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Rapid Ascent From Zero Quality to International Organization for Standardization Accreditation:

A Case Study of Hai Duong Preventive Medicine Center in Vietnam, 2012–2013

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Abstract

Objectives: In 2012, the Vietnam Ministry of Health sought to improve the quality of health laboratories by introducing international quality standards.

Methods: Strengthening Laboratory Management Toward Accreditation (SLMTA), a year-long, structured, quality improvement curriculum (including projects and mentorship) was piloted in 12 laboratories. Progress was measured using a standardized audit tool (Stepwise Laboratory Quality Improvement Process Towards Accreditation).

Results: All 12 pilot laboratories (a mix of hospital and public health) demonstrated improvement; median scores rose from 44% to 78% compliance. The public health laboratory in Hai Duong Province entered the program with the lowest score of the group (28%) yet concluded with the highest score (86%). Five months after the completion of the program, without any additional external support, they were accredited. Laboratory management/staff describe factors key to their success: support from the facility senior management, how-to guidance provided by SLMTA, support from the site mentor, and strong commitment of laboratory staff.

Conclusions: Hai Duong preventive medical center is one of only a handful of laboratories to reach accreditation after participation in SLMTA and the only laboratory to do so without additional support. Due to the success seen in Hai Duong and other pilot laboratories, Vietnam has expanded the use of SLMTA.

Keywords

Quality; ISO; SLMTA; Accreditation; Vietnam

By all accounts, Vietnam is a development success story. Political and economic reforms launched in the mid-1980s have transformed the country from one of the poorest in the world (per capita income of US\$100) to lower middle-income status within a quarter of a century (by the end of 2015, per capita income had reached US\$2,100). This reclassification did signal the departure of numerous development partners after supporting Vietnam for only a few short decades.¹ As a result, the Ministry of Health (MOH) is struggling to keep up with the demands of an overburdened health care system and issues related to the quality of laboratory testing (lack of laboratory standards, quality monitoring systems, and continuing medical education). Over the past 7 years the US Centers for Disease Control and Prevention (CDC), with funding from the US President's Emergency Plan for AIDS Relief (PEPFAR), has introduced a quality management system (QMS) approach to laboratory management. One component of that package has been a program focused on the introduction of international quality standards with the ultimate goal of reaching accreditation (Strengthening Laboratory Management Toward Accreditation [SLMTA]). As described previously,^{2,3} SLMTA is a structured, quality improvement curriculum delivered in three workshops; each is followed by a period of several months, allowing for laboratories to implement improvement projects, with onsite support and mentorship. Laboratories implementing this program are evaluated using the Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) checklist, which addresses the 12 Quality Systems Essentials (QSEs)⁴ as defined by the Clinical and Laboratory Standards Institute (CLSI).⁵ To further simplify scoring, "stars" are awarded for meeting different levels of compliance (between 0 and 5).³ This was implemented in Vietnam in 2012 with support from MOH leadership and in partnership with the national public hospital system (Vietnam Administration for Medical Services [VAMS]) at a variety of laboratories located in hospitals, provincial AIDS centers (PACs), and preventive medicine centers (PMCs).

The Hai Duong PMC was one of 12 laboratories that participated in the introduction of SLMTA into Vietnam. Hai Duong PMC serves as the provincial public health center, providing an array of testing services (human immunodeficiency virus [HIV] confirmation, biochemistry, hematology, chemistry, and food/water microbiology) to a northern province with a population of nearly two million. Thirteen laboratorians with varying levels of education—two university graduates (4–6 years specialized training), 10 with associate degrees (2–3 years of training), and one dedicated microscopist—perform 5,000 tests per month. At the beginning of the SLMTA program, baseline audits indicated that Hai Duong's score was the lowest (28%) for this group of laboratories (Figure 1). They were out of compliance for all QSEs covered in the SLIPTA checklist⁵ and scored zeros in sections covering internal audit and occurrence/incidence management and process improvement (Figure 2) since laboratory staff had no working knowledge of these requirements and no procedures were in place within the laboratory to address them. SLMTA exit audits performed 13 months later showed that the score for Hai Duong PMC had climbed to the highest among the 12 pilot laboratories (Figures 1 and 2). They scored 99% to 100% compliance for five of 12 QSEs, including occurrence/incidence management and process improvement; internal audits score had risen to 90%. The final overall score was 86% compliance, equivalent to four stars out of a possible five on the SLIPTA checklist.⁶

After this success, Hai Duong PMC then went one crucial step farther; although lacking any additional external technical or financial support (using only their regular operating budget), the laboratory continued to apply SLMTA's approach to pursue continuous quality improvement toward accreditation. In January 2014, just 18 months after initiating SLMTA, Hai Duong PMC was accredited to International Organization for Standardization (ISO) 17025 by Vietnam's Bureau of Accreditation.

We seek to uncover the secret of Hai Duong PMC's success. During Hai Duong's 12-month participation in SLMTA, the laboratory workload, funding, staffing, diagnostic equipment, and staff responsibilities did not change significantly. Progress toward improvement was not easy for the staff; twice they contemplated dropping out of the SLMTA program. In discussions with site management and staff, many of those requirements already known to be necessary for the success of SLMTA were mentioned. These included early engagement and support from the facility senior management,⁷⁻¹⁰ how-to guidance provided by the workshops,^{2,7,11} strong and consistent support from the site mentor,^{9,12} and strong commitment of laboratory staff.¹³

Commitment from site management was a VAMS pre-requisite for all laboratories participating in SLMTA, and this was certainly the case for the PMC management board. Unlike other "resource-poor" settings, this PMC has reliable and predictable funding; initially, though, QMS was not a priority for site management. SLMTA provided the recognition and momentum to raise awareness of the importance of QMS, resulting in those activities being funded at the appropriate levels. One example was the PMC management board's approval for procurement of instruments to validate laboratory equipment.

The laboratory director and vice-director reported that one of the hardest things to overcome was insufficient knowledge or competency of the laboratory staff in the areas of QMS. Both individuals participated in the three SLMTA workshops, which provided the step-by-step guidance on the implementation. This knowledge was then successfully transferred to the remaining laboratory staff after each workshop. Improvement projects were approached in a stepwise fashion; more basic, easier projects were performed first, setting the groundwork for more complex projects. This ensured that all laboratory staff fully understood the activity. During SLMTA, the Hai Duong PMC took advantage of the QMS focus to standardize their testing and implement a quality control system. The laboratory director felt that the most important contribution from SLMTA, toward accreditation, was that laboratory staff were trained to plan and conduct quality improvement projects, thus increasing their capacity in management and technical activities.

The SLMTA model requires that each site be paired with a mentor to provide regular follow-up and support. Mentors reinforce the curriculum delivered in workshops and assist the participants in correctly implementing QMS activities within their laboratories. In the case of Vietnam, mentors were pulled from the participants of the first SLMTA training of trainers (TOT) and were allowed to nominate sites for inclusion in the first cohort of laboratories (subsequently they served as mentors to those sites). This ensured that mentors and their sites had a prior relationship, would communicate effectively on a regular basis, and would likely work well together. For this first implementation of SLMTA in Vietnam,

mentors were not paid but assumed mentoring responsibilities as part of their day-to-day duties. Some countries have explored extended mentoring models,^{9,12} but in Vietnam, mentors visited sites once or twice a month (augmented with frequent text messages or phone calls) during the year-long implementation period. In the case of Hai Duong PMC, the assigned SLMTA mentor also played the key role of facilitating coordination between the site management and the laboratory director, resulting in a better organizational effort toward QMS goals.

Laboratory management and staff stated feeling embarrassed when the baseline scores were first published and they realized their laboratory was ranked the lowest; this provided some measure of motivation for the entire laboratory. When the laboratory director was asked what was the easiest part of the SLMTA-ISO process, he responded that he could always count on a “group effort” from his laboratory team along with their high morale and sense of responsibility for improving the quality of the laboratory. The laboratory staff, in contrast, suggested that the high SLIPTA score at the conclusion of SLMTA strengthened their confidence to next pursue ISO accreditation. When the director was asked what might have been his biggest mistake early on in the process, he responded, “Failing to encourage staff members when they faced difficult challenges.”

This is not the first example of a health laboratory using SLMTA as a stepping stone to then reach accreditation.¹⁴ The difference here is the accelerated pace (18 vs 36 months from initiation of SLMTA to ISO accreditation), lack of additional training for staff (in the area of ISO), and lack of additional external support (TA and/or funding).

When comparing Hai Duong PMC’s experience with other participating facilities (with similar profiles but with less improvement), SLMTA trainers and mentors identified the following barriers: regarding participants sent for SLMTA training, not all were equally committed, some simply lacked sufficient time in their workday to implement improvement projects, and not all returned to their home facilities with the goal of engaging all laboratory staff in improvement activities. Although efforts were made to create effective matches between sites and mentors (as discussed earlier), not all sites understood the mentoring model and took full advantage of this resource. Staff at some sites were so overloaded with scheduled trainings that there was little time to follow up training with actual implementation of new concepts or techniques. And despite the rigorous selection process and training provided to SLMTA trainers/mentors, not all mentors had adequate knowledge, skills, and experience in quality management programs. This last issue has become less relevant since trainers have gained more experience during subsequent rounds of SLMTA.

Overall, SLMTA Vietnam pilot laboratories demonstrated significant improvement in QMS (as measured by the SLIPTA checklist); median scores increased from 44% at baseline to 78% at conclusion.⁶ Hai Duong PMC’s story demonstrates that SLMTA can build sustainable laboratory capacity and motivate management and staff to work as a team to apply quality practices in a cost-effective and stepwise approach. Following the success of SLMTA at Hai Duong PMC and the other pilot laboratories, the MOH decided to continue the SLMTA program within the hospital laboratory system and extend its implementation to other health care systems, such as the National TB Program laboratory network, and

the public health laboratory system. In addition, SLMTA has been adopted by the Vietnam Ministry of Defense into the military health laboratories. The SLIPTA checklist has been adopted into the regulatory framework and will serve as a resource for the creation of national laboratory standards. After the pilot, the need to expand the number of qualified trainers, mentors, and auditors was immediately recognized, so subsequent TOTs were held and the curriculum was translated into Vietnamese, so a wider group of skilled laboratorians could support the program. With these efforts, Vietnam, like other countries that have seen the benefits of SLMTA, is working toward saturation of the program.^{9,13,15} These activities will enhance the development of laboratory QMS implementation throughout Vietnam.

A recent laboratory survey conducted in Uganda (using a detailed laboratory QMS survey tool) concluded that laboratories with higher testing volumes tend to also have higher laboratory quality. Hai Duong PMC would be categorized as a high-volume laboratory with demonstrated high quality as measured by both SLMTA and ISO.^{16,17}

When the Hai Duong PMC laboratory director was asked what advice he would give to other laboratories seeking accreditation, he responded, “Implementing the laboratory quality system will be very difficult at first, but once it starts showing effects, QMS will be the vital element for satisfying your customers.” Gradually, through a process of conducting quality improvement projects, the staff began to bring quality culture¹⁸ and behaviors into the laboratory, resulting in enhanced management and technical capacity.

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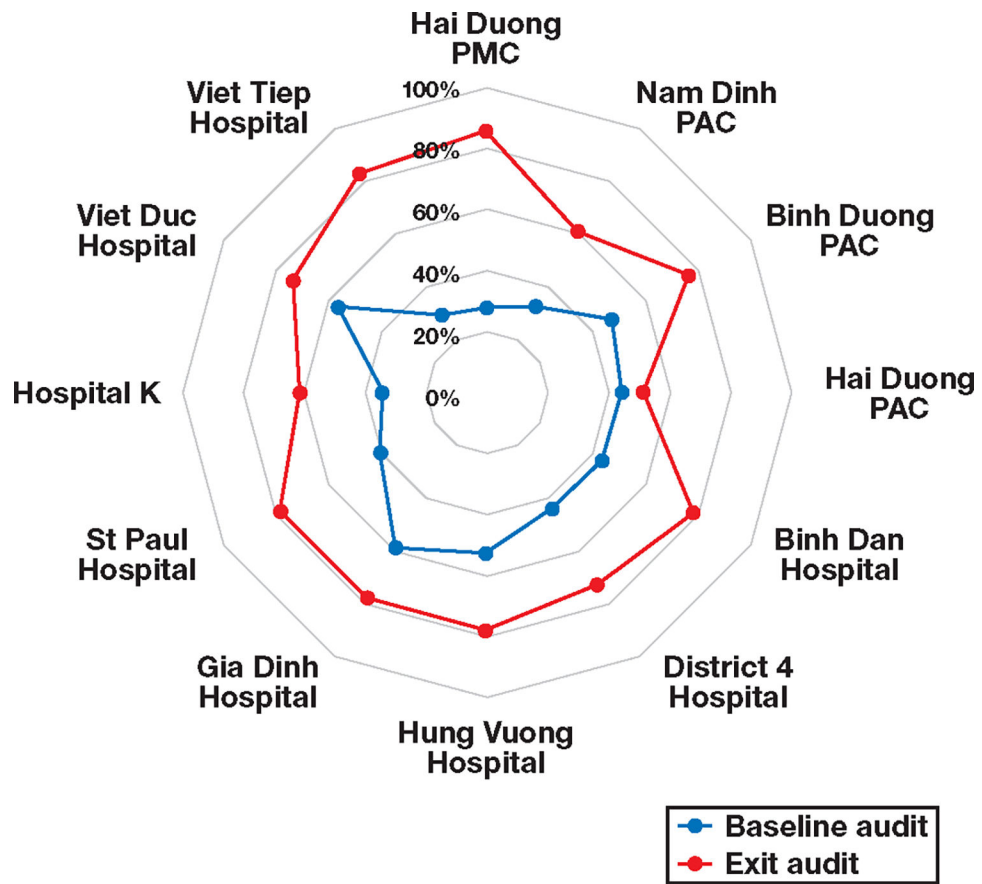


Figure 1. Baseline and exit Stepwise Laboratory Quality Improvement Process Towards Accreditation audit scores (percent compliance) for 12 laboratories enrolled in the first cohort of the Strengthening Laboratory Management Toward Accreditation program in Vietnam, 2012–2013.

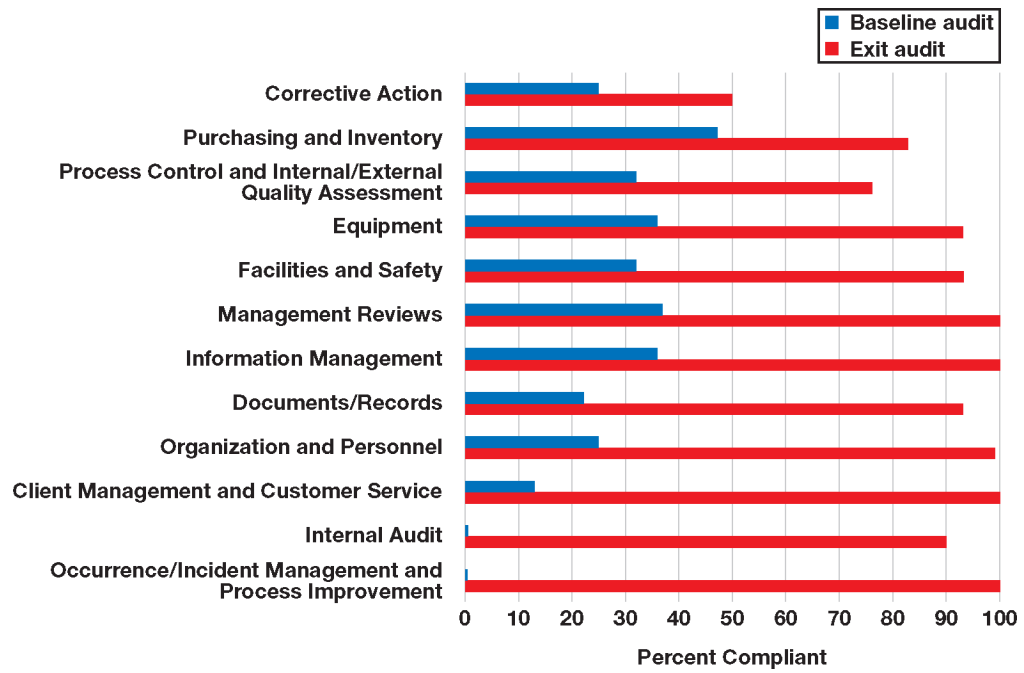


Figure 2. Baseline and exit audit scores for 12 Quality Systems Essentials of Stepwise Laboratory Quality Improvement Process Towards Accreditation for Hai Duong Preventive Medicine Center, ranked from lowest to highest percent improvement.