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RESEARCH AND EVALUATION REPORT

A Comparative Evaluation and Cost-effectiveness Analysis of Collaborative Improvement for Maternal and Newborn Care Services in Uganda

SEPTEMBER 2014

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DISCLAIMER

The views expressed in this publication do not necessarily reflect the views of the United States Agency for International Development or the United States Government.

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Abbreviations

AIDS	Acquired immune deficiency syndrome
AMTSL	Active management of third stage labor
ANC	Antenatal care
ARV	Antiretroviral
DALY	Disability-adjusted-life-years
ENC	Essential newborn care
HBB	Helping Babies Breathe
HC	Health center
HCI	USAID Health Care Improvement Project
HIV	Human immunodeficiency virus
ICER	Incremental cost-effectiveness ratio
IEC	Information, education, and communication
MNH	Maternal and newborn health
MOH	Ministry of Health
PMTCT	Prevention of mother-to-child transmission of HIV/AIDS
PNC	Postnatal care
QALY	Quality-adjusted life-years
QI	Quality improvement
URC	University Research Co., LLC
US	United States
USAID	United States Agency for International Development

EXECUTIVE SUMMARY

Introduction

The USAID Health Care Improvement Project implemented a collaborative improvement intervention in Luwero and Masaka districts, Uganda, from November 2010 to November 2012. Its aim was to improve maternal and newborn health services including active management of third stage of labor (AMTSL), prevention of mother-to-child transmission of HIV (PMTCT), essential newborn care, newborn resuscitation, and post-natal care. In this intervention, teams from different facilities worked on a common improvement aim and came together for structured exchange of ideas and changes. Successful improvement ideas developed through the approach were then spread to additional sites. This study evaluated the impact and cost-effectiveness of the collaborative improvement intervention by comparing pre- and post-implementation quality of care indicators for samples of patients from participating and non-participating sites.

Methods

This cluster-randomized, controlled evaluation compared health facilities that received clinical training and participated in the improvement collaborative to control sites that received only clinical training and not the improvement intervention. Clinical training in essential maternal and newborn care was provided at 44 facilities allocated to either intervention or control arms by randomization at the sub-county level. The 22 health center (HC) II and HC III facilities in the intervention arm received clinical training plus orientation to improvement approaches. The clinical training consisted of workshops in AMTSL, essential newborn care, and neonatal resuscitation techniques known as "Helping Babies Breathe." Newborn resuscitation equipment (tables, supplies of bag-and-mask ventilators, and other accessories) was also provided to facilities in intervention and control facilities that lacked them.

All study sites received clinical training and were provided basic inputs needed for care of mothers and newborns, including newborn resuscitation bag and masks, resuscitation tables and other accessories. Both control and intervention groups were provided with registers to document indicators, and both were given clear instructions to maintain accurate and complete records throughout the study. Intervention sites were also involved in the improvement collaborative that included basic training in improvement methods, coaching visits, and learning sessions.

Data on indicators of processes of care were collected from health facility registers that were routinely recorded. Baseline data on clinical indicators were collected for facility deliveries between February and May 2011. End line data were collected in July 2012 for deliveries from June to July 2012. Patient information and performance indicator data were also collected. Working to improve data collection is considered a quality improvement intervention but it was determined necessary to conduct at the control sites too because of the concern that we would be unable to get adequate and accurate data for this study from the control sites without supporting them to record their data.

The incremental cost of implementing the intervention was obtained from the accounting records of HCI. Incremental clinical costs were collected by improvement team leaders. Expenses incurred directly as a result of the improvement intervention were included. These did not include clinical content training costs or the cost of newborn resuscitation tables and masks provided. Costs that resulted from changes because of the improvement collaborative such as job aids, were included. Costs were divided by the number of deliveries attended in the clinic during the intervention.

Quantitative data were analyzed using logistic regression with the dependent variables being the care performance indicators and the independent variables of interest being group (intervention or control) and time period (pre- or post-intervention). Potential confounders such as maternal age and parity were controlled for in the regressions.

Decision tree analysis was used to determine incremental cost-effectiveness. The probabilities of compliance with performance indicators were taken from the regression output controlling for potential confounders. Each of the ten performance indicators was calculated separately to give a ratio in US dollars per additional service delivered to compliance.

Results

Data were collected from 152 records in the control group in the baseline period, 218 in the intervention group in the baseline period, 175 in the control group in the end line period, and 231 in the intervention group in the end line period, for a total of 776 records. Despite efforts made during the clinical training to emphasize assiduous, accurate data collection, there were many data missing on several performance indicators, much more so in the control group. Due to data gaps at several sites, all missing data on compliance with indicators of quality of care were recorded as not compliant.

Difference-in-difference regression was conducted controlling for potential confounders of age, parity, risk age, and risk parity, with p-values calculated to account for clustering. There was a 32% to 59% improvement in compliance with the 10 measures of quality of delivery care attributable to the intervention. The highest improvements were in compliance with AMTSL (59%), umbilical cord care (58%), and eye care (58%). Considering the odds ratio results, there were statistically significant improvements in five of the 10 performance indicators and substantial (but not significant at alpha=0.05 level) improvements in four of the others. The only performance indicator for which the improvement was lower than five times the likelihood compared to the unexposed group was for breastfeeding within the first hour. The greatest improvement was seen in compliance with AMTSL.

In analysis conducted in which missing data were considered missing and only data marked as compliant or non-compliant were included in the analysis, the sample size was too small to detect statistically significant differences attributable to the intervention.

The overall cost of the program was $6.39 per delivery attended during the intervention. Considering the entire expenditure for the program which totaled $193,000, approximately 18,907 more women received care during childbirth compliant with AMTSL, 11,150 more infants received breast-feeding within the first hour after delivery, 15,173 more infants were wrapped and dried appropriately according to evidence-based recommendations, 17,498 more infants were provided with sterile umbilical cord care, 17,642 more infants received appropriate eye care after delivery, 13,601 more mothers were able to articulate their knowledge on the importance of breast-feeding the infant, 13,265 more mothers were able to articulate the danger signs that indicate health problems with the infant that require attention, 14,382 more infants attended the clinic for a health check in the first 24 hours of life, 14,382 more infants received a health check in the first three days, and 9,550 more infant receive a health check within four to seven days. These numbers are based on the very conservative assumption that improvements in the intervention sites would last for the 24 month duration of the intervention and no longer.

If we treat missing data from the registers on the compliance with the 10 maternal and newborn health performance indicators as non-compliance, then this study shows that there was a statistically significant improvement in half of the indicators that can be attributed to the intervention. However, this is based on a weak assumption that all missing data means non-compliance on all indicators for which data are missing. For one indicator (AMTSL), there was actually a decrease from 30% to 15% in the proportion of deliveries conducted that were compliant in the control group between the baseline and end line periods. While it is possible that such a decrease occurred despite training emphasizing the importance of AMTSL among other aspects of maternal and newborn health, an alternative and arguably more feasible explanation is that record-keeping during the same period decreased. We can confidently infer that clinical training, even with emphasis on the importance of maintaining good medical records, is not enough in this context to ensure that data will actually be collected on the performance indicators in this study.

Conclusion

The cost-effectiveness data show that a marginal expenditure of $20 or less will result in at least one unit increase in all indicators of quality performance in maternal and neonatal care measured. We used the assumption that improvements would only be seen in the two years of the intervention. It is highly likely that at least some of the improvements, if not all, would have continued beyond this time, because part of the intervention is to make health system changes to ensure that improvements efforts are maintained and built upon after technical assistance ends. However, data on these indicators beyond the period of outside assistance described above were not included in this analysis, nor was the cost of maintaining such an intervention. Therefore these estimates should be considered a worst-case scenario; the actual efficiency of the program is expected to be significantly better than that stated.

When missing data were considered as indicating non-compliance with the performance indicators, there is strong support for the conclusion that significant improvements in at least five indicators of maternal and newborn care are attributable to the intervention. Cost-effectiveness analysis showed that overall program costs were low relative to other interventions in Uganda aimed at addressing maternal and neonatal health and that it was relatively efficient in increasing compliance with treatment norms and standard practice.

Given this positive result based on the assumption about missing data, we recommend further implementation of collaborative improvement to increase uptake of evidence-based standards of care for mothers and newborns during and after delivery. However, given the poor data collection, particularly in the control sites, further study is recommended before a more confident determination of the effectiveness and efficiency of the improvement collaborative approach applied to maternal and newborn care can be made.

I. INTRODUCTION

Quality improvement has been recognized as having the potential to optimize the use of limited resources in developing countries [1] but evidence on the effectiveness and cost-effectiveness of various improvement interventions remains limited [2]. An evaluation by the USAID Health Care Improvement (HCI) Project summarizing the results of collaborative improvement in 12 countries by over 1300 teams during 1998-2008 showed that quality improvement teams were able to achieve large increases in compliance with health service standards and in some cases, in health outcomes, across all care areas addressed, regardless of the baseline level of quality [3]. Several other reports also demonstrate the cost-effectiveness of collaborative improvement interventions in achieving high compliance with standards of care and in improving outcomes [4-7]. However, due to operational limitations most assessments of collaborative improvement have been uncontrolled pretest–post-test designs that cannot rule out other plausible causes for observed improvements, such as secular trends [8]. Only a few controlled trials of improvement collaboratives have been conducted, and most of these have been limited to high-income country settings [9].

The USAID Health Care Improvement Project implemented several improvement interventions between 2008 and 2012. One was an improvement collaborative carried out in Uganda from November 2010 to November 2012. Its aim was to improve maternal and newborn health services, including active management of third stage of labor, prevention of mother-to-child transmission of HIV, essential newborn care, newborn resuscitation, and post-natal care. It was implemented in two districts in the central region of Uganda–Luwero and Masaka–with an estimated population of 416,000 and 250,000 respectively. Districts in Uganda are made up of several counties, sub-counties, parishes, and villages that form the administrative basis of health service organization. Table 1 gives a breakdown of the administrative divisions of Masaka and Luwero districts.

Table 1. Administrative make-up of Masaka and Luwero districts

	Number of counties	Number of sub counties	Number of parishes
Masaka	3	8	37
Luwero	3	14	67

In the improvement intervention that is the subject of this evaluation, teams from different facilities work on a common improvement aim and come together for structured, peer-to-peer exchange of ideas and changes. The successful improvement ideas developed through the collaborative approach are then spread to additional sites. Details of the intervention as implemented in Uganda are described in Section IIC below.

This study evaluated the impact and cost-effectiveness of a collaborative improvement intervention by comparing pre- and post-implementation quality of care indicators for samples of patients from participating sites and non-participating sites. This evaluation sought to determine whether there was added value, above clinical content training alone, of the improvement collaborative intervention in improving maternal and newborn health care quality. It also measured the relative efficiency of the improvement intervention compared to clinical training alone.

The specific research questions were:

1. In health center IIs and IIIs, did delivering mothers and newborns in intervention facilities (improvement intervention + clinical training) achieve better results in terms of performance indicators than delivering mothers and newborns in control facilities that received clinical training only?

2. What is the incremental cost-effectiveness of the improvement and clinical training intervention compared to the clinical training alone in terms of quality performance indicators for mothers and their children?

We also discuss the methodological challenges of conducting controlled operations research in this context.

II. METHODS

A. Study Design

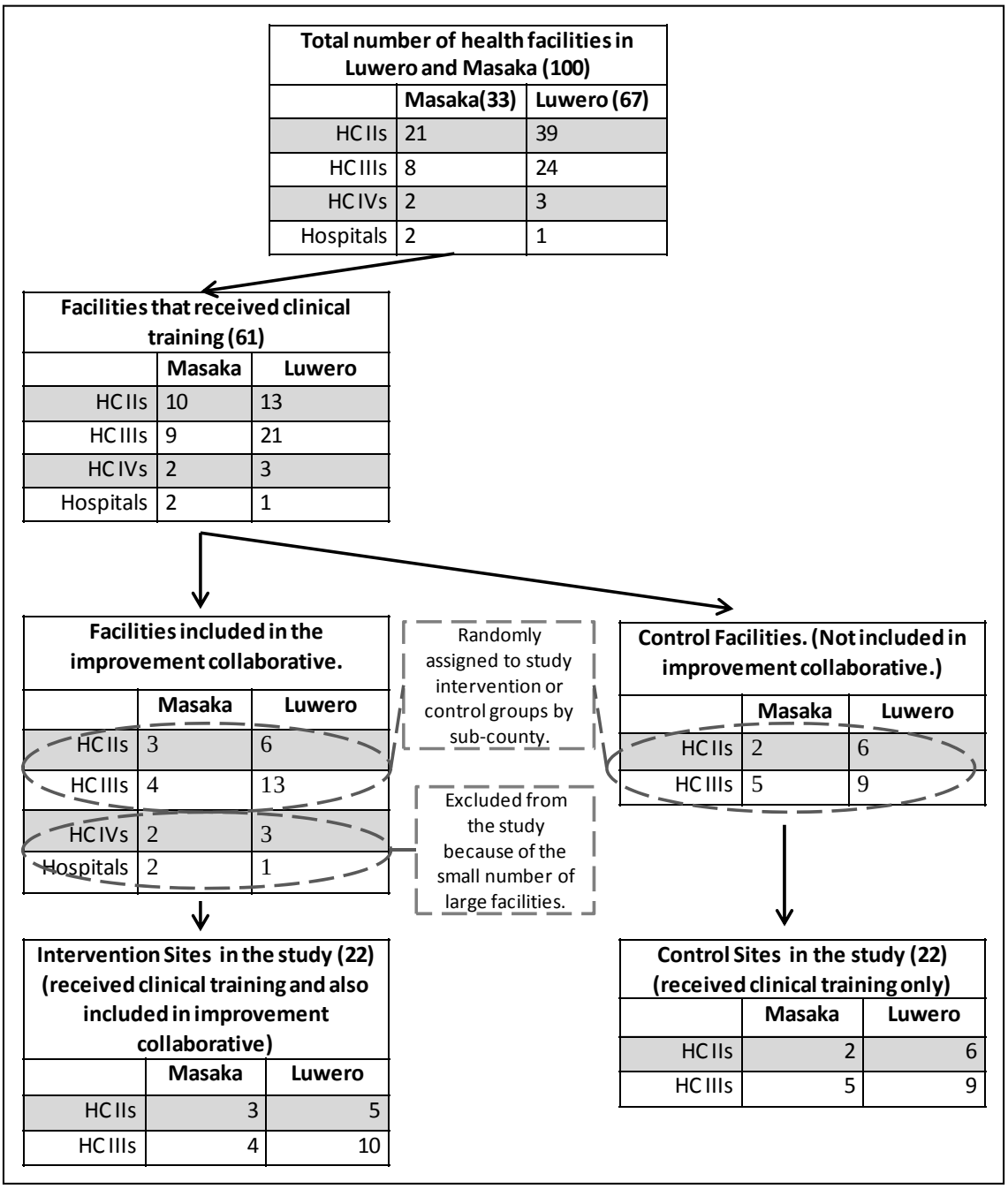
This cluster-randomized, controlled evaluation used intervention sites that received clinical training and participated in the improvement collaborative and control sites that received only clinical training at the start of the intervention period but did not participate in the improvement intervention. The units of analysis were the individual mother and her newborn for clinical measures and health facilities for others indicators of the performance of service delivery.

B. Sample Collection

The sampling universe was all mothers and their newborns and the health facilities from Luwero and Masaka. Inclusion criteria for sites for both intervention and control groups were facilities with current activity in both obstetric and neonatal health, and participation in clinical content training conducted by the USAID Health Care Improvement Project in February 2010. Sites were excluded if they were involved in prior quality improvement activity. Although there were five health center (HC) IVs included in the improvement intervention, we limited our evaluation to the HC IIs and IIIs because of the small number of larger facilities that were part of the intervention. Inclusion criteria for mothers and newborns were all those who delivered at the selected health facilities. Cesarean sections and still-births were excluded from active management third stage labor (AMTSL) and essential newborn care (ENC), respectively.

Clinical training in AMTSL and ENC was provided to 61 facilities: 38 in Luwero and 23 in Masaka. Participants in the training came from a total of 23 HC IIs and 30 HC IIIs, five HC IVs, and three hospitals. Each site sent one to three participants. Of the 61 sites, eight HC IIs were excluded from the study sample because they did not conduct deliveries at the time when this study was initiated; one HC III and three HC IVs were excluded because they had previously participated in another HCI improvement collaborative, and two HC IVs and three hospitals were excluded based on the small number of larger facilities. A total of 44 facilities (HC IIs and HC IIIs) were included in the study (see Figure 1).

Figure 1. Site selection and allocation to intervention and control groups



The selected 44 facilities were allocated to the intervention and control arm by randomization at the sub-county level. This was done to facilitate implementation by reducing distances between intervention facilities. Also, if two facilities within a sub-county were in different arms of the study, they would have the same supervisor and therefore a high likelihood that there would be a transfer of knowledge to control facilities, even though they were not active participants in the collaborative. This would have made it impossible to isolate the effect of the collaborative intervention. The 22 HC II and HC III facilities in the intervention arm received clinical training and orientation to the improvement approach and principles, whereas the 22 facilities in the control arm were only included in the clinical training (Table 2). The clinical training consisted of workshops on AMTSL, ENC, and neonatal resuscitation

techniques known as "Helping Babies Breathe" (HBB). Newborn resuscitation equipment (tables, supplies of bag-and-mask ventilators, and other accessories) was also provided to facilities in both the intervention and control arms that lacked them (Table 3).

Table 2. Intervention and control groups in Masaka and Luwero districts

	Total number of health facilities in Luwero and Masaka (100)		**Total number of facilities that received clinical training (61)**		**Intervention sites (included in collaborative improvement) (22)**		**Control Sites – received clinical training only (22)**	
	Masaka(33)	Luwero (67)	Masaka	Luwero	Masaka	Luwero	Masaka	Luwero
HC IIs	21	39	10	13	3	5	2	6
HC IIIs	8	24	9	21	4	10	5	9
HC IVs	2	3	2	3				
Hospitals	2	1	2	1				

Table 3. Activities in intervention and control sites

Program inputs	**Intervention**	**Control**
Clinical Content training in AMTSL, ENC, and HBB	Yes	Yes
Improving registers to document indicators	Yes	Yes
At least one newborn resuscitation bag for each facility including size 0 and size 1 masks	Yes	Yes
Provide newborn resuscitation table in facilities that are lacking one	Yes	Yes
Quality improvement training	Yes	No
Monthly coaching visits	Yes	No
Learning sessions	Yes	No

We sought a sample size of 151 deliveries based on the assumption of 20% compliance with standards at baseline with the ability to detect a 15% increase, with a power of 0.8 and an alpha of 0.05. However, during the study, collecting all of the delivery records from the participating facilities was possible therefore there was no specific selection of a sample. Data were collected from the Ministry of Health Delivery/Maternity Registers which were routinely completed by trained clinical staff as well as the Supplementary ENC registers that document services provided to the newborns during delivery and knowledge on newborn danger signs of the postpartum mothers.

Data were collected at baseline over a three-month period in 2011 while end line data were collected over one month in 2012. The intervention itself began in January 2012 and ended in November 2012 (Table 4).

Table 4. Timeline of activities in the improvement collaborative

November 2010	Training of district coaches in both clinical content and quality improvement
December 2010	Pre-intervention assessment
January/February 2011	Technical training of maternal and newborn health care providers
March 2011	Training in quality improvement principles
May 2011	First learning session
June 2011	Baseline data collection for the study
January 2012	Second learning session
June 2012	Third learning session
July 2012	End-line data collection exercise for the study
February 2011 – November 2012	Monthly on-site improvement coaching
September 2012	Harvest meeting
November 2012	Dissemination meeting

C. Improvement Intervention

All study sites received clinical training and were provided with basic inputs needed to ensure care for mothers and newborns, including newborn resuscitation bag and masks, newborn resuscitation tables, and other accessories. Both control and intervention groups were provided with registers to document indicators, and both were given clear instructions to maintain accurate and complete records throughout the study period and beyond. The intervention sites were also involved in the improvement collaborative that included basic training in improvement methods, coaching visits, and learning sessions (Table 3).

Collaborative improvement brings together teams from different facilities for structured exchange on shared goals to improve the delivery of health care in the given setting. In this intervention, peer-to-peer learning occurred in the periodic group meetings known as learning sessions where teams from different facilities shared experiences. In between learning sessions, facilities received visits from coaches with expertise in improvement methods whose job was to facilitate the facility's improvement team to use data to identify problems and implement potential solutions to them. In this intervention, the coaching visits were conducted by HCI quality improvement advisors and trained district coaches every month (Table 3).

D. Data Collection

Quality indicators

Data on indicators of the processes of care were collected from health facility registers. These data were routinely recorded in the facility as part of daily activities. Baseline data on clinical indicators were collected for facility deliveries between February and May 2011. End line data were collected in July 2012 for deliveries from June to July 2012. Patient information and performance indicator data (Table 5) were collected for each patient in the sample.

Working to improve data collection is considered a quality improvement intervention but it was determined necessary to conduct at the control sites too because of the concern that we would not be able to get adequately completed and accurate data for this study from the control sites without supporting them to record the correct information.

Table 5. Patient and performance indicator data collected

Focus area being improved	Performance indicators
Exclusive breast feeding	Baby put to breast within one hour of birth? Baby put skin to skin with the mother Mother able to explain importance of breast feeding
Early identification of danger signs	Mother able to explain importance of breast feeding Mother able to name 3 newborn danger signs Post-natal exam by skilled provider within 24 hours of delivery Post-natal exam by skilled provider at 2-3 days of age? Post-natal exam by skilled provider at 4-7 days
Infection prevention	Cord cut with new blade or sterilized instrument? Tetracycline or erythromycin eye drops or ointment within one hour of birth?
Prevention of hypothermia	Baby dried, put skin to skin and covered with warm clothing after birth?
Prevention of postpartum hemorrhage	Were 3 essential components of active management of the third stage of labor done? - Administration of oxytocin within one minute after delivery of the newborn and ruling out a multiple birth - Controlled cord traction with counter-traction to support the uterus - Uterine massage after delivery of the placenta

Data on the spread of change ideas

At the end of the study period, data on the types of changes that were implemented by control and intervention facilities during the study period were also collected to see if there was any natural diffusion of ideas from collaborative facilities to control facilities. This would lead to improvements in care at control sites and result in an underestimation of the contribution of the collaborative intervention to changes in care. At control facilities, these data were obtained by interviewing health workers involved in maternal and newborn care.

Cost data

The incremental cost of implementation of the improvement intervention was obtained from the accounting records of HCI. Incremental clinical costs were collected by the improvement team leader. Any expenses incurred directly as a result of the improvement intervention were included. These did not include costs associated with the clinical content training and cost of provision of inputs, such as newborn resuscitation tables and masks. They also did not include items associated with standard clinical practice, such as injectable oxytocin. Any costs incurred that resulted from changes implemented because of the improvement collaborative, such as job aids (e.g., AMTSL reminder poster), were

included. Incremental costs were divided by the number of deliveries attended in the clinic during the course of the intervention.

Table 6 provides an overview of the data collection tools and data sources. The items collected from each patient record to calculate compliance with care standards are shown in Appendix 1.

Table 6. Data collection tools and data sources

Data	Tool	Data Source
Quality indicators	Clinical data collection tool	Health facility records (registers and patient charts)
Data on costs incurred	Cost tool	HCI Project accounting records, coach and improvement team records
Data on the spread of change ideas	Spread tool	Interviews with the improvement team members and health care workers

E. Data Analysis

Patient characteristics recorded included age and parity. Although there is no universally accepted definition of a 'high-risk' pregnancy in this setting, for the purposes of this study we considered mothers whose age was less than 24 or greater than 40 years were at high risk and also those who were primiparous (first delivery) and multiparous (more than four deliveries) [10].

Mother's age, parity, high-risk age group, and high-risk parity group were reported as proportions, and the differences between control and intervention groups in both the baseline and end line period were analyzed using Fisher's exact tests for proportions and Student's t-test for continuous variables.

Quantitative data were analyzed using logistic regression with the dependent variables being the care performance indicators and the independent variables of interest being group (intervention or control), time period (pre- or post-intervention), and their interaction for the difference attributable to the intervention. Potential confounders, such as maternal age and parity, were controlled for in the regressions.

Decision tree analysis was used to determine the incremental cost-effectiveness of the improvement intervention. The probabilities of compliance with performance indicators were taken from the linear regression output when controlling for all of the potential confounders. The total cost of the intervention was divided by the total number of vaginal deliveries attended in the intervention clinics in the two years from December 2010 until November 2012, inclusive. Each of the 10 performance indicators were calculated separately using the incremental cost-effectiveness equation to give a ratio in US dollars per additional service delivered to compliance. To illustrate the total effect of the intervention, we used the total cost of the intervention, $193,000 and divided this by the incremental cost-effectiveness ratio (ICER) amounts from the calculations. This allowed summarization of the intervention's efficiency by stating that for total expenditure of the intervention, there were *x* additional deliveries performed compliant to AMTSL and *y* additional neonates who received breastfeeding in the first hour, etc. (see Figure 2). This reflects the cumulative nature of the effects of the program.

This study was reviewed and approved by the institutional review board of University Research Co., LLC and was exempt from review by a Ugandan institutional review board because the clinical data collection was part of routine clinical work and was not solely for the purposes of the research study. Clinical staff recorded data about each delivery from facility medical records without patient names. The data collectors for this study reviewed facility registers and transcribed the records for the given period and therefore did not interact with any human subjects or record any personal identifiers. Facilities were assigned numbers and type and were not recorded by name to ensure anonymity of the data.

Figure 2. Illustration of calculations to determine the efficiency of the intervention

Probability of a delivery being AMTSL compliant before the intervention = 0.18 (see Table 9)

Probability of a delivery being AMTSL compliant after the intervention = 0.77 (see Table 9)

Incremental cost of the intervention = $192,851

Number of deliveries attended in two years of intervention = 32,303

Incremental cost of the intervention per deliver attended in intervention sites = 192,851 / 32,303 = $5.97

Difference in effectiveness = Probability of AMTSL compliance after intervention – Probability of AMTSL compliance after intervention (controlling for confounders)

= (0.77 – 0.18)

= (0.59)

Incremental cost-effectiveness ratio (ICER) = Difference in costs / difference in effectiveness

ICER = $5.97 / 0.59

= $10.20

Therefore, for every $10.20 dollars spent, there is one additional delivery that is compliant with AMTSL norms.

Or, for $192,851 dollars spent, there is an additional (192,851 / 10.2 = 18,921) deliveries that are compliant with AMTSL norms. (This is in addition to the other improvements in the indicators that were calculated as attributable to the intervention.)

III. RESULTS

A. Patient Populations

Data were collected from 152 records in the control group in the baseline period, 218 in the intervention group in the baseline period, 175 in the control group in the end line period, and 231 in the intervention group in the end line period for a total of 776 records (Table 7).

Table 7. Total number of cases in the sample

Control	152	218	370
Intervention	175	231	406
Total	327	449	776

There was no significant difference between the mothers' ages in the intervention and control groups both at baseline and end line, but there were differences in parity. There was higher average parity of mothers in the control group which was greater in the baseline period than the end line (Table 8).

Table 8. Baseline patient characteristics

Sample size	152	175			218	242				
Mother's age (mean in years)	24.5	24.1	-0.40	0.546	25.5	25.1	-0.33	0.55	-0.39	0.358
Mothers in high-risk age group	48 %	51%	3.4%	0.560	41%	45%	4.1%	0.406	4%	0.285
Parity (mean)	3.9	3.1	-0.73	0.002**	3.28	3.21	-0.07	0.742	-0.34	0.029*
Mothers in high-risk parity group	43%	49%	6%	0.277	45%	50%	4.9%	0.314	5.1%	0.143

*= Statistically significant at p<0.05 **= Statistically significant at p<0.01

B. Performance Indicators

Despite efforts made during the clinical training to emphasize the importance of assiduously collecting relevant data on all deliveries occurring in the facilities, there were many data missing on several of the 10 performance indicators listed in Table 5. This was a much greater problem in facilities in the control group—those that did not benefit initially from participation in the learning sessions and coaching visits. Due to gaps in documentation at several sites in both groups, all missing data on compliance with indicators of quality of care were recorded as not compliant for the final analysis. In preliminary analysis in which the missing data were treated as missing and only data marked as compliant or non-compliant were included in the analysis, the sample size was too small to detect any statistically significant differences among any of the four groups attributable to the intervention with and without controlling for confounders (analysis results not shown).

It was hypothesized that patients coming to the same facility would receive a similar quality of care, thus we clustered the data by facility and checked for intra-class correlation on the variables for AMTSL, which was 0.43. Therefore, in performing the regression analysis, we accounted for the correlation to adjust for facility clustering.

Difference-in-difference regression was conducted controlling for potential confounders of age, parity, risk-age, and risk-parity, with p-values calculated to account for clustering (Table 9).

The "Change associated with intervention (%)" column in Table 9 shows regression results considering changes in compliance with performance indicators attributable to the intervention as continuous variables. This was to provide inputs for the cost-effectiveness model. An example of the interpretation in the first data row is that there was a 58.6% improvement in compliance with AMTSL in the intervention group attributable to the intervention. The "Change associated with intervention (odds ratio)" in Table 9 shows regression results considering changes in compliance with performance indicators attributable to the intervention as a proportion, which is the mathematically correct analysis but gives a result that is not possible to use in the cost-effectiveness model. An example of the interpretation in the first data row is that there is about a 30-times (odds ratio of 30.20) higher likelihood of compliance with AMTSL norms during normal deliveries in clinics exposed to the improvement intervention compared to those not exposed to the intervention.

Table 9. Results for the difference between baseline and end line in intervention and control groups on 10 performance indicators

Variable	Baseline		Post-intervention		Change associated with intervention (%)	p-value	Change associated with intervention (odds ratio)	p-value
	Control	Interven-tion	Control	Interven-tion				
AMTSL	19.7%	17.1%	6.9%	68.0%	58.6%	<0.001**	30.20	0.010*
Breastfeeding 1st hour	19.7%	24.0%	33.5%	77.5%	36.9%	0.094	4.58	0.216
Dry and wrap infant	19.7%	24.0%	33.5%	89.2%	50.2%	0.023*	13.60	0.031*
Sterile cord care	27.6%	24.0%	33.5%	88.7%	58.4%	0.010*	22.10	0.004**
Neonatal eye care	19.7%	15.4%	33.5%	88.7%	57.9%	0.007**	23.08	0.014*
Knows importance of breastfeeding	19.1%	30.3%	30.7%	87.9%	45.0%	0.040*	8.97	0.065
Knows neonatal danger signs	17.8%	28.0%	30.3%	86.1%	43.9%	0.044*	7.20	0.119
Examined in 1st 24 hours post-partum	19.7%	26.3%	34.4%	86.1%	45.0%	0.042*	8.99	0.064
Examined 2-3 days post-partum	15.8%	10.9%	11.9%	51.9%	47.6%	0.004**	15.52	0.049*
Examined 4-7 days post-partum	14.5%	8.6%	12.4%	36.4%	31.6%	0.046*	9.67	0.119

* = Statistically significant at p<0.05 ** = Statistically significant at p<0.01

Considering the odds ratio results, there were statistically significant improvements in five of the 10 performance indicators and substantial (but not significant at alpha=0.05 level) improvements in four of the others. The only performance indicator for which the improvement was lower than five times the likelihood compared to the unexposed group was for breastfeeding within the first hour. The greatest improvement was seen in compliance with AMTSL.

C. Changes Implemented

To assess changes made in the study sites, we interviewed facility staff at the end of the study period and reviewed the documentation journals that were used to track the improvement efforts made and describe changes in the processes of care implemented against the timeline.

Of the 21 intervention sites for which there were available data on improvement activities, all implemented system changes. Intervention sites reported making an average of 11 changes (range 1–22) during the course of the improvement intervention. In the control group, while 16 out of the 22 sites reported making improvements in their services, there was an average of only 1.5 changes made (range 0–3).

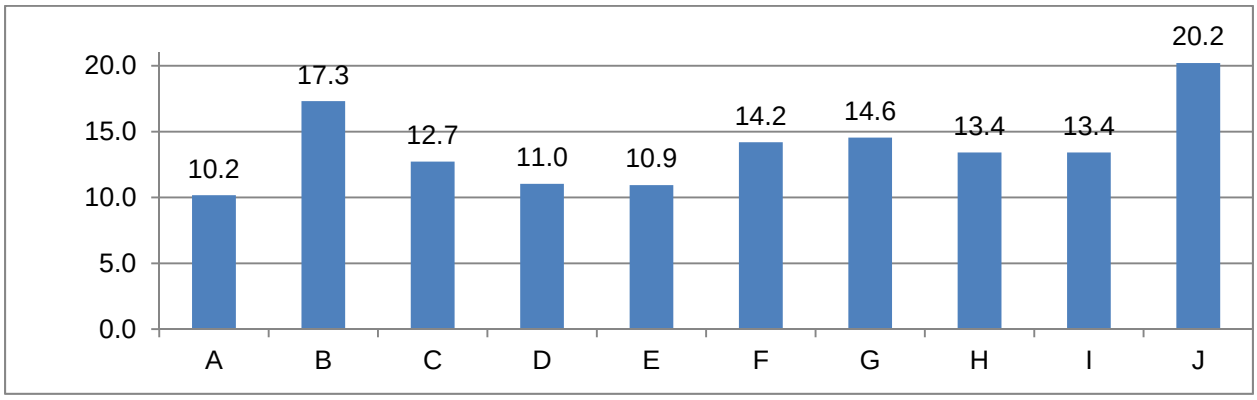
The changes implemented in the intervention sites as part of the improvement intervention are summarized in Appendix 2.

D. Cost-effectiveness Analysis

The overall cost of the improvement program was $6.39 per delivery attended during the period of the intervention. Incremental cost-effectiveness analysis calculations were conducted with the inputs for the mathematical model based on the results of the regression analysis presented in Table 9. The results are presented in Figure 3. The interpretation of the first column in the figure, for example, is: the incremental cost-effectiveness of the improvement intervention compared to business as usual is $10.20 per additional delivery that is compliant with AMTSL occurring at a facility involved in the collaborative. However, all of the effects shown in Figure 3 are cumulative.

Another way of expressing the efficiency of the program is to consider what the effect of a specific expenditure is. For example, if we consider the entire expenditure for the program which totaled $193,000, approximately 18,921 more women receive care during their childbirth compliant with AMTSL, 11,150 more infants receive breast-feeding within the first hour of delivery, 15,173 more infants are wrapped and dried appropriately according to evidence-based recommendations, 17,498 more infants are provided with sterile umbilical cord care, 17,642 more infants receive appropriate eye care after delivery, 13,601 more mothers are able to articulate their knowledge on the importance of breast-feeding the infant, 13,265 more mothers can articulate the danger signs that indicate health problems with the infant that require attention, 14,382 more infants attend the clinic for a health check in the first 24 hours of life, 14,382 more infants receive a health check in the first three days and 9,550 more infant receive a health check within four to seven days. These numbers are based on the conservative assumption that the improvements seen in intervention sites would last for the 24-month duration of the intervention and not any longer. For a less conservative estimate, for example, if the improvement were sustained for a period of 30 months instead, the expenditure of $193,000 would have led to approximately 40,000 more women who receive care during their childbirth compliant with AMTSL, 22,000 more infants who receive breast-feeding within the first hour of delivery, etc.

Figure 3. Incremental cost-effectiveness ratio ($/effect)



Key for Figure 4: Effects

ICER Denominator	X-axis above
AMTSL compliant delivery	A
Newborn is breastfed in first hour after birth	B
Newborn dried and wrapped	C
Sterile cord care observed	D
Newborn eye care completed	E
Mother has knowledge of importance of breast-feeding	F
Mother knows danger signs for newborn	G
Newborn examination in 24 hours following birth	H
Newborn examination 2-3 days following birth	I
Newborn examination in 4-7 days following birth	J

IV. DISCUSSION

If we treat missing data from the registers on compliance with the 10 maternal and newborn health performance indicators as non-compliance, then this study shows that there was a statistically significant improvement in half of the indicators that can be attributed to the intervention. However, this is based on a weak assumption that all missing data means non-compliance on all indicators for which data are missing. For one indicator (AMTSL), there was actually a decrease from 30% to 15% in the proportion of deliveries conducted that were compliant in the control group between the baseline and end line periods. While it is possible that such a decrease occurred despite there being a clinical training emphasizing the importance of AMTSL among other aspects of maternal and newborn health, an alternative and arguably more feasible explanation is that the record-keeping during that same period decreased independent of the level of compliance with the quality of care indicator.

The cost-effectiveness data show that a marginal expenditure of $20 or less will result in at least one unit increase in all of the indicators of quality performance in maternal and neonatal care measured. We used the assumption that improvements would only be seen in the two years of the intervention. It is highly likely that at least some of the improvements, if not all of them, would have continued to at least some extent beyond the period of the intervention. It is the stated aim of the intervention to develop policies and procedures at different level of the health system to ensure that improvements efforts are maintained and built upon following the period of outside technical assistance. However, data on these indicators beyond the period of outside assistance described above were not included in this analysis nor were the cost of maintaining such an intervention. The costs of continuing the improvement is likely to be significantly less than the amount spent in the first two years of the intervention. Consequently, these estimates of the efficiency of the program should be considered a very conservative estimate, and actual efficiency is expected to be significantly better than that stated.

We did not convert the effectiveness in terms of improved compliance with standards of treatment into hard endpoints such as deaths averted or utility measures such as disability-adjusted-life-years (DALYs) or quality-adjusted-life-years (QALYs) because this would have added another degree of uncertainty in the calculations where the degree of precision of the data was already questionable. If the outcome data were more certain, using QALYs, DALYs or lives saved would have allowed for easier comparison to other studies on the effectiveness and efficiency of interventions to improve maternal and neonatal health.

There have been some studies that have investigated the cost and efficiency of interventions for maternal and newborn health from the same or similar settings. In a study of the cost of individual peer counseling to promote exclusive breast-feeding among mothers in Uganda, Chola et al. [11] projected costs per mother counseled at $139 or approximately $15 per week. While this study did not measure the effectiveness of the counseling directly, it claimed that the program could potentially reduce overall costs by 60%. The initial expenditure of this breastfeeding intervention is substantially higher than the costs associated with the intervention in the present study. Another study of the cost-effectiveness of intermittent preventive treatment of malaria during pregnancy found that the incremental cost-effectiveness ratio of a community-based delivery system for the medication was $1.10 per DALY averted [12]. Given that we did not convert the effectiveness of our program into DALYs due to the complexities and uncertainties involved, a direct comparison is not possible with the efficiency of this program. A study of the cost and cost-effectiveness of training traditional birth attendants to decrease neonatal mortality in a district in Zambia showed a cost of $29 per delivery – 4.5 times the cost per delivery of the current intervention – and an incremental cost-effectiveness of $120 per DALY based on conservative estimates [7]. There is a study underway examining the effectiveness of an intervention linked to health facilities to improve newborn health and survival in rural Uganda but results are unavailable as of this writing [13].

A. Limitations

We can confidently infer that clinical training, even with substantial emphasis on having clinicians understand the importance of maintaining good medical records, is not enough to ensure that data will actually be collected on the performance indicators chosen for this study and for this improvement intervention. The researchers in cases such as this are left with a balancing act. On one side is the desire to keep the control group as valid a comparator to the intervention group as possible. This necessitates the provision of the clinical training and nothing else in terms of follow-up opportunities for technical assistance and to check on progress towards improving services, including data collection. With no additional input to emphasize the importance of collecting clinical data accurately, this aspect of professional practice may stay the same or even decrease over time. On the other side is the need to collect valid, reliable, and complete data, which may require substantial intervention on the part of the researchers in terms of additional training and follow-up to ensure good medical record-keeping practices by those clinicians delivering care. This kind of technical assistance is more likely to improve other areas of clinical practice and therefore may substantially reduce the effect that can be detected in the intervention group by comparison. In this case, the clinical trainers who provided training to both the intervention and control groups stressed the importance of maintaining accurate and complete medical records. However, in the case of the control group, this mostly did not occur, and there was actually deterioration in the completeness of the delivery register from baseline to end line in some clinics. A way to prevent this would be to collect data on compliance with best practice guidelines by other means, such as direct observation or exit interviews with patients. In this study, limited resources precluded this option.

Data from registries is essentially secondary data collected for purposes other than research. During the clinical training, registers were checked against the individual patient records to ensure they were in concordance. Additionally, during the clinical training that was conducted for all of those either in the control and intervention groups, the accuracy and completeness of these records were emphasized and instructions on how the records should accurately be updated was provided. Data in the registers were checked for completeness and accuracy during onsite coaching visits by the improvement advisor. However, there was no formal mechanism in place to validate the data in the registries after the clinical training period. Therefore it is possible that some inaccuracies may have occurred in collecting these data.

Data were collected from existing records at the facility. This precluded collection of additional socio-demographic characteristics such as maternal education and other indicators of socioeconomic status and other potential confounders. However, there was no reason to suspect that there would be major differences in these characteristics between the groups because they were selected at the population level to be matched on these characteristics.

V. CONCLUSION

When missing data were considered as indicating non-compliance with the performance indicators, there is strong support for the conclusion that significant improvements occurred in at least five of the indicators of maternal and newborn care that can be attributed to the intervention. Cost-effectiveness analysis showed that the overall cost of the program was low relative to other interventions in Uganda aimed at addressing maternal and neonatal health and that it was relatively efficient in terms of the effect of increasing compliance with treatment norms and standard practice.

Given this positive result based on the assumption about missing data, we recommend further implementation of collaborative improvement interventions to increase uptake of evidence-based standards of care for mothers and newborns during and after delivery. However, given the poor data collection, particularly in the control sites, further study is recommended before a more confident determination of the effectiveness and efficiency of collaborative improvement can be made.

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APPENDICES

Appendix 1. Clinical Data Collection Tool

Patient number	
Date delivered (dd/mm/yy)	
Where delivered (Home, TBA, facility, other - give detail)	
Mother's age in years	
AMTSL done? Y if all 3 were done N if any or all 3 were not done	
Baby put to breast within one hour of birth Y / N	
Baby dried, put skin to skin, head covered with dry towel? Y if all 3 were done N if any or all 3 were not done	
Cord cut with new blade, HLD or sterilized instrument? Y/N	
Eye drops or ointment within one hour of birth? Y/N	
Able to explain importance of exclusive breast feeding? Y/N	
Able to name 3 newborn danger signs? Y/N	
Exam by skilled provider in 24 hrs? Y/N	
Exam by skilled provider at 2-3 days of age? Y/N	
Exam by skilled provider at 4-7 days? Y/N	
Cadre of provider at delivery	
Cadre of provider at discharge	
Parity at discharge	
Mother's diagnosis (e.g., postpartum hemorrhage)	
On antiretroviral therapy? Y/N/NA	
Baby's Apgar score	

Appendix 2. Summary of Changes Implemented by the Health Facilities

FOCUS AREAS	CHANGE CONCEPTS	CHANGE IDEAS
Skilled birth attendance	Create a system for ensuring facility deliveries with skilled birth attendance	Organize the duty roster to ensure skilled birth attendance for all deliveries
		Make public notices about facility deliveries
		Motivate mothers to have facility deliveries
Knowledge	Create an on-going system of updating staff knowledge and skills	Introduce and schedule maternal and newborn health (MNH) topics in continuing medical education sessions
		Display posters in antenatal care (ANC)/maternity for reference by the health workers
		Provide on job training through orientation and one on one mentoring of students, new staff , untrained staff
		Regular practice sessions for midwives on how to provide services
	Create on-going process for health education	Provide health education to mothers and care takers on birth preparedness, safe delivery, newborn care and requirements
		Counsel mothers in groups or individually as when appropriate
		Displaying pictorial posters/ job for mothers and caretakers
		Provide health education for caretakers and partners on newborn care immediately after birth during postpartum period
	Ensure that mothers and care takers understand messages	Identify a member of staff to interpret information on posters for mothers with a language barrier
		Translate posters / IEC materials from English to the local language
Male involvement	Involve male partners	Give priority to couples during antenatal and postnatal care (PNC) visits
		Health educate mothers and their partners on importance of facility delivery
		Couple counseling in MNH department before discharge and during PNC visits
		Talk to men about the importance of PNC during ANC and at discharge
Logistic management	Create a system to ensure availability of supplies	Stock and monitor appropriate drugs and supplies using set minimum stock levels
		Use consumption rates to make regular (monthly/weekly) request to appropriate levels
		Request for medicines and other supplies from the health sub-district
	Create a backup system for supplies	Request for MNH supplies from nearest health facility in case of shortages
		Ask mothers/ husbands to buy drugs/supplies in case of out of stock

FOCUS AREAS	CHANGE CONCEPTS	CHANGE IDEAS
Documentation	Create / develop a system for regular review and feedback for documentation	Assign staff to review records and provide feedback to staff on a weekly basis
		Check registers at staff changeover of duty to identify any missing information and correct them
		Identify and re-allocate improvement team members for effective supervision in regards to documentation
		Pin up written notices to remind staff about recording/documentation at different locations within the maternity ward
HIV testing	Identify and test pregnant women with unknown HIV status within the facility	Identify mothers who have not been tested for HIV
		Midwife cross checks for PMTCT codes in mothers' passport or book on admission to the maternity / labor suites
	Reorganize services to improve access to HIV testing among pregnant women	Introduce HIV testing for women of unknown HIV status admitted on the maternity ward
		Assign a person responsible for offering HIV testing to mothers of unknown HIV status
	Re-align financing or cost to increase affordability of HIV testing services among pregnant women	Give a discount for user fees on HIV testing
		Incorporate HIV test bill on the general bill at discharge
	Set up reminder systems within the maternity ward on HIV testing	Display/ Use job aids on HIV testing algorithms within the maternity for reference
AMTSL	Procure and ensure proper storage of oxytocic drugs	Store keeper at HC IV considers available storage facilities when supplying Oxytocin
		Use ice packs to store oxytocin in the maternity at recommended temperatures
ENC	Support mothers to maintain thermal protection of newborn	Counsel and demonstrate to mothers how to keep babies warm with appropriate baby clothes
		Lobby for support from the community for baby clothes
		Loan unequipped mothers adequate baby clothes
Early initiation of breast feeding (within 1st hour)	Support mothers to make decisions on breast feeding	Initiate one on one counseling of HIV + mothers on the advantages of exclusive breastfeeding
		Utilize job aid to counsel mothers on early initiation of breastfeeding
	Enable mothers to have early initiation of breast feeding	Demonstrate proper positioning of the baby during breast feeding
		Assist mothers to put baby to breast within 1 hour of birth
		Provide pain management after birth as needed
		Use notices/ reminders for staff on breastfeeding within the first hour of birth

FOCUS AREAS	CHANGE CONCEPTS	CHANGE IDEAS
Knowledge on newborn danger signs	Make mothers become aware of newborn danger signs	Display pictorial posters/job aids of newborn danger signs/ on the walls for mothers and caretakers
Postnatal examination of newborns within 1st week	Re-organize care delivery options for convenience of mothers	Allocate staff daily to attend to postnatal mothers
		Retain mothers and discharge 24 hours after delivery
		Instruct C-section mothers to bring their babies back when they return to have their stitches removed.
		Refer mother/baby pairs (written or verbal) to nearby health facility in case she cannot come back due to transport
	Arrange infrastructure to allow provision of postnatal care	Create space for postnatal examinations within the health facility
	Provide specific appointments for postnatal care	Provide mothers with specific appointment dates and times to return for postnatal care
	Motivate or encourage mothers, husbands and care takers to return to the facility for postnatal care	Call mothers and remind them to bring babies to clinic for postnatal visits
		Give priority to postnatal mothers and attend to them first
		Give provisional birth notification or certificates during first week of birth

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