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RESEARCH AND EVALUATION REPORT

Reliability of newborn and child quality of care indicators in health facilities receiving support from the USAID ASSIST Project in Antigua

JUNE 2018

This research report was prepared by University Research Co., LLC (URC) for review by the United States Agency for International Development (USAID) and authored by Chris Andersen, Astou Coly, Tamar Chitashvili, and Salwan Hager of URC and Shivon Belle of the Antigua and Barbuda Ministry of Health. The work of the USAID ASSIST Project to improve Zika-related health services is made possible by the generous support of the American people through USAID.

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DISCLAIMER

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Abbreviations

ASSIST	Applying Science to Strengthen and Improve Systems
CZS	Congenital Zika syndrome
ESC	Eastern and Southern Caribbean
HC	Head circumference
IID	Improvement Indicator Database
N/A	Not applicable
NICU	Neonatal intensive care unit
QI	Quality improvement
SD	Standard deviation
T	Temperature
URC	University Research Company, LLC
USAID	United States Agency for International Development

Executive Summary

Introduction: The USAID-funded Applying Science to Strengthen and Improve Systems (ASSIST) Project has implemented Zika-related health systems strengthening efforts in Antigua since July 2018. The objectives of this study were to assess the validity of seven quality improvement indicators, understand the perceptions and practices of quality improvement teams with respect to data, and to recommend potential corrective actions.

Methodology: Validation data were extracted for deliveries (n=47) at the public hospital and well-baby visits (n=306) at six primary health care facilities and compared to data reported in collection forms submitted to the project's Improvement Indicator Database. Eight interviews were conducted with key informants and health facility personnel.

Results: The difference between main indicators as measured by the validation study as compared to the reported data was 4 to 47 percentage points, with the validation study finding lower values for six out of seven indicators. Qualitative results pointed to training, staff workload, tools and equipment, and the perceived benefits of data as influencers of data quality.

Recommendations: Key recommendations for newborn indicators are to use a single form for indicators to be kept in the maternal chart along with more precise guidance on indicator definitions. With regard to well-baby indicators, it is recommended that clinical providers conduct and monitor clinical encounters completely, that data entry personnel have a clear understanding of indicator definitions, and that internal audits of data quality be conducted.

Introduction

Purpose and relevance

Quality improvement (QI) is a data-driven approach to identify and address gaps in health care service quality. Data collected by QI teams are aggregated, transmitted, and interpreted before they are reported. Data can be corrupted at any point in this process, which can compromise decision-making at all levels, from the health facility where the data originated, through regional and national levels and to funders such as USAID. The USAID Applying Science to Strengthen and Improve Systems (ASSIST) Project was therefore mandated to validate 25% of the project's indicators.

Since July 2018, the USAID Applying Science to Strengthen and Improve Systems (ASSIST) Project has implemented Zika-related health systems strengthening efforts in four eastern and southern Caribbean (ESC) countries (Antigua and Barbuda, Dominica, St. Kitts and Nevis, and St. Vincent and the Grenadines).¹ The objectives of these efforts are to:

1. Improve newborn and well-baby care, specifically focused on the assessment of babies with suspected or confirmed congenital Zika syndrome (CZS), and thereby strengthen newborn and well-baby care systems.
2. Improve care and support of Zika-affected children and families.

In order to monitor the results associated with the USAID ASSIST Project Zika efforts in the four ESC countries, each country collects and reports on the same 23 improvement indicators at the health facility level. To ensure the validity of the results from quality improvement efforts, the project is mandated to validate 25% of indicators. Previous validations have used methodologies including duplicate data abstraction for medical charts, observation of clinical encounters, and client interviews.

Antigua and Barbuda was selected for data validation from among the four ESC countries because: a) it was more advanced in the data collection process as compared to other ESC countries, b) there is a relatively small number of health facilities, thereby allowing selection of a representative sample using a reasonable sample size, and c) access to health centers was more feasible in terms of time and financial resources. From the time of Zika introduction to Antigua and Barbuda until January 2018, 540 suspected and 25 confirmed Zika cases were identified among an estimated population of 94,000.² In Antigua, all 27 active primary health care facilities and one public hospital have received support from the USAID ASSIST Project. No USAID ASSIST Project activities have been undertaken in Barbuda due to population displacement and minimal health system functioning after hurricane Irma in 2017.

¹ USAID ASSIST Project. "FY 2018/2019 USAID ASSIST Core-Funded Activity Plan: Zika Response in Four Eastern and Southern Caribbean Countries." 2018.

² Pan American Health Organization. "Zika cases and congenital syndrome associated with Zika virus reported by countries and territories in the Americas, 2015 – 2018." 2018.

Objectives

The objectives of this study are:

1. To assess the validity of seven improvement indicators reported by facilities in Antigua receiving Zika-related support from the USAID ASSIST Project.
2. To understand the perceptions and processes of quality improvement teams which may influence the validity of reported indicators.
3. To propose potential corrective actions for any concerns which are identified.

Methodology

Study design

The validation exercise included two components, one quantitative and the other qualitative. The first was a retrospective chart review aimed at assessing the extent to which data reported by the project are similar to those collected by an external evaluator. The second component was interviews with key informants aimed at identifying factors driving the quantitative findings.

Quantitative validation

The catchment area was 27 primary health care facilities and one public hospital in Antigua supported by the USAID ASSIST Project. The target populations of interest within these facilities were newborns and children up to 5 years old attending well-baby visits.

Four indicators (**Table 1**) were assessed among deliveries occurring at the public hospital (delivery services are not performed at the primary health care facilities). Three other indicators (**Table 2**) were assessed among children ≤ 5 years attending well-baby visits at six primary health care facilities purposively sampled to reflect facility patient volume and geographic location. The primary health care facilities selected for inclusion were determined in consultation with the Ministry of Health USAID ASSIST Zika focal person, all three QI coaches, and the improvement indicator database (IID) consultant.

QI data collection efforts were fully enacted by the health facility QI teams beginning in January 2019. Validation data were extracted for clinical encounters during the weeks of January 21 and February 18 (data extraction occurred March 8 – 19, 2019). Births occurring at the public hospital are recorded in a register, which was used to identify the medical charts that should be referenced for validation data collection. A logbook of attendees at well-baby visits is kept at each primary health care facility and was used to identify child medical charts for data extraction. All charts for the validation time period were retrieved for extraction. Charts were pulled in advance of the validation consultant's arrival at each facility and stored in a locked cabinet to ensure patient data confidentiality. Since the frequency of well-baby visits differs by facility, the well-baby visits occurring at the facility closest to the dates indicated above were selected. Validation data were compared to the ASSIST data extraction forms. These forms are used to enter data in the IID.

Table 1. Hospital indicator number and description

D2	Number of live birth newborns.
N2.1.a	Head circumference is measured within 24 hours to one decimal point.
N2.1.b	Repeated measurement of head circumference before discharge.
N2.1.c	If preterm newborn (<37 weeks), results plotted at INTERGROWTH-21 (or Fenton) Size at Birth Standards for gestational age and sex, and this result was used to interpret measurements. (N/A if term newborn.)
N2.1	Criteria N.2.1.a, N.2.1.b, and N.2.1.c are all met.
N2.2	Results were correctly classified (microcephaly if head circumference [HC] < -2 standard deviations (SD) below the norm, macrocephaly if HC > 2 SD, normal if HC from -2 to +2 SD).
N2	Criteria N2.1 and N2.2 are both met.
H2	Proportion of newborns who were appropriately screened for microcephaly (calculated as N2 / D2).
D3	Number of live birth newborns.
N3.1	Documented presence or absence in the chart of any visible congenital abnormalities (such as craniofacial disproportion, congenital brain anomalies, congenital eye anomalies, hypertonia or hypotonia, congenital contractures, and dyskinesia or dystonia).
N3.2	Documented presence or absence in the chart of clinical signs and symptoms of Zika in the mother (rash, red eyes, joint pains, fever and/or laboratory confirmation of Zika virus infection during pregnancy).
N3	Criteria N3.1 and N3.2 are both met.
H3	Proportion of newborns who were appropriately evaluated for other symptoms of CZS and whose mothers were screened for Zika virus infection during pregnancy (calculated as N3 / D3).
D5	Number of live birth newborns whose temperature was recorded
N5	Newborn with documented hypothermia T <36.5 °C or <97.7 °F within the first 24 hours after birth (N/A if temperature was not measured)
H5	Proportion of newborns who had hypothermia (T <36.5oC or <97.7oF) within the first 24 hours after birth (calculated as N5 / D5).
D6	Newborn discharged alive
N6	Newborn was exclusively breastfed at the time of discharge (N/A if mother's HIV status is positive or unknown, or if newborn's weight is below 1500 g).
H6	Proportion of children with exclusive breastfeeding at discharge (calculated as N6 / D6).

Table 2. Well-baby indicator number and description

D2	Child ≤5 years old attending the well-baby visit.
N2.1	Head circumference measured and recorded to one decimal place.
N2.2	Results were correctly classified (microcephaly if HC < -2 SD, macrocephaly if HC > 2 SD, and normal if HC between -2 and +2 SD).
N2	Criteria N2.1 and N2.2 are both met.
W2	Proportion of children ≤5 years attending well-baby clinics who are appropriately screened for microcephaly (calculated as N2 / D2).
D3	Child ≤5 years old attending the well-baby visit.
N3.1	Documentation of absence or presence of developmental risk factors.
N3.2	Documentation of absence or presence of phenotypical alterations.
N3.3	Documentation of observed reflexes, skills, positions, and behaviors appropriate to his or her age group, including using a validated screening tool.
N3	Criteria N3.1, N3.2, and N3.3 are all met.
W3	Proportion of children ≤5 years attending well-baby clinics who are appropriately monitored or screened for development at their age (calculated as N3 / D3).
D4	Number of children classified as having a suspected development delay, or have at least one of the following criteria met: 1) head circumference is < -2 SD or > +2 SD, or 2) three or more phenotypical alterations documented, or 3) does not display one or more reflexes, positions, skills, or behaviors corresponding to the previous age group.
N4	Number of children meeting the criteria for D4 and who were referred for clinical care or support services.
W4	Proportion of children ≤5 years identified with suspected developmental delay referred to care or support services, including babies who exhibit negative outcomes suggestive of CZS (calculated as N4 / D4).

Qualitative evaluation

Qualitative data were collected to generate hypotheses about the factors driving the quantitative results and to design corrective practices for any concerns with data quality. Key informant interviews were conducted with individuals who are involved in the QI activities at various levels and could provide different perspectives on the process of data collection. These individuals included the ASSIST Project Zika focal person from the Ministry of Health, the IID consultant, two quality improvement coaches that oversee the QI activity in the primary care centers (the hospital QI coach could not be interviewed due to conflicting travel arrangements), and four health facility staff (one from the hospital and three from the primary health care facilities). The four health facility staff were selected based on their experience with extracting data from charts. Interviews were conducted in person at a location that ensured respondent confidentiality. Questions focused on understanding the participants' perspective on the design, collection, management, and use of quality improvement indicators. Ideas for how to improve data collection efforts were explored.

Data analysis

Statistical analyses were performed using Stata 13 software. The validation quantity of interest, δ , was defined as the difference in the value of an indicator as assessed by the quality improvement team compared to the assessment of the validation team. Good quality data was defined as failure to reject the hypothesis that $\delta=0$ for the sampled weeks with a 95% confidence bound of less than 10 percentage points. P-values are presented for well-baby indicators, but not for hospital indicators due to exhaustive sampling.

Qualitative data were transcribed and coded using Atlas.ti software to identify key barriers to good data quality as well as ideas for how to improve data collection efforts. De-identified quotes were included as illustrative evidence.

Ethical considerations

Ethical approval for the validation study was obtained from the URC Institutional Review Board before commencement of data collection. Permission to conduct data collection was obtained from the relevant authority at each selected health facility. Participation in the evaluation by interviewees was voluntary and confidential. Identifying information was not collected from medical records. Every effort was made to protect the confidentiality of the key informants, coaches and providers who participated in interviews. Written consent was obtained from each participant prior to interview.

Results

Quantitative analysis

Validation data captured 47 hospital live births for the periods of January 23-31 and February 18-24, as compared to 42 hospital live births in the reported data. **Table 3** presents results for hospital indicators. According to the validation data, approximately three quarters of newborns were appropriately screened for microcephaly (indicator H2; 74%) or for signs and symptoms of Zika (indicator H3; 74%), 24 percentage points lower than reported. The validation study found that over two thirds of children experienced hypothermia ($T < 36.5$ °C or < 97.7 °F) in the first 24 hours (indicator H5; 70%), as compared to about one quarter (23%) as reported. About half of newborns were exclusively breastfed at discharge (indicator H6; 51%), which was roughly equivalent to the figure reported (difference of 4 percentage points). Sub-indicators as reported and as assessed by the validation were similar (difference of less than 5 percentage points) for indicators N2.1a, N2.1c, and N3.1.

Table 3. Concordance between hospital newborn indicators reported per routine collection versus validation (Jan 23-31 and Feb 18-24).

		Routine n (%)	Validation n (%)	Validation – Routine (%)
D2	Number of live birth newborns	42	47	
N2.1.a	Head circumference is measured within 24 hours to one decimal point	41 (98)	47 (100)	(+2)
N2.1.b	Repeated measurement of head circumference before discharge	42 (100)	38 (81)	(-19)
N2.1.c	Preterm newborns with growth plotted for gestational age and sex	42 (100)	47 (100)	(0)
N2.1	Head circumference properly measured and documented	41 (98)	38 (81)	(-17)
N2.2	Head circumference properly classified	42 (100)	44 (94)	(-6)
H2	Appropriately screened for microcephaly	41 (98)	35 (74)	(-24)
N3.1	Documented presence or absence of any visible congenital abnormalities	41 (98)	45 (96)	(-2)
N3.2	Documented presence or absence of mother with clinical signs and symptoms of Zika	41 (98)	37 (79)	(-19)
H3	Infants and mothers appropriately screened for symptoms of Zika	41 (98)	35 (74)	(-24)
D5	Live birth newborn whose temperature was recorded	39	47	
H5	Documented hypothermia within the first 24 hours after birth	9 (23)	33 (70)	(+47)
D6	Newborn discharged alive	42	47	
H6	Exclusively breastfed at the time of discharge	23 (55)	24 (51)	(-4)

Data for 306 well-baby visits were collected by the validation study, as compared to 304 reported. **Table 4** presents results for well-baby indicators. According to the validation data, head circumference was measured in nearly all cases (indicator N2.1, 96%), but head circumference was less frequently correctly classified (indicator N2.2, 83%). Overall in the validation findings, 80% of children were appropriately screened for microcephaly, a figure 14 percentage points lower than reported. Over three quarters of children were correctly monitored for development (indicator W3, 77%), which was 11 percentage points lower than reported. The proportion of children classified as “high risk” who were appropriately referred to services is very low according to the validation data (indicator D4, 19%). Data reported by the validation study were statistically significantly lower than those reported for indicators W2 and W3. Despite a large difference in the proportion of “high risk” children referred to services according to the validation and reported data, this difference did not achieve statistical significance due to a small sample size.

Table 4. Concordance between child development indicators reported per routine collection versus validation at six primary health care facilities (weeks of Jan 21 and Feb 18).

		Routine n (%)	Validation n (%)	Validation – Routine (%)	p- value
D2	Child ≤5 years old attending well-baby visit	304	306		
N2.1	Head circumference measured and recorded to one decimal place	303 (100)	295 (96)	(-4)	0.063
N2.2	Head circumference results correctly classified	287 (94)	255 (83)	(-11)	0.070
W2	Children appropriately screened for microcephaly	287 (94)	244 (80)	(-14)	0.008
N3.1	Documentation of presence or absence of developmental risk factors	277 (91)	255 (83)	(-8)	0.039
N3.2	Documentation of absence or presence of phenotypical alterations	270 (89)	251 (82)	(-7)	0.039
N3.3	Documentation of observed capabilities appropriate to age group	270 (89)	264 (86)	(-3)	0.109
W3	Children who were appropriately monitored for development	267 (88)	235 (77)	(-11)	0.001
D4	Children classified as "high risk"	8	37		
N4	Children classified as "high risk" referred to support services	5 (63)	7 (19)	(-44)	0.125

Qualitative analysis

Six interviews were conducted with eight participants, including the Ministry of Health focal person, the IID consultant, two quality improvement coaches, and four hospital and primary health facility staff. These interviews revealed several key factors that were perceived to influence data quality.

Participants described that the training material disseminated by the USAID ASSIST Project team was presented directly to some members of the clinic staff, but many staff were not able to attend a training session due to conflicting responsibilities. Therefore, the staff who attended were in turn responsible for training their colleagues and for emphasizing the importance of assessing the indicators. As one participant described, "I haven't been to any workshop. But once or twice [the staff who had been trained] met with us ... for an hour and a half to introduce the program."

It is less certain the degree to which the training attendees completely understood all workshop material, and whether the information communicated by workshop attendees to non-attendees remained correct and consistent. Interviewees mentioned one indicator (W3) which was consistently misunderstood by staff, saying "they were not filling [the indicator] in because they didn't understand." Other participants mentioned that the trainings did not always result in learning of the material, and believed that hands-on computer training in the initial stages would have optimized the learning experience. One said, "I was present ... but I did not understand [the webinar]." Practical exercises, such as the "spot the error" exercise conducted in the third workshop, were said to be greatly beneficial.

Staff work load

Data quality was thought to be influenced by the work load of clinic staff, who expressed feeling over-burdened by both conducting clinical evaluations of neurodevelopment and by data entry responsibilities. At the hospital, the interviewee expressed that extracting data from the clinical charts for the database took 8 additional hours each week beyond her standard workload. The data extraction burden was reported to be less substantial for well-baby visits (15-30 minutes per week). However, the additional time added to each well-baby visit to assess developmental status (an additional 5 minutes added to visits that previously took 5 to 15 minutes in total) was thought to increase clinician stress and result in data not being recorded. As one participant expressed, "we are not documenting what we are doing."

Tools and equipment

Several participants expressed concern that materials to perform or record assessments were not always present in the clinics. For example, one of the developmental assessments requires the use of a ball, which was often not available in the clinic and would be left blank as a result. Furthermore, stock-outs of neurodevelopmental surveillance forms were often said to be a barrier to data collection.

Perceived benefits of data collection

Many participants indicated that they saw great benefit to the collection of the indicators due to resulting improvements in clinical care ("the overall benefit I'm seeing is the advantages to the baby... the breastfeeding rate has increased.") Supervisors also perceived the data collection as a way of assessing which clinics are performing well and which are in need of additional training support. One interviewee summarized by saying "We'll basically look at the data in the IID and say, these five clinics have been underperforming, these are the indicators they have been underperforming in, we need to go in and do an educational session."

Discussion

Newborn indicators

The number of newborns reported routinely (n=42) differed from those identified during the validation (n=47) because in January the data collection personnel reported only the first 20 births. According to hospital personnel involved in data collection, this was in accordance with current guidance on data collection for the Improvement Indicator Database. In the validation findings, head circumference was universally measured at least once (47/47, 100%) but repeated measurements before discharge were found to be documented less frequently (38/47, 81%). This was often due to the absence of the form in the medical file that indicated the head circumference at discharge. However, according to routine reporting, repeated measurement of head circumference before discharge was conducted universally (42/42, 100%). Among preterm newborns, both the routine and validation data indicate that growth was plotted according to gestational age and sex in all cases (routine: 42/42, validation 47/47). Head circumference was correctly classified as normal, macrocephalic, or microcephalic in 94% of cases for the validation data, and 100% of cases in the routine data. Due to the discrepancy in findings regarding repeated measurement of head circumference, the overall proportion of newborns appropriately screened for microcephaly in the routine data was 98%, compared to 74% in the validation.

The presence or absence of visible congenital anomalies was documented in nearly all cases according to both routine (41/42, 98%) and validation (45/47, 96%) reports. However, documentation of the presence or absence of clinical signs and symptoms of Zika in the mother was reported more frequently in the routine reports (41/42, 98%) compared to the validation (37/47, 79%). Notably, observation of the newborn records identified that maternal signs and symptoms were only reported in free-text notes written by the clinician at intake, meaning that the clinician was not prompted by the form to fill in this information. This would not explain, however, the higher rate reported by routine data as compared to the validation.

Hypothermia (i.e., a temperature <36.5 C or <97.7 F) within the first 24 hours was reported in about a quarter of newborns according to routine report. However, the validation found that 70% of newborns experienced hypothermia in the first 24 hours. Importantly, discussion with personnel responsible for routine data collection revealed that they had only marked a child as hypothermic if every temperature measurement taken in the first 24 hours was below the hypothermia threshold. To the contrary, the validation reported children who had at least one temperature measurement in the first 24 hours with hypothermia. Feedback from the clinical team indicated that they felt it was most appropriate to record data on whether hypothermia had been resolved, as this indicated that the condition had been treated. Review of the medical charts revealed that children were most frequently hypothermic at their first measure, but then temperatures would often subsequently rise to a normal level within a few hours.

A similar proportion of children were reported to be exclusively breastfed at discharge according to the routine data (23/42, 55%) as compared to the validation data (24/47, 51%). However, this similarity masks an important difference in definitions used by the clinical team between January and February for newborns treated in the neonatal intensive care unit (NICU). Newborns in the NICU at times receive formula for varied reasons, including maternal-infant separation and a lack of breast milk banks. In the routine data from January, these children were classified as not being breastfed, whereas in February they were classified as “not applicable”. In the validation, newborns were not marked as “not applicable” on the basis of admission to the NICU alone.

Well-baby indicators

There were 304 children reported to attend child health clinic visits according to the routine data. Three-hundred six records were located for children during the validation exercise, although this did not include all children listed in the register due to difficulty locating all files at the clinics. Head circumference was documented to one decimal place in nearly all cases (routine: 303/304, 100%; validation: 295/306, 96%). Head circumference results were less frequently classified correctly (i.e. normal, microcephalic, or macrocephalic), and there was a difference observed in the routine report (287/304, 94%) compared to the validation report (255/306, 83%). In the validation assessment, most cases of incorrect classification were due to no documentation of classification in the clinical record. The remaining cases were due to a head circumference measurement that was recorded but incorrectly classified and was typically the result of a macrocephalic child being classified as normal.

The routine data tended to report a higher proportion of children appropriately monitored for development (88%) than the validation data (77%). During the validation data collection, it was observed that the lack of documentation of developmental monitoring could either occur at all ages of assessment, or for only a single age-specific assessment. Clinician notes typically did not make any mention of developmental milestones or phenotypical alterations, although some notes did indicate “developmental milestones being met”. Notably, a redesign of the child development assessment forms was undertaken by the USAID ASSIST Project team, which allowed for a more comprehensive documentation of the indicators of interest.

A higher number of children were classified as “high risk” by the validation study (n=37) than by the routine reports (n=8). “High risk” children are those classified as having a suspected development delay, or having at least one of the following criteria met: 1) head circumference < -2 SDs or > +2 SDs; 2) three or more phenotypical alterations documented; 3) does not display one or more reflexes, positions, skills, behaviors corresponding to the previous age group. In most cases, children identified as “high risk” by the validation study were children with macrocephaly. In over four-fifths of cases (81%), children at “high risk” were not given referrals for care that differed from those of children not at “high risk”. Although the Pan American Health Organization considers macrocephaly alone as a criterion for referral, the clinical team in Antigua expressed during a feedback session that children with familial macrocephaly and normal development do not need to be referred, and that local practices should be considered in the indicator definition.

Recommendations

As a preface to the recommendations, it is important to consider the efforts that have already been made to ensure USAID ASSIST Project data quality in Antigua. To support data collection, quality improvement indicators and data collection guidebooks were co-developed by the USAID ASSIST team in partnership with the Ministry of Health and other stakeholders in September 2019 to enhance the feasibility of data collection. Next, two webinars were held in November 2018 with the three quality improvement coaches and 25 five health facility personnel to cover the data collection materials. Additional in-person trainings were held in December 2018 and March 2019, including interactive case exercises. Although the primary role of the IID Consultant is to train the health facility teams on data collection and analysis in the IID, the consultant also attended the portions of the in-country trainings that covered data collection and data quality, in order to provide better support to the QI teams in this regard. Documentation of the sessions included a recording of the webinars and printed guidebooks for the in-person trainings. Finally, the USAID ASSIST team remains in regular communication with the quality improvement coaches in Antigua to answer questions and raise any issues observed in the submitted data.

Qualitative and quantitative observations converged to suggest two key measures that could be considered to improve the quality of newborn indicators. First, a single form for newborn indicators could be created for inclusion in the newborn medical file. At present, newborn indicators are distributed across numerous forms in the patient's file and can be reported either through specified fields (e.g., head circumference, visible congenital anomalies) or through free-text notes from clinicians (e.g., parental symptoms of Zika). In many cases, some of the forms with specified fields for newborn indicators were missing from a child's file. A single form that contained all newborn indicators as specified fields would help ensure that all newborn indicators are reported in the file. Data collection personnel were supportive of creating a single form and indicated it would simplify the process of data collection during patient interactions as well as the process of data extraction for the Improvement Indicator Database. As a new maternal record will be introduced in Antigua in the coming months, it would be advantageous to evaluate whether such a single form would be useful in light of ongoing quality improvement priorities.

A second measure to improve newborn indicator data quality would be to provide precise guidance on the classification of newborn indicators within the holistic context of hospital data collection. Specifically, additional clarification could be provided in the tool on: 1) whether classifying indicator N3.2 (documented presence or absence in the chart of clinical signs and symptoms of Zika in the mother) as being met requires all four symptoms of potential Zika infection (rash, red eyes, joint pains, and fever) to be reported, or only a subset; 2) whether classifying N5 (newborn with documented hypothermia) as being met requires all temperature measurements in the first 24 hours to be hypothermic, or only one measurement to be hypothermic; 3) for what period of time prior to discharge should an infant be exclusively breastfed in order to classify N6 as being met; and 4) to specify that newborn admission to the NICU alone does not indicate that a child should be marked as "not applicable" for exclusive breastfeeding.

Three potential approaches may improve data quality for well-baby developmental indicators: 1) strengthen the capacity of clinical providers to conduct and document clinical encounters completely; 2) ensure that data entry personnel have a clear understanding of how to evaluate whether an indicator has been achieved; and 3) conduct internal audits of data quality. Regarding the first approach, focus group interviews highlighted that since the majority of clinical staff were not able to attend the USAID ASSIST Project trainings, they therefore learned about the indicators and data collection tools second-hand from their colleagues who did attend. This may have resulted in clinical encounters where children were not assessed for certain aspects of development, as well as incomplete documentation of procedures that did occur. Second, data collectors may benefit from detailed guidance and examples of when an indicator is or is not met. Two examples follow. First, seeing "developmental milestones are met" in the clinician notes is not sufficient documentation that a standardized assessment of child development was performed during that visit. Second, the data collector should independently assess whether a child is at high risk based on the symptoms recorded in the chart, rather than recording whether the child was marked in the form as being high risk. This will help facilities to monitor whether children in need of follow-up are being adequately identified during clinical encounters. Finally, duplicate extraction – as was conducted in this validation study – could be conducted by quality improvement staff (e.g., quality improvement coaches) at random intervals to ensure that best practices are being followed and identify additional measures that could be taken to improve data quality.

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