



ORIGINALS

English

Devising of a risk map on the management of high risk alert medication in a high level university hospital

Elaboracion de un mapa de riesgos sobre el manejo de medicamentos de alto riesgo en un hospital universitario de elevada complejidad

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Abstract

Objective: To classify hospital units into three risk levels in order to define and prioritise improvement and training measures in each of them.

Method: The risk map was developed in two phases: First phase involved the setting up of a multidisciplinary team, a bibliographic search, the identification of medications and of the criteria to design the map: (1) Location: number of high-alert medications; (2) Staff turnover: the units were classified in low turnover units = 1, medium turnover units = 2 and high turnover units = 3 according to data provided by the human resource department; (3) Frequency: quotient between the number of high alert medications in each unit and the total of medications used, and (4) Severity: voluntary survey of professionals. An accumulated risk of severity of each unit was calculated: Σ (severity of the drug x number of its units). The Neperian logarithm was applied to this value to reduce the variability of the values. Thus a risk probability index was established = staff turnover x frequency x Neperian logarithm of severity. In a

Resumen

Objetivo: Estratificar las unidades del hospital en tres niveles y elaborar un mapa de riesgos para priorizar las mejoras y la formación sobre el manejo de medicamentos de alto riesgo.

Método: La elaboración del mapa se realizó en dos fases: Primera fase, implicó la creación de un equipo multidisciplinar, búsqueda bibliográfica, identificación de medicamentos y de criterios para elaborar el mapa: (1) Localización: número de medicamentos de alto riesgo; (2) Rotación del personal: se clasificaron las unidades en rotación baja = 1, media = 2 y alta = 3, según datos de recursos humanos; (3) Frecuencia: cociente entre el número de medicamentos de alto riesgo en cada unidad y el total de medicamentos utilizados, y (4) Gravedad: encuesta voluntaria a profesionales. Se calculó un riesgo acumulado de gravedad de cada unidad: Σ (gravedad del medicamento x número de unidades del medicamento). Sobre este valor se aplicó el logaritmo neperiano para reducir la variabilidad de los valores. Con ello se estableció el índice de probabilidad de riesgo = rotación del personal x frecuencia x logaritmo neperiano del riesgo acumulado de gravedad. En una segunda fase, a partir

KEYWORDS

Drug Safety; High-alert medications; Medication Alert System; Medication Hospital System; Assessment Risk; Medication Errors.

PALABRAS CLAVE

Seguridad de los medicamentos; Medicamentos de alto riesgo; Sistema de alerta de medicamentos; Sistema hospitalario de medicación; Evaluación de riesgos; Errores de Medicación.



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second phase, the units were classified into three groups and the risk map of high-alert medication was elaborated in the hospital. In it, the units that had a risk probability index higher than 2.9 were classified as high risk units, those that had between 1-2.9 as intermediate risk units and those that had less than 1 as low risk units. According to the risk probability index, improvement measures were defined and priorities were set for each of them.

Results: A total 447 high-risk medications corresponding to 227 active ingredients were identified during the study period. The units showing a higher risk were: Intensive Care Medicine (10.51), Reanimation (4.01), and Palliative Care (3.90). Improvement actions (informative poster, visual identification, alerts, training and double checks) were defined and prioritised in accordance with the risk probability index.

Conclusions: Knowing the degree of risk of hospitalization units in the management of high-alert medications allows for the implementation of improvement plans in relation to the degree of vulnerability detected.

Introduction

Patients' safety in healthcare systems is a priority area and hence is reflected in the National Health System's 2015-2020 Patient Safety Strategy. Its objectives are focused on improving safety practices, risk management in healthcare, training and the involvement of patients-citizens¹.

The frequency of adverse events in hospitalised patients in the European Union (EU) is 8-12%, i.e., 1 death/100,000 inhabitants/year, which represents about 5,000 deaths/year².

In Spain, a number of studies have analyzed the inadequacy of the system in several healthcare areas. More precisely, ENEAS: a study of the adverse events related to hospitalisation, using a cohort of 5,624 inpatients from 24 Spanish hospitals, estimated that the incidence of patients with adverse healthcare-related events was 9.3% in one day. Of these events, 37.4% was related to medication³. Another study revealed that 53% of EU citizens reckoned that they could be potentially harmed when receiving hospital care. In Spain, 11.5% of respondents to the 2010 Health Barometer reported having suffered from medical error during hospital stay⁴.

All these events have an important socio-economic impact when one takes into account that they could be avoided 50-70% of the time and that they generate an additional annual budget expenditure of 5%. In the particular case of medication provided to inpatients, a 2011 study estimated that the cost of avoidable events to the National Health System (NHS) would be around € 1,779 million⁵.

This was the turning point on this subject. Many organisations like the Agency for Healthcare Research and Quality, the National Quality Forum, the Joint Commission and the World Health Organisation are working towards improving patients' safety. Their strategic lines establish working guidelines for implementing "safe practice standards". All of them lay particular emphasis on high-alert medications since they have a greater possibility of association with serious or fatal events. These organisations highlight that health institutions should identify such medications and establish procedures for their safe use in healthcare procedures¹.

The Institute for Safe Medication Practices (ISMP) has issued a classification of high-alert medications as well as the risk factors associated with their administration such as staff turnover, temporary jobs, training, identification, etc., and has in addition elaborated a guide to improve clinical practice when handling such medications⁶.

Ever since the 1950s and in a number of non-health related areas, the development and management of risk maps have been used as informative tools, which by means of descriptive information and appropriate indicators, facilitate the identification of certain activities or procedures subject to risk, and furthermore quantifies the probability of occurrence of such events and measures any associated potential harm^{7,8}.

Therefore, the objectives of this study are:

- To establish a risk map based on the use of high-alert medications in clinical units of a University Hospital.
- To classify hospital units into three risk levels in order to define and prioritise improvement and training measures in each of them.

de la ponderación de resultados, se clasificaron las unidades en tres grupos y se construyó el mapa de riesgo de medicamentos de alto riesgo en el hospital. En este se representaron las unidades que tuvieron un índice de probabilidad de riesgo mayor de 2,9 como unidades de alto riesgo, las que lo tuvieron entre 1-2,9 como unidades de riesgo intermedio y las que lo tuvieron menor a 1 como unidades de riesgo bajo. Y según el índice de probabilidad de riesgo en la unidad, se definieron y priorizaron las medidas de mejora para cada una de ellas.

Resultados: Se identificaron 447 medicamentos de alto riesgo en el hospital, correspondientes a 227 principios activos. Las unidades de mayor riesgo fueron: Medicina Intensiva (10,51), Reanimación (4,01) y Paliativos (3,90). Se definieron las acciones de mejora por índice de probabilidad de riesgo: póster informativo, identificación visual, alertas, formación y doble chequeo.

Conclusiones: Conocer el grado de riesgo de las unidades de hospitalización en el manejo de medicamentos de alto riesgo permite aplicar planes de mejora dirigidos en función de la mayor o menor vulnerabilidad detectada.

Methods

An observational and descriptive six month study was carried out in a high level University Hospital (with 1,200 beds and in area of 600,000 inhabitants). The scope of the study included adult clinical units at the hospital. It was developed in two phases:

1st Phase: "Design and development of a risk map relating to usage of high-alert medications"

A multidisciplinary group was first created (six pharmacists, two professionals from the quality assurance department and three consultants from the clinical-healthcare field: two doctors, one nurse). In a first stage, structured surveys were carried out to assess the opinion and knowledge of other professionals on high-alert medications.

A bibliography search was then conducted through PubMed on the handling of high-alert medications and the elaboration of risk maps. This information was used to identify the structure of the map⁹ and the severity levels of the high-alert medications. The high-alert medications from the Pharmacotherapy Guide were then identified using the ISMP^{6,10} classification as reference.

This information was used to define the criteria and factors that could bear a higher incidence when handling high-alert medications:

- Location: The number of high-alert medications handled (by location) in nursing units with adult inpatients (not performed by service since there were several services in one nursing unit).
- Staff turnover (ST): The high percentage of staff rotation in units requiring specialisation was considered to have a higher potential risk⁶. Data provided by the Human Resources Department was used to assess and classify units into three major groups: low rotation=1 point (average ratio-1 standard deviation), intermediate rotation=2 points (average ratio±1 standard deviation), and high rotation=3 points (average ratio medium+1 standard deviation).
- Frequency of event (FE): The occurrence of an event was considered to be related to the amount of high-alert medications handled in each unit. The rate of use of high-alert medications was defined as the *coefficient obtained upon dividing the number of high-alert medication units used in each clinical unit by the total number of medications used in that same unit*. Units with below average ratio -1 standard deviation were considered as low-risk (1 point), those with an average ratio+/-1 standard deviation were considered as medium risk (2 points), and units with an above average ratio+1 standard deviation were classified as high risk (3 points).
- Severity differences between high-alert medications: the lack of information on severity differences between high-alert medications events led us to survey medical and nursing staff, in order to weight in the severity of a possible high-alert medications adverse event, according to their perceptions in daily professional practice. It was voluntary, anonymous and targeted at professionals from different areas (medical, surgical and critical care units), in order to ensure that the final results were representative.

Table 1. Severity score of the different high-alert medications as per the score obtained in the perception survey of health professionals

	NURSING				DOCTORS				TOTAL			
	LEVEL 1	LEVEL 2	LEVEL 3	SEVERITY	LEVEL 1	LEVEL 2	LEVEL 3	SEVERITY	LEVEL 1	LEVEL 2	LEVEL 3	SEVERITY
Radiocontrast agents, IV	3	12	11	2.3	2	4	4	2.2	5	16	15	2.3
Inotropic medications, IV (e.g., digoxin, milrinone)	1	10	15	2.5	4	5	1	1.7	5	15	16	2.3
Adrenergic agonists, IV (e.g., epinephrine, phenylephrine, norepinephrine)		2	24	2.9	1	5	4	2.3	1	7	28	2.8
Anesthetic agents, general, inhaled and IV (e.g., propofol, ketamine)		5	21	2.8	2	2	6	2.4	2	7	27	2.7
Adrenergic antagonists, IV (e.g., propranolol, metoprolol, labetalol)	1	11	14	2.5	5	3	2	1.7	6	14	16	2.3
Antiplatelets agents IV (abciximab, tirofiban)	3	10	11	2.2	5	4	1	1.6	8	14	12	2.1
Antiarrhythmics, IV (e.g., lidocaine, amiodarone)	1	12	13	2.5	1	6	3	2.2	2	18	16	2.4
Anticoagulants (e.g., warfarin), factor Xa inhibitors (e.g., fondaparinux, apixaban, rivaroxaban)	4	14	8	2.2	4	4	2	1.8	8	18	10	2.1
Hypoglycemics, oral (acarbose, glimepirida, metformina...)	10	15	2	1.8	5	3	2	1.7	15	18	4	1.7
Neuromuscular blocking agents (e.g., succinylcholine, rocuronium)	1	13	11	2.3		4	6	2.6	1	17	17	2.5
Chemotherapeutic agents, parenteral and oral		11	15	2.6	1	2	6	2.3	1	13	21	2.6
Low molecular weight heparin, IV unfractionated heparin	2	20	7	2.4	4	5	1	1.7	6	25	8	2.1
Insulin, subcutaneous and IV (Actrapid®, Lantus®, Novorapid®...)	6	14	6	2.0	4	3	3	1.9	10	17	9	2.0
Moderate sedation agents, IV (e.g., dexmedetomidine, midazolam)	2	12	12	2.4	1	3	6	2.5	3	15	18	2.4
Liposomal forms of drugs (e.g., liposomal amphotericin B) Conventional counterparts (e.g., amphotericin B desoxycholate)	2	13	8	2.0	2	5	2	1.8	4	18	10	2.2
Epidural or intrathecal medications	1	7	16	2.4	1	5	3	2.0	2	12	19	2.5
Parenteral nutrition preparations	8	17	1	1.7	6	4		1.4	14	21	1	1.6
Narcotics/Opioids		11	15	2.6	4	5	1	1.7	4	16	16	2.3
Cardioplegic solutions	1	9	11	2.0	1	5	3	2.0	2	14	14	2.4
Dextrose, hypertonic, 20% or greater, sterile water for injection, inhalation, and irrigation (excluding pour bottles) in containers of 100 mL or more, sodium chloride for Injection, hypertonic, greater than 0.9% concentration	8	15	4	1.9	8	1		1.0	16	16	4	1.7
Dialysis solutions, peritoneal and hemodialysis	3	13	7	1.9	2	6	1	1.7	5	19	8	2.1
Thrombolytics (e.g., alteplase, reteplase, tenecteplase)	2	12	11	2.3		2	8	2.8	2	14	19	2.5
Potassium chloride for injection concentrate		3	23	2.9	1	2	7	2.6	1	5	30	2.8
Epoprostenol (Flolan®), IV	2	10	6	1.5	1	7		1.5	3	17	6	2.1
Methotrexate, oral, non oncologic use	8	14	2	1.6	6	4		1.4	14	18	2	1.6
Nitroprusside sodium for injection	1	11	12	2.3	2	8		1.8	3	19	12	2.3
Oxytocin, IV	3	18	4	2.0	2	7		1.6	5	25	4	2.0
Promethazine, IV	3	15	4	1.7	2	6		1.4	5	21	4	2.0
Magnesium sulfate injection	5	16	2	1.7	7	2		1.1	12	18	2	1.7

IV: intravenous.

Ten doctors and 26 nurses from the medical, surgical and critical care services that participated in the survey. Each high-alert medication was weighted 1-3 according to an average severity score (1=significant; 2=serious; 3=life-threatening). To obtain the final severity score, the average value was calculated taking into account the number of professionals who responded in each column and the severity they indicated. For example, a score of 20 corresponding to the Intravenous Contrast Agents = $[(3 \times 1) + (12 \times 2) + (11 \times 3)] / 3$ (Table 1).

A cumulative risk (CR) of severity for each unit was calculated using the formula: $\sum (\text{Severity of medication} \times \text{no. of medication units})$. The natural (Napierian) logarithm was applied to this score to reduce variability of values.

This was used to establish the risk probability index (RPI) = Staff Rotation (SR) \times FE \times LnCR.

For the descriptive analysis of the results the mean deviation standard was calculated in the case of the quantitative variables data, as well as the absolute and relative frequency in the case of the categorical variables.

2nd Phase: "Classification of hospitalisation units by risk"

The above parameters were used to classify units into three groups by assigning a colour code: high risk-red; medium risk-yellow; low risk-green.

Targeted risk prevention and training actions and strategies were then established in line with the risk map obtained^{6,10}.

Results

A total of 447 high-risk medications corresponding to 227 active ingredients were identified during the study period. The number of high-alert medications dosages dispensed was 195,287. Risk factors were assessed in 25 nursing units from 30 services.

The units that reported a greater use of high-alert medications as compared to the total number of medications used in the study period were Haematology (34.10%), Intensive Care Medicine (30.02%), Oncology (20.12%) and Reanimation (19.03%).

The severity survey results of the potential adverse events are shown in Table 1. Doctors indicated that thrombolytics/fibrinolytics, neuromuscular blocking agents and intravenous potassium can produce a higher severity event, while the nurses considered intravenous adrenergic agents, intravenous potassium and general anaesthetics as medications that can produce such an event. When asked what they believed could cause a high-alert medication event, 40.3% of the respondents mentioned dosage errors, 25.7% indicated lack of training or competence of staff high-alert medications, 18.2% thought that it could be caused by an incorrect administration route, while 15.8% felt that the type of population could determine the occurrence of a high-alert medication event.

The final map (after taking into account the factors described above) is shown in Table 2. Actions for improvement were agreed upon in accordance with the RPI risk number obtained, and they are described in Table 3. Low

Table 2. Event-probability risk map on the use of high-alert medications by hospitalization unit

Services	Staff rotation	Rate HAM/Med.	Ln cumulative risk	RPI
SSU/DT	2	0.09	9.34	1.63
ORT major/PS	3	0.11	10.33	3.38
ONC	1	0.20	9.95	1.99
ICC/ICS	3	0.11	8.21	2.80
NEF/DT	1	0.07	8.82	0.58
HAEM	1	0.34	10.30	3.54
CAR	3	0.11	9.37	3.04
URO/GDTS	2	0.06	9.06	1.05
PUL	1	0.08	9.35	0.72
IM	2	0.09	10.12	1.83
AVS/TS	2	0.10	9.48	1.92
GDTS	2	0.07	9.24	1.31
NRL/ICU	1	0.11	8.53	0.90
GYN	1	0.06	7.61	0.46
PSY	1	0.02	7.89	0.17
NRL/ENT	1	0.07	8.67	0.62
OBS	2	0.14	9.79	2.80
NRS	2	0.08	8.73	1.32
GER/RHEUM/REH/END/RDT	3	0.06	9.61	1.59
ORT minor	3	0.06	7.22	1.23
IMa	3	0.10	9.88	2.90
IMb	3	0.10	9.79	2.84
PCU/IM	3	0.14	9.60	3.90
ICM	3	0.30	11.64	10.51
ANR	2	0.19	10.81	4.01

ANR: anaesthesia and reanimation; AVS: angiology and vascular surgery; CAR: cardiology; DT: digestive tract; END: endocrinology; ENT: otorhinolaryngology; GDTS: general and digestive tract surgery; GER: geriatrics; GYN: gynaecology; HAM: high alert medication; HAEM: haematology; LN: neperian logarithm; ICC: intermediate care cardiology; ICM: intensive care medicine; ICS: intermediate cardiac risk surgery; ICU: stroke unit; IMa, IMb: internal medicine; Med: medication; NEF: nephrology; NRL: neurology; NRS: neurosurgery; OBS: obstetrics; ONC: oncology; ORT major: orthopedic major surgery; ORT minor: orthopedic minor surgery; PCU: palliative care unit; PS: plastic surgery; PSY: psychiatry; PUL: pulmonology; RDT: radiation therapy; REH: rehabilitation; RHEUM: rheumatology; RPI: risk probability index; SSU: short stay unit; TS: thoracic surgery; URO: urology.

Table 3. Strategies for prevention of adverse events with high-alert medications by risk classification

	Low risk	Medium risk	High risk
Availability of an informative poster on high-alert medications in the unit	Yes	Yes	Yes
Organisation of stock in the unit so that high-alert medications can be visually identified from the rest of the medications	Yes	Yes	Yes
Alert messages in the medical prescription informing about practical issues related to high-alert medications	Yes	Yes	Yes
Training in the use of high-alert medications prior to starting work in a clinical unit for the first time	No	To be considered	Yes
Double checking prior to dispensing medication with a high severity score	No	No	Yes
Regular update training about dispensation and administration of high-alert medications	No	No	Yes

risk measures were applied to clinical units with $RPI < 1$, medium risk measures to units with RPI between 1-2.9 and high-risk measures to units with $RPI > 2.9$.

Discussion

To the authors' knowledge, no similar study has been published to date and hence this work represents an innovative analysis model to address prevention strategies linked to high-alert medication errors in hospitals. Risk maps have exceptionally been used in the healthcare field and have always been focused on improving organisation¹¹.

The creation of a risk map permits assessment and knowledge of the risks inherent to each clinical unit in order to develop a structured corporate safety plan for high-alert medications in hospitalised patients based on real needs. This study has provided us with an insight not only into healthcare service provision relating to high-alert medications in a large hospital but also information on which units we need to establish more prevention measures in. These measures nevertheless follow the standards laid down by international safety bodies^{6,7}.

The criteria agreed upon to develop the map are not entirely novel. High staff turnover, temporary jobs, and the amount of high-alert medications have been recognised as key special action points for the prevention of errors^{1,6}. Nevertheless, to ascertain the influence of event severity in terms of whether error is due to one or more high-alert medications¹² or due to lack of training¹³, has been difficult to establish, as there are no standardised classification methods in this regard. Engels *et al.* (2015) presented a study carried out in the University of Michigan Health System (based on the use of surveys to determine training level and perceptions of high-alert medications), in which they concluded that the perception of high-alert medications differed depending on professional profile, and that specific educational measures needed to be implemented in each of them¹³. This conclusion is also reached in the present study, and therefore improvement strategies suggest the development of a tailored and targeted training itinerary.

Highest risk units detected in the study are similar to those documented in the bibliography section.

Critical care units are the ones at highest risk due to the amount of high-alert medications they handle and also in line with the results of this study, due to high staff turnover. It is striking to note that plastic and orthopedic surgery, which initially could be considered as low-risk units, are in fact at the top of the classification. This can be justified because of the large amount of low molecular weight heparins administered and the high staff rotation levels present.

The effectiveness of strategies for the prevention of medication administration errors with high-alert medications has been the subject of scientific study for years now. Examples are the use of smart infusion pumps¹⁴ or the reconciliation of medication in Emergency Departments¹⁵, and the implemen-

tation of administration protocols for high-alert medications in certain units. Additionally, Cuesta López *et al.* (2016) also analysed effectiveness in relation to vasoactive drugs in critical care units¹⁶. However, an analysis prior to overall handling of high-alert medications or the optimisation of measures to be implemented is hardly ever performed.

The main limitations of the study have been that we have not validated or calculated the sample size of the surveys on the potential severity of an error involving high-alert medications. Nevertheless, large prospective multicentre studies in hospitals of similar characteristics could improve this aspect.

In conclusion, this study describes a method of analysis to know how high-risk medication is managed in a high level hospital. The risk map allows us to detect, from a multidisciplinary approach, which are the most critical hospitalisation units. This makes it possible to prioritise which of them need more control and training measures on High alert medications.

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Conflict of interests

Second prize 2016 SEFH -VIFOR PHARMA on the quality of Pharmacy Services and Safety in the use of medications.

Contribution to scientific literature

This work presents the first mapping of the medication of high risk. This map is performed in a High level Hospital taking into account the rotation of personnel, the use of high-risk drugs and severity of them perceived by professionals. This has helped establish a stratification by risk in different hospital units in order to prioritise and implement actions of prevention and training, aimed at the needs of medical practice. On the other hand, the methodology used can serve as reference for any hospital in any health system.

Appendix 1

Coordinating Group on Safety in High-Alert-Medication in Xerencia de Xestión Integrada de Vigo, Vigo. Spain.

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