Abstract

**Objectives:** To carry out a Failure Mode and Effects Analysis (FMEA) to the use of oral syringes.

**Methods:** A multidisciplinary team was assembled within the Safety Committee. The stages of oral administration process of liquid medication were analysed, identifying the most critical and establishing the potential modes of failure that can cause errors. The impact associated with each mode of failure was calculated using the Risk Priority Number (RPN). Preventive actions were proposed.

**Results:** Five failure modes were identified, all classified as high risk (RPN> 100). Seven of the eight preventive actions were implemented.

**Conclusions:** The FMEA methodology was a useful tool. It has allowed to know the risks, analyse the causes that cause them, their effects on patient safety and the measures to reduce them.

**Keywords**
FMEA; Quality control; Safety; Oral administration; Syringes.

**Palabras clave**
AMFE; Calidad; Seguridad; Administración; Jeringas.

Resumen

**Objetivo:** Realizar un análisis modal de fallos y efectos (AMFE) aplicado a la utilización de jeringas orales.

**Métodos:** Un grupo multidisciplinar dentro del Comité de Seguridad analizó las etapas en la administración oral de los medicamentos líquidos, identificándose las más críticas y estableciendo los potenciales modos de fallo que podrían producir un error. El riesgo asociado a cada modo de fallo se calculó utilizando el número de prioridad de riesgo (NPR). Se sugirieron acciones preventivas.

**Resultados:** Se identificaron cinco modos de fallo, todos clasificados de alto riesgo (NPR> 100). Siete de las ocho recomendaciones fueron implementadas.

**Conclusiones:** La aplicación de la metodología AMFE ha sido un herramienta muy útil que ha permitido conocer los riesgos, analizar las causas que los pueden provocar y saber los efectos que tienen en la seguridad del paciente; todo ello con el fin de implantar acciones para reducirlas.

**Palabras clave**
AMFE; Calidad; Seguridad; Administración; Jeringas.
Introduction

Safety is an essential principle in patient care, as well as a critical component in quality management. Currently it is a priority for healthcare organizations; therefore, there has been an increased activity by national and international organizations working towards patient safety. Use of medications is one of the items to be reinforced, and more specifically, their administration stage.

The errors associated with the administration of medication through an incorrect way represent a cause for severe adverse events in patients. One of the first alerts came up from the United Kingdom in 2007, when the National Health System (NHS), through the National Patient Safety Agency (NPSA), issued a national safety alert regarding errors due to incorrect way of administration for medications that required the use of a nasogastric tube. This alert was generated as a response for 33 safety incidents which involved the intravenous administration of oral liquid medications. During the same year, the World Health Organization (WHO) recommended as a priority safety practice the use of oral syringes for the administration of medication orally or through nasogastric tube.

In Spain, the Institute for Safe Use of Medications (ISMP) publishes periodical newsletters and educational programs, which have highlighted the importance of using oral syringes for preparing and administering liquid medications through oral administration. Even though there has been an increase in the use of these syringes in recent years, there are still some centers where they are not available, or healthcare professionals are not using them, either due to lack or knowledge or because they think that this type of error will never happen to them.

FMEA is a method for prospective and systematic analysis, which allows to identify those scenarios where a process can fail, the reasons for this failure, to assess the effects of any potential errors, and to prioritize correcting measures. The FMEA-type methodology is recommended for the analysis of drug-associated risks, and there are different publications on this topic, such as the article by Rodríguez-González applied to administration of medications, or those conducted in our hospital, applied to the process of medication prescription, validation and dispensing for hospitalized patients. The Safety Committee of our hospital has decided to conduct a FMEA-type study in order to ensure that oral syringes will be used, after the report of medication errors such as the intravenous administration of the oral solution for mucositis, or methadone in one case.

Methods

A prospective study was conducted, following the FMEA-type methodology, in a tertiary hospital with 1,070 beds.

A multidisciplinary work team was created within the Safety Committee, including three physicians, two pharmacists and four supervisors (from the Oncology, Emergency, Cardiology and Central Services Departments), an expert in this methodology was its coordinator. The study was scheduled to be conducted during a period of six months, with 4 face-to-face meetings with an approximate duration of one hour and a half. The implementation of recommendations was planned within a twelve-month period.

The work team analyzed the stages of administration for oral liquid medications, the most critical were selected, and the causes that could originate them were analyzed, as well as their potential effects on patients. The brainstorming method was used for this task.

In order to estimate the risk associated with every failure mode, the Risk Priority Number (RPN) was obtained by multiplying frequency, severity and detectability. Frequency was defined as the probability of the failure to occur, and it was assigned a value from 1 (the lowest probability that it occurs) to 10 (the highest probability that it occurs). Each failure received a severity number from 1 (no danger for the patient) to 10 (catastrophic, the highest harm possible). Detectability is the likelihood to detect a failure; in this case, it was assigned a value from 1 (the highest likelihood of being detected) to 10 (the lowest likelihood of being detected). The cut-off point was chosen by consensus within the team, and all failure modes with a RPN>100 were selected.

Results

Table 1 shows the risk analysis results, stating failure modes, their cause, effects, actions suggested to prevent errors and the strategy to conduct them.

A poster was prepared (Figure 1) and disseminated through the hospital intranet; it was sent to all nursing controls, and presented by the supervisors in their sessions for each hospitalization unit.

After these recommendations were implemented, it was confirmed that there was a 100% availability of syringes in the nursing unit storage rooms; this was personally verified by the nursing supervisors. The analysis of the use of oral syringes by hospitalization units showed an increase from 400 to 800 units for 1mL, from 1,600 to 4,200 units for 5mL and from 1,700 to 4,300 units for 10mL syringes.

Discussion

FMEA has allowed an in-depth analysis of the use of oral syringes at hospital, improving their use and increasing safety in the process of oral administration for liquid medications.

Our study described the first FMEA applied to the use of oral syringes for the administration of oral medication. Even though other authors have used the FMEA methodology in order to analyze the process of administering medication, no study has referred to this device, and therefore it is not possible to conduct any comparisons.

When analyzing the critical points, we identified as a failure mode that oral syringes were not available in the hospitalization unit, because the supply department was out of stock, or these had not been included in the stock for the unit. Therefore, there was a review of the policy for use and availability at hospitalization units, ensuring their availability. After an
Table 1. Analysis of failure modes, effects and causes, in the use of oral syringes for oral administration of medications.

<table>
<thead>
<tr>
<th>Failure modes</th>
<th>Causes</th>
<th>Effects</th>
<th>Frequency (F)</th>
<th>Severity (S)</th>
<th>Detection (D)</th>
<th>RPN (F<em>S</em>D)</th>
<th>Action</th>
<th>Responsible</th>
<th>Deadline</th>
</tr>
</thead>
<tbody>
<tr>
<td>No availability at the Hospitalization Units.</td>
<td>No stock at Supplies. The supervisor does not include stock in the Agreement for Use. Their use has not been widely adopted.</td>
<td>The promotion of the use of a safety device is not achieved.</td>
<td>9</td>
<td>6</td>
<td>8</td>
<td>432</td>
<td>Policy of use and recommendation of use mandatory for the Nursing Management. Include in the annual objectives for Nursing Units. Review of the availability at hospitalization units.</td>
<td>Chief of the Safety Committee</td>
<td>2016</td>
</tr>
<tr>
<td>Insufficient access to syringes.</td>
<td>Insufficient communication between supervisor and nurse, and between nurse and student.</td>
<td>Oral medication might get administered intravenously.</td>
<td>9</td>
<td>6</td>
<td>7</td>
<td>378</td>
<td>Place the oral syringes in the area for preparing medication. Training. Awareness posters. Update in the protocol for oral medication administration.</td>
<td>Chief of the Safety Committee. Hospital Ramón y Cajal Pharmacists.</td>
<td>2016</td>
</tr>
<tr>
<td>Lack of knowledge of their existence.</td>
<td>The supervisor is not aware of the existence of syringes. The supervisor does not inform the nurse about their existence.</td>
<td>Oral medication might get administered intravenously.</td>
<td>8</td>
<td>6</td>
<td>8</td>
<td>384</td>
<td>Training. Awareness posters. Update in the protocol for oral medication administration.</td>
<td>Chief of the Safety Committee. ICU Supervisor.</td>
<td>2016</td>
</tr>
<tr>
<td>Difficulties in syringe handling.</td>
<td>Difficulties for labelling syringes. The device does not meet the expectations by professionals (adequate material due to the tip lumen / syringe colour). Difficulties to use the oral syringe in nasogastric tubes due to their port.</td>
<td>The promotion of the use of a safety device is not achieved.</td>
<td>8</td>
<td>7</td>
<td>8</td>
<td>448</td>
<td>Standardize the process of use of oral syringes. Establish as Mandatory Rule.</td>
<td>Chairwoman of the Safety Committee Supervisor</td>
<td>2015</td>
</tr>
<tr>
<td>Resistance to change</td>
<td>Low perception of risk. Excessive trust in “what has always been done”.</td>
<td>The promotion of the use of a safety device is not achieved. Oral medication might get administered intravenously.</td>
<td>8</td>
<td>6</td>
<td>8</td>
<td>384</td>
<td>Training. Awareness posters. Update in the protocol for medication administration.</td>
<td>Chairwoman of the Safety Committee Hospital Pharmacists.</td>
<td>2015</td>
</tr>
</tbody>
</table>
The application of the FMEA methodology has been a very useful tool that has allowed to understand the failures and risks associated with the administration of liquid medications, to analyze their causes as well as their effects on patient safety, with the objective of issuing recommendations and implementing actions in order to reduce said risks.

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**Conflict of interests**

The authors hereby declare that there is no conflict of interests whatsoever.

**Contribution to scientific literature**

This is the first study to describe a FMEA applied to the use of oral syringes for the administration of oral medication in the hospital setting. The application of the FMEA methodology has been a very useful tool in order to increase safety in the process of administration for liquid oral medication.

**Bibliography**