Using the WHO Safe Childbirth Checklist to Improve Essential Care Delivery as Part of the District-Wide Maternal and Newborn Health Quality Improvement Initiative, a Time Series Study

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Abstract

Background: Care bundles are a set of three to five evidence-informed practices which, when performed collectively and reliably, may improve health system performance and patient care. To date, many studies conducted to improve the quality of essential birth care practices (EBPs) have focused primarily on provider-level and have fallen short of the predicted impact on care quality, indicating that a systems approach is needed to improve the delivery of reliable quality care.

This study evaluates the effectiveness of integrating the use of the World Health Organization Safe Childbirth Checklist (WHO-SCC) into a district-wide system improvement collaborative program designed to improve and sustain the delivery of EBPs as measured by “clinical bundle” adherence over-time.

Methods: The WHO-SCC was introduced in the context of a district-wide Maternal and Newborn Health (MNH) collaborative quality of care improvement program in four agrarian Ethiopia regions. Three "clinical bundles" were created from the WHO-SCC: On Admission, Before Pushing, and Soon After Birth bundles. The outcome of each bundle was measured using all-or-none adherence. Adherence was assessed monthly by reviewing charts of live births.

A time-series analysis was employed to assess the effectiveness of system-level interventions on clinical bundle adherence. STATA version 13.1 was used to analyze the trend of each bundle adherence over-time.

Autocorrelation was checked to assess if the assumption of independence in observations collected over-time was valid. Prais-Winsten was used to minimize the effect of autocorrelation.

Findings: Quality improvement interventions targeting the three clinical bundles resulted in improved adherence over time across the four regions. In Tigray region, adherence to “On Admission” bundle was increased monthly on average by $B = 1.39$ (95% CI; 0.47 - 2.32; $P<0.005$).

Similarly, adherence to the “Before Pushing” bundle in Southern Nations, Nationalities and People’s (SNNP) region increased monthly on average by $B = 2.3$ (95% CI; 0.89 - 3.74; $P<0.005$).

Conclusion: Use of the WHO-SCC paired with a system-wide quality improvement approach improved and sustained quality of EBPs delivery. Further studies should be conducted to evaluate the impact on patient-level outcomes.

Introduction

Poor quality care during institutional births, particularly in low and middle-income countries (LMIC), has been recognized as a major contributing factor to childbirth-related harms as care providers may fail to execute essential birth practices (EBPs) in real time (1).

The ‘know-do’ gap – the difference between a provider’s knowledge and behavior – has often been cited as a phenomenon in care delivery, which many believe may relate to the failure to remember critical steps
during clinical care (2–5).

Checklists have been used as a tool to improve healthcare worker practices to deliver high quality essential care during institutional births (6,7). However, evidence shows that when implemented alone they may not result in change or improvement in quality of care (8).

In complex health system, determining the best way to translate novel checklists to improve adherence to evidence based practices by the end users may require system redesign at multiple interconnected levels, including behavioral change interventions (9–11).

To help skilled birth attendants (end-users) remember EBPs in real time and adhere to it, the World Health Organization Safe Childbirth Checklist (WHO-SCC) was developed by WHO and partners (12). The Checklist is an organized list of evidence-based essential birth practices which guides the end-users to pause and check at four critical points during childbirth: On Admission, Before Pushing (or before Caesarian), Soon After Birth (within one hour), and Before Discharge. The checklist was designed to address the major causes of maternal and neonatal deaths (12,13).

Based on promising preliminary results to improve EBP delivery, “The Better Birth Trial”- was designed to measure the impact of the WHO-SCC. There was no significant effect found on maternal or perinatal mortality or maternal morbidity despite having positive effects on EBPs during the intervention. Furthermore, adherence to EBPs was not sustained beyond the intervention period when the coaches were absent (14,15). The authors suggest that provider-level interventions may not fully translate into improved patient outcomes if not incorporated into a broader system-level improvement across facilities and referral systems.

A study implemented in Rwanda using WHO-SCC found an overall improvement in the EBPs compliance rate. Significant improvements were seen in 11 out of 29 EBPs. The reasons for low compliance to other EBPs were not identified even though clinical care providers received training on the use of WHO-SCC prior to implementation(16). These results indicate that systems improvement efforts may be required to close remaining gaps and achieve high enough reliability of adherence to achieve change in patient outcomes.

Clinical bundles have been developed and used in improvement science efforts as an approach to achieve system level change. A clinical bundle is defined as a small set of evidence-based interventions for a defined clinical domain that when implemented together at high reliability, will result in significantly better outcomes than when implemented individually(17).

Bundles are thought to promote awareness that an entire care team must work together in a system designed for reliability. Bundles also promote the use of improvement methods to redesign care processes (17).

Using standard quality improvement (QI) methods, bundles have been found to drive performance to new levels with the theory that in order to achieve high levels of reliable bundle implementation it will require
fundamental system change which lead to better and sustained results (18–22). For instance, if each of five bundle elements are delivered at 90 percent reliability, then the bundle is reliably delivered at 59 percent, as bundle reliability is the product of each element’s reliability (90% x 90% x 90% x 90% x 90%) (23). Studies indicate that all-or-none bundle measurement can help achieve new levels of performance and improved patient outcomes (18,24).

The Institute for Healthcare Improvement (IHI) in partnership with the Ethiopian Ministry of Health (MOH) integrated the Ethiopian-adapted WHO-SCC checklist into a broader district-wide MNH quality of care (QoC) improvement effort, with the ultimate aim of improving QoC and reducing maternal and newborn mortality.

This study evaluates the effectiveness of integrating the MOH-adapted WHO-SCC into a broader district-wide system improvement collaborative program. The program was measured by clinical bundle adherence over time in four districts of Ethiopia's major regions: Oromia, Amhara, Southern Nations Nationalities People (SNNP), and Tigray.

**Methods**

**Program Description**

The WHO-SCC was introduced in the context of a large-scale QI program being tested within the Ethiopian public health system. This intervention used a district-wide improvement collaborative designed to improve the quality of maternal and newborn health (MNH) care. The collaborative design was based on IHI's Breakthrough Series collaborative model. The goal of the collaborative is to convene a group of facilities around accelerating improvement in a common priority area using improvement methods and an established learning network (25).

The improvement collaborative were aligned to the administrative structure of the district, and had the following basic elements: selection of priority area and target indicators, QI training for QI teams, baseline data collection, and action plans to address key gaps in essential commodities and clinical skills. IHI was requested by the Ethiopian MOH to include WHO-SCC introduction as part of the Maternal and Newborn Health (MNH) QI effort. This checklist was introduced to collaborative health care facilities during the initiation of the program as a reminder for clinical care providers to practice evidenced-based EBPs in real-time. Coaching teams included support for WHO-SCC use with patients and QI support for projects aimed to improve system performance measured by clinical bundles. Adequate orientation for the proper use of the WHO-SCC was given to facility QI teams as part of the QI initiative and implemented in line with similar studies in LMIC(16,26,27).

The program team collaborated with professional associations to support clinical trainings such as Helping Babies Survive (HBS) and Basic Emergency Obstetric Newborn Care (BEmONC) as needed. Subsequently, QI teams from health centers and hospitals within each district convened in a series of “learning sessions”. This is intermittent face-to-face meetings with facility QI teams and leaders to share
their progress, challenges, receive targeted QI support and share critical learnings from the testing process.

Between learning sessions, facility teams implemented their QI projects using the Model for Improvement (MFI) as a framework for developing, testing, and implementing changes in a system to improve process reliability and outcomes of interest(28).

Teams tested newly developed change ideas and received on-site integrated clinical/QI coaching support from joint IHI-district leadership coaches. The collaborative was organized in four sessions during a 12-15-month period in the selected districts.

**Setting and Site Selection**

The first phase of the program was implemented in one district improvement collaborative at Tankua Abergele, Dugna Fango, Lemmu Bilbilo and Fogera districts located in the regions of Tigray, SNNP, Oromia, and Amhara respectively (four of Ethiopia's most populous regions).

All facilities in each district were included to ensure a district-wide approach, which consisted of three primary hospitals and twenty-seven health centers across the four district improvement collaborative. Districts were selected by regional leadership based on need for improvement, lack of other MNH partner-supported initiatives and the local leadership's desire for the approach. Leaders from the districts also demonstrated commitment to generate honest data for improvement.

**Outcome Measures**

In consultation with MOH-MNCH Directorate, we designed three clinical bundles (selected from the WHO-SCC) which were measured using all-or-none bundle adherence (adherence = yes if all bundle elements achieved) to include among the collaborative target indicators. The outcome measures for this study are all-or-none adherence to On Admission, Before Pushing and Soon After Birth bundles.

**Table 1.** Elements of the clinical bundle extracted from MOH adapted Safe Childbirth Checklist.
### Clinical Bundles

| Safe Childbirth Checklist Bundle Element |
|-----------------------------------------|
| **On Admission Bundle**                 |
| Danger sign assessment                   |
| Partograph initiated when cervical dilation at least 4 cm |
| Availability of soap, water, alcohol hand rub and gloves |
| Birth companion encouraged to be present during labor and at birth |
| Mothers privacy maintained during labor and delivery |
| **Before Pushing Bundle**               |
| Availability of gloves, soap/savlon and clean water |
| Preparation of 10 IU IV/IM Oxytocin in syringe |
| Availability of two clean, dry, warm towels and suction device |
| Availability of bag and mask (size 0 and 1) |
| Helper/Assistant identified and informed for resuscitation |
| **Soon After Birth Bundle (within 1 hour)** |
| Newborn assessment                       |
| Immediate skin to skin and initiate breastfeeding within the 1st hour |
| Baby weighed and recorded                |
| Administer Vitamin K1                    |
| Administer tetracycline eye ointment     |

### Data Collection

The data sources included audits of WHO-SCC and medical records. In health facilities where the number of monthly deliveries were greater than 30, a systematic random sampling method was used to retrieve 30 charts to calculate all-or-none bundle adherence using an excel template design as part of the program monitoring tool. In health centers where the number of facility births was less than 30, the total number of monthly deliveries was selected to calculate bundle adherence by regional IHI senior project officers.

Periodic data quality assessments were performed by coaches comparing clinical observation with recorded data. On a monthly basis, the data from respective collaborative health facilities were aggregated to create collaborative wide all-or-none bundle adherence—a dependent variable of our study.

The study period in Oromia, Tigray and SNNP was from November 2016 to December 2018. Unlike other regions, the start date of collaborative in the Amhara region was delayed by 7 months due to political instability in the region. Consequently, the study period was June 2017 to December 2018. No baseline
data were collected before the start of the intervention (study period) because the WHO-SCC was introduced for the first time as part of the quality improvement program.

Analysis

The trend of adherence to each clinical bundle over time was analyzed from the collaborative start date to the end of the project. Sustainability was assessed using a follow-up period of twelve months for all districts except Fogera (Amhara region).

For each clinical bundle, a time series analysis using STATA version 13.1 was used to assess the effectiveness of system-level interventions on all-or-none bundle adherence over time for the four districts.

Durbin Watson statics—a test for autocorrelation in the residuals from a statistical regression analysis was used to check if the assumption of independence in observations collected over time was valid. To fit the purpose, monthly collaborative-wide clinical bundle adherence mean was calculated and equally spaced for respective district. Furthermore, Prais-Winsten — a procedure meant to take care of the serial correlation of type Auto-regression (AR (1)) in a linear model — was used to minimize the effect of autocorrelation.

Results

Table 2 describes the characteristics of study districts and the interventions. Facility-level QI teams received an average of about 20 coaching visits throughout the intervention period with some variability. This achieved the program’s target which was to hold at least one joint coaching visit per month per district.

All-or-none bundle adherence to On Admission, Before Pushing, and Soon After Birth bundles in all districts have shown a positive monthly adherence increment. For instance, in Tigray region, Tankua Abargele district, adherence to on Admission bundle increased monthly on the average by $\beta=1.4$ (95% CI; 0.47 - 2.3) (Table 3). Similarly, adherence to Before Pushing in SNNP region, Dugna Fango was increased monthly on the average by $\beta=2.3$ (95% CI; 0.89 - 3.7) (Table 4) and adherence to the Soon After Birth bundle in Amhara region (Fogera district) and Oromia region (Lemmu Bilbilo district) was increased monthly on average by $\beta=0.15$ (95% CI; -0.45 - 0.74) and $\beta=0.7$ (95% CI; -1.2 - 2.5) respectively (Table 5).

In addition, adherence to the clinical bundles was sustained in all districts beyond the intervention period (December 2017 to December 2018) (Fig.1,2,3).

Table 2: Characteristics of MNH quality improvement collaborative prototype districts with interventions. November 2016-December 2018, Ethiopia
| Characteristics                                      | Tigray Region | Amhara Region | Oromia Region | SNNPR Region |
|------------------------------------------------------|---------------|---------------|---------------|--------------|
| District                                             | Tankua Abargele| Fogera        | Lemmu Bilbilo | Dugna Fango  |
| Total number health centers                          | 5             | 10            | 7             | 5            |
| Total number primary hospitals                        | 1             | 0             | 1             | 1            |
| Geographical characteristics                          | Agrarian      | Agrarian      | Agrarian      | Agrarian     |
| Total population (beginning of project)              | 115,841       | 296,844       | 213,032       | 122,316      |
| Total number of learning sessions conducted          | 4             | 4             | 4             | 4            |
| Average number of coaching/mentoring visits received per QI team/facility/month | 2.1 | 1.3 | 1.2 | 1.8 |
| Number of health care providers trained on BEmONC* per collaborative district | 15 | 11 | 0 | 6 |
| Number of health care providers trained on HBS* per collaborative district | 16 | 30 | 24 | 15 |
| Number of health care providers trained on NICU* per hospital | 5 | 4 | 5 | 5 |
| Number of system leaders trained on QILM* per collaborative district | 27 | 52 | 14 | 36 |
| Number of healthcare providers trained on QI*         | 19            | 33            | 15            | 27           |

*BEmONC- Basic Emergency Obstetrics and Newborn Care *HBS- Helping Baby Survive *NICU- Neonatal Intensive Care Unit *QILM-Quality Improvement and Leadership Management *QI –Quality Improvement

Table 3. Prais-Winsten AR (1) regression coefficients result of On Admission Bundle across district. November 2016- December 2018, Ethiopia.
| District       | Constant  | Slope  |
|----------------|-----------|--------|
|                | Coefficient | P   | Coefficient | P   |
|                | (95% CI)   |     | (95% CI)   |     |
| Tankua Abergele | 69.7       | < 0.001 | 1.4 | 0.005 |
|                | (55.4,83.9) |     | (0.47, 2.32) |     |
| Dugna Fango    | 46.1       | < 0.001 | 2.3 | < 0.005 |
|                | (26.9, 65.3) |     | (1.1, 3.5) |     |
| Lemmu Bilbilo  | 26.2       | 0.18  | 2.9 | 0.020 |
|                | (-13.63, 66.04) |     | (0.86, 4.8) |     |
| Fogera         | 50.1       | 22.85 | 0.12 | 1.4 |
|                | (22.85, 77.4) |     | (1.6, 1.9) |     |

**Table 4.** Prais-Winsten AR (1) regression coefficients result of Before Pushing Bundle across district. November 2016- December 2018, Ethiopia.

| District       | Constant  | Slope  |
|----------------|-----------|--------|
|                | Coefficient | P   | Coefficient | P   |
|                | (95% CI)   |     | (95% CI)   |     |
| Tankua Abergele | 69.6       | < 0.001 | 1.5 | < 0.005 |
|                | (51.5,81.8) |     | (0.47, 2.32) |     |
| Dugna Fango    | 44.24      | < 0.001 | 2.3 | < 0.005 |
|                | (21.8, 66.6) |     | (0.89, 3.7) |     |
| Lemmu Bilbilo  | 26.27      | 0.088 | 2.8 | 0.008 |
|                | (-4.31,57.86) |     | (0.86, 4.8) |     |
| Fogera         | 53.2       | < 0.001 | 0.31 | 0.579 |
|                | (22.85, 77.4) |     | (-.83,1.4) |     |

**Table 5.** Prais-Winsten AR (1) regression coefficients result of Soon After Birth Bundle
across district. November 2016- December 2018, Ethiopia.

| District          | Constant Coefficient (95% CI) | P (95% CI) | Slope Coefficient (95% CI) | P (95% CI) |
|-------------------|-------------------------------|------------|---------------------------|------------|
| Tankua Abergele   | 55.65 (5.6,97.7)              | 0.030      | 1.4 (-1.41, 4.3)          | 0.308      |
| Dugna Fango       | 57.3 (9.53, 105)              | 0.021      | 0.3 (-2.7,3.3)            | 0.841      |
| Lemmu Bilbilo     | 58.7 (29.2,88.2)              | < 0.001    | 0.7 (-1.2,2.54)           | 0.464      |
| Fogera            | 58.1 (47.5, 68.8)             | < 0.001    | 0.1 (-.45,0.74)           | 1.4        |

### Discussion

To the best of our knowledge, using the all-or-none bundle approach to measure adherence to evidence-based EBPs extracted from the WHO-SCC is the first of its kind. System-level interventions through the integration of the WHO-SCC into the district-wide MNH QI collaborative program has led to a marked increase in delivery of EBPs over time.

This has been made evident by improved adherence to On Admission, Before Pushing and Soon After Birth bundles both during the intervention period and for twelve months after the intervention period. The sustained improvement could indicate integration of changes into the routine system and ownership of the quality improvement approach.

Our study has several strengths. A standardized WHO-SCC was used to facilitate quality care in the context of a guided approach with clinical mentorship, measurement introduction, data collection, monitoring and response in a variety of health facilities across a large geographic area of rural Ethiopia. Monthly data was collected allowing for a time-series analytic approach, which can be a rigorous way of assessing change using routine programmatic data.

The On Admission and Before Pushing bundles were highly reliable in all study districts. However, a marked drop in adherence to the Soon after birth bundle was observed from October 2017-December 2017 at Lemmu Bilbilo, which we believe was due to political instability in the district which caused disruption in the supply chain of Vitamin K and tetracycline eye ointment from the regional capital to the district.
One possible explanation for the higher levels of reliability of the On Admission and Before Pushing bundles could be due to the fact that both bundles do not include any elements related to supply chain management; whereas the Soon After Birth bundle elements required stock management of Vitamin K and tetracycline.

All-or-none adherence to the Soon After Birth bundle across all regions took a considerable time to achieve a higher level of reliability. This is primarily due to the shortage of Vitamin K and the lengthy procurement process to purchase Vitamin K from private drug vendors. In response, facility QI teams have shifted focus of QI efforts onto supply chain measurement as a result significant improvement was observed after the period of low compliance (October- December 2017) across all districts.

Following the introduction of the WHO-SCC in the MNH QoC improvement collaborative facilities, the health care workers were able to identify and document newborns with complications and initiate higher level care in the effort to reduce mortality, a common recommendation of many studies (29–31). This, in turn, led to the establishment of level II neonatal intensive care units (NICU) and implementation of feasible evidence-based interventions such as kangaroo mother care at 3 primary Hospitals of the three districts.

While we used bundle adherence to reliably improve EBPs extracted from the WHO-SCC, adherence to individual EBPs also significantly improved during the intervention period and was consistent with other studies (6,16,32). However, unlike other studies (14,15), adherence to EBPs was sustained in our program beyond the intervention period.

This could be attributed to the engagement of local leadership from the baseline assessment to the fourth learning session, enablement of local ownership via joint coaching visits, ensuring local relevance and acceptability by running multiple Plan-Do-Study-Act cycles (PDSAs) before initial implementation of the WHO-SCC, and creating the intrinsic motivation of the end-users for successful adaptation of the WHO-SCC. This comprehensive behavior change strategy facilitated by our program has led to habits of continuous QI across the system as evidenced by incremental and sustained adherence to the three clinical bundles over time.

Our study has a number of limitations. Due to feasibility constraints and the nature of the quality improvement methodology in which QI teams ideally own the data collection and analysis themselves, we were limited to the use of routinely available data. Comparison facilities were not included in this study due to feasibility. Finally, due to the small volume of facilities, measuring impact on neonatal mortality was not feasible, and is the subject of a larger program evaluation.

**Conclusion**

Embedding the use of the WHO-SCC with rigorous measures and system improvement methods to address system gaps beyond the individual provider-patient interaction could be a promising approach to
improving the delivery of essential MNH interventions. Further study is underway to evaluate impact on patient-level outcomes.

**Keywords:** Quality, Bundle, WHO Safe Childbirth Checklist, Ethiopia, System

**Abbreviations**

AC: autocorrelation; BEmONC: basic emergency obstetric and newborn care; EBP: essential birth practice; MOH: Ministry of Health; HBS: Helping Babies Survive; IHI: Institute for Healthcare Improvement; LMIC: low and middle income countries; MFI: Model for Improvement; MNH: maternal and newborn health; QILM: quality improvement, leadership and management; QI: quality improvement; QoC: quality of care; SNNP: Southern Nations Nationalities and People; WHO-SCC: World Health Organization Safe Childbirth Checklist

**Declarations**

**Ethical approval and consent to participate**

The study proposal was reviewed by the Institutional Review Board (IRB) and was approved by University of North Carolina and Addis Ababa University.

**Availability of data and material**

Data used to synthesize the analysis is available from the authors and permission from the Institute for Healthcare Improvement should be obtained.

**Competing interests**

We declare no competing interests.

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**Contributors**

Befikadu Bitewulign and Dereje Abdissa contributed to the analytic design, managed the data and performed data analysis with Samir Awol, and wrote the first draft of the manuscript. Dr. Hema Magge, Prof. Alemayehu Worku, Prof. Yemane Berhane, Dr. Jane Roessner, and Dr. Gareth Parry conceptualized the study, contributed to the development of the research questions, reviewed the data analytical methods, and contributed to writing the manuscript. All coauthors reviewed and commented on the subsequent versions of the manuscript. All authors have read and approved the final manuscript.

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Figures
Figure 1

Trend of all or none bundle adherence to On Admission bundle across the four regions.
Figure 2

Trend of all or none bundle adherence to Before Pushing bundle across the four regions.
Figure 3

Trend of all or none bundle adherence to Soon After Birth bundle across the four regions.