Sustainable Scale-up of Active Management of the Third Stage of Labor for Prevention of Postpartum Hemorrhage in Ecuador

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The sponsor of the study had no role in study design; data collection, analysis, or interpretation; or manuscript preparation

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Synopsis: Ecuador’s implementation of collaborative improvement is a compelling model for the successful scale-up of active management of the third stage of labor.

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Short Title: Prevention of Postpartum Hemorrhage Scale-up
Structured Abstract

Objective
To analyze the Ecuadorian experience in the adoption, scale-up, and institutionalization of active management of the third stage of labor (AMTSL) for prevention of postpartum hemorrhage using continuous quality improvement (CQI) processes.

Methods
Average rates of AMTSL implementation for women with vaginal deliveries are compared using Chi-square tests of unweighted provincial aggregate data from systematic chart reviews in health facilities participating in three phases of AMTSL programming. Months taken to implement AMTSL at \( \geq 80\% \) and \( \geq 90\% \) compliance are compared across phases using Student’s t-test.

Results
The rate of oxytocin administration during the first three months was 5.0% in Phase 1, 9.8% in Phase 2, and 72.2% in Phase 3 (\( p \leq 0.001 \) v Phase 1 and 2). The average number of months it took provinces to raise oxytocin administration to \( \geq 80\% \) and \( \geq 90\% \) of women with vaginal deliveries was, respectively, 21.6±18.7 and 30.6±16.4 in Phase 1, 23.5±15.1 and 30.1±14.9 in Phase 2, and 4.7±4.9 (\( p \leq 0.01 \) v Phase 1, \( p \leq 0.001 \) v Phase 2) and 4.0±3.4 (\( p \leq 0.001 \) v Phase 1 and 2) in Phase 3. By December 2009, AMTSL implementation was sustained at \( \geq 90\% \) in all provinces.

Conclusion
The CQI process identified resistance and operational barriers and developed mechanisms to overcome them.
**Introduction**

Every year, 343,000 women die from pregnancy-related complications, >98% of them in developing countries [1]. Twenty-eight percent of maternal mortality is caused by blood loss ≥500 ml, called postpartum hemorrhage (PPH) [2,3,4]. As PPH accounts for more maternal mortality than any other single condition, preventing PPH can significantly advance achieving Millennium Development Goal (MDG) 5, to reduce maternal mortality rates (MMRs) by three quarters [1,5,6]. Active management of the third stage of labor (AMTSL) has three elements: administration of an uterotonic, uterine massage, and controlled cord traction. AMTSL reduces PPH by >50% when administered immediately after delivery, but only uterotonic provision is supported by strong evidence [2, 7-9], particularly as most PPH is caused by uterine atony [10]. International guidelines define oxytocin as the preferred uterotonic for AMTSL [10,11].

Between 1994 and 2004, MMR in Ecuador was 107/100,000 live births, with PPH the leading cause of maternal death [12]. Most women deliver in healthcare facilities where more than half of all maternal deaths occur [12]. To reduce MMR, the Ecuadorian Ministry of Health (MOH) established the National Free Maternity Care Program in 1998 guaranteeing universal access to essential maternal and child health services [13].

Although World Health Organization guidelines, supported by Cochrane Reviews, recommended oxytocin for PPH prevention [2, 7-10], some decision makers and healthcare providers in Ecuador questioned its safety. In 2003, the Quality Assurance Project (QAP) funded by the United States Agency for International Development...
(USAID) initiated a dialogue with the MOH about the international evidence supporting AMTSL and the importance of including it in national guidelines.

**Materials and methods**

Oxytocin (Laboratorio Sanderson S.A., Santiago, Chile) for PPH prevention was introduced and scaled up using continuous quality improvement (CQI) [13]. CQI is based on five principles: 1) understanding and focusing on patient needs, 2) analyzing how processes of care function within the system, 3) changing processes and systems of care to achieve better outcomes, 4) using data to gauge results, and 5) engaging teams of healthcare providers in improvement. Over the past decade, CQI has been applied in numerous low-income countries and produced rapid and sustained improvement in quality healthcare [14].

In Ecuador, QAP and its follow-on project, the USAID Health Care Improvement Project (HCI), assisted the MOH to implement and take AMTSL to scale in three phases (Figure 1). QAP/ HCI applied the “collaborative improvement” approach; the approach relies on the adaptation, discussion, and dissemination of evidence-based best practices by teams of healthcare providers. Teams are taught to regularly measure and graphically plot their progress in complying with best practices to identify gaps between optimal and actual care at each facility [14]. Measurement facilitates learning and contributes to locally adapted, improved processes of care [15]. Improvement is further motivated by interaction and teamwork within and between facilities.
The MOH agreed to initially pilot AMTSL, recommending provision of 10 IU intramuscular (IM) oxytocin immediately after delivery in one of its 24 provinces. Coaches from the MOH and QAP reviewed site data and taught EOC teams how to monitor and evaluate implementation. Through CQI team collaboration and spontaneous diffusion, AMTSL quickly began spreading to other facilities and provinces.

International literature on AMTSL for PPH prevention was shared among Phase 1 sites, creating fora for its discussion and health worker trainings. An interactive website was established allowing CQI teams to share results and experiences with other practitioners. Between June 2003 and December 2005, 44 facilities in nine provinces participated in Phase 1.

Phase 2 began with the formation of a central MOH CQI Steering Committee with representatives from USAID, the Pan American Health Organization, the UN Population Fund, UNICEF, and the School of Professional Midwives. Obstetricians, donors, and implementing partners were also invited to provide technical guidance and expertise on EOC. Concurrently, providers leading EOC efforts intensively disseminated information on AMTSL to key MOH decision-makers to advocate for training in health facilities.

Initial implementation of AMTSL impressed MOH decision-makers and led to approval and inclusion of a key indicator, the provision of oxytocin, in the MOH’s monitoring of EOC standards. About 40% of EOC collaborative facilities began reporting this indicator. Advocacy with MOH authorities to establish AMTSL as a national policy intensified. In January 2006, the MOH convened an expert working group to compose
new AMTSL guidelines which were incorporated as an addendum into national obstetric care standards. The MOH officially launched the addendum at a national meeting in April 2006 to inaugurate its Maternal Mortality Reduction Plan, where AMTSL and CQI documents were disseminated. By the end of Phase 2, AMTSL was implemented in 33 additional facilities in seven provinces.

Despite sharp declines in external funding for EOC, the MOH unveiled an ambitious new segment of its National Campaign to Reduce Maternal Mortality focused on obstetric hemorrhage. The MOH systematically gathered, synthesized, and consolidated information to identify the best ideas developed by CQI teams for overcoming operational barriers. In May 2007 (Phase 3), the lessons learned (Table 1) were incorporated into a campaign to rapidly extend AMTSL to many facilities and practitioners with minimal resources. The campaign covered populous provinces not previously participating in CQI and non-participating facilities from provinces that had participated in prior CQI efforts. The campaign taught correct administration of oxytocin, uterine massage, implementation of controlled cord traction, documentation, correct PPH management, and monitoring and evaluation. The campaign began with a one-day meeting attended by two influential obstetricians from each of Ecuador’s seven main regional hospitals and a representative from each MOH provincial directorate. In June 2007, the MOH conducted one-day workshops in each regional hospital for doctors and professional midwives designated as facility AMTSL leaders. Attended by 394 providers from provincial and county hospitals, the workshops included practical training in AMTSL’s three elements. The recently approved national guidelines for AMTSL
were discussed, a training module presented, and a strategy for scaling up to neighboring provincial and county hospitals was promoted. Participants then replicated the workshop package at their hospitals. Recognized obstetricians and provincial EOC coordinators served as coaches and provided assistance to these hospitals on clinical background, monitoring, reporting, and CQI mechanisms.

In 2008, the MOH intensified expansion in five of the 13 Phase 3 provinces covering more deliveries than all previous efforts combined. Provincial teams from these five provinces participated in additional training and experiences were shared in large workshops held in the country’s three largest cities. Implementers from earlier phases were engaged as champions to coach and support teams. The MOH developed and distributed to health facilities throughout the country new supportive materials, including a package of scientific evidence, an AMTSL and CQI lessons-learned summary, and copies of the Prevention of Post-Partum Hemorrhage Initiative AMTSL poster and CD-ROM with video instruction [16-18]. Between 2007 and 2009, 61 mostly high-volume facilities from 13 provinces participated in Phase 3.

We present provincial level chart review data from public health facilities participating in the three phases of Ecuador’s AMTSL program. Individuals trained at each facility reported key national EOC quality indicators monthly as part of the CQI process of reviewing compliance to stimulate action. At each facility, 30 charts of patients who delivered vaginally in the prior month were selected randomly for review, including administration of 10 IU IM oxytocin for PPH prevention; however the cause of PPH
cases was not reported, Facilities commonly began reporting data a few months after initiating Phase 1 and Phase 2 and promptly after Phase 3. The use of anonymous secondary data was approved by the MOH. Data were compiled by the MOH with assistance of University Research Co, LLC (URC). The study was considered exempt from full URC ethical review as it did not involve patient contact or new data collection.

As data are aggregated by province, statistics presented are unweighted averages of charts reviewed and do not represent per patient averages. These averages underrepresent patients delivering in high-volume facilities as smaller facilities disproportionately participated in Phase 1; the largest facilities disproportionately participated in Phase 3. Average compliance rates in the first three months of each phase with the last three months of 2009, when nearly all provinces were providing oxytocin to ≥90% of women delivering vaginally, were compared by Chi-square tests. We used the average number of months per phase to accomplish and maintain for ≥2 months’ provision of oxytocin for PPH prevention to ≥80% and ≥90% of vaginal deliveries is compared by Student’s t-tests. The study used reported aggregate data and did not pose a priori hypotheses. A one-tailed test to identify p≤.05, with nine Phase 1, seven phase 2, and eleven Phase 3 provinces, post-hoc calculation of the observed improvement has 11% power (Phase 1 to 2), 68% power (Phase 1 to 3), and 45% power (Phase 2 to 3).

Using the same statistical assumptions, the increase between baseline and endline for Phase 1 has >95% power, 77% power for Phase 2, and 40% power for Phase 3. The reduction in number of months to reach ≥80% AMTSL has 89% power (Phase 1 to 2), >99% power (Phase 1 to 3), and 49% power (Phase 2 to 3). The reduction in number of
months to reach ≥90% AMTSL has 55% power (Phase 1 to 2), >99% power (Phase 1 to 3), and 53% power (Phase 2 to 3). Analyses were conducted using MS Office 12 Excel and Stata Version 8.0.

Results

In August 2003, only one Ecuadorian province was implementing AMTSL. By June 2010, it was implemented in 108 facilities in 20 of 24 provinces. Between 2003 and 2009, Phase 1 facilities attended approximately 92,000 vaginal deliveries. Phase 2 facilities attended 149,000 between 2005 and 2009, and Phase 3 facilities attended 242,500 between 2007 and 2009.

Oxytocin was administered to 29% of women delivering vaginally during the first three months of Phase 1, compared with 38% in Phase 2 (not statistically significant), and 75%, in Phase 3 (p≤0.05 vs. Phase 1, Table 2). Rates of oxytocin administration were 94%-96% across phases in the last three months of 2009. On average, it took 30.4±16.9 months to achieve oxytocin administration to ≥80% of women delivering vaginally in Phase 1 (Figure 2), 11.0± 9.6 months in Phase 2 (p≤0.05 vs. Phase 1), and 4.7±4.9 months in Phase 3 (p≤0.001 vs. Phase 1 and p≤0.10 vs. Phase 2). On average, it took 33.4±14.0 months to achieve oxytocin administration to ≥90% of women delivering vaginally in Phase 1, 17.4± 20.4 months in Phase 2 (p≤0.10 vs. Phase 1), and 4.0± 3.4 months in Phase 3 (p≤0.001 vs. Phase 1 and p≤0.05 vs. Phase 2). The monthly increase to reach ≥90% compliance increased with each phase (not statistically significant).
Discussion

The statistical power of the comparisons was limited because data were aggregated at the provincial level and nearly half of the comparisons were not statistically significant. However, the data represent numerous facilities and thousands of individuals. Even with larger variation, individual and facility-specific analyses would likely be highly significant, were the data available in these forms.

The CQI process implemented in Phase 1 educated providers, dispelled misperceptions that uterotonics would lead to placental retention, and found ways to overcome supply constraints. Phase 1 coaching and sharing experiences built provider confidence and encouraged healthy competition that stimulated continuous improvement of team performance. The process enhanced policy makers’ support for AMTSL and led to AMTSL implementation rates that were nearly a third higher in the first few months of Phase 2, although not statistically different.

During Phase 2, the process strengthened legitimacy. AMTSL began to receive official policy support, and responsibilities including purchase of the necessary drugs and supplies, continued training, and materials distribution augmented implementation. The Phase 2 expansion significantly reduced the time to reach ≥80% and ≥90% compliance to one-third and one-half that of Phase 1, respectively, and covered 50% more deliveries than Phase 1. Phase 2 activities were relatively low-cost, primarily paid for by the MOH.
Resistance to AMTSL was overcome during Phase 2, and its adoption became widespread. Phases 1 and 2 stimulated AMTSL implementation >70% observed at the beginning of Phase 3 and created the opportunity for a new low-cost, rapid expansion using large one-day regional workshops in the most populous areas to quickly propel subsequent local workshops led by those who had attended the regional workshops. This substantially sped expansion and extended coverage to most of Ecuador. Phase 3 facilities achieved AMTSL implementation ≥80% and ≥90% in, respectively, one-half and one-third of the time of Phase 2, partially due to the high Phase 3 baseline implementation, itself a consequence of Phases 1 and 2. Phase 2 experienced a 19% faster monthly increase to achieve AMTSL implementation ≥90% than Phase 1. Phase 3 experienced a 29% and a 54% faster time to achieve AMTSL implementation ≥90% than Phase 2 and Phase 1, respectively. Because the unweighted aggregate data give equal weight to each province, the data presented likely underestimate Phase 2 effectiveness compared with Phase 1 and Phase 3 compared with Phases 1 and 2, because Phase 1 facilities disproportionately included facilities with lower patient volume where effectiveness was least; Phase 2 facilities included mostly low and moderate-volume facilities; and Phase 3 facilities disproportionately included high-volume facilities where effectiveness was greatest.

Furthermore, this experience demonstrated that AMTSL implementation has been institutionalized and remained high well beyond the phasing out of substantial donor support for EOC. AMTSL implementation in reporting facilities has been ≥80% since June 2007 (38 months) and ≥90% for 29 consecutive months.
CQI methods improve practice and health outcomes in developing countries because they strengthen management capacity, leadership, and accountability and optimize use of limited resources. The experience improving AMTSL in Ecuador highlights the components of collaborative CQI processes that are most successful. These include familiarization (with the evidence) and engagement (in training, measuring and reviewing compliance, and decision-making that takes responsive action) in the establishment of an ongoing improvement process and its integration into practice. By engaging teams of frontline providers, experts and national “champions,” a culture of CQI is fostered that enhances communication, coordination, and the motivation, satisfaction, and retention of health workers while improving flow and quality of care [14,19-22]. CQI addresses the elements that are major contributors to poor quality of care [23].

Other mechanisms with greater financial support have also been successful in introducing, scaling up, and institutionalizing AMTSL. The Prevention of Postpartum Hemorrhage Initiative (POPHI), a multi-million dollar, 10-year global program supported by USAID and implemented in partnership with the International Federation on Gynecology and Obstetrics and the International Confederation of Midwives Task Forces, used similar approaches to CQI to successfully establish, scale up, and sustain PPH prevention at in facilities and communities [24, 25].

Conclusion
With limited external support, the Ecuadorian MOH has created an environment that has achieved significant improvements in maternal health, including institutionalization of >90% provision of oxytocin in most of the country. Ecuador’s experience with AMTSL demonstrates CQI is effective for successful scale-up of high-impact clinical interventions and a powerful tool for improving health care and ultimately maternal health outcomes.

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Conflicts of interest: The authors declare no conflicts of interest.
Table 1: Lessons Learned about Improving AMTSL Implementation in Ecuador

<table>
<thead>
<tr>
<th>Operational barriers area</th>
<th>Actions taken by CQI teams</th>
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<tbody>
<tr>
<td>Human Resource Constraints</td>
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<tr>
<td>Insufficient technical knowledge, building confidence, retention of health care personnel</td>
<td>Dissemination and AMTSL training, including demonstration, and advocacy</td>
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<td></td>
<td>Meetings to sensitize healthcare workers, including case review</td>
</tr>
<tr>
<td></td>
<td>Written policy for AMTSL</td>
</tr>
<tr>
<td></td>
<td>In-service training and supervision</td>
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<tr>
<td>Management constraints</td>
<td></td>
</tr>
<tr>
<td>Ensuring supplies, improving clarity of roles and responsibilities, monitoring and evaluation (M&amp;E)/ documentation of compliance with the standards, commitment by health service leaders</td>
<td>Incorporating oxytocin into standard delivery kits</td>
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<td></td>
<td>Monitoring and evaluation (M&amp;E) and augmented supervision to manage supplies via CQI teams</td>
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<td></td>
<td>In-service meetings designating AMTSL roles and responsibilities, including creation of diagrams showing roles/ responsibilities</td>
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<td></td>
<td>Clinical charts and M&amp;E revised to verify correct application of AMTSL</td>
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<td></td>
<td>Dissemination of national AMTSL guidelines</td>
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<td></td>
<td>Providing posters and job aids depicting and emphasizing standards of care for AMTSL</td>
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Table 2: Average Rate of AMTSL Implementation and Months to Achieve and Maintain ≥80% and ≥90% Implementation

<table>
<thead>
<tr>
<th></th>
<th>Phase 1 (n = 9 provinces)</th>
<th>Phase 2 (n = 7 provinces)</th>
<th>Phase 3 (n = 11 provinces)</th>
</tr>
</thead>
<tbody>
<tr>
<td>AMTSL rate in first 3 months of phase&lt;sup&gt;a&lt;/sup&gt;</td>
<td>28.79%</td>
<td>38.00%</td>
<td>74.63%**</td>
</tr>
<tr>
<td>AMTSL rate in last 3 months of 2009&lt;sup&gt;b&lt;/sup&gt;</td>
<td>94.20%</td>
<td>95.47%</td>
<td>96.02%+</td>
</tr>
<tr>
<td>Months from first report to reach ≥80% AMTSL rate</td>
<td>30.44±16.92</td>
<td>11.0±9.59**</td>
<td>4.73±4.92***,+</td>
</tr>
<tr>
<td>Months from first report to reach ≥90% AMTSL rate&lt;sup&gt;c&lt;/sup&gt;</td>
<td>33.44±13.98</td>
<td>17.43±20.42*</td>
<td>4.00±3.44***,**</td>
</tr>
<tr>
<td>Average monthly percentage increase to reach ≥90% AMTSL rate&lt;sup&gt;c&lt;/sup&gt;</td>
<td>1.82%</td>
<td>2.17%</td>
<td>2.81%</td>
</tr>
</tbody>
</table>

<sup>a</sup> n=the number of provinces reporting data in the first three months of each phase

<sup>b</sup> n=the number of provinces reporting data in the last three months of each phase

<sup>c</sup> n=the number of provinces reporting data in any month of each phase

vs. Phase 1  *p≤0.10  **p≤0.05  ***p≤0.001

vs. Phase 2  †p≤0.10  ‡p≤0.05
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Figure 1: Summary of Continuous Quality Improvement (CQI) Activities to Scale-Up Active Management of the Third Stage of Labor (AMTSL) in Ecuador

<table>
<thead>
<tr>
<th>Phase</th>
<th>Date</th>
<th>Provinces</th>
<th>Facilities</th>
<th>Major Activities</th>
<th>Activities Spanning All Three Phases</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>August 2003 – December 2005</td>
<td>9</td>
<td><strong>Total: 44 Facilities</strong>&lt;br&gt; 9 Health Centers&lt;br&gt; 30 Basic Hospitals&lt;br&gt; 5 Provincial Hospitals</td>
<td>• Pilot provision of 10 IU IM oxytocin in 1 provincial hospital (Tungurahua)&lt;br&gt; • AMTSL introduced under Free Maternity EOC Program in 1 Provincial Hospital and 5 Health Centers&lt;br&gt; • CQI interactive website launched (<a href="http://www.maternoinfantil.org">www.maternoinfantil.org</a>)</td>
<td>Coaching&lt;br&gt; AMTSL training&lt;br&gt; M&amp;E training&lt;br&gt; Data review&lt;br&gt; Responsive actions</td>
</tr>
<tr>
<td>2</td>
<td>January 2006 – December 2006</td>
<td>7</td>
<td><strong>Total: 33 Facilities</strong>&lt;br&gt; 8 Health Centers&lt;br&gt; 16 Basic Hospitals&lt;br&gt; 9 Provincial Hospitals</td>
<td>• CQI Steering Committee formed&lt;br&gt; • Intensive AMTSL advocacy/information dissemination by EOC champions to key MOH decision-makers&lt;br&gt; • Expert working group composed new AMTSL guidelines and incorporated them into the national EOC standards&lt;br&gt; • Inauguration of MOH National Maternal Mortality Reduction Plan and wide dissemination of AMTSL guidelines&lt;br&gt; • Inclusion of oxytocin for PPH prevention as key MOH EOC standard monitoring indicator</td>
<td>Dissemination&lt;br&gt; Champion motivation&lt;br&gt; Team collaboration&lt;br&gt; Spontaneous diffusion&lt;br&gt; Meetings with providers&lt;br&gt; Meetings with MOH</td>
</tr>
<tr>
<td>3</td>
<td>January 2007 – December 2009</td>
<td>11</td>
<td><strong>Total: 61 Facilities</strong>&lt;br&gt; 20 Health Centers&lt;br&gt; 25 Basic Hospitals&lt;br&gt; 16 Provincial Hospitals</td>
<td>• MOH identified and disseminated lessons on how to overcome operational barriers&lt;br&gt; • 2007 National Campaign to Reduce Maternal Mortality promoted AMTSL in all country hospitals via meetings and workshops.&lt;br&gt; • 2008-9 Workshops held in Guayaquil, Cuenca, and Quito, followed by participant replication.</td>
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Figure 2: Rates of AMTSL Implementation in Phase 1, 2 and 3