

Quality in practice: preventing and managing neonatal sepsis in Nicaragua

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Abstract

Quality problem or issue. Incorrect and excessive diagnosis of newborn infections in Nicaragua caused overcrowding in the neonatal intensive care units and unnecessary hospitalization.

Initial assessment. A baseline study in nine hospitals found that none correctly utilized disinfectants, sterilization or hand hygiene and that diagnosis of neonatal sepsis was based primarily on clinical manifestations.

Choice of solution. In 2007, the Ministry of Health (MINSa), with Unites States Agency for the International Development technical assistance, began developing guidelines and implementing quality improvement in infection prevention and control to reduce neonatal infections. In a second intervention phase, the MINSa introduced an algorithm for correct identification of maternal risk factors and standardized laboratory tests for neonatal sepsis.

Implementation. Interventions included developing national guidelines on correct use of disinfectants and hand hygiene; training medical staff on the guidelines; revising the basic medical supply list to support appropriate antiseptics; defining a package of diagnostic tests for neonatal sepsis and systematically measuring compliance with the new procedures.

Evaluation. The 18 hospitals achieved appropriate use of disinfectants in a 12-month period. In seven hospitals that introduced improvements in diagnosis and management of neonatal sepsis, application of the standardized laboratory package in suspected sepsis cases increased from 0% in April 2009 to 93% in July 2011, and the median incidence of neonatal sepsis was reduced by 67%.

Lessons learned. The organizational changes implemented for the diagnosis and verification of neonatal sepsis led to a reduction in the newborn sepsis admissions and expenditures for antibiotics, allowing resources to be redirected to treating other critically ill newborns.

Quality problem

The Ministry of Health of Nicaragua (MINSa) provides preventive and treatment services to the majority of the Nicaraguan people, with services organized in 17 Local Health Care Systems (SILAIS). Of the total population, an estimated 42.6% live below the poverty line [1]. The maternal mortality ratio is 66.73 deaths per 100 000 live births, and 73.8% of births are assisted by a skilled attendant [2]. The neonatal mortality rate in 2006 was 16 per 1000 live births [1]. The main causes of neonatal mortality in 2009 were respiratory disorders, infections and asphyxia [3]. The rate of infant mortality is 33 deaths per 1000 live births [2].

Incorrect or excessive diagnosis of newborn infections caused overcrowding in the neonatal intensive care unit (NICU)

and unnecessarily prolonged hospitalization for newborns, stretching the few human resources assigned to these units. Overuse of costly antibiotics was also a problem.

Previously, MINSa had rarely addressed intra-hospital infections, and as a result, there was little information for providers and no data collected before technical assistance from the Unites States Agency for the International Development (USAID) Health Care Improvement Project (HCI) began.

Initial assessment

In 2007, MINSa requested assistance from USAID in the area of infection control and prevention. In September 2007, HCI carried out a baseline assessment to determine the current practices related to antiseptics, disinfectants, sterilization and

hand washing in 9 MINSA hospitals in 9 of the country's 17 SILAIS. The assessment found the following [4]:

- (i) A chlorhexidine mix with cetrimide was used to disinfect non-metallic surfaces, instead of chlorine solution, which would be less costly and more effective.
- (ii) The majority of critical instruments were sterilized using the same chlorhexidine mix, instead of sterilized in the autoclave.
- (iii) Instruments were sterilized for arbitrary periods of time in the autoclave.
- (iv) Operating rooms were divided for infectious and non-infected patients, and disinfected with glutaraldehyde; sometimes the rooms would be shut for several hours or days.
- (v) Many staff were unfamiliar with the concepts of hand washing and alcohol gel as an acceptable antiseptic. Alcohol gel was not included on MINSA's basic supplies list and was therefore not available at many facilities.

Based on these results, at the beginning of 2008, MINSA proposed to promote the rational use of disinfectants, sterilization and hand hygiene in obstetric and neonatal hospital areas at high risk of infection (surgeries, delivery rooms, NICUs) in the nine hospitals to both guarantee safe delivery and reduce the risk of intra-hospital infection in neonates.

In addition to preventing intra-hospital infections, MINSA was also interested in addressing early neonatal sepsis (i.e. due to maternal risk factors, not intra-hospital infection), the leading cause of deaths among newborns. In 2009, a chart review conducted by HCI found that charts did not include documentation of clinical symptoms or laboratory test results and that medical staff did not use standardized protocols for diagnosis and management. Medical personnel did not have a clear understanding of maternal risk factors for early-onset newborn sepsis, and often clinical suspicion was not supported by laboratory tests. At the same time, suspected cases of intra-hospital infection (specifically, catheter line-associated bloodstream infection or ventilator-associated pneumonia) were reported as sepsis.

Often, if a provider identified any maternal risk factors for neonatal sepsis, antibiotic treatment was initiated, but frequently the risk factors were not well documented. For example, upon reviewing the clinical records for the 33 cases of neonatal sepsis reported in March 2009 in the Jinotega Hospital, 20 did not identify any maternal risk factor and 15 had normal complete blood counts (CBCs) or qualitatively normal polymerase chain reaction values, yet were diagnosed as sepsis based on clinical criteria or identified as 'at risk of sepsis'.

The chart review found that most cases were based solely on clinical manifestations that were often non-specific and also observed in non-infectious conditions [5]. If laboratory tests were ordered, these were at the discretion of each doctor, for example, CBC or C-reactive protein (CRP). No cases were found where tests ordered included hemocult or immature granulocyte count. Additionally, doctors and nurses did not have confidence in the test results reported by the laboratory

as they had already formed an opinion on the case and so laboratory results were not considered reliable.

These practices resulted in unnecessary or prolonged hospitalizations, a higher demand on beds and staff and overuse of antibiotics.

Choice of solution

The first intervention, begun in 2008, was to develop a new technical norm and set of guidelines for the rational use of disinfectants, sterilization and hand hygiene, which were approved by MINSA and disseminated nationally through 2008 [4]. The guidelines specified a disinfection process for operating rooms that enabled their availability for any type of surgical intervention 20 min after disinfection with chlorine and benzalkonium chloride. The guidelines also standardized the time and temperature of autoclave sterilization. Simultaneously, trainings were held in the nine hospitals on the guidelines, emphasizing the Spaulding risk classification of intra-hospital infection transmission for different objects and EPA classifications of different disinfectants [6]. HCI worked with staff in each hospital to implement rapid improvement cycles (following the Plan-Do-Study-Act cycle) to increase and measure (monthly) compliance with the guidelines in areas with high infection risk.

Implementation

The first intervention phase, centered on the rational use of disinfectants and hygiene, was carried out in nine hospitals, and was later expanded to an additional nine hospitals.

The use of alcohol gel became the principal method for controlling infections through indirect contact. HCI supported quality improvement (QI) teams in hospitals to determine the most effective actions to increase the use of alcohol gel in NICUs and pediatrics units. In parallel, HCI petitioned MINSA to include alcohol gel for hand hygiene on its basic supplies list so that it would be distributed to all health facilities nationally. Chlorhexidine-cetrimide were removed from the basic supplies list as they were not effective disinfectants.

A second intervention, specifically directed to address neonatal sepsis, was begun in the Jinotega Hospital in April 2009, where the medical director and head nurse of neonatology, chief of obstetrics, laboratory chief, and director of the epidemiology and medical records office formed a multidisciplinary team to respond to these issues. The team was trained on quality improvement methodology to identify gaps and their causes and carry out rapid cycles to introduce changes to overcome them [7, 8]. The team was also trained on the clinical definition of neonatal sepsis, its risk factors [8–10], clinical manifestations [7, 8, 11] and laboratory tests available to confirm a diagnosis [7, 12–14].

The changes implemented by the team included the following:

- (i) Obstetricians began to note maternal risk factors for neonatal sepsis in charts so that they could be easily identified and taken into account by the pediatricians.

Definition: Bacterial infection in the blood stream of the newborn, with non-specific inflammatory response and atypical clinical signs, acquired from the mother through the placenta or due to maternal risk factors [7,8]

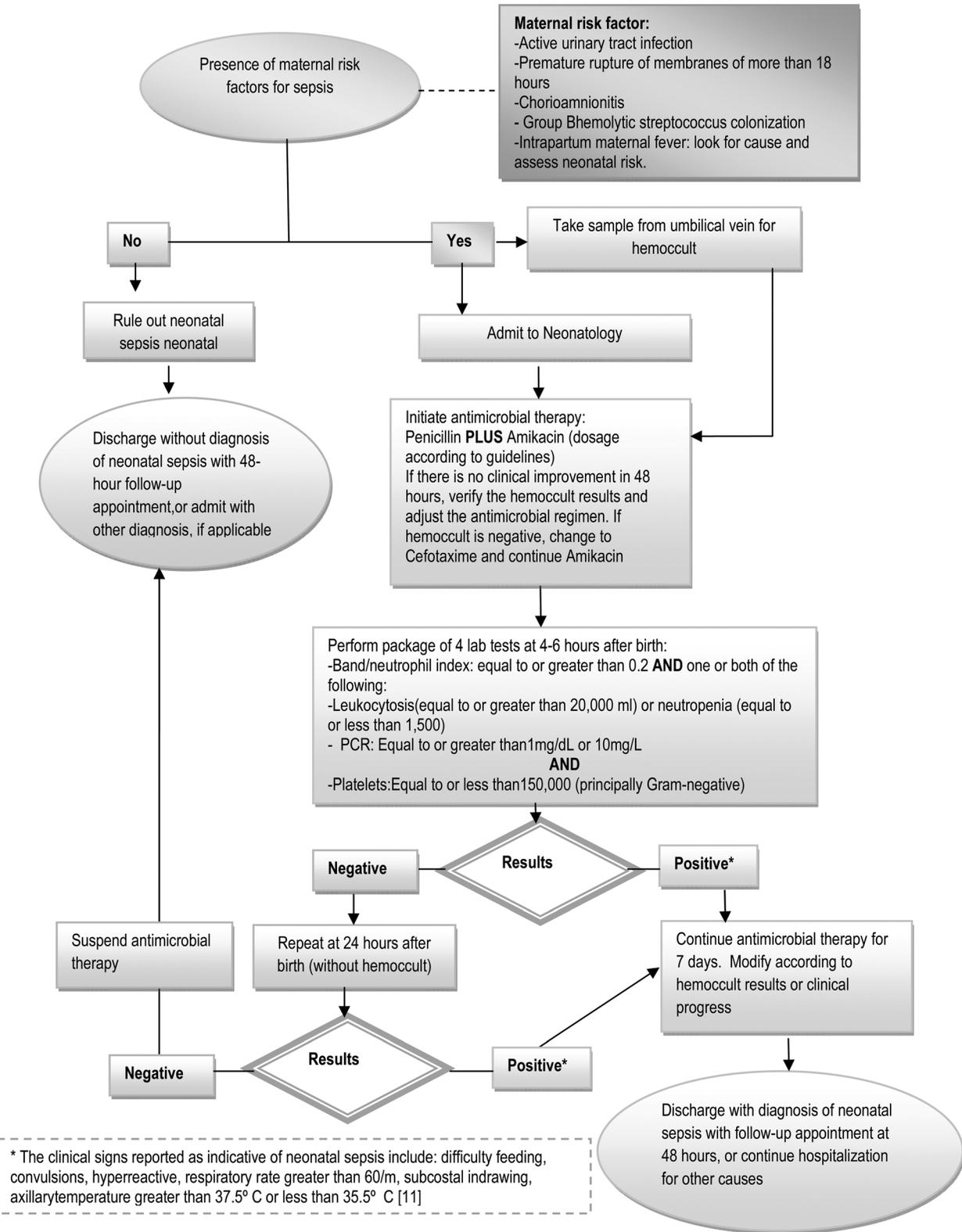


Figure 1 Algorithm for diagnosis and treatment of neonatal sepsis.

- (ii) A list of maternal risk factors was designed as criteria for admission to the NICU for sepsis; the criteria included all newborns with any risk factor for neonatal sepsis independent of gestational age and birth weight, even though it is recognized that premature and low birth weight infants have a higher risk of developing sepsis [5].
- (iii) A package of five laboratory tests was defined for the newborn: blood culture, leukocyte count, immature to total neutrophil ratio, CRP and platelet count. These tests, with the exception of the blood culture, were repeated at 24 h if the first tests were negative. The sepsis admission criteria did not include clinical signs, but if clinical signs were present, physicians had to differentiate them from other infectious (for example, newborn pneumonia) or non-infectious (for example, asphyxia) causes.
- (iv) A clinical form was designed to register the results of laboratory tests. Laboratory personnel were trained to return results within 2 h.
- (v) If a second set of laboratory tests was negative at 48 h, the newborn could be discharged with an appointment for follow-up in 48 h.
- (vi) A pediatrician was designated to coordinate and monitor the implementation of the improvement changes daily.
- (vii) Diagnosis was recorded at discharge so that it could be reviewed by the QI coordinator.
- (viii) The improvement process led to the design of an algorithm for the diagnosis and management of neonatal sepsis (Fig. 1), which included the definition of sepsis, risk factors, confirmatory laboratory tests and a decision tree based on the test results. In view of the complexity of the algorithm, the first improvement

cycles address obstacles to monitoring, including provider knowledge of maternal risk factors for sepsis (changes a and b), reliability and delivery of laboratory results in <2 h (c–f) and cooperation of the hospital statistics office in not assigning diagnosis of sepsis to any case that had not been verified by the QI team (g).

The organizational changes implemented by the Jinotega hospital included forms designed for the capture and registration of information. From May 2009 to November 2010, six more hospitals adopted these forms and the clinical algorithm, and achieved similar results in less time than at the Jinotega Hospital.

Evaluation

Figure 2 shows the use of the three main disinfectants—chlorine, glutaraldehyde and benzalkonium—in the 18 hospitals during the period October 2007 through November 2008. The first nine hospitals achieved 100% appropriate use of the three disinfectants in a 12-month period; the second nine hospitals achieved 100% appropriate use in only 7 months. The second nine hospitals achieved compliance with the guidelines much more quickly as they were able to apply the lessons learned and best practices from the first group.

At the Jinotega Hospital, the team was able to sharply reduce incorrect sepsis diagnosis over a 4-month period. In April 2009, when improvements were initiated, the package of the five laboratory tests was applied to 0% of newborns with identified risk factors for neonatal sepsis. In May, June and July 2009, the package was applied to 53, 46 and 93 of identified newborns, respectively. A sepsis diagnosis was confirmed

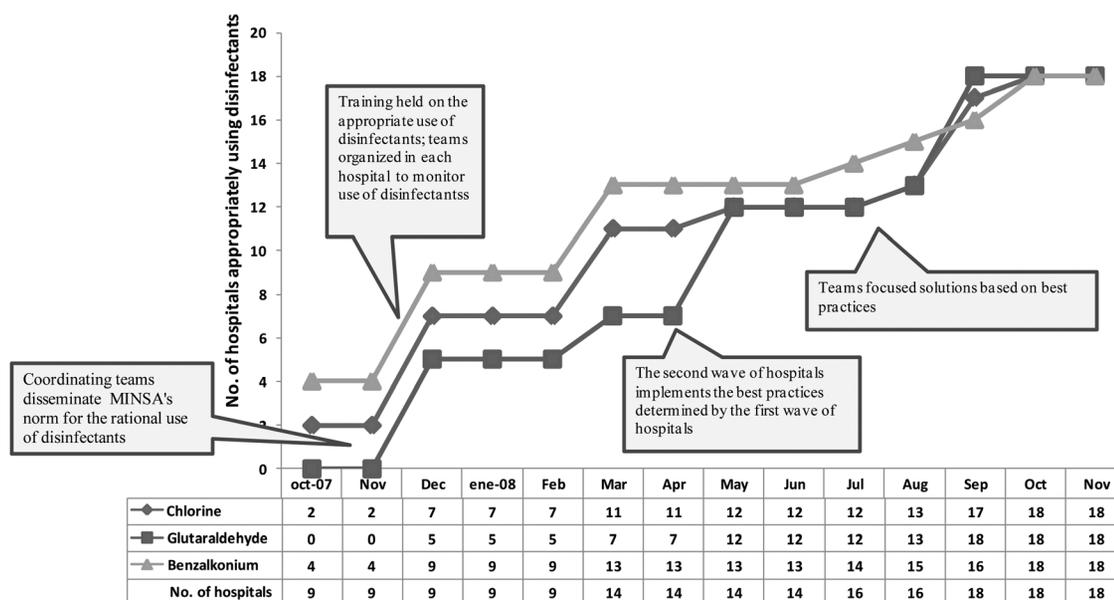


Figure 2 Spreading the appropriate use of disinfectants in 18 hospitals in Nicaragua (October 2007–November 2008).

for 29 of 47 suspected cases in April, for 24 of 53 in May, for 3 of 57 in June and for 1 of 42 in July. Since then, a sepsis diagnosis has been a rare event, even among newborns with identified risk factors, and the number of newborns identified as at risk has decreased to 6–10 per month. These improvements were the result of clarifying and correctly identifying maternal risk factors for neonatal sepsis, consistently applying the laboratory package and algorithm to those cases and assuring that only cases confirmed with laboratory results were recorded as neonatal sepsis.

Compared with hospitals that did not confirm sepsis diagnosis using laboratory tests, where sepsis diagnosis was reduced by 2% in 1 year, the seven hospitals saw an 84% reduction in the number of cases in that period (see Table 1). In these seven hospitals, the median total incidence of newborn sepsis was 48 per 1000 live births per month; after the intervention, this decreased to 16 per 1000 live births per month ($P < 0.001$) (see Fig. 3). The sharp drop in reported cases suggests that there had been an over-diagnosis of neonatal sepsis and that the intervention served to correct this problem. Data for the USA show an incidence of 1–2 neonatal sepsis cases per 1000 live births [15]. The neonatal sepsis death rate seen in Nicaragua before the intervention was 1.55 per 1000 live births and dropped to 0.64 per 1000 live births during the intervention period.

The initial version of the sepsis management algorithm was revised, and the intervention was expanded to 10 more hospitals by December 2011, to cover a total of 18 of Nicaragua's 22 hospitals. In the latest edition of the official Guide for Management of Neonates (currently being updated), MINSA has included the algorithm developed by the Jinotega Hospital to diagnose neonatal sepsis properly and accurately.

Limitations

There was no control group and so there is the possibility that other factors were at least partly responsible for the improvement seen in the decreasing cases of sepsis.

Data on compliance with standardized protocols for neonatal sepsis were collected from chart reviews and were not validated through other means, such as observation of actual practice or independent confirmation of reported neonatal sepsis cases. It is possible that some of the improvements in compliance were the result of more complete documentation of infection control procedures that may have been performed prior to the intervention but not documented.

Several factors limited the timely implementation of the improvements in the appropriate use of disinfectants, sterilization and hand hygiene. At first, there was resistance to the use of alcohol gel for hand disinfection, since the idea and practice of washing hands in soap and water was very deeply rooted. Limited understanding, reinforced by decades of practice in Nicaragua, that indirect contact infections can be transmitted by air and surfaces (i.e. by direct contact), made the change in operating room disinfection (including no longer closing the operating rooms for long periods following use by infectious patients) slow and difficult to implement.

Table 1. Comparing improvement in sepsis diagnosis in hospitals that did and did not use confirmatory tests for neonatal sepsis

Hospitals that used confirmatory tests for neonatal sepsis	No. cases: 2009	Live births: 2009	No. cases: 2010	Live births: 2010	Difference	Difference (cases/1000 live births)	P-value for difference between 2009 and 2010	Hospitals that did not use confirmatory tests for neonatal sepsis	No. cases: 2009	Live births: 2009	No. cases: 2010	Live births: 2010	Difference	Difference (cases/1000 live births)	P-value for difference between 2009 and 2010
Jinotega	174	4593	23	5109	-0.033	-33.38	<0.001	Matagalpa	160	7128	175	6867	0.003	3.04	0.240
Estelí	56	3336	26	3246	-0.009	-8.78	0.0013	Bluefields	48	1756	139	1910	0.045	45.44	<0.001
Chinandega	37	6057	9	6291	-0.005	-4.68	<0.001	Madriz	42	2014	40	2042	-0.001	-1.27	0.775
RAAN	13	2117	8	2059	-0.002	-2.26	0.3029	Boaco	167	2710	110	2869	-0.023	-23.28	<0.001
Ocotal	0	2851	0	3120	0.000	0.00	NA	Granada	23	3447	27	3059	0.002	2.15	0.321
Juigalpa	273	3690	22	4284	-0.069	-68.85	<0.001	Masaya	293	4234	227	3986	-0.012	-12.25	0.023
Total	553	22 644	88	24 109	-0.021	-20.77	<0.001	Total	733	21 289	718	20 733	0.000	0.20	0.911

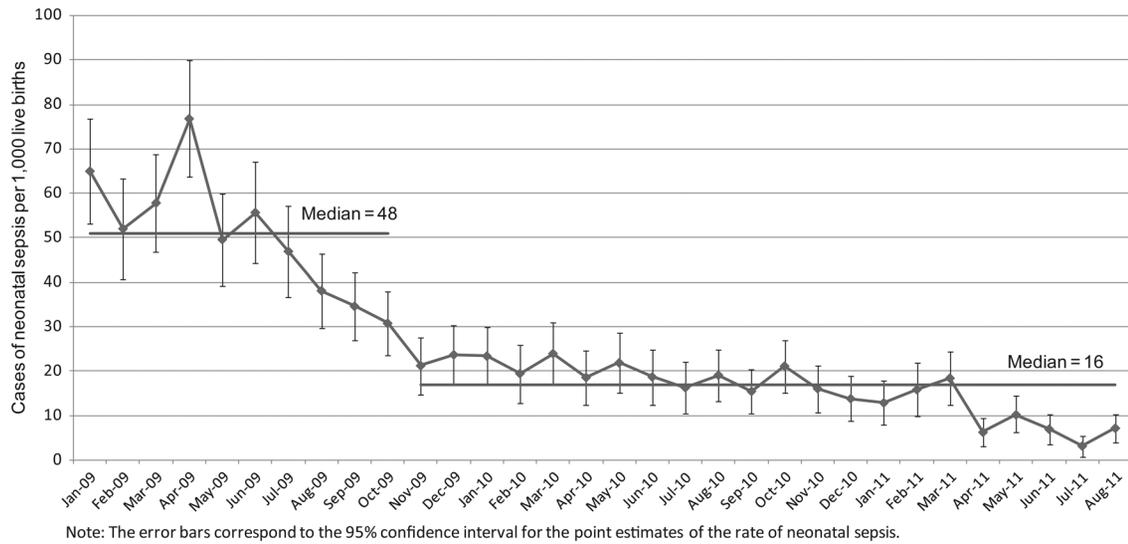


Figure 3 Diagnosis of sepsis in seven hospitals participating in the quality improvement intervention in Nicaragua, January 2009–August 2011.

Lessons learned

The interventions to improve surveillance, diagnosis and management of neonatal sepsis illustrate the need to dig deeper to understand high reported rates of neonatal sepsis. To improve management of both antisepsis/hand hygiene and newborn sepsis, MINSA's consent and HCI's good relationship with MINSA were key to arranging technical assistance visits in each hospital.

It was important that there were not more than four members on the QI team, as most of the staff were busy caring for patients. In Jinotega, the heads of the pediatrics, neonatal and hospital management were on this team.

Teams achieved better results if they had authority from hospital management to implement changes. It was also necessary to teach teams about QI methodology as a path to identifying solutions to problems.

The organizational changes implemented through rapid cycles related to the diagnosis and verification of neonatal sepsis through the use of laboratory tests have shown their effectiveness in reducing the number of newborns admitted for sepsis. In turn, the cost of antibiotic therapies and other supplies have been reduced, allowing neonatology staff more time to treat other critically ill newborns.

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