

Evaluation of the identification protocol for newborns in a private hospital

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This exploratory-descriptive quantitative study aimed to evaluate the protocol for identifying newborns admitted to the Neonatal Intensive and Semi-intensive Therapy Unit of a private hospital. The case series was made up of 540 observation opportunities, selected by simple random probability sampling. The data was collected between May and August 2010 according to a form and analyzed by descriptive statistic. The protocol's general performance had a conformity index of 82.2%. There were three stages to the protocol: identification components, the identification wristbands' condition and the number of identification wristbands. The highest percentage of conformity (93%) was attributed to the second stage and the lowest (89.3%) to the third, presenting a statistically significant difference of $p=0.046$. In the group of 'special' neonates, 88.5% conformity was achieved. These results will make it possible to restructure the protocol for identifying newborns and to establish care and managerial goals so as to improve the quality of care and the patients' safety.

Descriptors: Quality of Health Care; Health Services Evaluation; Patient Safety; Neonatal Nursing.

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Avaliação do protocolo de identificação do neonato de um hospital privado

Trata-se de estudo exploratório-descritivo quantitativo cujo objetivo foi avaliar o protocolo de identificação do neonato admitido na unidade de terapia intensiva e semi-intensiva neonatal de um hospital privado. A casuística foi composta por 540 oportunidades de observações, selecionadas por amostragem probabilística aleatória simples. Os dados foram coletados de maio a agosto de 2010, segundo um formulário, e analisados pela estatística descritiva e teste com significância de 5%. No desempenho geral do protocolo, o índice de conformidade foi de 82,2%. Quanto às três etapas do protocolo: componentes de identificação, condições das pulseiras e quantitativo das pulseiras, o maior percentual de conformidade (93%) foi atribuído à segunda etapa e a menor (89,3%) à terceira etapa, apresentando diferença estatística significativa, $p=0,046$. No grupo de neonatos especiais, obteve-se 88,5% de conformidade. Esses resultados possibilitarão reestruturar o protocolo de identificação dos recém-nascidos e estabelecer metas assistenciais e gerenciais, para melhorar a qualidade e a segurança dos pacientes.

Descritores: Qualidade da Assistência à Saúde; Avaliação de Serviços de Saúde; Segurança do Paciente; Enfermagem Neonatal.

Evaluación del protocolo de identificación de los recién nacidos en un hospital privado.

El objetivo de este estudio exploratorio-descritivo, cuantitativo fue evaluar protocolo de identificación de recién nacidos ingresados en Unidad de Cuidados Intensivos y Semi-intensiva Neonatal de hospital privado. La muestra consistió de 540 oportunidades de observaciones, seleccionados por muestreo probabilístico aleatorio simple. Datos colectados entre mayo y agosto 2010, según formulario y analizados por estadística descriptiva y con significación 5%. Referente desempeño global del protocolo, índice de conformidad fue de 82,2%. Referente tres etapas del protocolo, porcentaje más alto de conformidad (93%) se atribuyó a la manera correcta de hacer pulseras de identificación y el más bajo (89,3%) referente a presencia de tres pulseras de identificación, con diferencia estadística significativa $p = 0,046$. En el grupo especial de recién nacidos, se obtuvo índice 88,5% conformidad. Estos resultados permitirán reestructurar protocolo de identificación de recién nacidos y establecer metas de cuidado y gestión para mejorar calidad y seguridad del paciente.

Descriptorios: Calidad de la Atención de la Salud; Evaluación de Servicios de Salud; Seguridad del Paciente; Enfermería Neonatal.

Introduction

The themes of quality and patient safety are intrinsically related and have been discussed nationally and internationally by professionals, governmental organizations, accrediting bodies and representatives of bodies linked with health.

Services of direct care to the patient form the majority of health care actions and are characterized by the interaction of the user with the health care

professionals and by the procedures developed. They also include the highest concentration of critical processes and high-risk processes in health institutions. Another relevant aspect in health care is the incorporation of new technologies, products and management practices⁽¹⁾.

When treating the newborn (NB) these issues are accentuated, above all for those babies admitted to the Neonatal Intensive Care Units (NICU), as these

are exposed to innumerable invasive procedures and to sophisticated equipment and need lengthy hospitalization, which creates risks which can lead to severe, irreversible harm and even death.

In intensive care, any iatrogenic event, rather than being merely undesirable, is extremely prejudicial, raising questions of quality of care and safety of care, which leads inevitably to the evaluation of the health care services⁽²⁾.

In this context, a study carried out in NICU pointed out the risks which NBs are exposed to because of identity errors, resulting from the similarity between names and hospital identification numbers⁽³⁾.

Government initiatives have been developed and implemented with the aim of identifying health service users and resolving events which compromise their safety and quality of care. In respect to this issue, in 2007 the World Health Organization proposed nine actions aimed at reducing problems related to safety, emphasizing as the most important an increase in the level of conformity in identification of the patient⁽⁴⁾. In Brazil, it is specified in the Statute of Children and Adolescents through Law Nº 8.069 of 7/13/1990, in Title II about Basic Rights, Chapter I on the Right to Life and Health, article 10, that hospitals and other establishments (private or public) which provide maternity health care have the duty to "identify the newborn through registering his sole print and finger prints, and the finger print of the mother, in addition to other means put in place by the competent authority"⁽⁵⁾.

As the NICU is the place where most adverse events occur, it falls to the health team to identify them, as well as create a culture where they can take responsibility for the presence of the events, creating perspectives for correcting faults and implementing improvements in the process⁽⁶⁾.

Other authors have cited that the work flow and human and material resources, as well as the health care professionals' way of approaching identity checking, are directly involved in the performance of the protocol. They reiterate that the NICU's clients, due to their characteristics, lack mechanisms which can effectively contribute to the conformity of the process⁽⁷⁾.

In the health sector, quality is defined as a set of attributes which includes a level of professional excellence, the efficient use of resources, a minimum of risk to the patient/client and a high degree of satisfaction on the part of service users, considering the existing social values⁽⁸⁻⁹⁾.

Any organization whose essential mission is to help human beings concerns itself with the constant

improving of care, aiming for harmony between the dimensions of management, economy, technology, care, teaching and research⁽¹⁰⁾.

Thus, it is believed that ensuring and guaranteeing work protocols based on quality and the avoidance of risks to the health of the users and workers is an inseparable element of health institutions which seek excellence in their services.

Safety consists of the act of avoiding, preventing and improving the adverse results arising from the process of health care; safety lives in the systems and in the people and because of this needs to be actively sought after and stimulated, with a view to reduction of all types of errors, aiming for high reliability as an essential component of quality care⁽¹¹⁾.

In the view of a group of authors, the meaning of patient safety best translates as reducing the occurrence of unnecessary harm to the patient to an acceptable minimum. In the same way, for these authors, the term 'safety' is defined as the reduction to the minimum possible of risk of harm by the situation created, by an action or a potential agent⁽¹²⁾.

It is crucial to think of safety as a systematic approach and to use methods for analyzing the risks existing in processes. Such methods provide information which is indispensable for identifying the risks and enabling managers to plan new, corrective and preventive processes and actions, such that everybody involved should aim for practices of continuous improvement of the services⁽¹³⁾.

To this effect, risk management has been used, along with other tools, to guarantee safety and quality in the health sector. Among those used for managing risk is the *Failure Model and Effect Analysis (FMEA)*; an analytic and pro-active method of systematically identifying and documenting potential flaws or possible problems perhaps unforeseen when a given process was designed, such as to eliminate them or reduce their occurrence⁽¹⁴⁻¹⁵⁾.

The *FMEA* permits one to diagnose problems and to develop and carry out projects, processes or services while considering at every stage the advantages and disadvantages based on the cost-benefit relationship; and the more it is used by a team of professionals, the more efficient it becomes in identifying and preventing possible flaws⁽¹³⁾.

Changes having been made in the identification protocols in the institution where this study was undertaken, aimed at improving the quality of the services provided, and believing that for the safety of

the NB and her family this is an over-riding condition, which care and management dimensions, along with ethical and legal dimensions of health professionals' practice, enter into, the authors set out to undertake this investigation. The general objective was to evaluate the protocol for identifying neonates admitted to the NICU and Neonatal Semi-Intensive Care Unit at a private hospital in the city of São Paulo; more specifically, an aim was to calculate the index for conformity and non-conformity relating to the protocol for identification, and to analyze the risk factor in identifying the neonate based on the *FMEA* tool.

Method

This is an exploratory-descriptive study, with a quantitative approach, with prospective data collection.

The research was carried out in a private hospital, a center of excellence for the care of high-risk pregnant women and newborns, situated in the city of São Paulo. As a center of excellence for high-risk pregnancies, it has a 60-bed NICU and a Neonatal Semi-intensive Care Unit with 22 beds. These are allocated in three distinct areas, with 22 beds located on the first storey, 30 on the second and a further 30 on the third. It should be clarified that only neonates born in the hospital are admitted to these units.

The sample was composed of 540 opportunities to evaluate the protocol for identification of the newborn admitted to the NICU and Neonatal Semi-intensive Care Unit, selected by simple probability sampling. In this way, there were 144 (26.7%) observations during the morning shift, 216 (40%) during the afternoon shift, and 180 (33.3%) during the night shift. In relation to the storeys, 150 (27.8%) of the observations took place on the first storey, while 195 (36.1%) took place on the second and third.

The data was collected between May and August 2010, by means of a form containing the three stages of the protocol for identifying neonates.

The protocol for identifying neonates in the institution where the study took place is made up of three stages, to know: *the components of identification* (the presence of the complete name of the mother, the mother's name on all of the NB's identification wristbands, the hospitalization number on the bar code, and the type of hospitalization, whether paid for as an individual service or via medical insurance), *the condition of the identification wristband* (the mother's name legible on all three wristbands, the wristbands made up correctly, with name-labels and plastic bracelets appropriate to the

size of the NB) and *the quantity of wristbands* (presence of the three wristbands for identification of the NB – two on the upper limbs and one on a lower limb). When the NB has special conditions (those with a gestational age of ≤ 37 weeks, who have edema in upper or lower limbs, who have malformative syndromes or who are allergic to the wristband material), the wristbands are fixed to the inner wall of the cot.

All of the stages are carried out by the nursing team, as is the daily checking of the wristbands by all shifts. It is also the team's responsibility to change or substitute the wristbands whenever they breach the protocol described above.

For sampling, the total of beds in the three areas was used, followed by random choice of beds using a computational resource, considering the morning, afternoon and evening shifts and the seven days of the week. Possessing the list obtained in the simple random probability sample, the researcher filled in the form next to the cot. In the event of there being no NB hospitalized in the cot randomly selected, an observation would be made at the next cot selected by the process, until the total number of opportunities stipulated for the day, storey or shift had been achieved. It should be mentioned that a NB could be observed more than once, depending on the length of her hospitalization or if the cot she occupied was randomly selected again over the four months of data collection.

Descriptive statistics were used to analyze the data and Chi-Squared tests were used for comparing the conformities. The parameter of conformity or non-conformity was evaluated on the basis of meeting or not the protocol explained above. The level of significance chosen was 5%.

Estimation of risk was undertaken with the *FMEA* tool according to its seriousness, respecting the following situations: 1. Slight Clinical/Non-clinical; 2. Serious Clinical/Non-clinical; 3. Very serious Clinical/Non-clinical and 4. Death/Extreme) multiplied by the probability (1. Highly improbable; 2. Improbable; 3. Probable and 4. Highly probable). This means that if one multiplies seriousness by probability, one obtains a final value indicating that the higher the value, the greater the chance of an event occurring. The highest level possible, in the estimation described above, corresponds to the value 16.

The research project was approved by the Research Ethics Committee (REC) at the institution where the investigation was carried out, with the registration number 02/10.

Results

During the period of the study, 540 opportunities involving the NB identification protocol were observed.

The data from Figure 1 represent the general conformity of the NB identification protocol in the NICU and Neonatal Semi-intensive Care Unit.

From analysis of Figure 1, it may be observed that the identification of the NB in NICU and Neonatal Semi-intensive Care Unit obtained a percentage of general conformity of 82.2%.

Below, the conformity and non-conformity involving the three phases of the neonate identification protocol are presented.

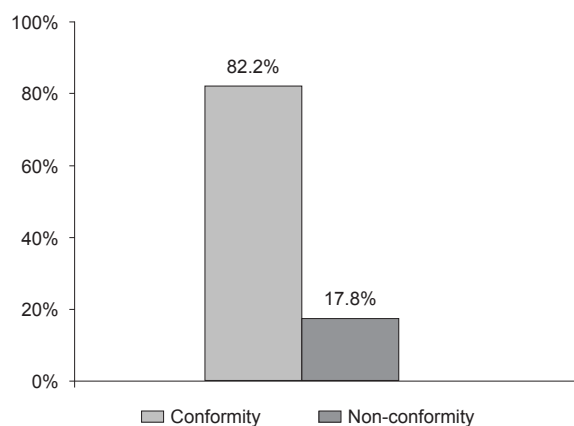


Figure 1 – Distribution of conformity and non-conformity in the NB identification protocol, São Paulo, SP, Brazil, 2010

Table 1 – Distribution of conformity and non-conformity, considering the three stages of the NB identification protocol, São Paulo, SP, Brazil, 2010

Stages	Conform		Not conform		Total		p-value
	N	%	N	%	N	%	
Components of identification of NB	501	92.8	39	7.2	540	100.0	0.046*
Condition of Wristband	502	93.0	38	7.0	540	100.0	
Quantity of Wristbands	482	89.3	58	10.7	540	100.0	

*Chi-Squared test. n=540

In Table 1, it was demonstrated that of the three stages of the NB identification protocol, the highest percentage of conformity was concentrated in the second stage, registering 502 (93%), and the lowest percentage found (482 – 89.3%) corresponded to the presence of three wristbands on the NB’s limbs.

It is worth highlighting that referring to the first phase of the protocol – *components of identification*, the presence of the hospitalization number corresponded to 532 (98.5%) of the conformity and the type of hospitalization to 531 (98.3%). The smallest percentage found, on the other hand, was related to the presence of the mother’s complete name on the wristband - 504 (93.3%). However, in 100% of the opportunities observed, the mother’s name corresponded to that on the neonate’s medical records, there being no mix-ups in identities.

The second stage analyzed was related to the condition of the wristbands, which analyzed the correct putting together of the NB’s identification wristband, indicating 539 (99.8%) conformity. Only 1 (0.2%)

instance of nonconformity was found, involving the use at that moment on a newborn of a wristband of a type which should be used for adults. Still with this stage, the item concerning legibility noted that there were 37 instances (6.9%) of nonconformity.

The data analyzed in the third stage of the protocol, which corresponded to the presence of the three identification wristbands on the NB’s limbs, showed the smallest percentage of conformity found, at 482 (89.3%).

Considering the factors demonstrated, one may accept the importance of establishing criteria for standardizing the data and the language printed on the identification label.

Nevertheless, the long periods that neonates spend in NICU, added to the fact of being unable to participate in the identification protocol, puts them at greater risk of non-conformity.

The table below gives the percentages for conformity and non-conformity in the identification of neonates with special conditions.

Table 2 – Distribution of conformity and non-conformity, according to the neonate's clinical condition, São Paulo, SP, Brazil, 2010

Condition	Conformity		Non-conformity		Total		p-value
	N	%	N	%	N	%	
Non-special NB	374	89.5	44	10.5	418	100.0	0.895*
Special NB	108	88.5	14	11.5	122	100.0	

*Chi-Squared test. N=540

The findings in Table 2 show that, of the total of 540 observations, 122 (22.6%) correspond to neonates with special conditions, in which cases the identification wristbands must be attached to the cot, because of: size, the presence of edema or allergy, among other specificities. In this group of NBs, the conformity of the protocol in place was 108 (88.5%) and for the other group, the index of conformity corresponded to 374

(89.5%) and 44 (10.5%) non-conformity. With $p=0.895$, there was no statistically significant difference between the groups.

For dealing with evaluation of risk in the identification of the newborn, the institution where the present study was carried out uses the *FMEA* tool, as shown in Figure 2.

Risk	Seriousness	Probability	Estimate of Risk
Absence of one or more of the NB's wristbands	3	3	9
NB's identification wristband legible	2	2	4

Figure 2 – Distribution of estimate of risk, according to the *FMEA* in two stages of the NB identification protocol, São Paulo, SP, Brazil, 2010

The data shown in Figure 2 demonstrates that after a calculation of seriousness and probability of a mistake occurring in this event, the absence of an identification wristband was estimated as a level 9 risk, on a scale from 0 to 16, while the legibility of the name label was estimated as a level 4. These values, therefore, deserve to be examined by the institution, as the data found in tables 1 and 3 were the indexes with the greatest values for non-conformity, these being 10.7% and 6.9% respectively.

Discussion

In NICU, the general rate of conformity for the protocol reached the percentage of 82.2%, while that for non-conformity reached 17.8%. This rate is higher than in a multicentric study, which noted an error rate in the identification of patients hospitalized in NICU of 11%⁽¹⁶⁾. The same study found that children are more exposed to the occurrence of adverse events, due to early gestational age and the length of time they spend in the unit.

The percentage of 11% non-conformity related to the identification of the NB in NICU was also found in the report issued by the *Vermont Oxford Network* system. In

its description of Accreditation Standards for Hospitals, the *Joint Commission International (JCI)*, states that the question of patients' identification continues to be its first international target, and approaches patient safety from two angles: that individuals should be identified securely, and that services and/or treatment should be given to the correct person⁽¹⁷⁻¹⁸⁾.

In comparing the present study with those mentioned above, it was determined that the protocol's general percentage of non-conformity was higher than that found elsewhere in the literature by approximately 7%, which deserves attention on the part of managers and the nursing team.

In the analysis of the protocol's three stages, it was determined that the highest rate of conformity was related to the condition of the wristband, as the correct assembly of the wristband corresponded to the highest percentage of conformity (99.8%), with the legibility of its content having 93.1% of conformity.

Another study revealed that the *Veterans Affairs National Center for Patient Safety Root Cause Analyses (VA NCPS RCA)* databank was notified of more than 100 recorded instances involving errors in the identification of patients, which reflected other non-conformity events, such as the carrying out of incorrect surgery

due to similarity of names, or the incorrect collection of blood samples in patients admitted to the same room or hospital ward⁽¹⁹⁾.

In another investigation, the authors acknowledged that 2.7% of medication errors were related to the lack of confirmation of the patient's identity prior to the administration of the medication⁽²⁰⁾.

It is difficult to keep the identification wristbands on neonates, above all on those babies born premature or with very low weight, because of their specific characteristics. This contributes to non-conformity with the protocol, in addition to the neonate's vulnerability related to its limited autonomy⁽²¹⁻²²⁾.

This may have contributed to the results of the present study, as it was the quantity of the wristbands that had the worst rate evaluated. It must be highlighted that in the present investigation, all the data recorded refers to neonates.

Another fact to emphasize is that although Nursing holds responsibility for identifying the NB because of working directly in the care provided, the identification protocol is more than just the steps of recording data and assembling the wristbands; thus it should be understood as a multidisciplinary activity, bearing in mind that every health care professional plays a role in this protocol⁽¹⁴⁾.

Referring to the first stage of the protocol, the best percentages were related to the presence of the barcode and type of hospitalization, and the lowest percentage corresponded to the mother's complete name being on all the wristbands.

The importance of adapting the content of the information necessary for identifying the NB to the size of the label utilized for printing should be emphasized, as well as the establishment of norms for recording the mother's name, the abbreviation of the same, when necessary, situations involving people with the same names and the presence of twins, among others.

The exposure of the neonate to some sort of risk relating to its identification, considering the period of hospitalization in NICU was also the subject of investigation and in 44.1% of the days of hospitalization, the most common cause of identification errors was related to similarity between patients' names or hospital registration numbers. The risk of identical surnames was 34% over the period of hospitalization, and 9.7% for names which sound similar*. The presence of twins contributed with one third of patient days in NICU for this risk. On average, 26% of patients hospitalized

in this NICU were at risk of non-conformity in their identification⁽³⁾.

Illegibility of data may result from the material used for the label used in making the wristband or from the ink used in printing it off. In this regard, it is necessary to be able to rely on the involvement of the person responsible for managing the institution's materials and on the nurse, for analysis and use of appropriate materials, considering that the wristband is subject to wear and tear resulting from its length of use and exposure to water or to antiseptic products.

Another study established that 25% of serious medication errors resulted from mistakes in the identification of the NBs⁽²³⁾.

Identification errors also occurred in the distribution of breast milk, although recording the rate of 0.007% over 9 years, not ignoring the risks related to the transmission of illnesses which, most of the time, are immeasurable and irreversible⁽²⁴⁾.

One may observe that on the risk evaluation sheet currently used, only two situations were envisioned where the *FMEA* tool might be used. However, it is necessary to rethink this precondition, as other stages involve the identification of the patient, extending the actions involving the institution's risk management, in the search for safe and appropriate protocols.

Final considerations

This study demonstrated the complexity which surrounds the protocol of identification of the neonate on hospitalization in the NICU and Neonatal Semi-intensive Care Unit in a private institution. It also allowed the establishing of a situational diagnostic considering the protocol currently used, identifying the vulnerable aspects which need to be revised for the continuous improvement of quality and safety of the neonates and their families.

In this respect, it indicates that the protocol should be discussed and revised by the institution's Committee for Risk Management and Quality such that actions for improvement may be implanted, above all educative actions concerning the presence of the three wristbands.

It should be emphasized that identification is considered a process which involves factors referring to the clinical state of the child, to the adaptation of the material to the size of the NB and to the checking of the number of wristbands by health care professionals, as

* Common Brazilian surnames such as 'Silva' are extremely common. Translator's note.

well as to the collaboration of family members or other persons accompanying the child.

It is recognized that there is a necessity for other studies to verticalize the theme and consider evaluative steps in the health services, to make it possible to establish goals for continuous improvement in the quality of care and in the safety of service users.

Concluding this investigation, the magnitude of the dimensions surrounding quality and safety in health is confirmed, although it is crucial to understand the realities of work protocols, stimulating people's participation and the use of tools designed for managing risks, with a view to minimizing the occurrence of adverse events or harm to service users.

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