Farmacia HOSPITALARIA
Órgano oficial de expresión científica de la Sociedad Española de Farmacia Hospitalaria

How to cite this article:
Aranaz-Andrés JM, Bermejo-Vicedo T, Muñoz-Ojeda I, Delgado-Silveira E, Chamorro-Rubio S, Fernández-Puentes A, et al. Failure mode and effects analysis applied to the administration of liquid medication by oral syringes. Farm Hosp. 2017;41(6):674-677.

ORIGINALS
Bilingual edition english/spanish

Failure mode and effects analysis applied to the administration of liquid medication by oral syringes

Análisis modal de fallos y efectos de la utilización de jeringas orales para administrar medicamentos líquidos

Jesús María Aranaz-Andrés[1], Teresa Bermejo-Vicedo[2], Isabel Muñoz-Ojeda[2], Eva Delgado-Silveira[2], Sonia Chamorro-Rubio[3], Ángeles Fernández-Puentes[4], Marta García-Collía[5], Eva María Guerra-Alia[4]

[1]Preventive Medicine Department, Ramon y Cajal Hospital, Madrid. Spain. [2]Servicio de Farmacia, Hospital Ramón y Cajal, Madrid. Spain. [3]Accident and Emergency Deparment, Ramon y Cajal Hospital, Madrid. Spain. [4]Oncology Department, Ramon y Cajal Hospital, Madrid. Spain. [5]Biochemistry Department, Ramon y Cajal Hospital, Madrid. Spain.

Author of correspondence
Isabel Muñoz-Ojeda
Servicio de Farmacia.
Hospital Ramón y Cajal.
Ctra. de Colmenar Viejo km. 9,100.
28034 Madrid.

Correo electrónico:
mmojeda@salud.madrid.org

Recibido el 6 de marzo de 2017;
aceptado el 22 de junio de 2017.
DOI: 10.7399/fh.10792

Abstract

Objective: 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.

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 modos potenciales 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 una 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 reducirlos.

KEYWORDS
FMEA; Quality control; Safety; Oral administration; Syringes.

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[1-3]. 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[4]. 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[3]. During the same year, the World Health Organization (WHO) recommended as a priority safety practice the use of oral syringes for the administration of oral medication orally or through nasogastric tube[2].

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[4,5]. Even though there has been an increase in the use of these syringes in recent years, there are still some centres 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[5].

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[6], or those conducted in our hospital, applied to the process of medication prescription, validation and dispensing for hospitalized patients[7,8]. 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

Figure 1. *Poster with recommendations on the use of oral syringes.*

Table 1. Analysis of failure modes, effects and causes, in the use of oral syringes for oral administration of medications.

Risk Analysis							Actions and results		
Failure modes	**Causes**	**Effects**	**Frequency (F)**	**Saverity (S)**	**Detection (D)**	**RPN (F*S*D)**	**Action**	**Responsible**	**Deadline**
No availability at the Hospitalization Units.	No stock at Supplies. The supervisor does not include stock in the Agreement for Use. Their use has not been widely adopted.	The promotion of the use of a safety device is not achieved.	9	6	8	432	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.	Chief of the Safety Committee	2016
Insufficient access to syringes.	Insufficient communication between supervisor and nurse, and between nurse and student.	Oral medication might get administered intravenously.	9	6	7	378	Place the oral syringes in the area for preparing medication. Training. Awareness posters. Update in the protocol for oral medication administration.	Chief of the Safety Committee. Hospital Ramón y Cajal Pharmacists.	2016
Lack of knowledge of their existence.	The supervisor is not aware of the existence of syringes. The supervisor does not inform the nurse about their existence.	Oral medication might get administered intravenously.	8	6	8	384	Training. Awareness posters. Update in the protocol for oral medication administration.	Chief of the Safety Committee. ICU Supervisor.	2016
Difficulties in syringe handling.	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.	The promotion of the use of a safety device is not achieved.	8	7	8	448	Standardize the process of use of oral syringes. Establish as Mandatory Rule.	Chairwoman of the Safety Committee. Supervisor	2015
Resistance to change	Low perception of risk. Excessive trust in "what has always been done".	The promotion of the use of a safety device is not achieved. Oral medication might get administered intravenously.	8	6	8	384	Training. Awareness posters. Update in the protocol for medication administration.	Chairwoman of the Safety Committee Hospital Pharmacists.	2015

analysis of their subsequent use, an increase was observed, which led to assuming a higher implementation of their use at the hospital.

Regarding the "lack of knowledge of their existence", the measures adopted in terms of training, and an improved communication between professionals, have contributed to an inclusion by the entire staff of this safer practice in their working routine. In a previous study conducted by us[7], it was considered essential to train all professionals involved in the process.

Another problem detected was the difficulty in handling syringes because of poor adaptation to devices (such as, for example, the nasogastric tube); this was overcome by an adequate management of the oral syringes to be purchased.

Regarding the resistance to a change in routines and working habits, a major effort is required by everyone, and even a cultural change in the entire organization. This is also closely associated with an excess in confidence and low perception of the risk, which prevents accepting that certain practices that have been conducted for a long time are not necessarily safe. In this sense, the Safety Committee considered that it was essential to train professionals through sessions in each hospitalization unit.

The only measure that could not be implemented was an update in the protocol for medication administration, because during the implementation process there was a change of staff in Nursing Management and Safety Committee, which made it difficult to complete said implementation by the deadline established. This task remained as a pending objective for the Committee.

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.

Funding

No funding has been received for this article.

Acknowledgements

Our thanks to all the members of the *Ramón y Cajal* Safety Committee, and to the Pharmacy Unit specialists.

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

1. Institute for Safe Medication Practices Canada. Inadvertent administration of oral solutions by injection. ISMP Canada Safety Bulletin. January, 2002. (Consultado 30/09/2015). Disponible en http://www.ismp-canada.org/
2. World Health Organization. World Alliance for Patient Safety. Avoiding catheter and tubing mis-connections. Patient Safety Solutions. Solution 7. May 2007. (Consultado 25/09/2015). Disponible en http://www.who.int/patientsafety/solutions/patientsafety/PS-solution7.pdf
3. National Patient Safety Agency. Patient Safety Alert 19. Promoting safer measurement and administration of liquid medicines via oral and other enteral routes. March, 2007. (Consultado 28/09/2015). Disponible en http://www.nrls.npsa.nhs.uk/resources
4. ISMP-España. Errores por administración de medicamentos orales líquidos por vía intravenosa. Recomendaciones para la prevención de errores de medicación. Boletín 29. Mayo, 2009. (Consultado 26/06/2015). Disponible en:http:/ismespana.org/ficheros
5. ISMP-España. Uso de jeringas orales para administrar medicamentos orales líquidos: una práctica de seguridad prioritaria que no está suficientemente implantada. Recomendaciones para la prevención de errores de medicación. Boletín 35. Octubre, 2012. (Consultado 25/09/2015). Disponible en https://www.sinasp.es/acrs
6. Rodríguez-González CG, Martín-Barbero ML, Herranz-Alonso A, Durango-Limarquez MI, Hernández-Sampelayo P, Sanjurjo-Saez M. Use of failure mode, effect and criticality analysis to improve safety in the medication administration process. J Eval Clin Pract. 2015;21:549-59.
7. Delgado E, Álvarez A, Pérez C, Serna J, Rodríguez MA, Bermejo T. Análisis modal de fallos y efectos del proceso de prescripción, validación y dispensación de medicamentos. Farm Hosp. 2012;36:24-32.
8. Vélez M, Bermejo T, Delgado E, Carretero E. Using Healthcare Failure Mode and Effect Analysis to reduce medication errors in the process of drug prescription, validation and dispensing in hospitalised patients. BMJ Qual Saf. 2013;22:42-52.