

Opinion
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Moving Forward to Improve Safety and Quality of Neonatal Intensive Care in Korea

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UNFORTUNATE INCIDENT OF THE DEATH OF FOUR PRETERM INFANTS

On December 16, 2017, four preterm infants died consecutively in 81 minutes in the neonatal intensive care unit (NICU) of Ewha Womans University Mokdong Hospital, Seoul, Korea, which triggered an immediate police investigation.¹ Combining the results of the epidemiological investigation by the Korea Centers for Disease Control and Prevention and those of the autopsies conducted by the National Forensic Service, the police have concluded that the four newborn infants died of sepsis, caused by hospital-acquired infection with multidrug-resistant *Citrobacter freundii*. According to the report of the investigation, this antibiotic-resistant *C. freundii* was found in blood cultures taken from three infants prior to their deaths, confirmed as the same genetic sequence, as well as in the lipid solution administered to these four infants prior to death. The autopsies finally confirmed the presence of the same bacterium in the blood of all four infants. Therefore, it was suspected that the infections occurred because the lipid solutions intravenously infused to these 4 patients were already contaminated or contaminated in the preparation process before infusion in the NICU.² Based on circumstantial evidence, the police are suspecting that bacterial contamination might have occurred during the process of preparation of small volumes before infusion from one original 500 mL Smoflipid® bottle by nurses in the NICU. In addition, only two residents were covering not only the NICU but also the pediatric general wards and the emergency room simultaneously on night duty when cardiopulmonary resuscitation occurred consecutively for these 4 newborn infants who ultimately died in the NICU.³ Finally, five medical staff, two doctors and three nurses who cared for those patients were charged and booked with involuntary manslaughter.² However, the exact route of infection is not confirmed and the investigation is still underway at present.

This unfortunate and shocking incident raises not only explosive awareness of the NICU itself to the public but also the suspicion that NICUs where sick and tiny newborn infants are admitted, may no longer be safe, contrary to previous expectation. Controversies and concerns arise explosively regarding the safety and quality of NICUs in Korea, which in turn, necessitate revealing and discussing various existing problems that have not been fixed so far. They are as follows: shortage of manpower dealing with neonatal care including neonatologists during day and night duties and well-trained neonatal nurses, weak and old equipment in some regional NICUs, absence of unit-dose delivery system for NICU by pharmacists, lack of production of small packaged drugs for pediatric and neonatal use by pharmaceutical companies, lack of

standardized protocols and guidelines as well as systemic supervision for infection control and prevention in NICU conducted by the infection control tower not only in hospital but also from the government, and lack of adequate reimbursement from the government's insurance to enable proper and strict infection control in the settings of NICUs in Korea.

RECENT ADVANCES IN NEONATAL INTENSIVE CARE IN KOREA

Currently, Korea faces the serious national problem of an extremely low fertility rate of 1.17 as of 2016,⁴ one of the lowest levels in the world, and thus, very low total annual number of births of 406,243 in 2016,⁵ which is about 40% lower than those of the two preceding decades. On the other hand, various social changes, including advanced maternal age⁶ and subsequently increased infertility rate⁷ with increased support by developed assisted reproductive technologies⁸ lead to remarkably increased multiple and preterm births, which result in an absolute increase in the number of high-risk newborn infants.

Over the past few decades, neonatal intensive care for high-risk newborn infants, including preterm infants, has developed markedly due to the commitment of individual neonatologists and neonatal healthcare workers, as well as the continuous investments by the government. Generally, outcomes of very low birth weight infants (VLBWIs, < 1,500 g at birth) among preterm infants are regarded as a reflection of the quality of neonatal care in the NICU.⁹ Thus, the Korean Neonatal Network (KNN), a national registry for VLBWI was started in 2013 by the Korean Society of Neonatology with support from the Korea Centers for Disease Control and Prevention as an infrastructure to improve the quality of neonatal care in Korea.¹⁰ Furthermore, "assessment of appropriateness for treatment in the NICU" will be conducted by the Health Insurance Review and Assessment Service through collaboration with the Korean Society of Neonatology from 2018.^{11,12}

As a result, the survival rate of high-risk newborn infants, including premature infants, has dramatically increased in Korea. Recent studies have shown that the survival rate of VLBWI is nearly close to that of the United States (US),¹³ but still lower than those of Japan and Europe.¹⁴ In addition, infant mortality rate (IMR) calculated as the number of deaths among infants (< 12 months of age) per 1,000 annual live births and indicated as one of the most important healthcare indices of the nation, reached 3.0 in 2015 from 3.5 in 2007 in Korea. The IMR of 3.0 in Korea is lower than the average of 4.0 for the Organization for Economic Co-operation and Development (OECD) countries.¹⁵ Neonatal deaths per 1,000 annual live births significantly reduced from 2 in 2007 to 1.6 in 2015. Neonatal deaths (< 28 days of age) account for 57% of IMR, and preterm infants who comprised 6.9% of the annual number of births, accounts for 60.7% of IMR.¹⁵ Most neonatal deaths occur among preterm infants, especially VLBWIs. Collectively, the recent decrease in IMR in Korea is greatly attributed to the increased survival rate of preterm infants such as VLBWI by the improved neonatal intensive care. Therefore, NICUs are one of the most important infrastructure to enhance the national healthcare quality and thus, have to be continuously supported as one of the public health care systems by the government.

EXPANDED NICU BEDS IN KOREA

The Regional (outside of Seoul) Neonatal Intensive Care Unit (NICU) Support Project was started by the Ministry of Health and Welfare in 2008 on the basis of governmental

recognition of poor nationwide NICU status with an estimated shortage of 500–600 NICU beds, as well as severe regional disparity at that time.¹⁶ By 2016, this project had provided a total of 430 NICU beds in 56 regional hospitals, except the Seoul area with 64.5 billion won investment in total and 8 million won (about \$7,000 USD equivalent) of annual funding offered per bed, contributing to the marked enhancement of the NICU infrastructure for treating high-risk newborn infants in Korea. About 80% of hospitals running NICUs in the regions outside Seoul have received governmental support from this project.¹⁷ In addition, since 2013, the government has increased the reimbursement for daily NICU admission fee almost two-fold to compensate for the low medical costs, a main cause of deficit for operating a NICU in hospital.¹⁸ Further, with the recent stepwise increase in NICU nursing care fees and various medical charges, the chronic deficit of NICU running is gradually improved. These governmental efforts make the NICU-operating hospitals include more NICU beds or to upgrade existing facilities and equipment nationally. Finally, the total number of NICU beds in Korea increased from 1,252 in 2010¹⁹ to 1,716 in 2015, which nearly meets the requirement of 3.9 NICU beds per 1,000 live births. The total required number of NICU beds is estimated as 4.3 per 1,000 live births, including the operation of 10% supplementary beds.¹⁷ According to the “investigation of the actual condition of NICU” conducted by the Ministry of Health and Welfare in December 2017, there was a total of 97 NICUs and 1,866 beds running at present,¹² calculated as 4.6 beds per 1,000 annual live births, which meets the requirements for NICU beds in Korea. Therefore, this is the right time of paradigm shift for the Korean government to switch its comprehensive efforts for NICUs from support for quantitative expansion of bed capacity to support for qualitative improvement of neonatal intensive care nationwide.

SHORTAGE OF HUMAN RESOURCES AND REGIONAL DISPARITY IN NEONATAL INTENSIVE CARE

Because health care professionals in the NICU not only require an extraordinarily high level of expertise, but also a labor-intensive nature along all day with day and night duties, the increase in the bed capacity of NICUs should be accompanied by medical infrastructure, including proper supply of human resources. However, the size of the gap in the current status is alarming. The report from the Ministry of Health and Welfare in 2016 showed that as the total number of NICU beds increased, the number of medical professionals in the NICU also increased, although not adequately so.¹⁷ Although the total number of NICU beds has increased by 32.1% from 1,229 in 2011 to 1,716 in 2015, the total number of nurses working in the NICU has increased by 22%, from 1,454 to 1,781 and the number of certified neonatologists only increased by 11.8% from 119 to 132. In other words, the number of NICU beds per neonatologist in charge in Korea increased by 26.2% from 10.3 beds in 2011 to 13 beds in 2015. Furthermore, the proportion of manpower working in the NICU per bed significantly decreased from 2011 to 2015 as follows: pediatric residents on day duty by -8.8%, (from 0.13 to 0.12), certified pediatrician on day duty by -8.8% (from 0.12 to 0.11), residents on night duty by -12.5% (from 0.08 to 0.07), certified pediatricians on night duty by -33.3% (from 0.09 to 0.06), certified neonatologists by -2% (from 0.1 to 0.08), and NICU nurses by -11% (from 1.18 to 1.04). In addition, the report by the Health Insurance Review and Assessment Service on 61 NICUs in hospitals across the country, including university-affiliated institutions in 2017, revealed that the number of NICU beds per neonatologist in each hospital was 9 or less in only 11 hospitals (18%), 11–15 in 15 hospitals (25%), 16–20 in 10 hospitals (16%), and more than 20 in eight hospitals (13%).¹¹ Whereas, a study of the US

population showed that one neonatologist was in charge of roughly 7 NICU beds and lower supply of neonatologists was closely related with higher mortality among extremely low birth weight infants (ELBWIs, < 1,000 g at birth).²⁰ A recent report has shown that the survival rate of ELBWI in Korea (71.8%) is still far lower compared to that in the US (85.5%).¹³ Therefore, high mortality of Korean ELBWI might be attributed to the general lag of human resources behind those of the US. Collectively, the current increase in the number of NICU beds should be supported with an adequate supply of human resources under the systemic and comprehensive approach led by government. The currently existing excessive workload with tiredness of medical personnel in the NICU is an urgent problem which should be resolved primarily to ensure the safety and quality of neonatal intensive care in Korea.

On the other hand, regional disparity is another problem in neonatal intensive care in Korea.¹⁹ Although slightly improved in recent years,²¹ regional disparities still exist in the survival rate of VLBWI, one of the indicators of the quality of neonatal intensive care, attributable basically to the NICU facilities, equipment, and personnel, rather than regional characteristics.²² These disparities in mortality of VLBWI in Korea are most marked in the lowest birth weight group, < 750 g at birth, and is primarily due to lack of resources for neonatal intensive care in most provincial areas. Therefore, further comprehensive supports through proper regionalization and transfer system with efficient distribution of medical services throughout the nation are urgently needed to resolve these regional disparities in Korea.

NEED FOR ORGANIZATION AND REGIONALIZATION OF THE PERINATAL CARE SYSTEM

Since high-risk newborns and high-risk pregnancies are inevitably related, the scope of care for high-risk neonates should be extended to perinatal care, seeking to provide an integrated medical care for high-risk pregnancies.²³ Since both high-risk pregnancies and high-risk newborns are constantly placed at risk of unpredictable emergency situations, it is essential to ensure their accessibility to emergency services including NICU care at all times. Furthermore, maternal and neonatal mortality rates can be substantially reduced via organization of the nationwide perinatal care system by setting up proper regionalization and transfer systems across the country. The US has pursued a series of “Toward Improving the Outcome of Pregnancy (TIOP)” project since as early as 1976, with the TIOP III project currently ongoing.²⁴ Japan commenced initiatives to build successful perinatal care and transport systems in the 1980s by beginning with the regionalization of perinatal care centers and extending its scope to the perinatal emergency care systems established in each prefecture across the country, resulting in the world’s lowest infant, neonatal, and perinatal mortality rates.²³ In addition to “Regional (outside Seoul) NICU Support Project” started from 2008 mentioned above, Ministry of Health and Welfare has launched the project of “Integration Center for High-risk Pregnancy and Newborn Infants” to establish perinatal care systems of Korea in 2014²⁵ and has supported 17 hospitals across the nation by 2017.²⁶ However, to make efficient national perinatal care system including neonatal care, integrated and big-picturing efforts and supports by government are obligatory needed, which include proper institutional leveling of neonatal and perinatal care centers according to the patient's care level with legalization of qualifications including obtaining mandatory human, facility, and equipment resources as well as making efficient transfer system by proper medical delivery for perinatal care with benchmarking the emergency care system already operating in Korea.²⁷

UNRESOLVED ISSUES FOR INFECTION CONTROL IN NICU

Hospital-acquired infections or nosocomial infections are one of the major causes of mortality and morbidity of the newborn infants admitted in NICU. The incidence of blood-proven sepsis varies widely among NICUs, but generally high especially in preterm infants because they usually have not only immunological immaturity but also frequent use of invasive procedures and prolonged hospitalization. A study from the National Institute of Health and Human Development Neonatal Research Network in US has reported that 21% of VLBWI and up to 43% of ELBWI with birthweights of 401–750 g developed proven sepsis.²⁸ Studies from Japan Neonatal Research Network²⁹ and from Korean Neonatal Network³⁰ among VLBWI showed that blood proven sepsis was 8% and 21.1% respectively. Taken together, the facts are clear that making the rate of sepsis of high-risk newborn infants admitted in NICU as 0% would be impossible and there are only ways to make an effort to reduce the infection rate in NICU settings.

Infection control in NICU is not a matter of one person, process, or factor. Rather, it must be achieved through systemic and logical approach with continuing education. Each member not only of NICU but also hospital has a duty to play a role in infection control. The government is also responsible for the establishment of effective policies for infection control. Comprehensive efforts with guideline and supervision by organized infection control tower in hospital as well as from the government should be made to reduce hospital-acquired nosocomial infection in NICU, including using single-use injections with unit dose delivery by pharmacists, adhering aseptic technique during the preparation and administration of injectable drugs, increasing the compliance of hand and environment hygiene, as well as the acquisition of adequate manpower and equipment, the expansion of isolation room with the resolution of over-crowdedness of NICU. Therefore, governmental supports with appropriate polices and official legalization are obligatory required to enable structured infection control in NICU.

MOVING FORWARD FOR SAFETY AND QUALITY OF NICU

The death of 4 preterm infants in Ewha Womans University Mokdong Hospital due to bacterial sepsis should be viewed as the Korean equivalent of the Libby Zion case.³¹ In 1984, a university student named Libby Zion died after taking medication prescribed by a resident at emergency room who had been working for 36 hours straight. A grand jury was summoned to prosecute the hospital and the doctors, but the jury brought no criminal charges, but instead indicted a medical education system that allowed residents to work overtired without sleep. After much debate, excessive working hours of the residents and inadequate training environment were deemed the culprit, and a law preventing residents from working more than 80 hours per week was passed.

At the base of 4 preterm infants' deaths the various problems of a poorly functioning health care system lie with hampered infection control in NICUs. These problems should be solved primarily by proper reflection on the systemic failures not by direct blaming and punishment of individual doctors and nurses, who cared these 4 premature infants and had a good will for the patients. Therefore, this unfortunate incident should become an initiator for moving forward to achieve safety and quality of neonatal intensive care by making ultimately new and appropriate medical system with legalization. Moreover, if the incident is to be resolved only by blaming individuals, it will make latent criminals of all the hard-working and committed

medical personnel caring for high-risk newborns susceptible to infection in NICU. This will result in a worsening cycle where it becomes even more difficult to recruit new staffs in NICU where there is already a lack of specialist personnel.

With regard to the incident, the Ministry of Health and Welfare devised and announced short-term and immediate measures for NICU safety management to prevent any such events in the future. These measures included improving reporting system for multiple deaths of unknown causes, improving infection management, infrastructure, and evaluation standards for NICU, and establishing a national patient safety system,¹² However, in-depth discussions in conjunction with government and academic professionals are needed regarding not only the details for these measures but also making a practical long-term measures in order to prepare proper policies to improve the safety and quality of medical systems including NICUs in Korea.

CONCLUSION

For the past several years, the public health authorities have worked tirelessly towards the goal of resolving the shortcomings of NICU nationwide, and there have been visible improvements. Survival rate of high risk newborn infants along with preterm infants has improved remarkably. NICU beds were greatly expanded and economic burden for guardians of sick newborn infants due to hospitalization in a NICU was greatly reduced. Nevertheless, to advance beyond basic survival to improve the quality of care through prevention of infection and thorough safety control, more investment is urgently needed.

Neonatal intensive care requires more specialized personnel and resources than adult patients, including perinatal care for the mother from pregnancy through birth, but also postnatal care for the infant until they safely cross the threshold between life and death. Although the effects of this investment may not be immediate, change of idea for paradigm shift to improve safety and quality with societal empathy and cooperation are essential for overcoming the serious problem of low birth rate, and thus to prepare the country for the future. To prevent the second or third tragedy like the Ewha Womans University Mokdong Hospital incident, bold investment and institutional reinforcement for developing proper medical care systems during the vulnerable perinatal period and for newborn infants should be led by the government.

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