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PRE-ANALYTICAL NON-CONFORMITIES OF THE KARYOTYPE

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ABSTRACT

Purpose: Quality assurance applied to the three phases of karyotype examination namely pre-analytical, analytical and post-analytical allows reliable results to be provider. However, errors or non-conformities (NC) such as insufficient information on the analysis report were noted during the first phase. The objective of this work is to evaluate the pre-analytical non-conformities of the karyotype inherent in the analysis report at the Histology-Embryology- Cytogenetic laboratory of the University Hospital in Cocody-Abidjan. **Material and methods:** This was a retrospective and descriptive study that was carried out in the Histology-Embryology-Cytogenetic laboratory of the Cocody University Hospital. The non-conformities of the karyotype prescription bulletins from 2014 to 2019 were listed on a data collection sheet. These analysis reports came from various health facilities. **Results:** 12 types of NC were identified on 59 bulletins. The non-conformities of the bulletin relating to the identification of the patient concerned the absence of sex (18.64%), age (28.81%), profession (100%), place of residence (100%) and the phone number (100%). The last three were the most recurrent. The other non-conformities relating to the prescription that had a low percentage were the absence of the reason for the prescription (1.69%), the identification of the prescriber and the requesting Department (52.24%). In contrast, the absence of the date and time of the sample, the maternal age at conception, recent treatments likely to affect the quality of the examination as well as the family history was the most frequent (100%). **Conclusion:** The performance of this evaluation made it possible to detect non-conformities related to the reports that could have an effect on the transmission of the result and the quality of the examination. To remedy these errors, the laboratory should carry out preventive and corrective actions such as, the establishment of a model prescription bulletin for the karyotype and the sampling compliance criteria sheet to be offered to the requesting Departments.

KEYWORDS: Karyotype, Pre-analytical phase, Non-conformities (NC), Quality assurance.

INTRODUCTION

The execution of biomedical analyzes goes through several steps and is under the control of new reforms in biology, quality standards, in particular the ISO 15189 standard relating to the accreditation of medical biology laboratories.[1]

The karyotype is a biomedical examination which makes it possible to highlight chromosomal abnormalities (changes in the number or structure of chromosomes).[2] The results of this examination enter into the diagnostic and therapeutic processes of patients, hence the importance of having reliable results. This reliability requires the control and monitoring of the various phases, namely the pre-analytical, analytical and post-analytical.[3,4]

The pre-analytical phase of the examination includes an external step and an internal step in the analytical laboratory. The first begins with the ordering of examinations by the clinician, then the sample collection, preserving and transport of the samples. It takes place outside the laboratory, therefore outside of any control by the biologist. The second concerns the receipt of the sample by the laboratory technician.[1]

According to the ISO 9000 definition, a non-conformity (NC) corresponds to the non-satisfaction of a requirement.[5] In pre-analysis, it concerns the various dysfunctional situations affecting prescription, sampling, identification, preserving or others.[6] The pre-analytical phase would be at the origin of 85% of the errors and malfunctions that affect the results of analyzes [7]. During

the medical prescription (the examination request), the samples must be associated with an examination request sheet (or analysis report) in accordance with the regulations in force. This request must include precisely and legibly all the information necessary for the proper execution of the examinations and the interpretation of their results.[8]

However, errors or non-conformities such as insufficient information on the analysis report and the sample have been noted.[3]

In order to improve the progress of the pre-analytical phase of the karyotype, the objective of this work is to evaluate the pre-analytical non-conformities of the karyotype inherent in the analysis report at the Histology-Embryology-Cytogenetic laboratory of the University Hospital in Cocody-Abidjan.

MATERIAL AND METHODS

Part of the Study

This was a retrospective and descriptive study of the non-conformities of the karyotype pre-analytical phase which be held at the Histology-Embryology-Cytogenetic laboratory of the Cocody-Abidjan University Hospital.
The internal pre-analytical in the laboratory corresponding to the reception of the samples takes into account the verification of the samples and the analysis reports from various health facilities, then the registration.

Study Material

The technical material included the karyotype prescription bulletins, the examination registration register and a data collection sheet.

The data entry and statistical analysis equipment consisted of a computer, Microsoft Word 2010, Excel 2010 and Epi info version 7 software.

Data collection

All patient reports sent to the laboratory for the realization of the karyotype from 2014 to 2019 were included in the study.The confidentiality of the documents was respected.

A data collection sheet made it possible to identify the different types of NC relating to the prescription of the karyotype. The verification of the bulletin focused on the following parameters :

- patient identification (name, first names, sex, date of birth, profession, place of residence and phone number),
- prescriber identification (name, first names, function, stamp, phone number),
- requesting Department,
- reason for requesting the karyotype,
- recent treatments that may affect the quality of the examination,
- family history (with a family tree if possible),
- maternal age of conception,
- type of sample, the nature of the examinations prescribed, the date and time of the sample collection were also taken into account.[1, 9,10]

Data analysis and processing

Epi info version 7 and Microsoft Excel 2010 software were used to analys the data. Results were expressed as a percentage and represented as histograms.

RESULTS

During the study period, 12 types of non-conformities were identified on 59 karyotype prescription bulletins (Figures 1 and 2).

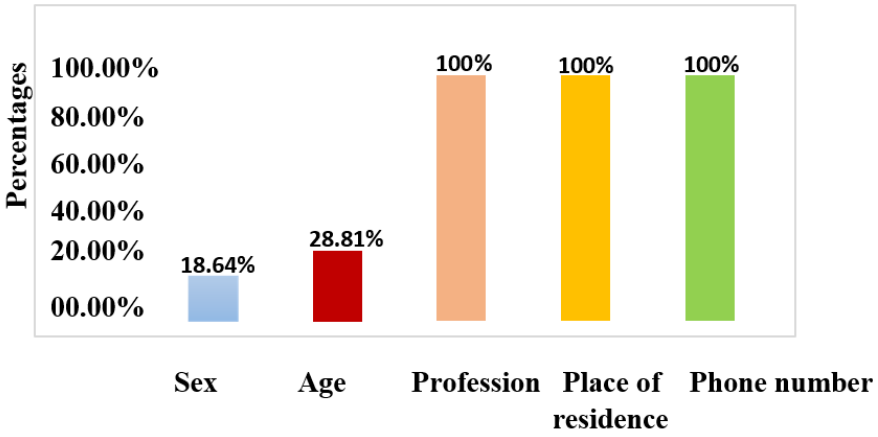

Figure 1 : Non-conformities relating to patient identification

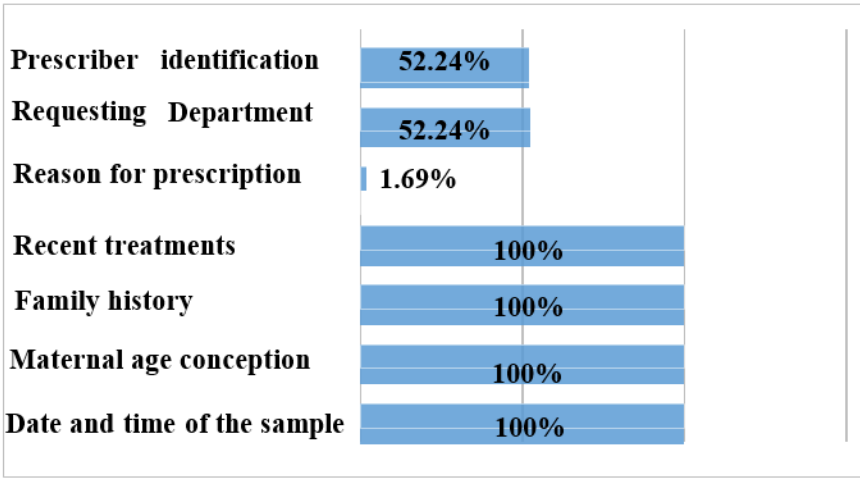

Figure 2 : Other types of non-conformities relating to the karyotype prescription

DISCUSSION

The prescription of biological examinations, in particular the karyotype, is an act carried out by personnel authorized to prescribe. It must contain with precision and legibility all the informations for which the prescriber expects results to support his clinical diagnosis.[1]

The non-conformities relating to the identification of the patient identified during our study concerned the absence of patients' age (28.81%), sex (18.64%), place of residence, profession and phone number. The last three were the highest with a rate of 100%. The purpose of patient identification is to create a unique identifier linking the patient to their biological record and to ensure secure treatment until the result.[6,11,12] Consequently, the non-conformities relating to the identification could cause a delay or an inversion in the transmission of the results.

In the event of a recurrent cytogenetic pathology, the patient's profession and place of residence appearing on the bulletin should facilitate the rapid triggering of an alert in order to better define the etiological factor.[6, 7]

Among the non-conformities relating to the prescription, some could influence the quality of the results such as the failure to mention the requesting Department and the prescriber identification. In addition, there is the absence of the date and time of collection, maternal age at conception, recent treatments that could affect the quality of the examination and family history.

Indeed, the first two elements make it possible to establish a communication protocol between the laboratory that receives the samples and the reference Department.[13] The importance of mentioning the maternal age at conception lies in the fact that it has been established a strong correlation between advanced maternal age and the occurrence of certain genetic pathologies including Down's syndrome.[14]

We have also identified 100% of cases of NC relating to the lack of precision of the date and time of the sample. This percentage is very significant in relation to the importance of these two parameters in the demand for biological examinations. The date and time must be mentioned in order to ensure the traceability of the sample, that is to say to correctly assess the time elapsed between the collection and the next steps of the analysis.[3] Better, the indication of the exact time of the sample allows the biologist to predict bad conservation.

The absence of recent treatments and the family history represents in our study 100% of cases of NC, this is one of the highest percentages of NC identified. Other studies have also reported the absence of this clinical information. Thus, Saadouni[15] in 2011 and Oudghir[16] in 2012 have shown that the absence of clinical information represented respectively 53.6% and 18.71% of cases of NC. It is important to indicate the recent treatments likely to affect the quality of the examination, such as radiotherapy or chemotherapy.[17] As for information relating to family history, it provides information on the patient's ancestry, personal history, contagious diseases or any other relevant clinical information that may also influence the performance of the examinations and their interpretation.[1,7,18]

Several studies have reported some causes of non-conformities related to bulletins such as lack of knowledge, distracted work and haste.[1,7] Besides this, failure to meet certain criteria results in systematic rejection of the sample. This is the case of a sample received without a bulletin.[19]

Furthermore, non-conformities do not only apply to the pre-anatytic phase[20]; in analytics, it could be a stock

shortage, a analyser failure due to a lack of maintenance.[21] In post-analysis, the NC can concern the failure to meet the deadlines for submission of results and failure to communicate the results of urgent examinations.[12]

Thus, to remedy these errors, corrective and preventive actions should be implemented[22] at the Histology-Embryology-Cytogenetic laboratory of the Cocody-Abidjan University hospital. It comes to establishing of a model prescription bulletin for the karyotype and the sampling compliance criteria sheet to be offered to the requesting Departments.

The correct completion of the karyotype prescription bulletin, including all the data mentioned above, would make it possible to establish a more refined profile of patients with genetic pathology and to guide the biologist in carrying out the examination and its interpretation.

In addition, for the realization of the karyotype, the samples allowing to obtain the cellular material are, the peripheral venous blood, amniotic fluid, chorionic villi, tumor tissue and gametes.[23,24,25] The sampling compliance sheet would provide details on the sample parameters such as storage temperatures, transport conditions, hygiene and biosecurity measures. This sheet constitutes a guide which presents certain requirements formulated by quality reference manuals in order to inform the requesting Departments concerning compliance elements that could improve the quality of the examinations. It will also allow authorized laboratory personnel to evaluate the samples received to ensure that they meet the acceptance criteria.[1,7]

CONCLUSION

The performance of this evaluation made it possible to detect non-conformities related to the reports that could have an effect on the transmission of the result and the quality of the examination. To remedy these errors, the laboratory should carry out preventive and corrective actions such as, the establishment of a model prescription bulletin for the karyotype and the sampling compliance criteria sheet to be offered to the requesting Departments.

Conflict of interest

The authors declared no conflict of interest.

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