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Development of neonatal death clinical audit instrument



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ABSTRACT

Introduction: A neonatal death clinical audit is needed to improve the quality of care and prevent similar preventable neonatal deaths. This study aims to develop a neonatal death clinical audit instrument.

Method: We developed a neonatal clinical death audit instrument for all death cases admitted to the nursery. The audit was started from the place of delivery for the inborn and arrival at the emergency room for the outborn. The instrument contains all aspect all aspects of case management. The audit was carried out by comparing the patient's management practices with the standard operating procedures. The last part of the instrument was the death information, assessment of deviations, and determination of avoidability. The instrument was tested twice, and pediatricians and neonatologists conducted an audit at several types of hospitals in Indonesia. The instrument was tested to audit 20 cases at six hospitals in 4 Provinces, and the second test was 37 cases at six hospitals in East Nusa Tenggara. The auditors of the first test were neonatologists and general pediatricians, while for the second test were general pediatricians. The average time of audit was 30 minutes.

Results: The instrument could detect the deviations, cause of death, and avoidably.

Conclusions: The instrument could identify deviations and determine avoidably neonatal death. Recommendations based on the deviations may improve the quality of care and prevent similar neonatal death.

Keywords: neonatal, death, audit, instrument.

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BACKGROUND

Neonatal mortality is still a major global health problem, even though it has decreased gradually for decades.^{1,2} If this trend continues, it is estimated that only 60 countries will achieve the Sustainable Development Goals (SDGs) target by 2030. More efforts are needed to achieve this target.¹⁻³

The neonatal mortality rate (NMR) in Indonesia is 12.4/1000 live births or more than 60,000 neonatal deaths per year, most of which are preventable.²⁻⁵ The three most common causes of death are preterm birth, intrapartum complication, and neonatal sepsis.⁶ One-third of neonatal deaths occur in the first 24 hours and 75% in the first week.² Most neonatal death with preventable causes was in the hospitals.² Prevention of neonatal death in hospitals is the adequate quality of service and skilled

health workers, especially during delivery, at birth, and a few days after birth. 1-3

The clinical audit is a global recommendation to improve the quality of service and prevent similar preventable neonatal deaths.⁷ Guidelines for medical auditing in hospitals are contained in the Decree of the Minister of Health of the Republic of Indonesia in 2005.⁸ There is a Maternal-Perinatal Audit Surveillance and Response. However, this guideline does not contain the clinical management instruments.⁹

The neonatal death clinical audit at the hospital needs an instrument to evaluate the management of the neonate during hospitalization. A simple instrument of neonatal death clinical audit was developed in 2015, but it needs some revision. The clinical audit should be done at every phase of hospitalization, for inborn starting from the delivery room

and emergency room for outborn or referral cases.¹¹ The objective of this study is to develop a neonatal death clinical audit instrument that the general pediatrician can widely use in a hospital setting.

METHODS

An instrument of neonatal clinical death audit was developed in 2015.¹⁰ This instrument was used to audit six hospitals in Indonesia by a neonatologist. The lack of instrument was limited in interpretation and implementation and was not tested before being used. Therefore, we developed a new instrument based on this.

The audit process was comparing the case management and SOPs. The inappropriateness between management and SOPs was considered a deviation. Management of inborn was started from delivery and for outborn from arrival at ER. Information collected on inborn cases included in the instrument included maternal, pregnancy, fetus, delivery, resuscitation. stabilization, essential newborn care (ENC), and anthropometry. Pregnancy information was aimed at identifying maternal risk factors during pregnancy. Maternal morbidities occurred during pregnancy, amniotic conditions, and antenatal steroids for premature cases. Fetal information was about gestational age, fetal growth, and fetal presentation. Delivery risk factors were obstructed labor, prolonged membrane rupture, amniotic fluid condition, fetal heart rate, and the number of fetuses. The delivery information was birth attendance, type of delivery, and indication.

In the delivery room, information collected were resuscitation, Apgar score, health personnel who performed and resuscitation, stabilization. Information about essential newborn care audited was for delayed cord clamping, breastfeeding initiation, umbilical cord care, eye antibiotic, vitamin K, hepatitis B-0, time of first bathing, and anthropometry. For breastfeeding initiation, information about health personnel carried out and duration was audited, and for vitamin K injection was site and time of injection. Of hepatitis B-0 vaccination, time, and site of injection. Anthropometry measurement was birth weight, body length, and head circumference.

Times (minute, hour, and day) were collected at every phase of hospitalization. The time was on arrival at ER, examination by triage, admission to nursery, and examination by the pediatrician at nursery. For outborn patients or referral cases, initial information was the time of birth, time of arrival at ER, sex, birth weight, body weight at ER, gestational age, and time: the referring health facility and health personnel, and referral letter. In the referral letter, information was the diagnosis, previous management, pre-referral management, and reason for referral. The communication used, pre-referral process, and stabilization. In the pre-referral process, information was delayed in referral, care-seeking, refusal to be referred, and pre-referral stabilization. Stabilization was blood glucose, temperature, and airway.

Information collected at ER was the general condition on arrival, clinical condition, emergency, and management. Laboratory work, imaging, and other diagnosis support at ER and time carried out. Information about medical and nursing action and stabilization before transport to the nursery. Diagnosis made by triage, communication with a pediatrician, any attendance of pediatrician at ER, approving of diagnosis and management by the pediatrician, and time of examination by a pediatrician.

For all cases (inborn and outborn) in the nursery, information about nutrition, respiratory distress, hypothermia, hypoglycemia, and seizure were audited. For nutrition, the information was enteral feeding, parenteral nutrition, fluid and caloric intake, and appropriateness to SOPs. If the patient was LBW/preterm, additional information was about trophic feeding and anthropometric monitoring if any information on respiratory distress, hypothermia, hypoglycemia, and seizure were signs, diagnosis, laboratory and management, imaging, respiratory support, and monitoring.

There were three main diseases, i.e., LBW/preterm, neonatal asphyxia, and neonatal sepsis. The audit was carried out if one or more of these diseases occurred during hospitalization. The point of LBW/preterm was the estimation of gestational age, time of birth weight measurement, monitoring, laboratory workup, thermoregulation, duration of kangaroo mother care (KMC), if any, nutritional program, post-natal growth monitoring, and complication of that occurred if any. Neonatal asphyxia was clinical monitoring, complications to any organs or systems. Neonatal sepsis was risk factors, diagnosis, sepsis workup, antibiotics, monitoring, management, and complication that may be occurred.

The last part of the instrument was the death information, assessment of deviations during referral for outborn and during hospitalization for all cases, time of death, the main cause of death, and determination of avoidability and the reason. Time of death, place of death, age of death, and main diagnosis cause of death were the information taken. The

place of death was the resuscitation room (delivery room or operating room), ER, or nursery. Deviation of an outborn patient was about the delay of care-seeking, refusal of referral, delay of referral, inadequacy pre-referral stabilization, communication between health facilities. While deviations during hospitalization were delay of emergency management, the inadequacy of emergency detection, the inappropriateness of main diagnosis and complication diagnosis, inadequacy of management, inadequacy of monitoring or follow up, delay of starting treatment, unavailability of drugs, and lack of barriers of the facility. The facility was the laboratory, radiology, medical equipment, nursing equipment, blood transfusion, and NICU. Based on the deviation found. the auditor determined the avoidably. Supporting data for this audit were SOP, medical equipment at ER/delivery room/operating room/neonatal nursery/ neonatal intensive care unit (NICU), register and medical records, drugs, laboratory and radiology facilities, and training of health personnel.

RESULTS

There was 2 step test of the instrument. The first test was to know the instrument's completeness and reliability at six hospitals around Indonesia. The first test in September and October 2021 was at six hospitals consisting of type B and type C, public, and teaching hospitals. Auditors were neonatologists and pediatricians. (Table 1)

Feedback and improvement of the first test were the instruction to fill the instrument, completeness and relevancy items, editing, and supporting documents. Editing was grammar, numbering, consistency of writing, standard medical term, and omitting redundancy. Items revision and addition were risk factors, equipment (for resuscitation, thermoregulation), medication (drug, route of injection, fluid), essential newborn care, irrelevant question, answer option, timing, management of hypoglycemia, health personnel who perform service or action, and method of blood drawn. After being improved, the instrument was tested in October at the same hospitals and auditors. The result of this test was only

Table 1. The first trial of the instrument

No	Hospital	Туре	Location	Auditor		Cases
1	Wates	B, public, district	Kulon Progo, Yogyakarta Special Region	Dian Anggraini	Neonatologist	4
2	Wonosari	B, public, district	Gunung Kidul, Yogyakarta Special Region	Setya Wandita	Neonatologist	2
3	Soeradji Tirtonegoro	A, public teaching, central hospital	Klaten, Central Java	Muslichah Y Farhati	Neonatologist	2
4	Soedirman	B, public, district	Kebumen, Central Java	Wahyu Adiwinanto	Neonatologist	4
5	Soemarno Sosroatmojo	C, public, district	Kapuas, Central Kalimantan	Suci Harini	Neonatologist	4
6	Bahteramas	B, public, provincial teaching hospital	Kendari, South East Sulawesi	Jumhari Baco	General pediatrician	4

a minor editorial and declared feasible, clear, and easy to fill and interpret.

The second test was conducted at six hospitals (WZ Yohannes, Naibonat, Soe, TC Hillers, Karitas, and Umbu Rara Meha) in East Nusa Tenggara in December 2021 and January 2022. All of the auditors were home staff general pediatricians. Explanation about content and how to fill the instrument by the author to the auditors was less than 10 minutes. On average, it was about 30 minutes to audit each case. The inclusion criteria were death <7 days after birth, birth weight >1,500 g, gestational age >32 weeks, and inborn and outborn. The exclusion criteria were any congenital anomaly and stillbirth. The death cases audited were 37 cases.

By auditing the death case with this instrument, auditors were able to identify the deviations and concluded avoidably the neonatal death. The results of the audit could be analyzed qualitatively and quantitatively. The quantitative results were the number and percentage of avoidable neonatal deaths, main diagnosis as the cause of death, and deviations; sub-analysis can be divided into inborn and outborn, avoidably, and the main diagnosis.

Deviations of the main diagnosis were able to be counted. Deviation according to the place of care, inborn or outborn, management of the clinical problem, facilities (radiology, laboratory, equipment), availability of drugs, medication, and pharmacy. For

outborn, pre-referral deviations could be detected—for instance, inadequate pre-referral stabilization and referral delay. Deviations were lag time at the delivery, ER, and nursery; between arrival and triage examination, pediatrician examination, and duration of stay at delivery room/operating room/ER. Age and duration of hospitalization also be counted. According to the main diagnosis, it can be analyzed as outborn and inborn, avoidable and unavoidable.

The qualitative analysis was case illustration and description based on filled instrument, deviations according to the description of the case, and comments. From this description, the author could detect the deviations, main cause of death, avoidably, and the reasons. For inborn, the deviations detected were at the room of delivery and nursery, while for outborn were from ER. The deviations of management in the delivery, ER, and nursery room could be detected. Long lag time at every phase can be detected; diagnostic and management support, pharmacy, and equipment as well. Deviation of management at the previous health facility or referring health personnel and referral system were found in the referral letter; it was the clinical condition, management, and stabilization. It was clear for auditors to decide the avoidably of neonatal death and its reason. Completeness of medical records, hospital management, incomplete SOPs, and neonatal health personnel was also

identified.

Recommendations can be made to the hospital and district health offices based on avoidable cases and the deviations found—specific recommendations for hospital level and district health office based on deviations. At the hospital level, the recommendations were diagnosis, case management, support (laboratory, radiology, and pharmacy), monitoring, and competencies of neonatal health personnel (pediatrician, medical doctors, nurses, and midwives) at every phase of care. The phases were delivery room, operating room, emergency room, and neonatal nursery. Other recommendations were about revising medical records, equipment, and SOPs (update, revise, and develop new SOPs), for hospital management was coordination between units, health personnel privilege, and improved competencies of neonatal health workers. Recommendations for the maternal unit also can be made. It was about peripartum management, antenatal steroid, peripartum antibiotics, competency of neonatal resuscitation, and stabilization.

For District Health Office, the recommendations are based on referral cases. It was for community level, maternity clinics, and Primary Health centers. Empowerment of community health workers, improvement (neonatal visit, counsel dangers signs), quality improvement of labor and delivery, neonatal resuscitation, stabilization and

transport, ENC, management at birth and before referring, equipment support, competencies of health personnel.

DISCUSSIONS

A neonatal death clinical audit is a global recommendation to reduce NMR by avoiding preventable neonatal death.⁷ As most neonatal death in hospitals are preventable, quality of care improvement may avoid similar death. The medical audit is an obligation to every death case within 14 days. The AMP-SR is a tool to audit neonatal death, but the clinical management process is not detailed.⁹ An instrument that consists of clinical management of every phase of hospitalization is needed. The developed instrument covers all of this and all aspects of clinical case management.

Patient management in hospitals is a complex process. It starts from birth in the delivery room for inborn and on arrival at ER for outborn or referral cases. Clinicians perform anamnesis, physical examination, diagnosis, laboratory working radiology examinations, therapy (causative and supportive), and followup. For this management, support from other units and qualified human resources is needed. Some cases need equipment for physical examination, diagnostic, and management. The outcome of some hospitalized neonates die. All supporting aspects of clinical management should be available to prevent avoidable neonatal death.11

The instrument's second test in NTT focused on early neonatal death. About one-third of neonatal deaths occurred in the first 24 hours after birth, and 75% in the first week or early neonatal death. ^{2,3} Maternal, fetal, peripartum, delivery, and factors affect the early neonatal death. These factors and improvement of early management at birth and a few days after birth can prevent avoidable neonatal death. Case management of maternal, fetal, delivery and neonatal need skilled and competent health workers. ¹⁻³

The main diagnosis included in this instrument was LBW/prematurity, neonatal asphyxia, and sepsis. These diseases are three of the main cause of death in Indonesia. The common causes of death in Indonesia are LBW/ prematurity (32.1%), neonatal asphyxia (21.0%), congenital anomaly (16.3%), and infection (5.1%). The two main causes of death do not change for decades.⁵ To reduce avoidable neonatal death is much easier to focus on LBW/prematurity, neonatal asphyxia, and neonatal sepsis.¹² Preventing neonatal death caused by congenital anomaly is harder than other causes and costly because some cases need sub-specialist and multi-disciplinary intervention. It will be the focus when the proportion of prematurity and asphyxia as the cause of death is low.¹¹

The prevalence of LBW within the last three years is stationary, about 11.3 to 13.0%. ¹³ The prevalence of preterm infant is 11.7%, which consist of moderate preterm (85%), very preterm (10%), and extremely preterm (5%).5,14 The focus on avoiding preventable neonatal death is LBW/ preterm, especially moderate preterm.12 Improvement of the quality of care of preterm/LBW, neonatal resuscitation, and prevention/treatment of infection are important. The basic need of health personnel must be fulfilled, including competency in neonatal resuscitation and care of asphyxiated/LBW/preterm/ neonatal infection.12 Care of very and extremely preterm need neonatal intensive care unit (NICU). The availability of NICU and human resources who has competency is limited.11 The instrument tested was able to identify the deviation of management of LBW/prematurity, other supporting aspects, and antenatal steroids.

The maternal, fetal, and delivery risk factors for asphyxia, resuscitation and stabilization were included in the instrument. It might detect the deviations in antenatal and delivery management, the domain of the obstetrician, and deviations in avoidable death caused by neonatal asphyxia. This instrument contains risk factors for neonatal sepsis, especially the early-onset and its management. The earlyonset neonatal sepsis (EONS) is the onset of infection within <72 hours after birth. Maternal, fetal, and delivery risk factors of early-onset neonatal sepsis were included in the instrument. The prevalence and mortality of EONS are higher than LONS. Therefore an improvement in the quality of care of the prenatal and early management of EONS has a greater impact than on

LONS. Prenatal management is the domain of obstetricians and needs proper coordination and cooperation between maternal and neonatal units.

CONCLUSIONS

The instrument contained a comprehensive item on neonatal management during hospitalization. All aspect management was able to be identified of the avoidable neonatal death. It was the diagnosis, deviations, contributing factors, and quality of care of neonatal health personnel. From this point, specific recommendations can be drawn to the hospital and District Health Office. Followup of these recommendations is necessary to prevent similar neonatal death in the future. Therefore, decrease NMR can be decreased further. This instrument is open for continuing development according to the epidemiology of neonatal death or regional needs.

CONFLICT OF INTEREST

none.

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ETHICAL CLEARANCE

This research does not violate ethics

AUTHOR'S CONTRIBUTION

All of the authors contributed equally to this study.

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