ANALYSIS OF BLOOD QUALITY SCREENING IN NEONATAL
ANÁLISE DE INDICADORES DE QUALIDADE DA TRIAGEM NEONATAL SANGUÍNEA
ANÁLISIS DE INDICADORES DE LA SELECCIÓN DE CALIDAD DE SANGRE EN NEONATAL

ABSTRACT
Objective: to analyze quality indicators of Blood Neonatal Screening in Piauí in 2013. Method: documentary, evaluative study, developed from records in blood sample envelopes and in NetLab software in the Central Laboratory of Public Health, Teresina-PI. The data were collected after approval of a research project on the Ethics Committee in Research, CAAE number 17907213.2.0000.5214. Results: of 327 properly collected sample envelopes and negative screening (p=94.6%), only 36.8% were held between the 3rd and the 7th day of life; 53.1% took less than 5 days of collecting to the arrival at the laboratory; 18.3% took until 7 days of arrival the release of screening result; 12.6% screening process were completed within the first 30 days of life of the newborn. Conclusion: a long time showed inappropriate procedure during the steps of the process, suggesting improvement to its performance, especially for early detection of diseases.Descriptors: Neonatal Screening; Indicators of Quality in Healthcare; Processes and Results Assessment (Healthcare).

RESUMO
Objetivo: analisar indicadores de qualidade da Triagem Neonatal Sanguínea no Piauí em 2013. Método: estudo documental, avaliativo, desenvolvido a partir de registros em envelopes de amostra sanguínea e no software NetLab no Laboratório Central de Saúde Pública, Teresina-PI. Os dados foram coletados após aprovação do projeto de pesquisa no Comitê de Ética em Pesquisa, CAAE nº 17907213.2.0000.5214. Resultados: de 327 envelopes de amostras adequadamente coletadas e negativas à triagem (p=94,6%), apenas 36,8% destas foram realizadas entre o 3º e o 7º dia de vida; 53,1% levaram menos de 5 dias da coleta a chegada ao Laboratório; 18,3% levaram até 7 dias da chegada a liberação do resultado da triagem; 12,6% obtiveram processo de triagem concluído dentro dos primeiros 30 dias de vida do recém-nascido. Conclusão: longos tempos decorridos sinalizam articulações inadequadas entre as etapas do processo, sugerindo ajustes para melhoria de desempenho, sobretudo, para detecção precoce das doenças rastreadas. Descrições: Triagem Neonatal; Indicadores de Qualidade em Assistência à Saúde; Avaliação de Processos e Resultados (Cuidados de Saúde).

RESUMEN
Objetivo: analizar indicadores de calidad de la selección Neonatal Sanguínea en Piauí en 2013. Método: estudio documental, evaluativo, desarrollado a partir de registros en sobres de muestra sanguínea y en el software NetLab en el Laboratorio Central de Salud Pública, Teresina-PI. Los datos fueron recogidos después aprobación del proyecto de investigación en el Comité de Ética en Investigación, CAAE número 17907213.2.0000.5214. Resultados: de 327 sobres de muestras adecuadamente recogidas y negativas a la selección (p=94,6%), apenas 36,8% de estas fueron realizadas entre el 3º y el 7º día de vida; 53,1% llevaron menos de 5 días de recolección a la llegada al Laboratorio; 18,3% llevaron hasta 7 días de la llegada a la liberación del resultado de la selección; 12,6% obtuvieron proceso de selección concluido dentro de los primeros 30 días de vida del recién nacido. Conclusión: largos tiempos ocurridos señalan articulaciones inadequadas entre las etapas del proceso, sugiriendo ajustes para mejoría de desempeño, sobretodo, para detección precoz de las enfermedades rastreadas. Palabras clave: Selección Neonatal; Indicadores de Calidad en Asistencia a la Salud; Evaluación de Procesos y Resultados (Cuidados de Salud).
INTRODUCTION

The National Neonatal Screening Program (PNTN) is one of the main means of early detection of metabolic, infectious, hematological and genetic diseases through tests applied in the population aged 0 to 30 days. These congenital diseases may compromise the metabolism, impacting on the growth and development of the affected. The PNTN, by providing early diagnosis and specific treatment, is the central point to the reduction of morbidity and mortality for these harms to health. Popularly known as “screening test”, the Blood Neonatal Screening was instituted by the Ministry of Health together with the State and Municipal Health secretaries.

In Brazil, the neonatal screening became mandatory by determination of the Statute of the Child and Adolescent in 1990 (Law 8069/1990), being reaffirmed in 1992 by the Ministry of Health through Ordinance Number 22/1992. However, only in June 6, 2001, PNTN was created with the regulations of Ordinance Number 822/2001. The program should be implemented by Reference Services in Neonatal Screening, which are order and guidelines instances of the entire network of neonatal screening, and aims to detect, confirm the diagnosis, treat and monitor the cases.

In 2001, Blood Neonatal Screening covered the monitoring of Phenylketonuria (PKU), Congenital Hypothyroidism (HC), Sickle Cell Disease and other Hemoglobinopathies, Cistic Fibrosis. In 2012, by Ordinance Number 2829 MS/GM, the monitoring of Biotinidase Deficiency and Congenital Adrenal Hyperplasia were included.

Piauí has been enabled on the PNTN in 2004 with the creation of Reference Service in Neonatal Screening of the State in the Hospital Infantil Lucídio Portella (HILP) and the centralization of the Neonatal Screening in Central Laboratory of Public Health Dr. Costa Alvarenga (LACEN).

Blood Neonatal Screening in Piauí began in January 2005. Since then, the collections are held in maternity wards of Teresina and basic health units from other municipalities and, subsequently, submitted to LACEN for monitoring HC and PKU. The suspected cases are then sent to the HILP for definition of diagnosis, treatment and periodical follow-ups.

Since the implementation of PNTN in Piauí, the State remains in first stage, performing monitoring for PKU and HC, which configures the shy and discreet contribution at the national level. In the face of PNTN relevance for public health, this study aims to analyze quality indicators of Blood Neonatal Screening in Piauí in 2013.

OBJECTIVE

• To analyze quality indicators of Blood Neonatal Screening in Piauí in 2013.

METHOD

This article was elaborated from the dissertation << Results evaluation of the National Program of Neonatal screening in Piauí >> presented to the Nursing Master’s degree Program in Nursing at the Federal University of Piauí. Teresina-PI, Brazil. 2014.

Cross-sectional, documentary and evaluative study, developed in the city of Teresina-PI, in the field of Neonatal Screening of LACEN.

The data were secondary and extracted from documental analysis of records in blood sample collection envelopes for screening and NetLab software Neonatal Screening, deployed in 2013.

The data were extracted from secondary and analysis of documentary records in blood sample collection envelopes for screening and Neonatal screening, NetLab deployed software in 2013.

The estimated population was 34,335 envelopes of appropriate samples and negative to screening in Piauí in 2013. The simple calculation of the size of the sample was used for the delimitation of 327 envelopes, considering confidence level of 94.6%. The selection of envelopes was performed by systematic sampling, a variation of simple random sampling.

For the extraction of data contained in the envelope of the sample, a structured form that included the date and time of birth and the date and time of collection was used. Other structured form was used in gathering data on the NetLab system, which covered: the date of receipt of the sample by LACEN; the release date of the result; and the date of printing of the result by the responsible center for collection.

After the collection a database was created in double typing, to be able to calculate the time between the key steps of the process, quality indicators to be analysed: between the birth and the collection, between the collection and receipt of the sample in the laboratory, between the reception and the release of the result by the biochemist, between liberation and printing the result by the responsible center on collecting the
sample. The data were processed in the program Statistical Package for the Social Sciences (SPSS, version 18.0 for Windows).

Data collection occurred from January to February 2014 after fellow-agents and institutions authorization and approval by the Ethics Committee in Research of the Federal University of Piauí, with CAAE number 17907213.2.0000.5214, complying with the provisions of the National Health Council Resolution Number 466, of December 12, 2012 approving guidelines and regulatory norms for research involving human beings.

RESULTS

This study considered the following steps: birth of the child until the release of the test result by the biochemist and the availability of the test at the NetLab Neonatal Screening for printing by the unit.

In Figure 1, the is the time from the flow of blood in neonatal screening in LACEN between the dates of steps relating to the Birth of the child to the Collection of the blood sample (T1); The reception of the sample collection in LACEN (T2); Reception to the Release of the result by the biochemist (T3); Release of the Printing result by the responsible collection unit (T4); and Birth to Impression (T5), as well as the order in which these steps occur. Understanding the time enables a critique about how the variability of them to interfere directly in the course of PNTN.

![Timeline for appropriate negative samples to Blood Neonatal Screening in Piauí in 2013. Teresina (PI), 2014.](image)

Note:

[T1] Time between Birth and blood sample Collection (child's age at the time of sample collection);

[T2] Time between the Collection and Receipt of the sample in the laboratory (Sample transport Time, from the collecting unit to the laboratory);

[T3] Time between Receipt of the sample in the Laboratory and Releasing of the result by the biochemist;

[T4] Time between the Release of the result by the biochemist and Printing of the result by the responsible collecting unit;

[T5] Time between Birth and Printing of the result by the responsible collecting unit (age of the child at the conclusion of the Neonatal Blood Screening);

Figure 1. Timeline for appropriate negative samples to Blood Neonatal Screening in Piauí in 2013. Teresina (PI), 2014.

In T1, corresponding to the child's age at the time of collection, there were minimum values of 2 days, median of 9 days, an average of 13 days and maximum of 162 days. T2 is also known as transport time obtaining minimum value of 0 day, median of 5 days, averaging 7.2 days and maximum of 102 days. In T3, there was a minimum values of 2 days, median 13 days, an average of 17.4 days and maximum of 147 days. In T4 was observed minimum time of 0 days, median of 20 days, average of 33.7 days and maximum of 314 days. T5 presented minimum time of 13 days, median of 56 days, average of 70.9 days and maximum of 354 days, as displayed in Table 1.
Table 1. Minimum, maximum, median, average times, in days, for the time between birth and collecting, collection and reception, reception and release of the result, release of the result and printing and birth to printing of the result to appropriate negative samples to Blood Neonatal Screening in Piauí in 2013. Teresina (PI), 2014.

<table>
<thead>
<tr>
<th>TIME</th>
<th>(\bar{X}_1)</th>
<th>((\bar{X}_2))</th>
<th>min-max3</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before the 3rd day of life</td>
<td>13,05</td>
<td>(9)</td>
<td>2 - 162</td>
<td>326</td>
<td>100</td>
</tr>
<tr>
<td>Between the 3rd and the 7th day of life</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>After the 7th day of life</td>
<td>7,20</td>
<td>(5)</td>
<td>0 - 102</td>
<td>326</td>
<td>100</td>
</tr>
<tr>
<td>Same day of the collection</td>
<td>17,40</td>
<td>(13)</td>
<td>2 - 147</td>
<td>327</td>
<td>100</td>
</tr>
<tr>
<td>From 1 to 5 days</td>
<td>28,90</td>
<td>(12)</td>
<td>5 - 302</td>
<td>284</td>
<td>100</td>
</tr>
<tr>
<td>More than 5 days</td>
<td>33,70</td>
<td>(20)</td>
<td>0 - 314</td>
<td>5</td>
<td>1.7</td>
</tr>
<tr>
<td>T2</td>
<td>46,30</td>
<td>(36)</td>
<td>13 - 354</td>
<td>285</td>
<td>0</td>
</tr>
<tr>
<td>T5</td>
<td>68,90</td>
<td>(56)</td>
<td></td>
<td>36</td>
<td>12.6</td>
</tr>
<tr>
<td>T4</td>
<td>70,90</td>
<td>(56)</td>
<td></td>
<td>249</td>
<td>87.4</td>
</tr>
</tbody>
</table>

1Media; 2Average; 3Minimum-Maximum.

DISCUSSION

The main goal of the neonatal screening is to conduct the test in a timely manner, enabling the proper beginning of the treatment and prevention of mental disabilities and other sequels. The delay at any stage of neonatal screening - collection, reception, registration, test result, among others, may cause permanent damage to the lives of children affected by the disease and their families, therefore, understanding and researching become relevant to evaluation of the PNTN.

In the analysis of the data, it was found that in T1, 36.8% of samples were collected between the third and seventh day of life, obeying the goal set by the Ministry of Health. However, there was a case in which the collection occurred on the second day of life, and the median presented was 13 days exceeding this goal. It is important to note that the age of the child at the time of collection is a restrictive factor in the screening of phenylketonuria, because children under 48 hours of life have not ingested enough protein to be safely detected at screening, and can be found false normal results.

The Brazilian Government has invested in neonatal screening. However, it is still possible to notice that many cases have late access to the collection, often damaging the viability of the process so that, if necessary, treatment is initiated in the first month of life. The involvement of units of collecting on the uptake of newborns in a timely manner is fundamental for the recommendation of the Ministry of Health is accomplished. To achieve this goal, it is imperative that the maternity hospitals and health centers perform, respectively, collecting the blood sample for screening at the time of the newborn and collecting blood sample from those born at home.

The T2 showed 30.7% of the cases arriving at LACEN on the same day that the collection was carried out, the median of 5 days showed that the recommendation of the Ministry of Health is followed several times. It is the unit responsibility to send the samples with regularity every two or three days, and should never exceed five working days after the date of collection. These numbers can be justified by the priority use of the post office by the municipalities. The contract established between the State Secretary of Health of the State of Piauí and post office provides that transport time is up to five days regardless of the distance between the municipalities and the Central Post Office that receives all the samples.

The time between the receipt of the sample and the release of the result by the biochemist must not exceed 7 days. The present study identified a great variability of time in this process with a minimum of 2 days and maximum of 147 days. The median obtained was of 13 days, which exceeds the time recommended by the Ministry of Health. The numbers suggest some deficiencies in the actions developed by the screening of the State sector, since one of the goals of the PNTN is the prevention of sequels and it is
emphasized that the neurological prognosis for congenital hypothyroidism is related to the precocity of the beginning of the treatment in the first three weeks of life and, in the cases of phenylketonuria, the patient may lose, on average, five units of intelligence quotient every ten weeks of delay in treatment.15,16

In relation to the time between the release of the result by the biochemist and printing the result in the collection unit, it is worth noting that the date of printing is not always corresponding to the date on which the unit responsible for collecting was informed of the result by NetLab-Neonatal Screening, taking into account the existence of collection units that do not have material resources available for the regular printing of results. This reality reveals the need for an identified evaluation process for action managers because delays that accumulate in the various stages of the screening process can negate the benefits of early detection, foundation of neonatal screening.11,17

T5, which corresponds to the age of the child at the time the health unit prints the result of the test, showed that only 12.6% of newborns were with 30 days of life, identifying a weakness of the program, since the result should come out and be communicated to the family of the child in a timely manner to the beginning of the treatment, if necessary in the first month.18

Nursing has a relevant and indispensable role in the PNTN, due to the profession interacting with the mother and the newborn from the prenatal care in basic health units until the birth in hospital units. This professional must inform and guide the mother after the birth of the baby, she must require the examination performance at the right time for her child.19,20

CONCLUSION

The study enable the analysis of quality indicators of Blood Neonatal Screening in Piauí, which showed, in general, that the program did not reach the goals established by the Ministry of Health, while data suggest limitations in the process.

Thereby, it is very important to sensitize managers and practitioners as achieving goals advocated by the Ministry of Health to conduct the examination between the third and seventh day of life of the newborn and release the results in a timely manner to begin treatment, if necessary, in the first month of life in order to avoid significant sequels in the development of the child.

It is suggested that further studies are compiled in examining the PNTN in Piauí, in order to undertake improvement actions in the program, enabling thus an adequate assistance to children who receive positive diagnostic confirmation at the end of the screening process.

REFERENCES

Análise de indicadores de qualidade da triagem neonatal...