initiation of highly active antiretroviral treatment (HAART) during pregnancy, delivery of infants by caesarean section, and avoidance of all breastmilk, transmission rates in South Africa remain near 20%.
Although most South African provinces cannot expect to achieve the results seen in developed nations, due to limitations in PMTCT protocols, unnecessary and unacceptable gaps in performance remain (Project KZN 20,000+, unpublished data, 2008). Transmission rates in the absence of any intervention are estimated at 25%, demonstrating that the efforts to reduce HIV infection in children in South Africa through PMTCT programs are hardly having any impact.

Introduction to Project 20,000+

KwaZulu-Natal (KZN) has the highest HIV prevalence of all South African provinces. According to a 2005 survey, 40.7% of pregnant women attending antenatal clinics tested HIV-positive (Project KZN 20,000+, unpublished data, 2008). Based on this prevalence, it is estimated that effective health care delivery design and provision of dual therapy (zidovudine and single-dose nevirapine) could prevent at least 20,000 new infections amongst infants each year in KZN. Such interventions have already proven successful in the Western Cape where MTCT rates are below 8%. While the South African government has begun to support PMTCT programs in its hospitals and clinics, there is much need for improvement in order to achieve the intended gains and save thousands of lives by preventing HIV infection among infants.

Recognizing the need to improve PMTCT programs in KZN, in August 2006, the Department of Health (DoH) called for a multidisciplinary team to develop a plan for improving the quality of PMTCT services. The team consisted of academics from the University of KwaZulu-Natal (UKZN) in the fields of pediatrics, obstetrics and gynecology, health economics, HIV/AIDS research, and rural and community health, along with representatives from each of the eleven districts in KZN. Under the leadership of Dr. Nigel Rollins, a Professor of Maternal and Child Health in the Department of Pediatrics, the DoH and UKZN began the project now known as 20,000+, in reference to the number of HIV infections that the project aims to prevent.
in KZN each year. Project 20,000+ partnered with the Institute for Healthcare Improvement for their expertise in health systems design and measurement. The project has started with three of the eleven districts in KZN and then will spread to the remaining eight districts when best practices and lessons have been learned. These districts—Ugu, Ethekwini, and Umgungundlovu—contain more than half of the entire KZN population and have high antenatal HIV prevalence rates (Project KZN 20,000+, unpublished data, 2008).

Project leaders recognize the challenges posed by human and physical resource limitations, but also note “the widespread failure to reliably deliver the sequence of simple processes of care.” Project 20,000+ focuses on working within existing resource allocations to improve the PMTCT system and implement appropriate protocols for HIV-positive mothers and their infants in KZN. As shown in the figure, there are many steps in the process of PMTCT care, and each step serves as an area of potential failure. It is breakdown in these areas which the project seeks to improve. The three primary objectives are to: increase the number of pregnant women who know their HIV status; identify women in need of lifelong HAART through CD4 testing and provide fast and efficient HAART initiation; and provide at least dual drug prophylaxis for HIV-positive pregnant women.

**Figure.** Process of PMTCT Care in KwaZulu-Natal, South Africa
Strategies and Structure of 20,000+

Project 20,000+ includes key stakeholders in both the design of the project and the implementation of changes to the PMTCT system. Engagement of leadership at the provincial, district, and municipal levels, through regular meetings and feedback of data, has helped generate necessary support and enthusiasm for the project. The project builds on existing health system structures by intervening with leaders who are already engaged with clinical sites. Throughout South Africa, publicly-provided healthcare is offered in Primary Health Care (PHC) clinics, Community Health Care (CHC) clinics, and hospitals. 20,000+ provides training in improvement methods to administrators and clinical staff at these sites to enable them to implement changes to their own system. This training is given by a team of quality mentors, comprised of former healthcare providers who work with and are trained by a full-time project manager from IHI in QI methods, including system analysis, process and outcome measurement, and data analysis. Many of the quality mentors have strong relationships within the healthcare community as a result of their clinical experience in the province, which helps gain greater buy-in from administrators and providers.

Quality mentors work with PHC supervisors, who oversee four to ten clinics, to identify areas for improvement in the PMTCT program within their network of sites. Each month, the supervisors in each district meet to share information about successful interventions and receive further training in QI methods. With almost 300 sites in the three districts, the PHC supervisors offer a means of rapidly reaching a larger network of facilities to provide needed improvements. Sometimes PHC supervisors may form a multidisciplinary improvement team within a particular facility to focus efforts and drive change. Quality mentors also form improvement teams at CHC clinics and hospitals. Like the teams in the PHC clinics, these teams are often comprised of
nursing staff, an HIV counselor, and a facility manager, who can identify areas for improvement, generate ideas, and implement changes. Quality mentors provide assistance with data collection and help ensure that each site properly reports PMTCT measures as required by the district.

Use of QI to Improve PMTCT Programs

Like many treatment of many infectious diseases, PMTCT requires adherence to a sequence of protocols in order to achieve its aim—in this case, prevention of HIV infection in infants born to HIV-positive mothers. As stated previously, it has been shown that transmission rates can be lower than 8% with dual therapy for the mother and the infant if all processes of PMTCT care are carried out. Due to the multiplicity of required steps, essential components are often missed, and the PMTCT program frequently fails to prevent infection of the newborn. Though the protocols are clinically simple, they are systematically complex. With 20,000+, improvement teams and quality mentors seek to identify which aspects of the system are failing and simplify processes.

At Wentworth Hospital, the improvement team noted that women often failed to return to the antenatal clinic (ANC) for a CD4 count after learning that they tested positive for HIV. All other needed antenatal care for the first visit had been provided, so they frequently left the clinic despite being told about the CD4 test. Failure to have a CD4 count resulted in inability to start therapy, which has serious implications for the health of the mother as well as transmission to the infant. The team made the simple decision to conduct the HIV counseling and testing for all pregnant women on their first visit to the ANC prior to drawing any routine bloods. Because most women recognized the importance of this routine blood work, though they did not understand the importance of the CD4 test, they were much more likely to stay and receive all needed tests. The change was tested for one week, and, after considerable improvement in the
number of CD4 tests, was implemented on full-scale. Though this change was very simple, moving HIV testing and counseling to the beginning of the visit has dramatically improved PMTCT program delivery at Wentworth. The formation of the improvement team and the guidance of the quality mentors has challenged the staff at Wentworth to examine gaps in their system and empowered them to implement mechanisms for improvement in a way that they had never done before.

Phoenix CHC also was able to overcome a major problem by implementing a simple solution in their labor ward. The improvement team noted that the status of HIV-positive women was often not identified until after delivery, when it was too late to start NVP and AZT. Though the majority of these women had been tested during their antenatal care and had results documented in their record, the labor ward staff often was unaware. It was discovered that HIV status and PMTCT care were being recorded in a book that was separate from the book used to document all other patient information in the labor ward. The PMTCT book was kept in a drawer in the nurse supervisor’s office, and, as a result, the nursing staff rarely used it. Members of the improvement team, led by a junior member of the labor ward staff, added three columns to the main labor ward book: HIV status, NVP given, and AZT given. This book, which was already regularly used by all members of the staff, would now enable nurses to identify HIV-positive women and determine whether appropriate treatment had been administered to mother and baby. The other PMTCT book was moved to a central location in the labor ward and was used to document detailed information about PMTCT care. In this instance, we again see the impact of simple interventions to empower staff members and improve care for patients.

There are numerous examples of how the 20,000+ partnership has helped administrators and providers work together to identify areas of change. Some of the other implemented changes
aim to improve data collection, ensure adherence to medications, reduce the waiting time for test results, improve the integrity of data reported to the DoH, and track the care of patients over time. The applicability of QI methods to the PMTCT program in South Africa has become clear through 20,000+ and the interventions carried out in KZN. The types of improvements, which aim to increase efficiency and improve care, can be translated into numerous other disease identification and treatment programs. They are particularly useful for diseases, such as HIV and tuberculosis, which require a continuum of care in order to adequately treat the disease.

*Importance of Measurement and Quality Data*

Complete and accurate data is important for any improvement effort. While some healthcare settings in the developed world have complex systems to capture and report data, facilities in developing countries typically rely on manual recording and reporting of data. Early in the 20,000+ partnership, the need to improve the completeness and accuracy of this data for PMTCT became clear. A separate research study, which evaluates rates of MTCT in the province, will ultimately determine whether 20,000+ has been a success. There are a number of process measures, however, that can be used by the quality mentors and the improvement teams to monitor the impact of the changes they have put in place. Each month, the province requires every facility with a PMTCT program to report on several process measures, which are shown in the table. Every item addresses one of the components of the PMTCT protocol. The 20,000+ team has been given access to the provincial database so that team members can use this data to identify gaps in performance and measure improvement. For example, review of the data may reveal that only a third of the women who tested positive were started on appropriate therapies. The team could then work to determine why this gap in performance occurred and where to focus improvement efforts.
Table. KwaZulu-Natal PMTCT Monthly Summary Measures

<table>
<thead>
<tr>
<th>Program</th>
<th>Measure Reported</th>
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<tbody>
<tr>
<td>Antenatal Clinic</td>
<td>ANC first time visits</td>
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<tr>
<td></td>
<td>ANC clients tested for HIV</td>
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<td></td>
<td>ANC clients tested positive for HIV</td>
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<td></td>
<td>Women on HAART</td>
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<td></td>
<td>Woman issued NVP at ANC</td>
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<td>Women issued AZT at ANC</td>
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<td></td>
<td>Women with WHO Clinical Stage 4</td>
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<td></td>
<td>CD4 tests for pregnant women</td>
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<td></td>
<td>CD4 turn around time &lt; 6 days</td>
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<td></td>
<td>CD4 turn around time &gt; 6 days</td>
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<tr>
<td></td>
<td>CD4 results &lt; 200</td>
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<tr>
<td></td>
<td>CD4 results &gt; 200</td>
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<tr>
<td>Labor Ward</td>
<td>NVP taken at onset of labor</td>
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<tr>
<td></td>
<td>AZT taken at onset of labor</td>
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<td></td>
<td>AZT issued three hourly in labor</td>
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<td></td>
<td>Number of women on AZT &gt; 4 weeks</td>
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<tr>
<td></td>
<td>Number of women on AZT &lt; 4 weeks</td>
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<td></td>
<td>Live births to women with HIV</td>
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<td></td>
<td>NVP dose to baby born to woman with HIV</td>
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<td></td>
<td>HIV positive mothers - breastfeeding on discharge</td>
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<td></td>
<td>HIV positive mothers - formula feeding on discharge</td>
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<td></td>
<td>Mothers that are part of the dual therapy program</td>
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<td></td>
<td>Number of infants given NVP</td>
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<tr>
<td>Baby</td>
<td>Number of infants given AZT for 7 days</td>
</tr>
<tr>
<td></td>
<td>Number of infants given AZT for 28 days</td>
</tr>
<tr>
<td></td>
<td>PCR test of baby born to HIV positive woman at 6 weeks or later</td>
</tr>
<tr>
<td></td>
<td>PCR test positive of baby born to HIV positive woman at 6 weeks or later</td>
</tr>
<tr>
<td></td>
<td>HIV test of baby born to HIV positive woman at 9 months or later</td>
</tr>
<tr>
<td></td>
<td>HIV test positive of baby born to HIV positive woman at 9 months or later</td>
</tr>
<tr>
<td></td>
<td>Rapid test at 18 months or older</td>
</tr>
<tr>
<td></td>
<td>Confirmatory HIV tests done - baby</td>
</tr>
</tbody>
</table>

After review of monthly summaries for a number of facilities, it was quickly noted that many facilities fail to provide complete information to the province each month. Also, a review of the on-site records showed that these numbers did not always agree with what was reported to the province. For this reason, quality mentors were challenged to expand their scope to examine not only gaps in clinical performance but also ways in which data collection and reporting could be improved. One simple change that showed considerable impact was to have two people, one
clinical and one administrative, work on the monthly summary together. Often, a clerk who had limited knowledge of the clinical processes about which she was reporting was responsible for completing the summary. By partnering with a member of the clinical staff, the reports became more complete and more accurate. Additionally, many facilities had no existing mechanism for data collection. Though the province provided registers on which they were asked to record PMTCT information, staff members often found these to be difficult to understand. The improvement teams worked with quality mentors to develop their own tools for collecting data, so that they were able to complete the summaries at the end of each month.

Members of the nursing staff in KZN often perceive data collection and reporting as a useless task that further complicates their already hectic schedules. In many contexts, clinics and hospitals are required to report countless statistics to the provincial DoH and never receive any feedback about their data. Project 20,000+ has recognized the need to train staff about the importance of measurement in order to encourage their completion of required statistics. Quality mentors, through short training activities during improvement meetings, have taught team members how to use data to inform their improvement efforts. Short exercises called “Data for Learning” require that team members and quality members collect data prior to the session. This data is then used to calculate performance measures that can highlight areas of needed change. One such example looked at the percentage of pregnant women who were HIV tested at their first ANC visit. A nurse from the ANC looked at the records and recorded the number of first-time visitors in a three-day span from the previous week and the number of women tested during that same time period. At the meeting, the quality mentor showed the team how these two values could be used to compute the desired performance measure.
When the data revealed that fewer than half of the first-time visitors were tested, members of the team argued that the numbers must have been wrong; they were certain that every woman who visits the clinic is tested for HIV. Upon closer examination, they realized that the counselor often did not record all women in the register. They also remembered that the counselor was in another part of the hospital on one of those days, so no tests were given. By examining a small piece of data during a recent and short time span, the members of the team not only gained better understanding of the importance of accurate and complete data, but also were able to identify areas for changes that may improve their performance. Exercises such as “Data for Learning” can be applied in any improvement setting and are particularly important in the context of developing countries where staff may be less familiar with the use of data. The 20,000+ team continues to work with staff from each facility on improving data so that changes can be accurately and completely measured and the overall success of the project can be evaluated.

The project also provides a means for facilities to compare data and shared learning through peer-to-peer learning networks. By sharing successful ideas and developing a culture of support, these collaboratives can accelerate change. Small teams from each healthcare site are brought together every six months to set aims, identify challenges and solutions, and learn how to map processes, test changes, and collect data to track improvement. High performing sites share their experiences and strategies so that struggling sites can learn ways to improve. This collaboration relies on accurate and complete data to measure performance and demonstrate the effectiveness of implemented changes.
Ongoing Challenges Posed by QI Work in KwaZulu-Natal

Improvement work is replete with challenges that require unique solutions in order to achieve the intended gains. Similarly, work in developing countries can present challenges that are functions of distinct cultures, infrastructures, resources, and policies. It is no surprise that those who pursue improvement work in a developing country will face barriers of all kinds. While the QI methodologies include previously-discussed mechanisms for approaching obstacles and overcoming challenges, there are some issues that remain unresolved.

One of the great challenges of the PMTCT program in South Africa is the tendency of many patients to concurrently seek care in multiple facilities. A woman may go to the nearest PHC clinic for her first antenatal visit, but then go to the hospital for subsequent visits and delivery. Because HIV-positive individuals, particularly pregnant women, require continuity of care, this utilization of multiple healthcare facilities can compromise care if not managed properly. The KZN DoH is aware of this common behavior, and therefore requires that all antenatal records are patient held. At her first ANC visit, a woman receives a folder that will house all medical records throughout her pregnancy. Though efforts by the province to standardized record keeping are underway, it can sometimes be difficult for nursing staff to determine what care has been provided to the patient in other facilities. This issue is complicated by the fact that many HIV-positive patients fear the stigma that remains in South African society and do not want any records pertaining to HIV care to be kept in their folder. Additionally, the province requires that labor wards store all patient folders after a woman delivers, so there is no complete history of previous pregnancies in that can be retained by the patient and shared with providers. As a result, providers are at the mercy of their patients to disclose a complete history of their HIV status and treatment as well as other medical information. The partnership between
the 20,000+ team and the DoH has enabled team members to express these concerns to DoH administrators and begin to work towards improvement in these areas.

The most common challenge cited by quality mentors is general resistance to participation by both administrators and clinical providers. The quality mentors rely on these staff members to carry out the QI work and have often experienced avoidance or reluctance to meet. In settings both at home and abroad, healthcare workers often feel overburdened and underappreciated and see little reason to take on what is perceived as additional work. The 20,000+ team has support from the KZN DoH which sometimes enables quality mentors to engage administrators when people fail to show up for meetings or do not carry out expected tasks. The most reasonable approach, however, has been to focus on the “early adopters” and hope that their success will show the way for those who may have been initially resistant.

The early adopters recognize that 20,000+ aims to create more efficient work and not more work. Because the quality mentors have limited time and numerous facilities to cover, their ability to work with those who are most interested still allows them to have great impact. Though some may argue that working only with early adopters inflates the success of the project, the magnitude of the crisis in South Africa and the need for immediate solutions warrants the continued involvement with these groups. Over time, however, it will be necessary for all facilities to participate in the project. Opportunities for shared learning amongst providers and administrators are expected to demonstrate dramatic results from the early adopters and will make it unreasonable and irresponsible for other facilities to not adopt these strategies.

As is also true in developed countries, issues surrounding limited human and physical resources continue to provide opportunities for health systems to accept the status quo. “If only we had more staff,” “if only we had more space,” and “if only we had more money” remain
common excuses for complacency. Within most healthcare systems in developing countries, substantive increases in resource allocations cannot be relied upon. In KZN, even the availability of better HIV therapies would not lead to improved outcomes because of the poor system design and delivery of care. In this case, and likely many others, system improvements rather than increased availability of resources will narrow gaps in performance and provide better outcomes.

While an initial investment of resources for QI training and project support are required for any improvement project, changes are intended to work within existing resource limitations. These “start up” costs are required for any intervention and are generally provided by outside funding sources rather than the healthcare system itself. As is the case with the PMTCT program in KZN, the resources (e.g. staff, drugs, facilities) needed for adequate PMTCT delivery are already present, but the system design hinders a higher level of performance. Though organizations and individuals may initially look to increases in resource allocations to drive improvement, QI offers a means to generate positive change without the need for additional resources.

*Training for Sustainability*

One of the great challenges of work in developing countries can be the resistance of providers and administrators to yet another intervention or initiative. Many people have been abused by researchers who offer short-term interventions, study their effect, and then move on without leaving any lasting impact. Project 20,000+ differs from these interventions in that it equips local staff with the skills that they need to do the improvement work themselves. Using flow charts, cause and effect diagrams, and check sheets, the improvement teams identify flaws and implement solutions.
Advocates for application of QI to public health in the United States in the 1990s pointed to similar advantages of QI methodologies in response to resistance in their field. They were able to demonstrate the value of collective responsibility and broad participation of QI activities. These leaders challenged interdisciplinary work groups to take ownership of processes and accept responsibility for improvement. They found that participants were eager to draw on their own knowledge and use their creative energy to revitalize a commitment to higher standards. Staff members were given capacity to self-monitor, detect problems, and devise solutions in unprecedented ways.\textsuperscript{15,16}

In South Africa, 20,000+ has ignited a sense of enthusiasm and dedication with regard to PMTCT throughout the province. Many of the people in this nurse-led system have never been empowered to make changes to the system in which they work everyday. Low morale and lack of ownership are often cited as obstacles to health system interventions in developing countries, and this partnership has helped counter these barriers by offering tools for improvement and the ability to change the system. By working with DoH administrators to ensure that staff in each facility have the authority to both generate and implement ideas for change, clinical and administrative staff have found themselves in the unusual position of being able to alter their environment and dramatically improve the care that they provide. In doing so, 20,000+ will lead to a sustainable culture of improvement that is led by the people who are most familiar with and committed to the PMTCT program.

**Looking Forward - The Role of Quality Improvement in Reducing the Burden of Disease in Developing Countries**

The use of QI to improve systems and processes has particular relevance for developing countries where many of the major health problems, such as malaria and tuberculosis, are
diseases with known cures. Even HIV/AIDS can be combated with drugs that reduce morbidity and extend life longer than ever before. In these instances, it is often poor healthcare system design and inadequate delivery of care, not lack of known treatments, which result in a high burden of disease. Even with considerable resource limitations, healthcare systems can use QI to improve performance and efficiency and provide better care to those in need.

While the number of organizations conducting QI work in developing countries is limited, there are examples of successful programs throughout the world. A project in Ghana was initiated in 2001 to improve the quality of primary health care delivery and management. Faced with multiple complex problems, including staff dissatisfaction and poor health system management, application of QI methodologies have provided an appropriate means of addressing issues around access and quality. Although not a developing country, a QI project conducted in an impoverished region of Russia by a U.S.-based organization, University Research Company, used collaborative learning sessions to link several clinics and foster improvement. These clinics saw a “sevenfold increase in the management of hypertension in primary care” and “a 60 percent reduction in hospitalization for hypertension.” USAID-funded projects launched in 2005 in Rwanda, Ecuador, Honduras, and Nicaragua have demonstrated the feasibility and affordability of using information technology to foster collaboration amongst facility-based QI teams. In addition to the work around PMTCT in KwaZulu-Natal, the Institute for Healthcare Improvement also conducts other HIV work in the Western Cape, Eastern Cape, Gauteng, North West provinces which address pediatric and adult HIV. Their work in Malawi, which began in 2006, aims to reduce maternal and neonatal death through partnership with three other organizations in The Health Foundation Consortium.
Although it is critical that QI projects are tailored to the individual context and problems, the increasing number of organizations that are successfully implementing QI projects throughout the developing world and in resource-constrained settings lends credence to the acceptability of these approaches and the applicability of Western methodologies to improve healthcare in other parts of the world. While efforts to develop improved technologies and better drugs are undoubtedly worthwhile, considerable gains could be achieved if more organizations would use QI to alter systems so that existing medical technologies could be utilized to their full potential. As seen with PMTCT programs in KwaZulu-Natal, South Africa, and throughout the world, deficiencies in systems rather deficiencies in science often restrict provision of care and result in the needless loss of life. As more organizations utilize QI, publication and other mechanisms of sharing knowledge will be instrumental in further spreading the application of QI to improve healthcare systems and save lives in developing countries.
Appendix A – Change Concepts

The change concepts included here were developed by Associates in Process Improvement. A complete list of change concepts can be found in *The Improvement Guide* (Langley GJ, Nolan KM, Nolan TW, Norman CL, Provost LP. San Francisco, California, USA: Jossey-Bass Publishers, Inc.; 1996).

A. Eliminate Waste
B. Improve Work Flow
C. Optimize Inventory
D. Change the Work Environment
E. Enhance the Producer/Consumer Relationship
F. Manage Time
G. Manage Variation
H. Design Systems to Avoid Mistakes
I. Focus on the Product or Service
Appendix B – PMTCT Protocols in KZN

In each clinic or labor ward, the following processes should occur:

1) Mothers are tested for HIV during their first antenatal clinic (ANC) visit.
2) HIV status is recorded in patient-held chart.
3) HIV-positive mothers receive a CD4 test.
4) HIV-positive mothers receive a CD4 test result which is recorded in their chart.
5) HIV-positive mothers with CD4<200 complete required adherence counseling and are started on HAART (to be continued lifelong).
6) HIV-positive mothers with CD4>200 receive single-dose nevirapine (NVP) by 30 weeks to be taken at onset of labor.
7) HIV-positive mothers with CD4>200 begin taking AZT starting at 28 weeks.
8) HIV-positive mothers with CD4>200 take NVP at onset of labor.
9) HIV-positive mothers with CD4>200 are given AZT 3-hourly during labor.
10) Infants of HIV-positive mothers take AZT for 1 or 4 weeks (depending on when mother started AZT) after birth.
11) Infants of HIV-positive mothers take NVP within 24 hours of birth.
12) Infants of HIV-positive mothers are tested for HIV at 6 week immunization visit.


11. Institute for Healthcare Improvement: Implementing Changes.

12. Institute for Healthcare Improvement: Spreading Changes.


