

Ensuring quality of care in the scale-up of HIV care and treatment in resource-limited settings: a challenge for all

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Work to expand access to HIV care and treatment in resource-limited settings has been focused on reaching as many people living with HIV in as short a time as possible. As these programs mature and treatment continues to expand, there is a growing need to better understand how care is being delivered and where efforts need to be made to ensure that quality and effective services are being delivered. While there has been considerable work on measuring and improving the quality of HIV care in resource-rich settings, efforts have been much more limited in more resource-constrained settings. This article will present an argument for the need to expand and strengthen both work to measure and to improve quality. In addition, a case will be made that research and rigorous evaluation need to be integrated into this work to more rapidly and fully understand factors associated with gaps in quality, which models of care are more effective in delivering this care and the impact of quality improvement efforts as implemented and replicated. This collaboration between the different disciplines and stake holders, including research, quality management, care providers, people living with HIV, national programs and international funders, will help ensure that the scale-up efforts result in provision of quality and effective HIV care and treatment.

The work to expand HIV care and treatment, including life-saving antiretroviral therapy (ART) in resource-limited settings, has involved a wide range of partners focused on reaching the maximum number of people living with HIV in the shortest time possible. These efforts have seen a dramatic expansion in the number of people eligible being started on ART, as well as prophylaxis for prevention of mother-to-child transmission (PMTCT). The need to continue to expand access to care and treatment is particularly urgent in sub-Saharan Africa, where a substantial unmet need for treatment remains despite these national and international efforts [1]. At the same time, the need to ensure the quality of services provided is critical to improve program efficacy, improve the chance of long-term success with treatment, decrease the risk of drug resistance and promote optimal use of existing resources including personnel and drugs.

At the beginning of ART scale-up efforts, most programs focused on serving those in most urgent need and developing innovative efforts to expand capacity and numbers entering care. Success was measured more commonly by numbers in care and on treatment than on quality, consistency and outcomes of care [101,102]. As HIV care and treatment programs mature and the number of patients in care and on ART continues to

grow, increasing attention is being turned to measuring and ensuring quality and effectiveness of care [2–6]. This growing movement to broaden scale-up efforts to include systems to measure and improve quality will be critical to ensuring long-term success and sustainability.

However, efforts to promote quality of care in the context of ART scale-up need to address six important areas, many of which are still in the early stages of development in many resource-limited settings. These are:

- To define quality of care in the setting
- To know if quality care is being delivered (measuring quality)
- To understand factors contributing to identified gaps in quality
- To improve quality
- To understand what worked to improve quality and why
- To identify what models and interventions provide and improve quality of care and which can and should be replicated

A number of programs have begun to work towards incorporating these six tasks as they work to expand and strengthen HIV care and treatment efforts. As very few of these efforts are in published literature, much of the information discussed is derived from conference proceedings or websites. This paper will discuss

Keywords: antiretroviral therapy, HIV care and treatment, quality improvement, quality of care, resource-limited settings



the importance of these activities in identifying models that work to deliver and improve quality and outcomes of care. However, to achieve these goals, the paper will argue the need to expand efforts to integrate research into quality improvement to more rigorously evaluate efforts to strengthen quality and identify models of care and improvement for expansion and replication.

Data sources

A Pubmed search was conducted for English language publications using the terms 'quality' or 'quality improvement', plus 'developing countries' or 'resource-limited settings' and 'HIV' or 'AIDS'. In addition, websites from organizations involved in quality measurement or improvement in resource-limited settings were reviewed. The reference lists and bibliographies for relevant articles or other resources were also reviewed for additional references. Finally, the abstracts from the International AIDS Society meetings were searched using the terms 'quality' and 'quality improvement'.

What is quality & why it should matter

The Institute of Medicine defines quality as 'the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge' [7]. Providing quality care as defined by accepted standards is directly linked with improved outcomes in a number of critical areas of HIV care, including prophylaxis, regimen choice and adherence support.

One example of the link between the quality of HIV care received and outcomes is the increased risk of the development of resistance associated with poor prescribing patterns and treatment interruption [8,9]. Poor quality of provided care in any of a number of areas, such as ARV prescribing, adherence support or supply chain, can lead to poorer adherence or ineffective regimens, resulting in development of resistance and increased risk of HIV-related morbidity and mortality. A linkage between how well care is accessed and survival has also been reported, with a doubling risk of death among patients who do not remain linked into care as measured by receipt of clinical visits according to expected standards [10].

Measuring quality of care

A better understanding of the levels of quality in the setting of HIV care and treatment scale-up is critical in order to identify models and

systems that are able to provide quality and effective care, and where improvements are needed while working towards meeting the goal of HIV care, including ART, to all in need. Measuring quality of care is challenging in resource-limited settings, where the demands of providing care leave minimal time or resources to assess and improve care. In addition, systems of documentation of care, essential to providing and measuring quality care, are also often of poor quality.

Despite these constraints, there are a growing number of efforts to measure and improve quality in HIV medical care in resource-limited settings [11–13,103]. This includes work to strengthen capacity to measure quality of care in HIV as the first step towards improvement [2,4,5]. This work has been facilitated by international agencies that have worked to establish measures through which quality can be measured at the site and national level, including TB and HIV integration, cotrimoxazole use and survival on ART [14,104].

One approach to understanding how to measure quality, described by Donabedian, separates areas related to quality into three categories: structure, process and outcomes [15]. Measurements of structure include the quality of the inputs into the program (resources, staff and physical infrastructure), while process measurement focuses on how the care is provided (number served, percent of eligible on ART or prophylaxis and adherence to care). Measurement of outcomes is aimed at the effectiveness of the services (response to ART, decreased TB rates and lower rates of loss to follow-up). The areas of structure and process are the simplest to measure, and can be done at a clinic level and targeted to improve care in the short term, while outcomes are generally more the focus of longer-term evaluation or measurement at the larger-sites, district or national level.

To date, outcomes of treatment have been the most frequently reported measure published by programs who have reported largely on the results of the first years of implementation. These results have ranged from remarkable levels of success, with over 90% of individuals with virologic or immunologic response to ART, to response rates more comparable with those seen in the USA and other countries in which ART has been available for over a decade [16–23]. However, rates of other outcomes, particularly retention in care, has been more of a challenge for many programs.

While measuring outcomes is critical to understanding program effectiveness, measuring the processes of care is also an important part of improving scale-up efforts. Understanding which quality gaps in how care is delivered result in poorer outcomes is important in determining how to address the underlying problem and improve effectiveness. For example, if viral suppression rates are suboptimal, different etiologies require different solutions. While quality of prescribing patterns can be addressed through training and oversight, decreasing the risk of interruption due to poor adherence or unreliable supply chain will require a more comprehensive approach, which may include improving patient education and support, pharmacy or other systems of care. Therefore, understanding how to ensure that care is being delivered and received as planned can mean the difference between success and failure for the patient and the program.

Even in the setting of good outcomes, measuring processes and systems remain important. While one assumes that success in outcomes reflects a functioning system and processes, outcomes may instead reflect the quality of care as delivered months or even years ago rather than how it is currently functioning, and so are less sensitive as a measure of changes in systems and capacity for care. In addition, measuring care as delivered (system and process measures) for programs with good outcomes will allow program managers and funders to understand if care is being delivered as planned and which processes are critical for success. For example, if high rates of response to ART are seen in a program with an extensive adherence support

program, understanding if the adherence support was delivered as planned is important to be able to link the model as designed with the outcomes seen. Conversely, external forces such as conflict or famine may result in suboptimal outcomes that may not reflect problems with the quality of care delivered or model of care.

Therefore, measuring not just outcomes, but the quality of processes and systems related to care is also important to ensure that gaps are rapidly identified and understood, appropriate improvement efforts initiated and effective models and their components identified. A growing number of programs are starting to describe the results of measuring quality of care as delivered. While programs have found areas of excellence, many of the same programs identified challenges that will require work to address and improve (Table 1) [2,5,17,19,24,25]. These gaps include areas related to retention, screening and prevention of opportunistic infection and monitoring of treatment.

Many challenges exist in effectively and efficiently measuring quality. These include weak systems for documentation of longitudinal care, data collection and management, and lack of consistent definitions of how quality is defined and measured. The limited availability of quality data that can be collected without undue resources and be utilized in real time is one of the biggest challenges facing efforts to evaluate quality and improve care.

Infrastructure for measuring quality needs to be linked with work to improve documentation for care. This work must include development of simple approaches to document manually or

Table 1. Example of areas of excellence and challenge described by antiretroviral therapy programs in resource-limited settings.

| Study | Areas of excellence | Areas of challenge | Ref. |
|--------------------------|---|--|--------|
| Ningsanond <i>et al.</i> | ART coverage, OI prophylaxis (post interventions) | OI prophylaxis, TB screening, STI screening, cervical cancer screening | [2] |
| Chikuba <i>et al.</i> | Loss to follow-up, TB screening, risk-reduction counseling, cotrimoxazole prophylaxis | TB screening*, risk-reduction counseling, cotrimoxazole prophylaxis | [4,24] |
| Fairall <i>et al.</i> | – | Cotrimoxazole prophylaxis | [40] |
| Skufina <i>et al.</i> | – | CD4-count monitoring, TB and HCV screening | [5] |
| Kist <i>et al.</i> | Retention in care | – | [25] |

*Range in quality found across countries in all three areas.

ART: Antiretroviral therapy; HCV: Hepatitis C virus; OI: Opportunistic infection; STI: Sexually transmitted infection.

electronically key elements of care, the capacity to link data with other information systems such as laboratory, pharmacy and supply chain and integration with program monitoring and evaluation. Efforts are being made to improve information systems through innovative approaches that will improve the collection, accessibility and utilization of data for care and evaluation of quality [26,27,105]. These efforts are an important step towards measuring and improving quality and to understanding why some models are more or less effective as implemented or replicated. However, more work to harmonize efforts and develop sustainable and affordable systems for HIV in resource-limited settings is needed.

Improving quality

It is important that quality work does not stop at measuring, but that the work continues to identify and address factors associated with identified gaps. Understanding what factors associated with better or worse quality in different settings and in different models of care is the next step to improving quality at the individual site and on a broader scale.

At a site level, understanding the potential causes for quality gaps is important before beginning work to improve care. To achieve this work requires building capacity for quality improvement approaches, including training, engagement of staff involved in providing care, and support from leadership. These efforts are underway at the site, district/provincial and national level through a number of programs in a number of resource-constrained settings [2,28–31,106]. One example, reported by Stash and colleagues which allowed sites to select the areas of focus and resulted in improvement in a number of selected areas, including waiting time and medical records [29].

On a broader scale, understanding factors associated with commonly identified gaps in quality is also important in order to share lessons learned and to provide information in development or modification of models that can be successfully used in scale-up. In the USA and other resource-rich settings, work on measuring quality in HIV care has led to a better understanding of cross-cutting patient, provider and site factors associated with quality of care [32–36]. This research has highlighted areas in which broader policy and programmatic solutions are needed, with efforts to address these problems underway at site and national levels.

However, factors associated with gaps in quality across multiple sites and programs have not been as well explored in the context of scaling-up HIV care and treatment. A study of ART across multiple countries in resource-limited settings found worse survival based on system characteristics including absence of a TB clinic and provision of care that was not free [19]. Patient factors can also impact upon quality of care received, including distance from site and provider, and community-based stigma. Understanding these challenges can lead to improvements in systems of care to ensure that care is accessible for all. Healthcare worker performance is also affected by a number of factors, such as knowledge, skills, motivation, stigma and their own health [37]. A better understanding of how factors from these three categories (site, patient and provider) are associated with outcomes, both positive and negative, is necessary to further develop effective models that address challenges to quality.

To achieve the goals of understanding and improving quality, work must continue in strengthening data management and information systems to provide the data necessary for measuring quality and patient factors, as well as building capacity within programs to analyze and utilize this information. This includes application of rigorous approaches to quantitative and qualitative methodologies and identifies a growing role for research to be integrated into these improvement efforts, as discussed below [37,38].

Identifying and understanding gaps in quality needs to lead to effective efforts to improve. Work to improve quality of care has been ongoing in resource-limited settings for decades [13,39,103]. Berwick highlighted some of these innovative and effective efforts, which should serve as lessons for countries regardless of resources [11].

Work to improve care in HIV in resource-limited settings has started at program and national levels in a number of countries. Thailand is developing a national approach to quality improvement that has resulted in measurement and improvement in a number of areas of HIV care, including opportunistic infection (OI) prophylaxis, TB screening and cervical cancer screening (Table 2) [2]. Morris and colleagues used a combined approach of indicator development, training and routine quality audit with feedback of results, with improvement after 16 months in areas including laboratory monitoring, missed clinical visits and appropriate use of OI prophylaxis [3]. In South Africa and Mozambique, approaches to improve quality resulted in a

Table 2. Data from the Thailand national HIV quality-improvement efforts showing improvement in performance in a number of areas of focus.

| | Year | | |
|-----------------------------|------|------|------|
| | 2003 | 2004 | 2005 |
| Hospitals participating (n) | 7 | 18 | 37 |
| Area of care (%) | | | |
| OI prophylaxis | 70 | 75 | 84 |
| TB screening | 37 | 55 | 77 |
| Cervical cancer screening | 3 | 11 | 43 |

Adapted from [2].

decrease of stock out and default rates [30], although not all efforts have uniformly seen the desired effects [30,40]. Work to improve quality in other areas related to HIV, such as PMTCT services has also been increasing [41,42]. In a multi-country report of efforts to strengthen services, improvements were reported using approaches to increase space and use of opt-out approaches to HIV testing [42].

Partnering of research & quality

As efforts expand to measure and improve quality, there is also a growing need to rigorously evaluate the effectiveness of the models and interventions that are being implicated to provide and improve quality of care [38,107]. Quality improvement has traditionally been driven by the need to rapidly address and improve quality, with a greater emphasis on action and learning from rather than on research. There are many challenges to rigorous quality-improvement research, but there is a growing body of work evaluating quality-improvement interventions from resource-richer settings [38,43–45]. These research studies found variable efficacy in improving quality with multisite quality-improvement efforts in HIV as well as in other conditions. The studies utilized a range of research approaches, including case-control studies [43] and clinical trials [44], to evaluate the impact of collaborative-based improvement initiatives and qualitative methods to develop a rigorous understanding of the factors associated with successful improvement [45].

Auerbach and colleagues provide a strong argument that more rigorous evaluation and research is needed to provide evidence that quality improvement interventions achieve their planned goals [38]. They argue that the large opportunity costs associated with widespread implementation of an intervention to improve

quality that is ineffective outweigh the smaller investments needed for a rigorous evaluation of the initial efforts to ensure that it works. They also point out the dangers of using biased data and of assuming that interventions based on solid quality-improvement approaches will be effective as implemented. They acknowledge the complexity of understanding underlying factors associated with gaps in quality, but argue that this further highlights the need for rigorous study designs to be integrated into the work to address quality.

Similar arguments can be made in applying rigorous study design to the evaluation of quality of care, as provided by different models, and of factors that predict success or failure in delivering care as planned. As discussed above, research in resource-richer settings has identified cross-cutting factors associated with delivery and receipt of poorer quality and less effective care. Rowe *et al.* call for a research agenda to critically understand the factors associated with why care is not delivered as expected in the setting of efforts to improve performance [37]. They identify both intervention factors (those related to efforts to improve performance such as training or quality-improvement efforts), and non-intervention factors (such as patient characteristics, work and community environments and infrastructure) that need to be better studied. Also important is identifying the contextual factors that explain why certain aspects of an intervention work well or poorly and which can provide valuable evidence to help determine whether a model of care or quality improvement should be replicated and where modification may be needed.

There are a number of different disciplines that can respond to these calls for integration of research into quality efforts. These include operational, health systems and implementation

Executive summary

- Measuring and improving quality of care in the context of scale-up of antiretroviral therapy (ART) programs in resource-limited settings is critical to ensure that successful models are identified and gaps are addressed.
- Many challenges exist, including defining and measuring quality, identifying effective interventions to improve care and developing approaches to rapidly replicate and expand successful methods.
- A growing number of efforts are underway at the site, program and national levels to measure and improve quality, while continuing to meet the large demand for HIV care and treatment.
- The integration of research and quality improvement efforts will be critical to achieve rapid scale-up of effective approaches to provide and improve HIV care in resource-limited settings.

research. Implementation research has particular relevance to this area, and is defined as research to understand the gap between how care should be delivered and expected outcomes, and what happens in the real-world setting. This work, which can combine multiple disciplines using both qualitative and quantitative methodologies, focuses on the challenges of providing care that is evidence-based and of understanding why efforts fall short of anticipated goals. Disciplines that can promote a closer collaboration between research, implementation and quality improvement, such as implementation and operational research, can bring a rigorous but realistic approach to helping providers, funders and evaluators better understand gaps in quality and how they can best be improved.

Conclusion

While there is a growing recognition and effort to measure and improve the quality of HIV care and treatment within the efforts to scale-up to meet demand and need, many questions remain. Most efforts to date have focused on measuring and improving at the site level, and it is critical to identify innovative, effective and sustainable approaches and expand and integrate these efforts into all levels of the system. This work will help programs balance the inevitable tension between the need to provide care to as many as possible and ensuring that quality care is provided and maintained to all.

In addition to these efforts to measure and improve quality, research is also needed to critically evaluate the underlying causes of gaps in quality and outcomes and the impact of efforts developed to address these gaps. This research will provide the critical evidence needed to identify effective approaches and models to providing and improving quality care, and whether they can be effectively replicated. To achieve this goal, there must be an increase in collaboration between researchers, implementers on the ground, people living with HIV, national governments, funders and the quality-improvement community to develop rigorous, feasible research and evaluation of the effectiveness, cost and long-term impact of efforts to provide and improve quality care. Combining the work and knowledge of quality measurement and improvement with that of implementation research is essential to more rapidly ensure that care being scaled-up is as effective and meets the needs of the communities and individuals being served.

Financial & competing interests disclosure

The author has no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. This includes employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending or royalties.

No writing assistance was utilized in the production of this manuscript.

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