Analysis of non-conformity in continuous quality improvement in a Hospital Radiopharmacy Unit

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ABSTRACT

Aim: To perform an analysis of non-conformities (NC) registered between 2012 and 2015, as a part of the review process of the Quality Management System of our Radiopharmacy Unit.

Material and methods: Non-conformities registered in the Radiopharmacy Unit in the period 2012–2015 are analyzed and sorted by their impact on the process (critical, major, and minor), cause/origin of the non-conformity, and nature of radiopharmaceutical (PET vs. SPECT).

Results: A decrease in the NC of 20% per year is observed, especially in PET radiopharmaceuticals. Non-conformities in SPECT make up about 62–84% of the total of the NC, mainly related to the high number of doses prepared and not administered, which is about 1.5–3% in the non-administered/ administered per year.

Conclusions: Analysis of the NC can be considered as a useful indicator in assessment of quality assurance, and in our particular case, the decrease in the registration of NC indicates effectiveness in the corrective and preventive actions implemented.

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Análisis de las no conformidades en la mejora continua de la calidad en una unidad de radiofarmaclia hospitalaria

RESUMEN

Objetivo: Analizar las no conformidades (NC) registradas entre el 2012 y el 2015, como parte del proceso de revisión del sistema de gestión de calidad.

Material y métodos: Se analizan las NC registradas en la unidad de radiofarmaclia en el período indicado, incluyendo clasificación según repercusión en el proceso, origen de la incidencia y naturaleza del radiofarmaco.

Resultados: Se observa un descenso de las NC en torno al 20% cada año, provocado fundamentalmente por la disminución de las NC en PET. Las NC en convencional se deben en gran medida al número de dosis preparadas y no administradas (62-84% del total de NC), que en el cómputo global de dosis totales administradas representan un porcentaje del 1,5 al 3% en el ratio de las no administradas/administradas por año.

Conclusiones: El análisis de las NC se puede considerar como un indicador útil en la evaluación de la calidad asistencial. En nuestro caso, su disminución nos indica que las medidas correctoras y preventivas implantadas hasta ahora han sido efectivas.

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Introduction

For some time, concepts such as continuous improvement or quality assurance have been included in the concept of total quality, comprising all aspects of the organization, all its processes and results. The models of total quality management are aimed at raising awareness of quality, and have been widely used in all sectors, including health, through models such as EFQM and ISO tools.

Moreover, Spanish legislation (RD 1841/1997, of December 5, of quality criteria in Nuclear Medicine), addresses the importance of this tool, in order to optimize the administration of radiopharmaceuticals and protection radiological patient, ensuring good clinical practice.

UNE-EN ISO 9000 defines quality as the degree to which a set of inherent characteristics fulfills requirements. A Quality Management System should cover all aspects that affect the final quality of the product or service provided and must be documented in a Quality Manual and procedures and technical instructions, where the review of compliance is necessary.

According to ISO 9000:2005, non-conformity (NC) is a breach of a system requirement, whether it is specified or not. Requirement
is known as a need or expectation established, generally explicit or mandatory. Consequently, through methods of measurement and analysis, non-conformities are detected and put in place actions to minimize them. In our case, the NC are categorized according to the implications for the organization and above all, in terms of their implications for the patient; the patient is the cornerstone on which turns the quality management.

These non-conformities are one of the most useful channels to review the information management system, so that can help to decide between reorient the system or maintain the principles and guidelines. It is therefore common to perform a trend analysis, considering it as a management indicator, or if you will, an indicator of efficiency, i.e. capacity or success in achieving tasks and/or work. For this, it is necessary to establish a procedure that describes how to identify, solve and verify non-compliances, as well as actions to correct or prevent undesirable situations with particular emphasis on the registration and treatment system.

This paper is a review of non-conformities registered in our Radiopharmacy Unit in the period between 2012 and 2015. An analysis of the recorded NC is proposed, regarding the corrective and/or preventive actions implemented and their evolution over the time of study.

### Material and methods

All non-conformities documented in our Radiopharmacy Unit from 2012 to 2015 are analyzed. The model used for registering the non-conformity is included as an annex of the SOP called “Management of Non-conformities”, where the following data are included: reference code, date, description, cause analysis, grade assignment (minor, major, critical), corrective actions proposed and taken, preventive actions proposed and taken, person in charge of implementation, people involved, follow up period, follow up result, time frame to close and date of closure. Registers are transferred to a database for better management.

Any observation that after analysis is considered NC is grading (minor, major, critical) accordingly to the impact in the process of dispensing prescribed doses with quality, security and identity. Minor NC do not impact the capability to achieve the expected outcomes, major NC raises doubt about the capability to achieve the expected outcomes and critical NC represents a failure to fulfill one or more requirements that do not allow us for achieving our intended outputs. It is also taken into account the cost of non-quality, focused on the added expense of the cost of the process without incidents and the impact not only on the patient’s health, but also on the quality of service.

The origin of the NC is classified as follows:

- Radiopharmaceutical’s supplier.
- Nuclear Medicine Department (NMD): in this group are included those NC related to dose administration, dose prescription, etc.
- Radiopharmacy Unit (RU): in this group are included those NC related to the activity of a Radiopharmacy Unit and its support departments, as for example, maintenance or purchasing department.

Finally, the radiopharmaceutical type is included in the NC analysis since PET and SPECT radiopharmaceuticals have different management.

### Results

NC registered during the period of time from 2012 to 2015 are gathered in Table 1, classified by type of radiopharmaceutical.

![Fig. 1. Total NC, PET and SPECT between 2012 and 2015.](image)

<table>
<thead>
<tr>
<th>Year</th>
<th>Total NC</th>
<th>Total of prepared and unadministered doses</th>
<th>Unadministered doses</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>PET</td>
<td>SPECT</td>
</tr>
<tr>
<td>2015</td>
<td>57</td>
<td>40</td>
<td>2</td>
</tr>
<tr>
<td>2014</td>
<td>65</td>
<td>41</td>
<td>5</td>
</tr>
<tr>
<td>2013</td>
<td>85</td>
<td>41</td>
<td>9</td>
</tr>
<tr>
<td>2012</td>
<td>108</td>
<td>59</td>
<td>12</td>
</tr>
</tbody>
</table>

**Table 1**

<table>
<thead>
<tr>
<th>Year</th>
<th>Total NC</th>
<th>Cause:RU</th>
<th>Cause:NMD</th>
<th>Cause:supplier*</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>2013</td>
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<td></td>
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<tr>
<td>2015</td>
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</tr>
</tbody>
</table>

66% of the total NC were graded as major, most of them related to SPECT unadministered doses. Critical NC were 20% of the total registered and were linked to radiopharmaceutical’s supplier issues (i.e. 18F-FDG synthesis failure). Finally, the minor ones, 12% of the total NC, were of the sort of schedule errors.

Most of the registered NC are linked to unadministered doses, especially SPECT (see Table 2), and regarding the administered doses per year, the ratio of unadministered/administered doses is still higher in SPECT than in PET, as it is shown in Table 3.

The number of NC decreases during the period of study with a rate of 20% per year as is reflected in Table 1 and Figs. 1–5.

### Discussion

As it is shown in Fig. 1, there is a decrease in the number of NC of about 20% per year, specially marked in PET radiopharmaceuticals. This reduction is related to the corrective and preventive actions taken to improve resources management, chiefly, the staff training and their adaptation to the workflow (Hospital opened in 2011).
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