

Assessing risk of medication errors: a case study in a teaching hospital

Avaliação do risco de erro de medicação: estudo de caso em um hospital universitário

La evaluación del riesgo de errores de medicación: estudio de caso en un hospital universitario

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Abstract

In the health care process, patients are subjected to different hazards. Medication error is one of the most frequent causes of adverse events in hospitals. A risk assessment can provide evidence for the development of an action plan to mitigate, reduce or eliminate these hazards. The objective is to evaluate the risks to patients in the process of drug administration in a university hospital. A case study was carried out in a Brazilian teaching hospital with the use of the Failure Modes and Effects Analysis (FMEA) technique. Failures considered as high risks to cause adverse events to patients

are exchange of drugs delivered for dispensing, drug identified with the wrong label at the unitization process, lack of prescription standard for dose abbreviation, patient exchange due to inattention or name similarity, request for emergency care without prescription, and drug sent on the wrong shift. The use of FMEA was suitable for the identification and prioritization of risks, providing a basis to develop an action plan to enhance safety.

Key words: Medication Errors; Risk Management; Hospitals; Patient Safety.

Resumo

Nos processos de cuidados da saúde, os pacientes estão sujeitos a diferentes perigos. O erro de medicação é uma das causas de maior frequência dos eventos adversos que ocorrem nos hospitais. Uma avaliação de riscos pode subsidiar a elaboração de um plano de ação para mitigar, reduzir ou eliminar esses perigos. O objetivo é avaliar os riscos aos pacientes no processo de administração de medicamentos em um hospital universitário. Foi realizado em estudo de caso em um hospital

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universitário, localizado no Brasil, e a técnica utilizada foi *Failure Modes and Effects Analysis* (FMEA). As falhas com risco alto que podem ocasionar um evento adverso ao paciente são: troca de medicamentos na entrega para dispensação, medicamento identificado com a etiqueta errada no processo de unitarização, falta de padrão para abreviatura da dose na prescrição, troca do paciente por desatenção ou semelhança do nome, solicitação para atendimento de emergência sem prescrição e medicamento enviado no turno errado. O uso da ferramenta foi adequado para identificação e priorização dos riscos, possibilitando a elaboração de um plano de ações de melhoria para tornar o processo mais seguro.

Descritores: Erros de Medicação; Gestão de Riscos; Hospitais; Segurança do Paciente.

Resumen

En el proceso de atención de la salud, los pacientes están sujetas a diferentes peligros. El error de medicación es una de las causas más frecuentes de los eventos adversos que ocurren en los hospitales. La evaluación del riesgo puede apoyar el desarrollo de un plan de acción para mitigar, reducir o eliminar estos peligros. El objetivo es evaluar los

riesgos para los pacientes en el proceso de administración de medicamentos en un hospital universitario. Se llevó a cabo en un estudio de caso en un hospital universitario, que se encuentra en Brasil, y la técnica utilizada fue lo *Failure Modes and Effects Analysis* (FMEA). Las fallas de alto riesgo que pueden causar un efecto adverso para el paciente son: intercambio de administración de fármacos para dispensar, drogas identificado con la etiqueta equivocada en proceso unitarización, la falta de norma para acortar la dosis en la prescripción, paciente de cambio por falta de atención o nombre similar, solicitud de atención de emergencia sin receta y el intercambio de turno para enviar la droga. El uso de la herramienta es adecuado para la identificación y priorización de los riesgos, lo que permite el desarrollo de un plan de acciones de mejora para hacer el proceso más seguro.

Descriptores: Errores de Medicación; Gestión de Riesgos; Hospitales; Seguridad del Paciente.

1. Introduction

The potential result of an adverse event occurring in a hospital may be dramatic for the patient and in

an extreme situation it may lead to the patient's death. In a research conducted in the United States of America, adverse events were identified in 3.7% of hospital admissions and 27.6% of the events occurred due to negligence, which means they could have been avoided ^(1,2). Brennan *et al.* ⁽¹⁾ point out that not all adverse events result from low quality care; nor does its absence necessarily indicate good quality care – e.g., the reaction to a drug that has been appropriately prescribed for the first time to a patient is an adverse event that is often unavoidable. In another study conducted in Canadian hospitals, the adverse events rate was 7.5% per 100 hospital admissions; events judged to be preventable occurred in 36.9% and 20.8% resulted in the patient's death ⁽³⁾. More recently, De Vries *et al.* ⁽⁴⁾ conducted a literature review on the theme and identified a 9.2% average rate of adverse events, of which 43.5% were avoidable. In all these studies, medication error was among the most common adverse events.

In Brazil, medication error is included among the six critical themes of the patient safety policy. The themes are supported by protocols and are included in the National Patient Safety Program launched in April 2013 by the Ministry of Health (*Ministério da Saúde*

– MS) and the National Sanitary Surveillance Agency (*Agência Nacional de Vigilância Sanitária – ANVISA*) ⁽⁵⁾. The aim of the Program is to reduce the incidence of adverse events in the country's health services and establish measures to improve patient safety and the quality of services.

The objective of this article is to carry out a qualitative assessment of risks to patients in the processes of medication management (entry and storing) and dispensing in hospitals. The assessment technique used is the Failure Modes and Effects Analysis (FMEA). The work is structured in five sections: literature review, method, results and discussion, and final considerations.

2. Literature review

According to Runciman *et al.* ⁽⁶⁾, patient safety knowledge has been hampered by inconsistency in language use, meaning that similar concepts have different terms and the same term is used for different concepts. Runciman *et al.* ⁽⁶⁾ have conducted an ample research on terms and concepts, and have defined 48 preferential terms proposed for use in research on the theme of patient safety. In this article, we will use the term 'patient' for the

person who receives health care, i.e., services to promote, maintain, monitor, or restore his/her health; and the term ‘patient safety’ for the reduction to a minimum acceptable level of risk of unnecessary harm associated to health care. Additionally, the term ‘medication error’ will be considered, as defined in the Medication Errors Manual — Definitions and Prevention Strategies (“*Manual de Erros de Medicação - Definições e Estratégias de Prevenção*”) ⁽⁷⁾, as a preventable event occurred at any phase of medication therapy, which may or not cause harm to the patient. Medication errors can be classified in thirteen types: prescription error, dispensing error, omission error, timing error, non-authorized drug administration error, dose error, presentation error, preparation error, administration error, deteriorated drugs error, monitoring error, error due to non-adherence of patient and family, and other medication errors.

According to Reason ⁽⁸⁾, the notion that errors can be active (having immediate adverse results) or latent (possibly existing for a long period before combining with local generating factors and penetrating the system’s defense) justifies the creation of a model of ‘barriers’ to avoid that the error reaches the patient.

Reason ⁽⁸⁾ draws on the assumption that it is impossible to eliminate human and technical failures. To err is human, but there are mechanisms to avoid the error and mitigate adverse events. According to Leape *et al.* ⁽⁹⁾, the guiding principle of this approach is that adverse events are not caused by bad persons, but rather by systems that have been badly designed and produce negative results. This concept has been transforming the focus on the ‘individual error’ into the focus on the ‘systems defects’. Although the main focus regarding patient safety has been on the implementation of safety practices, it becomes increasingly more evident that reaching a high level of safety in health organizations requires much more than this. Two trends have been rising: the recognition of the importance of greater involvement of patients in their own care, and the need of transparency in the processes.

Reason ⁽⁸⁾ characterizes the main risk factor in hospitals as being the persons, because human error is the main cause of adverse events. The major contribution of human error is more a question of opportunity than the result of excessive lack of care, ignorance, or imprudence. However, regardless of the actual number, human behavior, for good or evil, clearly

prevails over the risks for the modern technological systems in all areas, not only in health. Therefore, adverse events are seldom determined by a sole error, be it human or technological, but rather result from a chain of errors and events in which the person responsible for the final error is only the last causal link.

In order to mitigate or eliminate errors, many organizations that manage human risks have been concentrating on trying to avoid the repetition of specific errors and violations. Internal common answers to these events are the definition of new procedures that forbid a particular behavior; the design of 'retro-fix' engineering that will hinder the actions with adverse results; sanctions and training of key persons in an effort to make them become more careful; and the introduction of more automation.

Counter-measures may create a false sensation of safety. As modern systems are usually highly trustworthy, there might be a span of time between the implementation of measures related to personnel and the next accident. During this period, those who have instituted the changes will be inclined to believe that the problem has been solved. But then another accident happens, and the cycle of corrective

actions begins once again. Such accidents tend to be seen as isolated, rather than being seen as a symptom of a systemic problem.

The aim of an efficient risk management is not to minimize particular errors and violations, but to improve human performance at all levels of the system. According to Pritchard ⁽¹⁰⁾, risk management is a method that concentrates on the identification and control of areas or events that have a potential to cause undesirable changes. Four pillars sustain the risk management process: procedures, tools, human resources, and training.

According to Kessels-Habraken *et al.* ⁽¹¹⁾, hospitals have been using retrospective methods to analyze errors and prevent recurrence. However, the aim to minimize harms to patients highlights the need to identify risks in a prospective way and foresee errors. Several prospective analysis techniques are available and, despite the differences between methods, all of them seek to identify, evaluate, and eliminate or reduce risks before they may occur: FMEA; Failure Modes, Effects, and Criticality Analysis (FMECA); Health Care Failure Modes and Effects Analysis (HFMEA); e Hazard Analysis and Critical Control

Point (HACCP) ^(6,11-19).

The Joint Commission on Accreditation of Health Care Organizations (JCAHO) is a United States-based not-for-profit organization that accredits health care organizations, and is considered the largest and most acknowledged worldwide organization in the health area. Since 2001, the JCAHO has been requiring that all accredited hospitals carry out yearly at least one proactive risk assessment. The recommended tool is FMEA ⁽¹⁸⁾. A step-by-step manual is provided to help implementing the technique ⁽²⁰⁾.

According to Cagliano, Grimaldi e Rafele ⁽¹⁵⁾, FMEA is the most used technique in the health area for the reduction of risks to patients. According to Kessels-Habraken *et al.* ⁽¹¹⁾, the analysis consists in the identification of risks and frequency evaluation, with a process of identification of the effects of errors associated to individual failures within a system. A limitation of the tool is that it does not analyze multiple risk factors together; it is always an individual analysis ⁽¹⁸⁾.

Bonnabry *et al.* and Kessels-Habraken *et al.* ^(11,14) have cited FMEA e HFMEA techniques as being synonymous; however, DeRosier *et al.* ⁽¹⁶⁾ define HFMEA as a hybrid model. HFMEA was developed by the

Department of Veterans Affairs (VA) National Center for Patient Safety (NCPS) with the support of Tenet Health System (Dallas). It is a prospective analysis model combining concepts found in FMEA and HACCP, as well as in tools and definitions of the root cause analysis (RCA) process, besides using a interdisciplinary team, process flow, failure modes and identification of failure mode causes, risk scoring matrix, and decision tree algorithm for the identification of vulnerabilities of the system, where actions and outcome measures are developed and managed.

3. Methodology

The method selected for this article was the single-case study and the technique applied was the FMEA. The main reason that health organizations use this technique is that there is evidence that it reduces error risks and increases process performance ⁽²⁰⁾. The selection of the particular hospital for the case study was made out of convenience, due to the possibility to carry out the research. The work was conducted in the following stages: (i) selection of a high risk process and definition of participants; (ii) development of research protocol; (iii)

detailing of process flow; (iv) brainstorming on potential failure modes and identification of their effects; (v) prioritization of failure modes; (vi) identification of root causes; and (vii) proposition of actions for processes improvement.

For the composition of the team, senior professionals were invited and staff responsible for the processes was selected. Hospital staff taking part in the risk assessment had over 20 years of experience in the area and post-graduate higher education. Production engineering master’s post-graduate students also took part in the team as facilitators for the FMEA technique implementation. Data collection was made by means of interviews, group discussions and in loco visits. The

interviews were based on the research protocol, which was structured in two sections: the first section was composed of general questions about the area, structure, responsibilities, and organization; the second part comprised specific questions about the processes, dangers, probability of occurrence, and consequences to patients. The interviews were recorded and transcribed soon after being recorded.

The prioritization of failure modes was made in three stages: probability of occurrence, severity, and risk assessment. The scales used for the assessment of the three parameters were previously discussed and validated. For the analysis of severity, four categories were considered, as described in Chart

CHART 1 – Categories of severity assessment.

Severity	Description of result to patient	Score
<i>Catastrophic</i>	<ul style="list-style-type: none"> ▪ Obit of patient ▪ Irreparable consequences to patient’s health ▪ Loss of function or organ 	4
<i>Severe</i>	<ul style="list-style-type: none"> ▪ Relevant worsening of patient’s health condition ▪ Consequences to patient’s general health condition ▪ Increase in hospitalization time 	3
<i>Moderate</i>	<ul style="list-style-type: none"> ▪ Temporary worsening with easy recovery of patient’s condition ▪ Without future consequences to patient’s health 	3

	condition <ul style="list-style-type: none"> ▪ No increase in hospitalization time 	
<i>Minor</i>	<ul style="list-style-type: none"> ▪ Without worsening to patient's condition ▪ Without consequences to general health condition ▪ No increase in hospitalization time 	1

Source: DeRosier *et al.* ⁽¹⁶⁾.

For the analysis of probability of occurrence, four categories were considered, as described in Chart 2. In this stage, when there were no available

data, the probability was estimated by the professionals drawing on their own experience.

CHART 2 – Categories of probability evaluation

Probability	Description	Score
<i>Frequent</i>	May occur immediately or within a short period of time (may occur a few times along the year)	4
<i>Ocasional</i>	Probably it will occur (may occur a few times along one or two years)	3
<i>Unusual</i>	Possibly it will occur (may occur once every 2 to 5 years)	2
<i>Remote</i>	Very small probability that it will occur (may occur once every 5 to 30 years)	1

Source: DeRosier *et al.* ⁽¹⁶⁾.

For the conclusion of the prioritization of risks, the Risk Priority Number (RPN) was calculated. The RPN was obtained from the multiplication of the scores of probability and severity. This index was used to establish the ranking of

priorities of failure modes. Chart 3 shows the categories of risks assessment. RPN values equal to or higher than 8 are considered as high and 'intolerable' risk, therefore in need of attention and a procedure revision.

CHART 3 – Categories of risk assessment

Probabili	Severity or Effect			
		Catastrophic	Higher	Moderate

	Frequent	16	12	8	4
	Ocasional	12	9	6	3
	Unusual	8	6	4	2
	Remote	4	3	2	1

Source: DeRosier *et al.* ⁽¹⁶⁾.

Note: grey cells indicate High risk category and white cells indicate Moderate or Low risk categories.

Subsequently, the root cause analysis was carried out and corrective actions were proposed. This study did not comprise the re-design of the process, the analysis and testing of a new process, nor its implementation.

4 Results and discussion

This section is structured in two parts. The first part presents the case study comprising a description of the assessed processes. The second part presents the risk analysis.

4.1 Case study

Data were collected at the division of pharmacy of a secondary public hospital in the State of São Paulo, Brazil. The study was carried out by means of the analysis of management and dispensing processes. Due to the existence of a large interface, the research identified some failure modes in the prescription process; the results presented in this article do not cover the entire process, but some are cited because of their relevance and

interdependence with the dispensing process.

The hospital’s division of pharmacy is structured in three basic services: (i) Hospital Pharmacy – management area responsible for the acquisition, stock control, and evaluation of the quality and quantity of medicaments; (ii) Pharmacothechnique and Dispensing – responsible for the supply to individual needs of hospitalized patients; the pharmacothechnique prepares non-sterile medication according to medical prescriptions, and the dispensing is responsible for supplying the medication to hospitalized patients according to the medical prescription, by means of the Direct Individualized System, duly revised by the pharmacist; oral use medication is dispensed, ready for administration, in the doses specified in the prescription; and (iii) Clinical Pharmacy – responsible for the development of activities to optimiz

the patient's medication therapy, hence contributing to reducing the patient's length of stay in hospital.

The management process is the entry door of medicaments to be used in patients' health care. The materials are initially received at the general storage, and when they are pharmacy supply they are forwarded to the Service of Hospital Pharmacy. Upon arrival, the medicaments are checked and registered in the stock control system. The qualitative check evaluates critical items such as batch, validity, specification, concentration, among others. After updating the system, the medicaments are stored in one of the three available storages: large volumes storage, inflammable materials storage (external area), and medicaments storage.

The stock control system has the registry of homologated suppliers, catalogs of active principles, and homologated trademarks. Those trademarks not yet registered are checked and, when necessary, adjustments are made in the registry, or the material is not accepted. The registry is made with information for quality control, validity, and batch. Batch control is the most important because it enables the product's traceability. There is also the action of

segregation of controlled medicaments according to Directive 344/98 of the Ministry of Health, medicaments that require refrigeration, and other medicaments. Additionally, there is an area of the storage named 'quarantine', where storage is made of batches under suspicion for quality problems, batches in which punctual problems are identified, expired medicaments, and medicaments brought to hospital by patients who did not take them away.

Before being sent to dispensing, there is the process of unitization of pills, i.e., separation in smaller units (individual or double) of medicaments that are packed in blisters with several units; these smaller units are then individually labeled. Controlled injectable medicaments (ampules) are individually labeled, with the batch, and are registered with the barcode for control of the patient's use, to enable traceability.

Liberation of medication from the medicaments stock is made after the request of the dispensing service. Medication is dispensed directly from the stock to patients only in some specific programs of the hospital, e.g., tobaccoism treatment program, requiring only medical prescription.

The dispensing process is part of

the process of medication use, which comprises three basic stages: (i) prescription, where the physician indicates the medication that the patient should receive, how, when, and in what dose; this is made in a specific form, with the participation of a dedicated pharmacist by clinical specialty – hence, prescription errors may be identified at the beginning of the process, avoiding greater deviations, as well as possible consequences to patients – and a copy is sent to the area of dispensing; (ii) dispensing, when the medication is collected at the pharmacy, for later liberation and distribution; and (iii) administration, when the nurse administers the medication to the patient.

At the dispensing, the confirmation of the supply of prescribed medication is made in a form (*protocolo de atendimento da prescrição*) that is filled by hand, since the hospital does not have an automatized system for this task. The identification of the patient on this form is made with an adhesive label, which has a barcode containing the patient's name, place of hospitalization, age, gender, and an

4.2 Risks Analysis

Table 1 shows the analysis of risks of the management process, using

internal identification code. In this stage, the medication is double-checked, by two technicians, with the purpose of mitigating errors. Another relevant aspect to be mentioned about the prescriptions is related to abbreviations; although many prescriptions admit abbreviations, there is a strong recommendation from the pharmacy's direction in the sense that these should not be used, with the purpose of not causing medication errors. Periodically, the hospital carries out campaigns and training on this theme.

Medication is sent separately by patient and by shift, according to the prescription, i.e., the prescription has a daily validity. For each shift there is a set of medication that is individually separated and sealed. Even though the procedures involve carefulness, some errors may occur, particularly regarding patients' names on the labels, and especially in the pediatrics sector. This problem usually occurs due to the birth of twins, or due to many children with similar names: famous artists' names in a specific period and football players' names, among others.

FMEA technique. For the evaluation of severity, it was considered that it will be higher when there is a medication error

that can possibly cause a direct impact on the patient. In the management process, the two failure modes with the highest potential risks are the exchange of medication and exchange of labels. In the first situation, the potential cause with higher impact is related to similarity of packages. As packages differentiation depends on the suppliers, in order to have a more extensive action it will be necessary to have changes in the legislation, so that the process becomes mandatory. Punctually, though, requests are made to industries; however, this is only dealt with on the

commercial sphere, during negotiation.

In the management process, another item with high potential risk is the wrong label, due to failure in the unitization of medication, since the process is quite manual due to the lack of blisters standardization. Some industries produce blisters with an identification code on every pill, and the implementation of a “data matrix” barcode reader would be the action with higher impact on the reduction of this risk.

TABLE 1 – Risk Evaluation (FMEA) – Medicaments Management Process.

Failure Modes	Potencial causes	Potencial Effects	S	P	RPN	Proposed actions for failure modes reduction
Refrigeration failure	Energy failure. Generator out of order. Refrigerator out of order upon energy re-establishment.	Lack of medicament, especially rare, more expensive or not standardized medicaments.	4	1	4	Increase contention measures: spare box, not open refrigerator. Increase refrigerators maintenance.
Exchange of medicaments at delivery for dispensing	Packages similarity. Not standardized packages, especially injectable drugs.	Medication error	4	3	12	Request suppliers to change packages. Individual labels. Send different ampule, from another batch, even if not following the rule of the older batch. Identify packages with colored ribbons.
Wrong medicament	Lack of attention. Lack of personnel. Work overload.	Medication error	4	1	4	Labels with codes for automatized reading. Double checking at dispensing.

Wrong label or package	Unitization failure.	Medication error	4	3	12	Second ckecking at dispensing.
	Lack of personnel.					Implementation of "data matrix" barcode reader. Blister standardization from suppliers.
	Work overload.					
Wrong entry in stock	Lack of attention.	Medication error	2	3	6	Revision of entry procedures.
	Wrongly made entry.					Increase training of staff responsible for entry.
	Wrong qualitative evaluation. Exchange of medicaments.					

Note: S = Severity; P = Probability; RPN = Risk.

Table 2 shows the analysis of risks for the processes of prescription receipt and dispensing. In the evaluation of risks in the dispensing process, the analysis started in the prescription stage. In this process, four failure modes were identified as high critical degree, i.e., RPN equal to or higher than eight: manual prescription with nomenclature error, wrong patient,

prescription without documentation for emergency care, and medication sent in the wrong shift. For the failures identified in the manual prescription, the implementation of a system would significantly contribute to the reduction of risk to patient. However, this action requires investment and approval from higher instances.

TABLE 2 – Risk Evaluation (FMEA) – Medication prescription and dispensing processes

Processes	Failure modes	Potencial causes	Potencial effects	S	P	RPN	Actions for recovery of failure modes
Prescription	Manual prescription	Nomenclature	Medication error	3	3	9	Training and apprenticeship practices.
	Prescription with errors	Doses error	Medication error	3	2	6	Follow-up by a pharmacist for each clinical specialty.
	Wrong patient	Lack of attention. Similar names	Medication error	3	4	12	Check medication versus prescription.

Dispensing	Prescription without document.	Urgent treatments	Medication error. Specific administration.	3	3	9	Guidance.
	Prescription error.	Illegible handwriting	Error at dispensing and administration	2	2	4	Guidance.
	Prescription error.	Abbreviations	Error at dispensing and administration	2	2	4	Standardize abbreviations.
	Prescription error.	Nomenclature	Error at dispensing and administration	2	3	6	Training
	Duplicity in prescription	Exchange of prescription	Error at dispensing and administration	2	3	6	Patients in more than one shift: checking prescription with previous shifts.
	Shift replacement in medication	Exchange of bags	Error at dispensing and administration, due to exchange of medication.	3	3	9	Training on procedures.

Note: S = Severity; P = Probability; RPN = Risk

5 Final considerations

From the evaluation of the process, it was possible to verify that there are high risks to patient safety in the process of medication administration, if prevention measures are not implemented. It is a process that and errors in information transfer from another, among others. However, safe processes and continued training are crucial.

It is also important to stress the increasing relevance of the issue of risk management in hospitals. The use of

is performed most of the time by people and, therefore, subject to errors.

Process computerization may significantly contribute to the reduction of some dangers: wrong reading of blisters, wrong patient, illegible handwriting, abbreviations, one form to FMEA technique has become a requirement for the accreditation of hospitals by JCAHO. In Brazil, less than 5% of all hospitals are accredited, and this article may help in the understanding of

the tool, with the presentation of a case study on a critical issue. The use of the technique was suitable, considering that the main risks were identified in the evaluated process.

Another aspect to be highlighted is the fact that the study was carried out with a multidisciplinary team. The health professionals have contributed with the technical knowledge of the process, and the production engineering professionals with the FMEA technique knowledge. In this movement of quality tools implementation in the health area, the production engineering area may offer great contribution by providing the tools that have already been consolidated in the industrial sector.

The factors considered as limiting to this research are the following: the assessment did not include all the processes involving the administration of medication in the hospital; the assessment was made in one single hospital; the analysis was restricted to patients, and did not consider the risks to workers involved, the hospital's image, among others.

In future researches, this study could be deepened with the analysis of the index of detectability for each failure mode. Additionally, it is suggested that a quantitative analysis of

the risks considered as high, i.e., with levels of risk equal to or higher than eight, is carried out, as well as the re-design of the process and its implementation.

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Participação dos autores:

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