

Research Article

Hospital-Acquired Neonatal Sepsis at Parirenyatwa Central Hospital, Neonatal Intensive Care Unit, Zimbabwe, 2016: A Cohort Study

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Keywords

- Neonatal sepsis
- *Klebsiella*
- Neonatal intensive care
- Hospital acquired

Abstract

Background: Neonatal sepsis is among the leading causes of morbidity and mortality among term and preterm infants particularly in Neonatal Intensive Care Units (NICU). Pathogens implicated are mostly hospital-acquired. Parirenyatwa NICU experienced a surge in neonatal sepsis incidences, recording 108 cases and 41 deaths in five months. We determined the source and the factors that facilitated the infection.

Methods: A cohort study of neonates admitted from 1 June to 31 October 2016 using secondary data, key informant interviews and checklists were conducted. Environmental and hand swabs were collected for laboratory analyses. Neonatal sepsis was defined as a clinical syndrome resultant from systemic infection. Epi Info™ was used to compute proportions, relative risks, attributable risks at 5% significance level.

Results: All 641 clinical records of admitted neonates were reviewed. One hundred and two (94%) of neonate sepsis patients were hospital-acquired. Suctioning (RR=9.6; 95%CI, 5.4-17.1) increased the risk for neonatal sepsis and 80.6% neonatal sepsis cases were attributable to mechanical ventilation (95%CI, 71.5-89.6). *Klebsiella* and *Pseudomonas* Species were isolated from ward equipment and sinks. Hand swabs yielded *Pseudomonas* and *Staphylococci* Species. Among neonatal sepsis patients, 78.2% (n=101) yielded positive *Klebsiella* cultures [RR 2.0; (95%CI 1.5-2.8), AR% 48.4; (95%CI 33.4-63.4)]. The excess risk of death from neonatal sepsis was 34.2 per 100.

Conclusion: Outbreak was driven by *Klebsiella* induced, hospital-acquired sepsis, from a common-continuous source and spread through cross infection. Suspending mechanical ventilation and thorough disinfection controlled the outbreak. Compliance with infection control protocol and surveillance of neonatal infections were considered for prevention of similar outbreaks.

ABBREVIATIONS

AIDS: Acquired Immunodeficiency Syndrome; EONNS: Early Onset Neonatal Sepsis; LONNS: Late-Onset Neonatal Sepsis; HIV: Human Immunodeficiency Virus; HSO: Health Studies Office; JREC: Joint Research Ethics Committee for University of Zimbabwe and Parirenyatwa Group of Hospitals; LBW: Low Birth Weight; MAS: Meconium Aspiration Syndrome; MCS: Microscopy, Culture and Sensitivity Test; MOHCC: Ministry of Health and Child Care; NNS: Neonatal Sepsis; NICU: Neonatal Intensive Care Unit; RDS: Respiratory Distress Syndrome; VLBW: Very Low Birth Weight; WHO: World Health Organization

INTRODUCTION

Neonatal sepsis is rated among the most common causes of

neonatal mortality, accounting for 30-50% of all neonatal deaths yearly in developing countries [1]. The condition is defined as a clinical syndrome that affects infants who are 28 days of life or younger and manifests through systemic infection characterised by septicaemia, pneumonia, meningitis, arthritis, osteomyelitis, as well as urinary tract infections [2].

In low to middle-income countries (LMIC's) such as sub-Saharan Africa, South Asia, and Latin America where neonatal infections are most prevalent, the case fatality risk associated with severe bacterial infections in the first month of life is as high as 9.8% [3]. Zimbabwe is no exception, with the current infant mortality rate standing at 46.6 per 1000 live births in 2015 [4]. In a country where infections are one of the three leading causes of neonatal mortality, accounting for approximately a quarter of

newborn deaths in the first month of life, neonatal infections are mainly acquired horizontally (from the environment) and also vertically (maternally) [5].

The syndrome frequently present as early-onset sepsis (EONS), known to be mainly caused by Group B Streptococci (GBS) or *Escherichia coli* (*E. coli*) that manifests within the first 72 hours of life [6]. EONS is commonly associated with low birth weight (<2500gms) or prematurity, maternal febrile illness within 2 weeks prior to delivery, meconium stained liquor or prolonged rupture of membrane (>24 hours) [7]. Late-onset sepsis (LONS) usually presents after 72 hours of age and is commonly caused by *Coagulase-negative staphylococci* (CoNS) and *Klebsiella Species*, with the source of infection being either nosocomial (hospital-acquired) or community acquired [8]. LONS may also be associated with Neonatal Intensive Care Unit (NICU) admission where poor hygiene, low birth weight (LBW), poor umbilical cord care, bottle feeding as well as invasive procedures are rampant [9].

A suspected first case of neonatal sepsis at Parirenyatwa Hospital was admitted as a transfer from a mission hospital, approximately 60 km outside the city. The neonate was diagnosed with neonatal sepsis, mechanically ventilated with some response before deteriorating and subsequently demised in 7 days. Neonatal sepsis incidences rose thereafter and the consultant paediatrician of the unit reported the outbreak for investigation on the 20th of October 2016. We sought to identify the source of infection and factors that facilitated neonatal sepsis morbidity and mortality at Parirenyatwa NICU, Central Hospital, Zimbabwe.

MATERIALS AND METHODS

A cohort study, using secondary data (hospital records) was conducted.

This study was conducted at Parirenyatwa Central Hospital in Zimbabwe's capital city (Harare), which houses a maternity unit under which the NICU is located. The unit admits locally delivered neonates as well as referrals, mainly from other central hospitals across the country as well as from local council clinics. No home born babies are admitted into the unit.

The unit is divided into NICU1 with 36 beds, which functions as a general ward and NICU2 with 2 beds, which is reserved for critical care and mechanical ventilation. The unit also has 4 private beds, making a total capacity of 42 admissions. It has a staff complement of two consultant paediatricians, 15 general nurses and 4 general hands that are responsible for cleaning the ward. Parirenyatwa NICU experienced a surge in neonatal sepsis incidences, recording 108 cases and 41 deaths in five months

Case definition

An exposed neonate, was one admitted at age 28 days or below into the NICU between 1 June and 31 October 2016 who were mechanically ventilated and or suctioned.

A participant who developed the outcome of interest was a neonate, admitted at age 28 days or below into the same NICU from the 1 June 2016 to 31 October 2016, who developed neonatal sepsis according to the CDC defined criteria of one or more of the

following symptoms; hyper/hypothermia, respiratory distress, diarrhoea, decreased bowel motion, hypoglycaemia, reduced movements, reduced feeding, seizures, tachycardia/bradycardia, abdominal distension or vomiting, with or without a laboratory confirmed, positive culture of the hospital-acquired pathogens (*Klebsiella species*) [10].

Subanalyses

Key informant interviews and checklists to evaluate the unit's compliance with National Infection Prevention and Control standards was also done. The key informants were Nurses and Doctors, Nurse Managers, Infection control staff, Laboratory, Pharmacy and Hospital equipment management personnel

Data collection and analysis

The entire population (641) of neonates admitted to the NICU at Parirenyatwa Hospital during the study period (1 June to 31 October 2016) was included in the study.

A pre-tested interviewer-administered questionnaire was used to collect data from key informants. Pre-testing of instruments was done at a distal paediatric unit and clarity adjustments factored in. a checklist, extrapolated from the National Infection Control guide was used to evaluate the extent of adherence to the protocol.

The investigation team included Public health officers, infection prevention and control specialists, paediatricians of the unit, Hospital equipment management representative, a pharmacist and a laboratory scientist. The plan of activities was to identify the infection source through swabs, observe and then interview unit staff to evaluate the level of compliance with the national guidelines. The unit was also evaluated in relation to set-up, in relation to standard practice.

We anonymously observed the unit's routine practices for two days, 20 and 21 October 2016, the outbreak before instituting response activities. A neonate found on mechanical ventilation passed on after 2 days, prompting the temporal closure of a section of the unit. The closure facilitated thorough investigation and disinfection of the unit. Neonatal sepsis incidences reached a peak of ten cases in a single week on the 23rd of August before declining rapidly, following interventions, to a single case on the 31st of October 2016.

Epi Info™ version 7.2 was used to generate frequencies, means and relative risks. Measures of impact were also calculated (AR and AR %) at 95% level of confidence. Environmental and hand swabs were collected from ward surfaces, health workers hands and ward equipment artefacts for laboratory analyses. The first collection was done on the 20th of October 2016, immediately after the outbreak was reported. Environmental swabs were collected during the outbreak on 13 September and 13 October 2016 and also following the temporal closure of the unit on 7 November and 14 November 2016, to evaluate the instituted thorough disinfection and equipping of the unit. Blood culture results for the neonates were reviewed and Infection Control checklists evaluated.

Ethical clearance was obtained from the Parirenyatwa Institutional Review Board (IRB), Joint Research Ethics

Committee for Parirenyatwa and University of Zimbabwe (JREC), Ministry of Health and Child Care, AIDS and TB unit Directorate, and the Health Studies Office (HSO) for Zimbabwe. Written informed consent was obtained from key informants.

RESULTS AND DISCUSSION

Descriptive epidemiology

Study population: Out of 641 neonates who were admitted at our NICU, 108 (16.8%) were diagnosed with neonatal sepsis. Of all neonatal sepsis diagnosed; 59/108 (55%) were females, 79/108 (73.1%) had obtained laboratory confirmation of *Klebsiella* Species through blood cultures (Table 1).

Twenty-nine (94%) of exposed participants were mechanically ventilated, while unfavourable neonatal outcomes were characterized by combination of low birth weight (54/108; 50%), HIV exposure (25/108; 28%), prematurity (48/108; 24%) and longer duration of stay (68/108; 63 %, > 7 days) (Table 2).

Time

Figure 1 illustrates the distribution of neonatal sepsis cases against time at the central hospital's NICU, Harare. The epi curve is suggestive of a continuous common source outbreak. The spread of the infection into the distal section of the unit was likely due to cross infection. The outbreak was reported on the 20th of October 2016 and the investigation commenced promptly.

Analytic epidemiology

One hundred and two (94%) of neonate sepsis patients were diagnosed after hospitalization, whilst six (6%) presented with neonatal sepsis on admission.

Participants who were suctioned (oropharyngeal and endotracheal) were 9.6 times more likely to develop neonatal sepsis than those who were not suctioned (95% CI, 5.4-17.1),

whereas participants who were mechanically ventilated were 7.2 times more likely to develop neonatal sepsis (95% CI, 5.8-9.0) than those who were not mechanically ventilated.

As high as 80.6% (n=29) of neonatal sepsis cases may be attributed to mechanical ventilation (95% CI, 71.5-89.6) and could have been avoided had the neonates not been exposed to mechanical ventilation. (Table 2).

Outcomes of neonatal sepsis

Among Hospital-acquired neonate sepsis patients (n=101), 78% of them yielded a positive *Klebsiella* blood culture. The neonate sepsis patients were twice more likely to have a positive *Klebsiella* blood culture, whilst 50% of neonatal deaths could be attributed to *Klebsiella* infection and could have been prevented if *Klebsiella* bacteria were eliminated. The relative risk of death was 10.11 times more in neonates who had neonatal sepsis than neonates who had no neonatal sepsis and the excess risk of death due to neonatal sepsis was 34.2 per 100 cases (Table 3).

Laboratory investigations

Laboratory analyses of environmental swabs were done on 4 different occasions. Heavy growths of *Klebsiella* and *Pseudomonas Species* were isolated from the suction machine in NICU2 on the first 2 occasions. The Vaseline exterior in NICU1 also cultured *Klebsiella* bacteria. Tap Water testing yielded *Sphingomonas Paucimobilis Species*.

A total of 15 health workers (three doctors and twelve nurses) found in the unit during the outbreak had their hands swabbed for microscopy, culture and sensitivity. The cultures obtained were mostly (60%) non-pathological *Enterobacter* and *Micrococcus Rods. Staphylococcus Species* constituted a combined 33% and *Pseudomonas Species* were 13%.

Level of adherence to infection control standards

An environmental assessment, facilitated by checklists derived from the national infection prevention and control guidelines revealed that bacterial filters were missing from suction and ventilator machines. Apparent overcrowding, as evidenced by bassinets positioned less than 1m apart in the general and ICU section of the unit was observed. Twelve suction machines were being shared among 22 neonates, against the recommended practice of a suction machine per neonate. In-adequate resource supply, characterised by stock-outs of disinfection solutions was exposed. Local sterilization and disinfecting equipment were not available.

Health worker practices were evaluated against universal precautions for infection prevention and control. Ten (67%) of the health workers used a hand antiseptic spray on entry into the unit and in between handling of the neonates. Proper surgical hand scrubbing was least practised at 7% (n=1). Thirteen (87%) of the health workers stated that they knew how to correctly clean the suction machines whilst 53% (n=8) did not know how to clean and disinfect laryngoscopes (Table 4).

Epidemic preparedness and response

The outbreak was detected and reported, only after five months, meanwhile, the death toll continued to rise. There w

Table 1: Demographic Characteristics of Study Participants, Central Hospital's NICU, Harare, Zimbabwe, 2016.

Variable	Category	Neonatal Sepsis n=108 (%)	No Neonatal Sepsis n=533 (%)
Gestational Age	<28 weeks	3 (3)	14 (3)
	28-36 weeks	47 (44)	139 (26)
	+36 weeks	58 (54)	380 (71)
Sex	Female	59 (55)	265 (50)
Birth Weight	ELBW<1000g	3 (3)	16 (3)
	VLBW 1000-1500g	6 (6)	57 (11)
	LBW 1500-2500g	54 (50)	131 (25)
	Normal 2500g+	45 (42)	329 (62)
Duration of Stay	<3days	10 (9)	351 (67)
	3-7 days	30 (28)	126 (24)
	7+ days	68 (63)	56 (11)

Abbreviations: ELBW: Extremely Low Birth Weight; VLBW: Very Low Birth Weight; LBW: Low Birth Weight

Table 2: Risk Factors Associated with Hospital-Acquired Neonatal Sepsis, Central Hospital's NICU, Harare, Zimbabwe, 2016.

	Neonatal Sepsis (%)	No Neonatal Sepsis (%)	RR	95% CI	AR%	95% CI
Suctioned	96 (32.9)	196 (67.1)	9.6	5.4-17.1	29.4	23.7-35.1
Mechanical Ventilation	29 (93.5)	2 (6.5)	7.2	5.8-9.0	80.6	71.5-89.6
Oxygen	101 (23.2)	335 (76.8)	6.8	3.2-14.2	19.7	15.1-24.4
HIV exposed	25(27.78)	65 (72.2)	1.97	1.32-2.92	13.7	3.9-23.4
Prematurity	48(23.9)	153 (76.1)	1.8	1.24-2.46	10.2	3.5-16.95
Low Birth weight	55 (21.9)	196 (78.1)	1.6	1.14-2.3	8.3	2.2-14.5

Abbreviations: RR: Relative Risk; CI: Confidence Intervals; AR%: Attributable Risk Percent

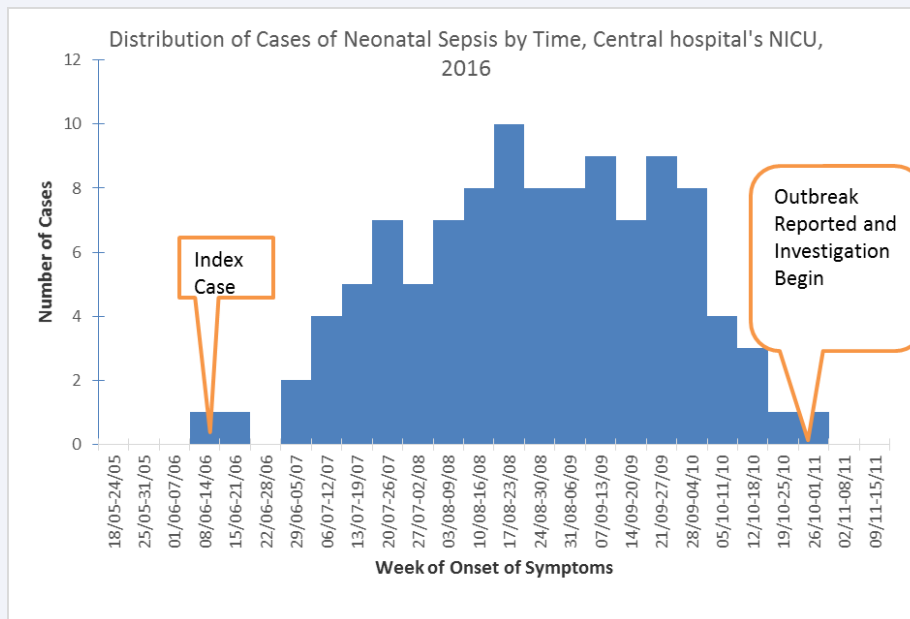


Figure 1 Timeline of the Neonatal Sepsis Outbreak, Central Hospital's NICU, Harare, Zimbabwe, 2016.

no infection prevention and control evaluation mechanism in place which delayed outbreak detection. Active case finding was initiated, immediately after the outbreak was reported. A section of the unit (NICU2) was temporarily closed to facilitate identification of the source of infection. The hospital availed a paediatrician, pharmacist, laboratory scientist, an infection control specialist and hospital equipment management staff to assist the investigation. Requisite medications were available and adequate to mitigate the outbreak, however appropriately trained personnel (ICN nurses) for the specialized area were not available.

The study sought to identify the source of infection and describe the factors that facilitated neonatal sepsis morbidity and mortality at a referral hospital's NICU in Harare, Zimbabwe. A cohort study design was preferred to identify the entire population of neonates that were admitted during the investigation period.

The investigating team promptly responded to the outbreak and managed to contain it as well as identify the causative factors, which facilitated the institution of measures to prevent future similar outbreaks.

A key finding in this study was the evidence of hospital-acquired infection with the source being identified as suction machines, which did not have bacterial filters fitted. This is supported by the temporality of symptoms; 102 (94%) of all neonate sepsis patients developed the infection whilst resident in the unit, having been admitted for reasons unrelated to the diagnosis.

The epi curve was also consistent with a continuous common source outbreak. The spread of the infection was likely facilitated by failure to adhere to minimum infection prevention standards for an ICU.

The isolation of *Klebsiella Species* from blood and environmental laboratory analyses confirmed the Hospital-acquired nature of the infection. This is consistent with the increased risk of acquiring the infection among participants who had longer (+7days) hospital stay and those who had low birth weight, which increased the risk of acquiring infection due to immune depression. This finding is consistent with Nathoo et al., (2013) who identified prematurity and low birth weight as significant risk factors for neonatal sepsis.

Table 3: Klebsiella Association with Neonatal Sepsis, Central Hospital's NICU, Harare, Zimbabwe, 2016.

Exposure	Outcome					
	Neonatal Sepsis n=101 (%)	No Neonatal Sepsis n=29 (%)	RR	95% CI	AR%	95% CI
Klebsiella	79(78.2)	4(14.8)	2	1.5-2.8	48.4	33.4-63.4
Outcome	Impact					
	Died n=61 (%)	Discharged n=580 (%)	RR	95%CI	AR%	95% CI
Neonatal Sepsis	41(67.2)	67(11.6)	10.11	6.2-6.6	34.2	24.9-43.5

Table 4: Environmental Swab Results, Central Hospital's NICU, Harare, Zimbabwe, 2016.

Variables			Testing Dates (2016)			
Location	Item Tested	Organisms Isolated	13/09	13/10	11-Jul	14/11
	HILROM humidifier 2	<i>Pseudomonas sp</i>	+	+	-	-
	Ventilator (8 sites)	<i>Pantoea sp</i>	+	-	-	-
	Suction machine	<i>Klebsiella pneumoniae; Pseudomonas</i>	+	+	-	-
NICU2	Sink drain	<i>Aeromonassp; E. coli, Klebsiella Pneumoniae;</i>	+	+	+	-*
NICU1	Vaseline exterior	<i>Klebsiella Sp; Enterobacter clocae; Gram positive cocci</i>	+	-	-	-
	Suction machine	<i>Klebsiella Pneumoniae; Pseudomonas</i>	-	-	-	-
NICU 1 - Reception	Sink 1 and 2	<i>Klebsiella Pneumoniae; Pos cocci</i>	+	+	+	-
Water testing:	<i>Sphingomonaspaucimobilis</i>					+

Abbreviations: NICU1: Neonatal Intensive Care Unit 1; NICU2: Neonatal Intensive Care Unit 2

Being mechanically ventilated is associated with increased production of secretions from the depressed respiratory tract, leading to endotracheal suctioning, an inevitable intervention whilst on ventilation. Some neonates were suctioned (oropharyngeal) without mechanical ventilation. Suctioning was identified as an independent risk factor for Neonatal sepsis in our study [11]. However, our results were contrary to findings by Dong et al., (2015) who identified Gram-negative bacillus such as *Escherichia coli*, *Klebsiella* spp., *Enterobacter* spp. and *Pseudomonas* spp as the most prevalent pathogens for neonatal sepsis invasive interventions [12].

Poor adherence to universal precautions and national infection control standards were associated with neonatal sepsis in our study. This was substantiated by the spread of the infection to the second section of the unit, likely through cross-infection, resulting in the infection becoming generalized. Positive *Klebsiella Pneumonia* cultures obtained from the NICU2 sink, which was being used by neonate caregivers and staff, combined with an erratic supply of disinfection solution may have facilitated transmission and spread of the infection. The occasional sharing of the suction machine, with inevitable backflow, in the absence of a bacterial filter, facilitated continuous infection, which could not be averted by a change of suction catheters among the patients. The staff was unaware of the necessity of the bacterial filters for ventilator and suction machines, which were supplied to the unit but remained unutilized.

A gap between theory and practice usually result from assumptions that a system functions as intended and is only refuted when the actual results reflect otherwise. The infection

control policy document, which was available at the institution, was being partially applied. Despite scoring high on infection prevention and control knowledge, the actual practices diverted significantly from it. Thorough terminal disinfection upon patient discharge was known but not practised, resulting in the next admitted neonate being infected by the same bacteria.

The bassinets in all the subunits were in close proximity (<1m), in contrast to the recommended minimum 1m in the general ward and 2m in the ICU unit. There was only one trained Intensive Care Nurse and the whole staff complement had not received any formal or informal infection prevention training. This was contrary to the guidelines that advocate for formal training in infection control and allocation of a departmental infection control focal person for ease of supervision [13].

Most (33%) of the hand swabs from the health workers yielded no pathologically significant pathogens. However, *Pseudomonas Species*, a pathological gram-negative bacteria, was found in 13% of the staff members, presenting a potential risk of a new wave of neonatal infections if not nipped in the bud.

In our study, death due to neonatal sepsis was significantly higher in the female gender and in low birth weight infants, no gender bias for neonatal sepsis was found in other studies [14]. *Klebsiella Pneumonia*, identified in this study, was sensitive to Ipramem, and prolonged life in infected neonates. However, repeated exposure to the bacteria led to unfavourable outcomes [15]. Our study had some limitations; As a retrospective design, there is the possibility of misclassification of exposures and outcomes. The laboratory tests were conducted at the hospital laboratory only, a second laboratory would have provided a

comparison of results. The missing records from the hospital records department may have possibly over or underestimated strengths of associations.

CONCLUSION

The source of infection in this outbreak was identified as suction machines, which did not have bacterial filters. The infection spread through the unit, facilitated by non-adherence to infection prevention and control standards. Hospital-acquired, *Klebsiella Pneumoniae* was isolated as the insulting pathogen, which was found in the unit's environmental surfaces and equipment.

Significant risk factors associated with Hospital-acquired neonatal sepsis were suctioning (oropharyngeal and endotracheal) and mechanical ventilation. Suspending mechanical ventilation and thorough disinfection (during temporal closure) controlled the outbreak and compliance with key infection control protocol and continuous surveillance of neonatal infections was advocated to prevent similar outbreaks.

As a result of the study, the following activities were done in order to control the outbreak:

1. Temporal closure of a section of the unit to facilitate thorough disinfection and equipping, assisted by Hospital Equipment Management (HEM) team.
2. The Investigators developed and recommended a Neonatal Sepsis Surveillance form
3. We identified an Infection Prevention and Control (IPC) nurse and a deputy to supervise the unit to ensure infection control standards adherence
4. The IPC Matron was supported in conducting in-service training refresher course for NICU staff which reinforced the importance of infection prevention and control
5. The investigators also developed a cleaning, disinfection and sterilization maintenance log for ICU which is evaluating compliance with routine and terminal disinfection protocol

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