Research Article

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Assessing effects of a data quality strengthening campaign on completeness of key fields in facility-based maternity registers in Kenya and Uganda

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BACKGROUND
Little is known about the accuracy of facility-based birth registry data for routine monitoring of birth outcomes. This report details the results of a data quality strengthening intervention aimed at improving completeness of birth registry data in Kenya and Uganda, as part of a package of interventions in an implementation science trial under the East Africa Preterm Birth Initiative.

METHODS
The intervention aimed to improve completeness of key intrapartum and post-partum data, including gestational age, birthweight, and newborn outcomes. We conducted data strengthening activities in 23 facilities in Uganda and Kenya. To test the effects of these interventions on completion of key variables, we compared completion rates at various time points.

RESULTS
In Uganda, the completion rate of all four fields of interest increased by 13% (95% CI: 10, 17) with the introduction of data quality training and mentoring. Documentation of the status of infant at discharge and gestational age increased by 12% (95% CI: 9, 14) and 22.3% (95% CI: 19, 17), respectively; while that of birthweight had a marginal increase of 3.2% (95% CI: 1, 5) and Apgar at 1 minute showed no significant change. In Kenya, there was no significant change in completion for most fields.

CONCLUSION
This study suggests that the data strengthening campaign had mixed effects on completion of facility-based maternity register fields and may be country specific. Given emerging international priorities around maternal and neonatal health, utilizing facility-based routine data sources will be key to ensuring sustainable monitoring and evaluation of interventions and outcomes.

Key words: *Data, quality, completeness, routine*

BACKGROUND

Preterm birth, defined as birth occurring before 37 completed weeks of gestation, and its subsequent health complications are now the leading cause of both neonatal and under-five child mortality (WHO, 2012). Globally, an estimated one million newborns die each year due to complications of prematurity, and another 0.9 million preterm survivors suffer from mild to severe neurodevelopment impairments (Blencowe, et al., 2013). Thus, to further decrease under-five and neonatal mortality, averting prematurity and helping preterm infants survive are a high priority.

East Africa Preterm Birth Initiative (PTBi-EA) is a multi-country initiative that seeks to strengthen and create locally-relevant solutions to address prematurity in a sustainable and scalable manner. In Kenya and Uganda, PTBi-EA is a collaboration among the Uganda Makerere Center of Excellence in Maternal Newborn Health, the Kenya Medical Research Institute, and the University of California, San Francisco, which strives to decrease preterm morbidity and mortality through a package of interventions including simulation training, quality improvement (QI), data strengthening and the use of a modified WHO safe childbirth checklist. To inform QI activities and evaluate project success, we must be able to confidently measure the births and outcomes that will make up the denominator of any facility-based outcome analysis. For this reason, the initiative focuses strongly on improved measurement and data use from existing facility-based data sources. In the two countries, maternity-based data collection occurs through use of paper-based records, which are aggregated on a monthly basis and reported through the online District Health Information System 2 (DHIS2) system.

Data quality challenges pose serious concerns for accurately measuring incidence of prematurity and monitoring service provision in low-resource settings. Most Kenya and Uganda facilities estimate gestational age from last known menstrual period or fundal height, both of which have been shown to be largely inaccurate in rural communities (Constant, et al., 2017; Deputy, et al., 2017). Given this inaccuracy, additional incompleteness of other birth data can severely impact birth registration; missing birthweight and Apgar can also inhibit classification of stillbirth or livebirth (Froen, et al., 2009).

To address these challenges, we implemented a data strengthening campaign which was executed through structured trainings and ongoing mentorship. We developed an on-going system to monitor progress and measure quality throughout the life of the project. The focus of this paper is on the findings from the data strengthening intervention package in Kenya and Uganda, specifically around improving documentation and completeness of register fields key to assessing preterm birth.

METHODS

Study design

We conducted a retrospective record review of completion of key fields recorded in the maternity register in PTBi-EA study sites. A total of four data elements related to preterm birth were assessed for completeness: gestational age (GA), birthweight, Apgar score at one minute, and status of infant at discharge. Data completeness was measured by assessing the number of data elements not missing. The study was approved by the University of California, San Francisco, Institutional Review Board (Study no: 16-19162), the Kenyan Medical Institute Scientific and Ethics Review Unit (SERU protocol no: KEMRI/SERU/CCR/0034/3251), and the Makerere University Higher Degrees, Research, and Ethics Committee (Protocol ID: IRB00011353).

Study sites

Twenty-three health facilities/sites in Central Eastern Uganda (6) and Western Kenya (17) were selected to participate in the study. A purposive sample of sites was selected to reflect preterm birth burden and the variety of service delivery models within a rural resource-limited setting. In Migori County, Kenya, one county referral hospital, 10 sub-county hospitals, four health centers, and two private mission hospitals were selected to be included in the study. In Uganda, one referral hospital and five district hospitals were selected in the Busoga region.

All selected facilities utilized paper-based registers, patient charts, and monthly aggregation tools to document and report on service utilization and outcomes. With regard to preterm birth-related metrics, both Ugandan and Kenyan sites documented GA and birthweight in maternity registers; Kenyan registers also had an additional field for last menstrual period (LMP).

Preliminary Data Quality Assessments

We conducted preliminary assessments at all facilities to assess overall readiness for the project (conducted in December 2015 and January 2016). As part of the assessment, we conducted a data quality assessment (DQA) to determine the overall baseline quality of PTB measurement by analyzing data for completeness. Facility assessment data were collected using a standardized questionnaire that included sections on service delivery and monitoring and evaluation (ME). Measurement domains included data flow, collection, and use, and data collection included review of registers at sites. A monthly count of key variables was taken from maternity registers, including number of newborns with the following variables recorded: GA, Apgar, discharge status, and birthweight. Facility assessments were conducted by members of the PTBi-EA headquarter team and the in-country partner team members over a three-week period in each country. Assessments were conducted in close collaboration with both service delivery and health records staff at sites.

Baseline Register Extraction

Register data were collected in aggregate at facilities via structured counts. Summary indicators were constructed and recorded with the facility data staff and then compared to indicators on reports submitted to the central Ministry of Health. Upon identification of discrepancies between constructed and reported indicators, study staff worked with facility staff to identify potential issues in data flow, such as conflicting operational indicator definitions, poor stationary supplies, and heavy staffing burden.

In response to data quality issues identified through the Preliminary DQA, we developed and implemented a series of data quality interventions at each site, beginning with an initial data strengthening package. These interventions included hiring country-level ME teams for the project, delivering training and mentoring, providing low-tech GA assessment tools (i.e., pregnancy wheels, tape measures), conducting skills-building sessions around routine data quality checks, and designing data validation approaches.

Data Strengthening Training of Trainers

Training and skills-building activities included Training of Trainers (TOT), which included training on and dissemination of slide decks, case studies, and exercises designed to raise awareness, provide solutions, and build skills for routine data quality checks. During the TOT, PTBi-EA staff – including ME team members and country-level data managers – trained maternity in-charge nurses, record officers, and senior nursing officers to disseminate data strengthening topics to colleagues working in the maternity, neonatal, and postnatal wards in their respective facilities. Areas of focus included completeness, accuracy (including training on standardized indicator definitions), and use of facility-based data for program improvement. An emphasis was placed on GA assessment, including the use of tools (i.e., pregnancy wheels, tape measures) to improve accuracy. The TOT was held in April 2016 in Uganda and June 2016 in Kenya.

Three-Month and Six-Month Mentoring

Country-level ME teams in Kenya and Uganda were trained to work with sites on a routine and ongoing basis around improving data quality and data use for decision-making. Each country's ME team, overseen by the country principal investigator, was comprised of one data manager and one data collector. Teams conducted routine mentoring with all sites on a monthly basis as part of routine data extraction from facility registers. Ongoing mentoring focused on increasing consistency and accuracy of documentation, and use of data with an emphasis on improving GA-related and newborn outcome reporting.

Ongoing Data Collection and Monitoring

To collect baseline data on measurement quality, country-led ME teams worked in collaboration with facility staff, using data abstraction tools to pull key indicators from exist-ing maternity registers and enter data into Open Data Kit tools. Data collection was conducted prior to imple-mentation of data strengthening interventions and contin-ued on a monthly basis post-intervention implementation. Key indicators abstracted included admission date, GA, birthweight, LMP (in Kenya only), Apgar score, delivery outcome, and final neonatal status at discharge.

Register data were routinely collected in batches offline and submitted to encrypted servers. MySQL – a version of Structured Query Language – queries automatically cleaned and constructed key indicators, which were then fed into password-protected dashboards. Processed data were exported and analyzed using R and Excel.

Data Analysis

To test for total effect on completion, we pooled data relating to 24,091 deliveries across all facilities for each country. Any register record indicating a facility-based birth greater than 500 grams or a GA greater than 24 weeks was included in this analysis. For each included record, we assessed the effect of data strengthening on completion of four fields: (1) G A; (2) b irthweight; (3) Apgar at 1 minute; and (4) status of infant at discharge. In addition, we assessed whether all four fields were completed for a given record. GA completion was defined as presence of any non-zero integer, Apgar at 1-minute completion was defined as any integer between 0 and 10, and birthweight was defined as presence of a non-zero number in either grams or kilograms. Status of infant at discharge was defined as complete if one the following were true: (1) a live birth delivery had documented baby discharge status (i.e., alive or dead) or (2) a stillbirth delivery had documented type (i.e., fresh or macerated). Completion of these variables were reported as a percentage of data values reported over the expected number of included register records. Completeness of reporting was calculated by summing up the number of values across all facilities each month and dividing by the expected number of values. All blank data were considered to be missing data.

We assessed the completion of these variables at five different time points: (1) Preliminary DQAs (Kenya: Dec 2015; Uganda: Jan 2016); (2) Baseline Register Extraction, prior to data strengthening TOT (Uganda: March 2016; Kenya: June 2016); (3) immediately after Data Strengthening TOT (Uganda: May 2016; Kenya: July 2016); (4) after Three Months of Mentoring (Uganda: August 2016; Kenya: October 2016); and (5) after Six Months of Mentoring (Uganda: November 2016; Kenya: January 2017). In addition, we also assessed the proportion of each of these fields t hat h ad been completed on a monthly basis.

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Data was cleaned in MySQL and each record was coded with binary variables. We used R for all of the analysis. A two-sided test of equal proportions was used to analyze difference in proportion between the two time points (Necombe, 1998).

RESULTS

We examined a total of 24,091 maternity register records indicating a facility-based birth weighing 500 grams or more. Since routine data collection began earlier at Uganda facilities, 16,388 records were included from Uganda facilities for the period 1 March 2016 to 30 November 2016, whereas 7,703 records were selected from Kenya facilities between 1 June 2016 and 31 January 2017. We assessed the com-pletion rates of four key fields: GA, birthweight, Apgar score at minute one, and status of infant at discharge. Table 1 shows average monthly completion rates, including minimum and maximum facility values.

Table 1. Average completion rates over time in Kenya (17 facilities) and Uganda (6 facilities)

Kenya					
Month	**Average Percent with GA Completed (min-max)**	**Average Percent with Birthweight Completed (min-max)**	**Average Percent with Apgar Score at 1min Completed (min-max)**	**Average Percent with Discharge Status Completed (min-max)**	**Average Percent with key fields completed (min-max)**
Dec 2015 (Preliminary Data Quality Assessment)	93% (74-99)	87% (0-100)	97% (88-100)	74% (34-100)	59% (0-91)
June 2016 (Baseline Register Extraction)	92% (74-100)	97% (95-100)	97% (94-100)	99% (97-100)	91% (66-100)
July 2016 (1-mo. Post TOT)	92% (81-100)	96% (93-100)	96% (93-100)	99% (97-100)	87% (79-100)
August 2016	96% (84-100)	97% (95-100)	96% (93-100)	99% (97-100)	91% (81-100)
September 2016	94% (86-100)	98% (96-100)	98% (96-100)	99% (92-100)	90% (83-100)
October 2016 (3-mo Mentoring)	96% (88-100)	97% (94-100)	98% (94-100)	88% (73-100)	82% (70-100)
November 2016	95% (90-100)	97% (94-100)	96% (84-100)	85% (62-100)	79% (61-100)
December 2016	98% (88-100)	99% (96-100)	99% (91-100)	86% (27-100)	83% (27-100)
January 2017 (6-mo Mentoring)	97% (92-100)	98% (88-100)	99% (96-100)	88% (46-100)	84% (45-100)
Uganda					
Jan 2016 (Preliminary Data Quality Assessment)	52% (0-92)	89% (77-100)	93% (84-99)	86% (61-100)	55% (8-97)
March 2016 (Baseline Register Extraction)	73% (13-100)	90% (80-100)	97% (94-100)	69% (10-100)	59 (1-100)
April 2016	75% (12-98)	91% (83-98)	97% (93-98)	66% (4-98)	59% (0-98)
May 2016 (1-mo. Post TOT)	72% (12-100)	92% (83-100)	98% (96-100)	70% (21-100)	59% (2-100)
June 2016	70% (8-99)	94% (86-99)	98% (95-99)	68% (25-99)	55% (2-99)
July 2016	86% (77-99)	96% (92-99)	98% (97-99)	87% (79-99)	74% (62-99)
August 2016 (3-mo. Mentoring)	83% (62-99)	96% (95-99)	98% (97-99)	87% (75-99)	71% (45-99)
September 2016	80% (53-100)	96% (92-100)	98% (95-100)	90% (74-100)	72% (36-100)
October 2016	81% (70-98)	95% (92-98)	96% (91-98)	85% (53-98)	68% (41-98)
November 2016 (6-mo Mentoring)	87% (75-96)	94% (92-96)	96% (94-96)	88% (70-96)	73% (49-96)

Preliminary Data Quality Assessment vs. Baseline Register Extraction

We compared completion rates between the preliminary data quality and the month before the data strengthening TOT (Table 2). This comparison tests for any effect that project preparations (e.g., updated registers, stationary provisions) may have had on completion rates before implementation of data strengthening training. Overall, there was significant improvement in completion rates in both Uganda (24.4, 95% CI: 21, 27) and Kenya (40.0, 95% CI: 36, 43) in this preparation period. At baseline register extraction, all of the indicators in Kenya had reached at least 90% or more, whereas there was much more room for additional improvement in Uganda.

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Table 2. Compared completion at Preliminary DQA and the start of Baseline Register Extraction

	Records with fields complete at preliminary DQA (%)*	Records with fields complete at baseline register extraction (%)**	Difference in completeness (P1-P2) (95% CI)	p-value
Kenya	**n=1150**	**n=965**		
Gestational age	94.2	94.8	0.6 (-1,2)	0.58
Birthweight	89.0	97.4	8.4 (6,11)	<0.01
Apgar at 1 minute	97.6	96.8	-0.8 (-2,1)	0.34
Status of baby at discharge	65.8	99.5	33.7 (31,37)	<0.01
All	51.1	91.1	40.0 (36,43)	<0.01
Uganda	**n=1876**	**n=1807**		
Gestational age	48.1	72.7	24.6 (21,28)	<0.01
Birthweight	86.6	90.0	3.4 (1,5)	<0.01
Apgar at 1 minute	92.8	97.1	4.3 (3,6)	<0.01
Status of baby at discharge	77.6	69.4	-8.2 (-11,-5)	<0.01
All	34.2	58.6	24.4 (21,27)	<0.01

*Preliminary DQA: Uganda = January 2016; Kenya = December 2015
**Baseline: Uganda = March 2016; Kenya = June 2016

Baseline Register Extraction vs. Data Strengthening TOT Training

To assess the immediate effect of centralized TOT training, we compared completion rates from before and after in-country teams held the data strengthening TOT (Table 3). Neither country demonstrated significant increase in completion rates except for a slight – but statistically significant – increase in birthweight completion in Uganda.

Baseline vs. TOT Training and Three-Month Mentoring Dose

To assess the combined effect of the centralized TOT and three months of facility-based mentoring, we compared baseline completion rates to those assessed four months after the TOT, allowing for implementation of mentoring visits (Table 4). Uganda showed considerable and significant increases in completion of status of infant at discharge, birthweight, and GA. Kenyan facilities demonstrated a significant decrease in outcome completion which resulted in a net decrease in overall completion (-9.0, 95% CI: –12, 6), whereas Ugandan facilities showed a considerable increase (12.1, 95% CI: 9, 15).

Table 3. Compared completion the month before and the month after the Data Strengthening TOT

	Proportion fields complete at baseline register extraction (%)*	Proportion fields complete 1 mo. post-TOT (%)*	Change in completeness (P1-P2) (95% CI)	p-value
Kenya	**n=965**	**n=1220**		
Gestational age	94.8	92.3	-2.5 (-5,0.4)	0.3
Birthweight	97.4	96.4	-1.0 (-2,1)	0.26
Apgar at 1 minute	96.8	95.4	-1.4 (-2,1)	0.13
Status of baby at discharge	99.5	99.4	-0.1 (-1,1)	1.0
All	91.1	87.4	-3.7 (-6,-1)	0.01
Uganda	**n=1807**	**n=1862**		
Gestational age	72.7	71.8	-0.9 (-3,2)	0.56
Birthweight	90.0	92.3	2.3 (3,4)	0.02
Apgar at 1 minute	97.1	97.6	0.5 (-1,2)	0.39
Status of baby at discharge	69.4	69.7	0.3 (-3,3)	0.87
All	58.6	59.3	0.7 (-2,4)	0.67

*Baseline: Uganda = March 2016; Kenya = June 2016
**1-mo. Post-TOT: Uganda = May 2016; Kenya = July 2016

Table 4. Compared completion the month before Data Strengthening TOT and three months mentoring

	Proportion fields complete at baseline register extraction (%)*	Proportion fields complete 1 mo. post-TOT (%)*	Change in completeness (P1-P2) (95% CI)	p-value
Kenya	**n=965**	**n=1021**		
Gestational age	94.8	95.8	1.0 (-1,3)	0.36
Birthweight	97.4	96.6	-0.8 (-2,1)	0.34
Apgar at 1 minute	96.8	97.6	0.8 (-1,2)	0.37
Status of baby at discharge	99.5	87.7	-11.8 (-14,10)	<0.01
All	91.1	82.1	-9.0 (-12,6)	<0.01
Uganda	**n=1807**	**n=1856**		
Gestational age	72.7	83.0	10.3 (7,13)	<0.01
Birthweight	90.0	96.3	6.3 (5,8)	<0.01
Apgar at 1 minute	97.1	98.3	1.2(0.2,2)	0.01
Status of baby at discharge	69.4	87.0	17.6 (14,20)	<0.01
All	58.6	70.7	12.1 (9.15)	<0.01

* Baseline: Uganda = March 2016; Kenya = June 2016
**3-mo Mentoring: Uganda = August 2016; Kenya = October 2016

Baseline vs. TOT Training and Six-Month Mentoring Dose

To assess the effect of centralized TOT training in combination with extended facility-based mentoring, we compared baseline completion rates to those assessed seven months after the TOT, allowing for six full months of mentoring visits (Table 5). Completion rates among Kenyan facilities showed a slight but statistically significant increase in Apgar score at one minute. Uganda facilities showed considerable and significant increases in status of baby at discharge, birthweight, and GA As with the previous comparison, Uganda demonstrated a greater improvement in overall completion (14.0, 95% CI: 11, 17), whereas Kenya demonstrated a decrease in completion of baby discharge status, which resulted in a net decrease in overall completion (-7.2, 95% CI: -10, -4).

Table 5. Compared completion the month before Data Strengthening TOT and six months mentoring

	Proportion fields complete at baseline register extraction (%)*	**Proportion fields complete 6 mo. post-TOT (%)***	**Change in completeness (P1-P2) (95% CI)**	**p-value**
Kenya	**n=965**	**n=874**		
Gestational age	94.8	96.8	2.0 (0.1,4)	0.05
Birthweight	97.4	98.2	0.8 (-1,2)	0.34
Apgar at 1 minute	96.8	99.0	2.2 (1,3)	<0.01
Status of baby at discharge	99.5	88.3	-11.2 (-13, -9)	<0.01
All	91.1	83.9	-7,2 (-10,-4)	<0.01
Uganda	**n=1807**	**n=1779**		
Gestational age	72.7	86.8	14.1 (11,17)	<0.01
Birthweight	90.0	94.4	4.4 (3,6)	<0.01
Apgar at 1 minute	97.1	95.8	-1.3 (-3,-0.1)	0.03
Status of baby at discharge	69.4	88.3	18.9 (16,21)	<0.01
All	58.6	72.6	14.0 (11,17)	<0.01

*Baseline: Uganda = March 2016; Kenya = June 2016
**Post 6-mo Mentoring: Uganda = November 2016; Kenya = January 2017

DISCUSSION

Completion rates demonstrated mixed improvements throughout the entire analysis period. While Uganda saw a significant increase in overall completion rates, Kenya facilities demonstrated significant decreases in outcome completion. Given only marginal increases before and after key data strengthening, it is difficult to causally link improvements to data strengthening efforts. While efforts may certainly have contributed to improved data quality, we must also consider the synergy from data strengthening coupled with clinical interventions and increased awareness of preterm birth.

Uganda facilities saw marked improvements in completion rates between preliminary facility assessments and baseline register extraction. The largest increase in completion for Kenya also occurred during this time period, demonstrating a 34% increase in baby discharge status completion. Similarly, Uganda also saw its largest increase in GA completion during this period. These changes occurred prior to any training or mentoring, further demonstrating the difficulty of attributing data strengthening efforts to improved data quality. While no training or mentoring occurred, the project did begin supplying facilities with registers and patient charts in preparation for project initiation. Furthermore, project teams also began to routinely engage facility leadership between these two time points, including providing feedback from the results of the facility assessment. As such, it is possible that these conversations and preparations may have had an impact on completion rates.

The immediate effects of the data strengthening TOT trainings demonstrated very little change in maternity register completion. Given that only the maternity ward leadership received direct training, day-to-day challenges may have limited the propagation of training throughout the facilities. TOT models are widely used to promote quality improvement activities, but these observed results suggest that the model alone is inadequate in changing practices. Of particular note is the slight – but significant – decrease in outcome completion in Kenya.

Three- and six-month doses of data strengthening mentoring had a stronger association with increased completion of maternity register fields, including Apgar score in Kenya facilities and baby discharge status in Uganda. Ugandan facilities demonstrated the greater increase in completion compared to Kenyan facilities, particularly with regards to GA and baby discharge status completion. Data strengthening was perhaps most successful in increasing completion of the baby discharge status field in Uganda.

Kenyan facilities demonstrated a significant decrease in the completion of outcome fields throughout the intervention period. However, this negative change is difficult to interpret for multiple reasons. First, Kenyan facilities started with a near perfect completion rate at baseline (99.5%). Second, a doctor's strike occurred toward the end of 2016, which is where Kenya facilities demonstrated the greatest downward trend in completion.

While looking at each of these data points individually can highlight gaps and strengths in specific measurement processes at the facility level, it is also important to analyze a facility's ability to capture comprehensive information across all patients. Total completion rates in Uganda rose from 12% from baseline to start of data strengthening, with slight variations throughout the analysis period. In Kenya, however, the decrease in outcome completion largely contributed to a net decrease in overall completion.

Several limitations must be considered. Capacity building is, by nature, difficult if not impossible to measure in terms of attribution. Sustainable capacity development works at the health systems level, in which multiple factors come into play (two of which are noted below) to inform the context of health care delivery. Staff turnovers are frequent in Kenya and Uganda facilities and could also have impacted capacity building efforts in the facilities. High staff turnover can lead to shortage of staff and/or loss of experienced and skillful staff. In addition, there could have been variability among the pooled facilities, such as staffing levels and training on data quality prior to PTBi-EA activities, that could have impacted the results. It also is difficult to determine if the results are solely due to data quality strengthening, since a package of interventions for PTBi-EA was implemented.

In addition, we chose to thread data quality strengthening throughout the project to ensure long-term capacity development. As a result, the analysis of pre- and post-intervention data–especially post-intervention data–can be problematic. We resolved this issue to the extent possible by holding steady the time period for post-intervention data collection. Overall, we do see some areas of improvement that suggest, at least temporally, that improvements could be associated with the intervention. The issue of context also becomes particularly difficult to account for in resource-limited settings. Events such as labor strikes or weather directly affect both service delivery and data quality and can greatly bias findings. For example, the doctor's strike in Kenya in 2016 may have created considerable challenges in both documentation and provision of patient care.

CONCLUSION

This paper provides a critical look into the effects of the PTBi-EA data strengthening campaign on completion of key fields in maternity registers. However, completeness is only one component of data quality. Poor estimation of GA is well documented in routine data sources. With respect to GA validation, additional efforts are underway to assess the accuracy of GA measures in this project. Additional papers from this initiative will describe comparative analyses of GA and birthweight data against established birthweight curves as a proxy for assessing accuracy.

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CONFLICT OF INTEREST

The authors have completed the Unified Competing Interest form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare no conflict of interest.

AUTHORS' CONTRIBUTIONS

RK analyzed the data and drafted the manuscript. RM reviewed and revised the manuscript. RM, PM, DK, DM, FW and CO contributed to the study design and implementation. PW, PO, LK, AW and DW are the principal investigators and a major contributor to all aspects of this study and manuscript. All authors read and approved the final manuscript.

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