INTRODUCTION

Iatrogenesis is defined as an unintended adverse outcome due to any therapeutic, diagnostic, prophylactic intervention, not considered natural course of disease ***(Srulovici et al., 2012).***

The occurrence of avoidable adverse events represents a problem of quality of care that is responsible for the increase in social costs, causing suffering to the patient, their family members and the professional involved ***(Srulovici et al., 2012).***

Patients who are more severely ill, those who are subjected to multiple interventions, and those who remain in hospital longer seem to be more likely to receive a serious injury as a result of medical mistakes ***(Wu et al., 2002)***. Thus, newborns in the Neonatal Intensive Care Unit (NICU) are a particularly vulnerable group, owing to their small size, physiological immaturity and limited compensatory abilities ***(Kanter et al., 2004)***.

One of every three to five hospitalized neonates in the NICU undergoes at least one iatrogenic event (IE). However, one third to half of those IEs are preventable, suggesting that a preventive intervention may reduce the rate of IE ***(Ligi et al., 2010)***.

To a nonprofessional observer, it may seem that these events result from malpractice. It is more likely, however, that iatrogenic events are unintentional, undesired, and perhaps unpreventable complications ***(Sharek et al., 2006).***

Iatrogenesis includes diagnostic errors, equipment failure, mishandled surgery, medication errors and iatrogenic environmental hazards such as exposure to light, sound, electromagnetic fields, radiation ***(Lai and Bearer, 2008)***.

Adopting newer technologies and preventive measures might decrease these complications and improve outcomes ***(Ligi et al., 2010).***

There is general agreement that the incidence of the most common complications of care in high-risk nurseries needs to be precise, but methodology is crucial in obtaining accurate information about the issue of iatrogenesis ***(Ligi et al., 2008)***. In addition, participation in national reporting systems will enhance education and provide an opportunity to compare outcomes with peer institutions ***(Sekar, 2010)***.

Aim of the Work

Iatrogenesis is an intrinsic facet of requiring care in the neonatal intensive care unit. Therefore, we conducted a prospective study to assess the incidence, nature, preventability, and severity of iatrogenic events in a neonatal center and to establish the association of patient characteristics with the occurrence of iatrogenic events in neonates.

STANDARDS OF NEONATAL INTENSIVE CARE UNITS STRUCTURE

I) Historical Background

In 1960, the idea of having a special intensive care unit for newborns—a neonatal intensive care unit (NICU)—represented a developmental milestone for the field of neonatology. With the increased sophistication developed since then, doctors now are able to save the lives of many premature or desperately ill newborns who in the past would have died soon after birth. The result is that the U.S. infant mortality rate has shown a steady decrease since the NICU first came into widespread use a quarter of a century ago and, concomitantly, survivors have fewer sequelae ***(Philip, 2005).***

II) Definition

The NICU is a highly technical and specialized unit in a hospital that provides medical and nursing care and support. The medical and nursing staff use the latest advances in medical technology, to help sick and/or high-risk preterm babies ***(Baker, 2000).***

The length of time preterm baby will be in the neonatal intensive care unit will depend on how early and small he/she was born and on how unwell they are. It is not always easy to predict how long a baby must stay in the neonatal intensive care ***(Martin and Menacker, 2007).***

III) Recommended Standards for NICU Design

A. *Introduction*

The creation of formal planning guidelines for newborn intensive care units NICUs first occurred when toward improving the outcome of pregnancy was published in 1976. It is defined as providing a combination of the lowest mortality and morbidity, the best cost effectiveness and the best baby and parent experience ***(Rayan, 1975).***

Since then, the American Academy of Pediatrics (AAP) and American College of Obstetricians and Gynecologists (ACOG) have published several editions of their comprehensive Guidelines for Perinatal Care, and The American Institute of Architects has likewise published several editions of their Guidelines for Construction of Hospital and Healthcare Facilities ***(White et al., 2013).***

The purpose of this committee was to provide health-care professionals, architects, interior designers, state health-care facility regulators and others involved in the planning of NICUs with a comprehensive set of standards based on clinical experience and an evolving scientific database. The design should creatively reflect the vision and spirit of the infants, families and staff of the unit ***(White et al., 2013).***

B. Levels of care

The American Academy of Pediatrics has defined NICU levels of care based primarily on availability of specialized equipment and staff, but many NICUs often encompass both intensive and step-down or intermediate care. The recommended minimum standards we have written encompass Level III subspecialty care in general, rather than distinguish criteria for each sub-level ***(American Academy of Pediatrics, 2014).***

One major difference in the 2012 updated policy statement from the American Academy of Pediatrics compared to the 2004 policy statement is the removal of subspecialty nurseries for levels II and III with the addition of a level IV NICU. The four distinct levels of neonatal care defined in the most recent policy statement from the AAP are:

Level I; Well newborn nursery: are typically referred to as the well-baby nursery. Well newborn nurseries have the capability to provide neonatal resuscitation at every delivery; evaluate and provide postnatal care to healthy newborn infants; stabilize and provide care for infants born at 35 to 37 weeks' gestation who remain physiologically stable; and stabilize newborn infants who are ill and those born less than 35 weeks' gestation until transfer to a facility that can provide the appropriate level of neonatal care. Required provider types for well newborn nurseries include pediatricians, family

physicians, nurse practitioners, and other advanced practice registered nurses ***(Halm et al., 2002)***.

Level II; Special care nursery: Previously, Level II units were subdivided into 2 categories (level IIA & level IIB) on the basis of their ability to provide assisted ventilation including continuous positive airway pressure. Level II units are also known as special care nurseries and have all of the capabilities of a level I nursery.

In addition to providing level I neonatal care, Level II units are able to provide care for infants born ≥32-week gestation and weighing ≥1500 g who have physiologic immaturity or who are moderately ill with problems that are expected to resolve rapidly and are not anticipated to need subspecialty services on an urgent basis, provide care for infants who are feeding and growing stronger or convalescing after intensive care, provide mechanical ventilation for a brief duration (<24 h) or continuous positive airway pressure. Requiring to have pediatric hospitalists, neonatologists, and neonatal nurse practitioners in addition to Level I health care providers ***(Oh and Gilstrap, 2002)***.

Level III NICU: are required to have pediatric surgeons in addition to care providers required for level II (pediatric hospitalists, neonatologists, and neonatal nurse practitioners) and level I (pediatricians, family physicians, nurse practitioners, and other advanced practice registered nurses).

Also, required provider types that must either be on site or at a closely related institution by prearranged consultative agreement include pediatric medical subspecialists, pediatric anesthesiologists, and pediatric ophthalmologists in addition to providing the care and having the capabilities of level I and level II nurseries. They are able to provide sustained life support, comprehensive care for infants born <32 weeks gestation and weighing <1500 g, provide comprehensive care for infants born at all gestational ages and birth weights with critical illness, provide prompt and readily available access to a full range of pediatric medical subspecialists, pediatric surgical specialists, pediatric anesthesiologists, and pediatric ophthalmologists, provide a full range of respiratory support that may include conventional and/or high-frequency ventilation and inhaled nitric oxide, perform advanced imaging, with interpretation on an urgent basis, including computed tomography, MRI, and echocardiography ***(American Academy of Pediatrics, 2012).***

Level IV; regional NICU: The highest level of neonatal care provided occurs at regional NICUs, or Level IV neonatal intensive-care units. They are required to have pediatric surgical subspecialists in addition to the care providers required for Level III units. Regional NICU's have all of the capabilities of Level I, II, and III units. In addition to providing the highest level of care, level IV NICU's: ability to provide surgical repair of complex congenital or acquired conditions, maintaining a

full range of pediatric medical subspecialists, pediatric surgical subspecialists, and pediatric anesthesiologists at the site ***(American Academy of Pediatrics, 2012).***

Every neonatal care unit should have its own plan of work depending on its facilities, equipment and team of work and through the general policy of community ***(Philip, 2005).***

C. Unit Configuration

The NICU design shall be driven by systematically developed program goals and objectives that define the purpose of the unit, service provision, space utilization, projected bed space demand, staffing requirements and other basic information related to the mission of the unit ***(White et al., 2013).***

NICUs are increasingly designed using either the single family room concept, semiprivate rooms to accommodate two infants, or a combination of both. Open-bay designs are primarily deployed where the constraints of existing space do not permit the other two options. To compare the space requirements between the Single family room, semiprivate room, and open-bay facility configuration concept, a space planning model was developed using common support space assumptions while varying the patient care space. The total department gross square feet per bed for different sizes of NICUs was also evaluated ***(DiLaura et al., 2011)***.

- **NICU Location within the Hospital**

The NICU shall be located within space designed for that purpose. It shall provide effective circulation of staff, family, and equipment. Traffic to other services shall not pass through the unit. Units receiving infants from other facilities shall have ready access to the hospital's transport receiving area and shall designate a space for transport equipment ***(Evans and Philbin, 2000).***

- **Family Entry and Reception Area**

The design of this area should contribute to positive first impressions for families. Facilitating contact with staff will also enhance security for infants in the NICU. This area may also include a hand washing and gowning area ***(Bullough et al., 2011).***

- **Minimum Space, Clearance and Privacy Requirements for the Infant Space**

Each infant space shall contain a minimum of 120 square feet (11.2 square meters) of clear floor space, excluding hand washing stations, columns, and aisles. There shall be an aisle adjacent to each infant space with a minimum width of 4 feet (1.2 meters) in multiple bed rooms. The width of aisles in multiple bed rooms should allow for easy movement of all equipment that might be brought to the infant's bedside ***(Rivkees, 2004).***

- **Private (Single-Family) Rooms**

Allowing improved ability to provide individualized and private environments for each baby and family when compared to multi-patient rooms. Family space shall be designated and be able to include, at a minimum a comfortable reclining chair suitable for kangaroo/skin-to-skin care**,** recumbent sleep surface for at least one parent ***(Bullough et al., 2011).***

One of the benefits of having the parents involved in the care process is the ability to provide kangaroo care which was originally developed in Colombia in the late 1970s. This practice was introduced because there were not enough incubators available for all the premature babies, so mothers or fathers carried their babies under their clothing all day long. Now skin-to skin contact is part of the daily routine in many hospitals. This will strengthen the baby's sense of touch and smell ***(Philip, 2005).***

Studies have proven that close proximity to their mother helps premature babies improve breastfeeding, to gain weight more quickly and to breathe more evenly ***(Baker, 2000).***

- **Airborne Infection Isolation Room(s)** shall provide a minimum of 150 square feet (14 square meters) of clear floor space, excluding the entry work area. A hands-free hand washing station for hand hygiene and areas for gowning and storage of clean and soiled materials shall be provided. Specific attention is required to the design of

noise-attenuating devices in the heating/ventilation/air-conditioning ductwork and to washable acoustic surfaces on the walls and ceilings to ensure that sound levels meet the Standard in these rooms. Glass partitions should be limited to that which is actually necessary for safe visualization. Proportional amounts of acoustically absorptive and acoustically reflective surfaces should be appropriate to achieve greater than 25% sound absorption ***(DiLaura et al., 2011).***

- **Operating Rooms Intended for Use by NICU Patients**

Procedure rooms designed for surgery shall have a minimum clear floor area of 360 square feet (33.5 square meters) with a minimum dimension of 16 feet (4.9 square meters) exclusive of built-in shelves or cabinets, hand washing stations, and columns. There is now sufficient experience to conclude that certain procedures can be performed in the NICU without compromising patient safety or outcomes ***(Bullough et al., 2011).***

- **Electrical, Gas Supply, and Mechanical Needs**

A system that includes easily accessible raceways for electrical conduit and gas piping, work space, and equipment placement is recommended because it permits flexibility to modify or upgrade mechanical, electrical or equipment features. Outlets should be positioned to maximize access and flexibility

and minimize repetitive movements such as bending and stretching by the staff ***(Rivkees, 2004).***

- **Proper hand hygiene** is a key component in the prevention and reduction of spread of infection in health care settings. Alcohol-based hand rubs have been shown to be more effective than soap-and-water handwashing in decontaminating hands that are not visibly soiled ***(Robbins and Meyers, 2011).***

- **Support Space for Ancillary Services** such as respiratory therapy, laboratory, pharmacy, radiology, developmental therapy, and specialized feeding preparation are common in the NICU ***(DiLaura et al., 2011).***

- **Ceiling Finishes**

The ceiling construction shall not be friable and shall have a noise reduction coefficient of at least 0.90 for 80% of the entire surface area. In most NICUs, the ceiling offers the largest available area for sound absorption ***(Bullough et al., 2011).***

- **Lighting**

It is preferable that the procedure light be either mounted on the headwall or incubator in lieu of a floor stand to prevent direct light from reaching the infant's eyes ***(Bullough et al., 2011)***.

IV) NICU Staff

A NICU is typically directed by one or more neonatologists and may consult other types of doctors based on the needs of the neonate as cardiologist, endocrinologist and geneticist ***(Young et al., 2014).***

Moreover, it is staffed by nurses, nurse practitioners who have pursued further education and training in order to provide special medical care for your baby and works under the supervision of a neonatologist, pharmacists who provide patient care that optimizes the use of medication and respiratory therapists. The members of the NICU team work together with parents to develop a plan of care for high-risk newborns ***(Rossano et al., 2015).***

V) Risk Factors for Admission

NICUs now concentrate on treating very small, premature, or congenitally ill babies. Some of these babies are from higher-order multiple births, but most are still single babies born too early. Premature labour, and how to prevent it, remains a perplexing problem for doctors. Even though medical advancements allow doctors to save low-birth-weight babies, it is almost invariably better to delay such births ***(American Academy of Pediatrics, 2012).***

There are some factors that can place a baby at high risk and increase the chances of being admitted to the NICU.

However, each baby must be evaluated individually to determine the need for admission. Some newborns are considered high risk. This means that a newborn has a greater chance of complications because of conditions that occur during fetal development, pregnancy conditions of the mother, or problems that may occur during labor and birth ***(Harrison and Goodman, 2015).***

A. ***Maternal risk factors***

1. **Teenage pregnancy** is an important public health problem, especially in developing countries, with a high rate of marriages at a young age, along with poor prenatal and postnatal care ***(Najati and Gojazadeh, 2010)***.

Medical complications in this age group during pregnancy include anemia, urinary tract infection, hypertension, pre-eclampsia, eclampsia, a high rate of instrument delivery and cesarean section, the rate of very low birth weight (VLBW) infants is twice that of all women of reproductive age, high risk for prematurity, still birth, and perinatal death. One million of their babies die before their first birthday ***(Najati and Gojazadeh, 2010)***.

2. **Age older than 40 years** are more likely to have pre-existing medical disorders such as gestational diabetes mellitus was significantly more common in the older age groups or hypertension, increased incidence of antepartum hemorrhage, mal-presentation and fetal death. Advanced