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Segurança no uso de medicamentos

CENÁRIO MUNDIAL E NACIONAL DO PROCESSO DE ADMINISTRAÇÃO DE MEDICAMENTOS

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Sistema de Medicação

“O sistema de medicação é complexo, aberto e, como os demais sistemas possui entradas (inputs), processos (process) e saídas (outputs).

“O resultados do sistema, assim como o de cada um de seus processos devem ser avaliados e devolvidos ao ambiente (feedback), como forma de informações que permitam identificar e corrigir possíveis desvios encontrados.”

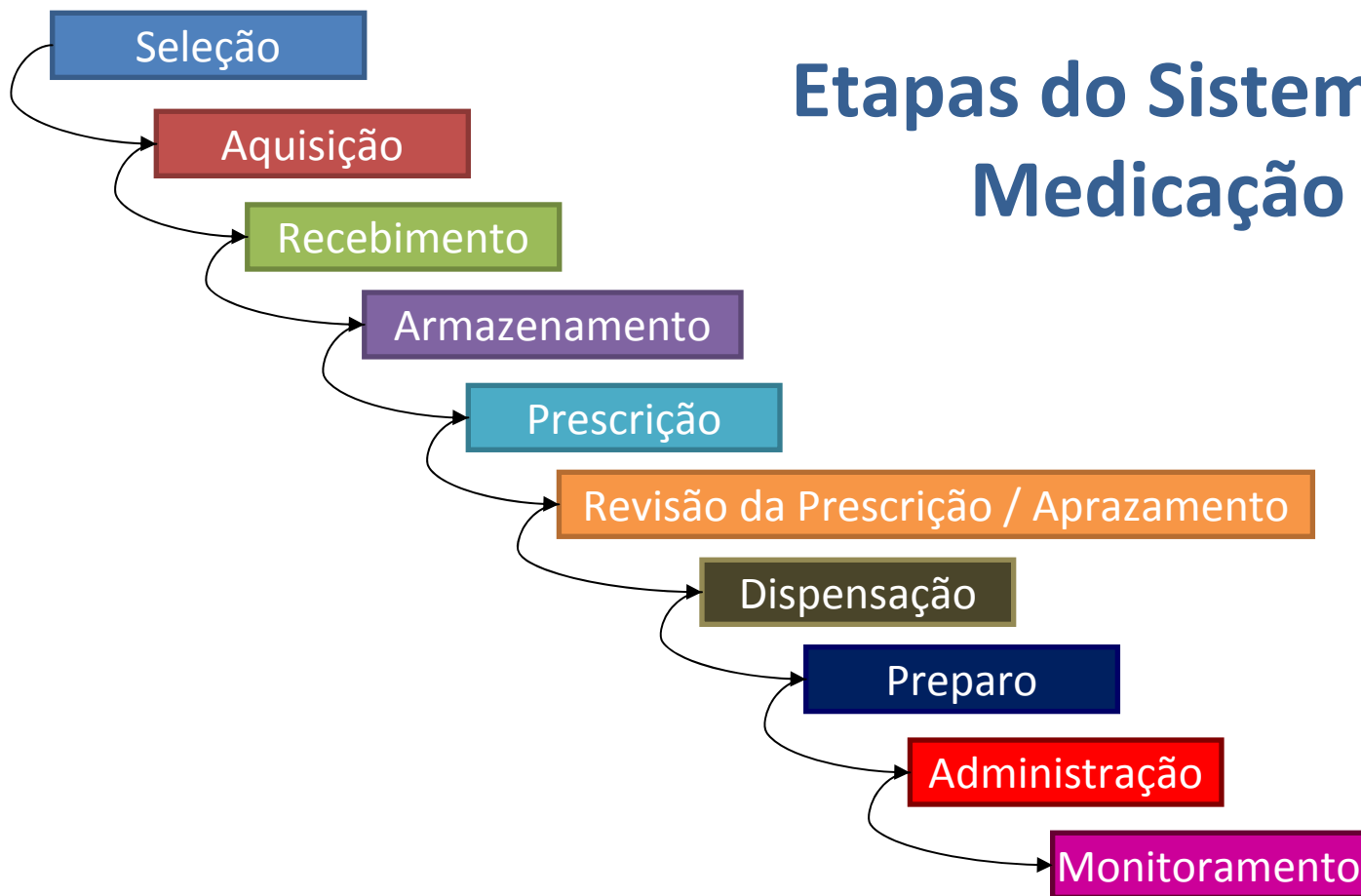
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Etapas do Sistema de Medicação



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Vulnerabilidade do Sistema de Medicação

“O sistema de medicação, composto por
vários processos interligados e interdependentes,
envolvendo multiplicidade de planejamento e
implementação de ações pela equipe de saúde,
produz um contexto entrelaçado de situações
que podem ser facilitadoras para erros.”

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Histórico – Alguns marcos relacionados a segurança do paciente na Administração de Medicamentos

1960

- Estudos nos EUA, Inglaterra e Canada, demonstravam taxa de erro de medicação nos hospitais aproximadamente 1 erro/paciente/dia (excluindo os erros de administração em hora errada)

1982

- *American Journal of Hospital Pharmacy* publicou um artigo que mensurou os erros de medicação em um residencial de idosos e pequenos hospitais.

1999

- IOM publica *“To Err is Human: Building a Safe Health System”*. (Intensifica a abordagem do tema, as consequências e os custos envolvidos).

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Histórico – Alguns marcos relacionados a segurança do paciente na Administração de Medicamentos

2001

- IOM publica “Crossing the Quality Chasm: A New Health System for the 21st Century”

2006

- WHO – Patient Safety Program – High 5s. Pontos abordados relacionados com a administração de medicamentos (**Manejo de Medicamentos injetáveis de alta concentração; Assegurar a continuidade do uso das medicações necessárias durante a transição dos cuidados**).

2006

- IHI - The 5 Million Lives Campaign. Pontos abordados relacionados com a administração de medicamentos (**Prevenir dano decorrente de uso de High-Alert/ Prevenção de Eventos Adversos relacionados a reconciliação medicamentosa**).

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Histórico – Construção de um Sistema de Notificação

1975

- ISMP divulga o sistema de notificação MER Program (Medication Errors Reporting): notificação voluntária.

1984

- FDA implanta um sistema eletrônico (MedWatch) para que os fabricantes notifiquem eventos com conseqüências graves e morte.

1990

- É ampliado o escopo de notificação ao FDA, passando a receber notificações de hospitais e residenciais de idosos.

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Histórico – Construção de um Sistema de Notificação

1995

- The National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) – criou um sistema de notificação para estimular a notificação de todos, com preocupação de comunicação entre as instituições.

1996

- A Joint Commission inicia sistema de notificação de eventos sentinelas. Os eventos notificados deveriam ser analisados por meio da aplicação de análise da causa-raiz.

1998

- NCC MERP definiu taxonomia para a notificação dos erros de medicação

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Histórico – Construção de um Sistema de Notificação

1998

- A USP (United States Pharmacopeia), disponibiliza o sistema de notificação MedMARx : notificação anônima das instituições cadastradas.

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O que é Erro de Medicação?

“Erro de medicação é definido como qualquer evento evitável que pode ser causado ou surgir do uso inconveniente ou falta de uma medicação, causando dano ao paciente, enquanto a medicação está sob o controle dos profissionais de saúde, pacientes ou consumidor. Tais eventos podem estar relacionados à prática profissional, aos produtos para o cuidado à saúde, procedimentos e sistemas, incluindo a prescrição, comunicação da prescrição, rótulo do produto, embalagem e nomenclatura; à composição, à distribuição, à administração; à educação dos enfermeiros e pacientes; à supervisão e uso.”

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Sistemas de Notificações Eletrônicas

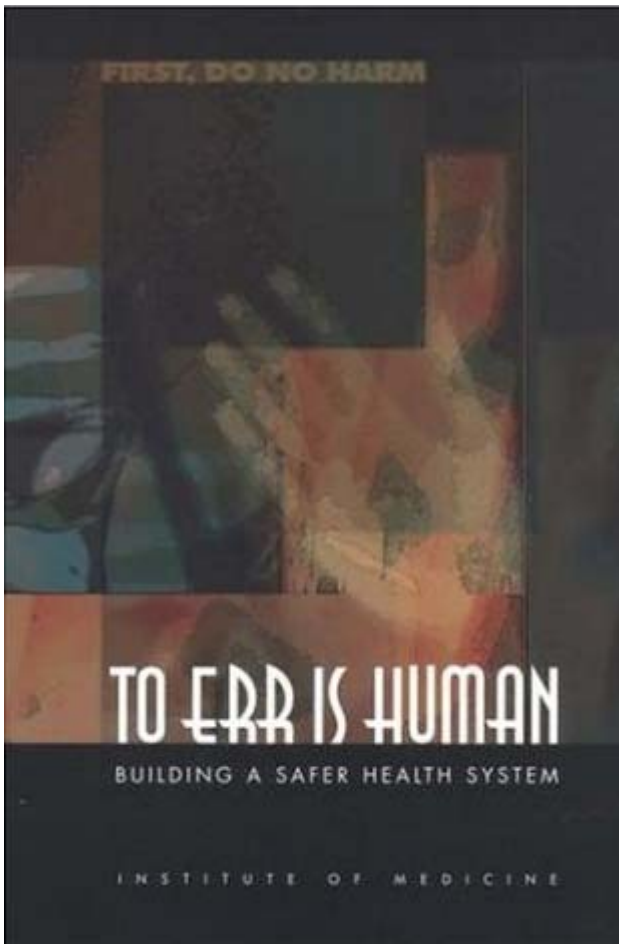
- State Adverse Event Tracking;
- FDA;
- MedWatch;
- Adverse Event Reporting System;
- Center for Biologics Evaluation and Research;
- Center for Error and Accident Reporting System;
- Vaccine Adverse Event Reporting System;
- Manufacturer and User Device Experience Database;
- JCAHO Sentinel Event Reporting;
- USP-ISMP Medication Error Reporting Program;
- Canada - ISMP
- USP MedMarx;
- Emergency Care Research Institute Medical Device Safety Reports.

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IOM (Institute of Medicine)



“When extrapolated to the over 33.6 million admissions to U.S. hospitals in 1997, the results of the study in Colorado and Utah imply that at least 44,000 Americans die each year as a result of medical errors.³ The results of the New York Study suggest the number may be as high as 98,000.⁴”

“Total national costs (lost income, lost household production, disability and health care costs) of preventable adverse events (medical errors resulting in injury) are estimated to be between \$17 billion and \$29 billion, of which health care costs represent over one-half.⁷”

Medication errors alone, occurring either in or out of the hospital, are estimated to account for over 7,000 deaths annually.⁹

“Errors are signs of sick systems, not bad people. It makes no sense to punish individuals for errors.”

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IOM (Institute of Medicine) - Recomendações

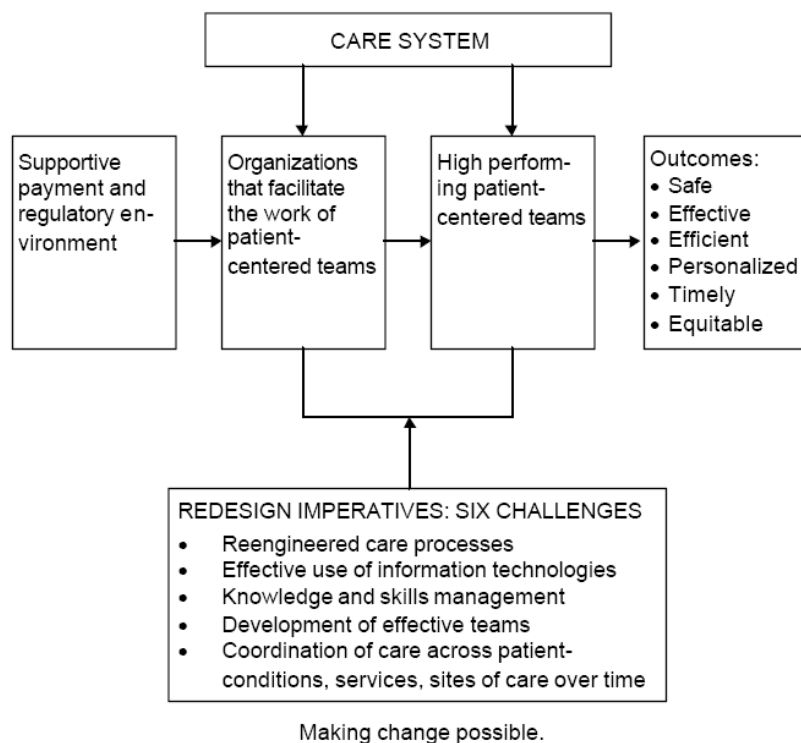
- Criação do “Center for Patient Safety” dentro da “Agency for Health Care Policy and Research” para definir metas nacionais de segurança em saúde.
- Sistema para notificação obrigatório de eventos com dano grave e morte.
- Criação de agência que certifiquem a qualidade dos serviços de saúde por meio de estabelecimento e checagem de padrões de qualidade.
- Implantação de um programa de segurança ao paciente nas organizações de saúde (cultura de não punição para a notificação dos erros, implementação de processos seguros na atuação, e adoção de práticas seguras no manejo de medicamentos).

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IOM (Institute of Medicine)



Strategy for Reinventing the System

Frente o diagnóstico de “To Error is Human”, a atual publicação orienta quais são os “passos” que as instituições de saúde devem seguir, para alcançar a segurança no atendimento aos pacientes.

INSTITUTE OF MEDICINE

March 2001

Shaping the Future for Health

CROSSING THE QUALITY CHASM: A NEW HEALTH SYSTEM FOR THE 21ST CENTURY

The U.S. health care delivery system does not provide consistent, high-quality medical care to all people. Americans should be able to count on receiving care that meets their needs and is based on the best scientific knowledge--yet there is strong evidence that this frequently is not the case. Health care harms patients too frequently and routinely fails to deliver



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IOM (Institute of Medicine)

- A Publicação do IOM “Crossing the Quality Chasm: A New Health System for the 21st Century”, reafirma que os erros de medicação são comuns e custam (o que nos dá a visão de que não somente se pensa no dano ao paciente mas também no custo que isso envolve).
- Os erros acontecem em todas as fases do processo de administração de medicamentos, porém foi identificados que estão em maior frequência na etapa de prescrição e administração (Recomendam fortemente o uso de prescrição eletrônica)
- Orienta uma maior participação do paciente no seu tratamento:
 - conhecendo o medicamento administrado,
 - fazendo parte na decisão do seu tratamento medicamentoso;
 - monitorando a administração de medicamentos e reportando eventos adversos
 - (o paciente passa a assumir papel importante na prevenção dos erros de medicação). – para isso deve-se disponibilizar informação ao paciente (internet, serviço de consulta telefônica).

Partin B, Prevention Medication error: A IOM Report. Nurse Practitioner. 2006. Dec; 31(12):8

Institute of Medicine. *Crossing the quality chasm: a new health system for the 21st century*. Committee on Quality Health Care in America, Institute of Medicine, National Academy Press, 2001

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Iniciativas - Legislação

2006 Publicação IOM

- Conclui que pelo o menos 1,5 milhões de eventos adversos relacionados ao uso de medicamentos acontecem nos Estados Unidos ao ano. Cada paciente tem pelo menos 1 evento adverso com medicamento por dia.

Legislação

- 15 estados aprovaram leis destinadas a reduzir os erros de prescrição de drogas, incluindo o Arizona, Colorado, Delaware, Flórida, Idaho, Illinois, Louisiana, Maryland , Massachusetts, Michigan, Montana, Dakota do Sul, Tennessee, Texas e Washington. (As leis referem-se a legibilidade das prescrições, rotulagem correta de medicamentos, incentivo ao uso de prescrição eletrônica).

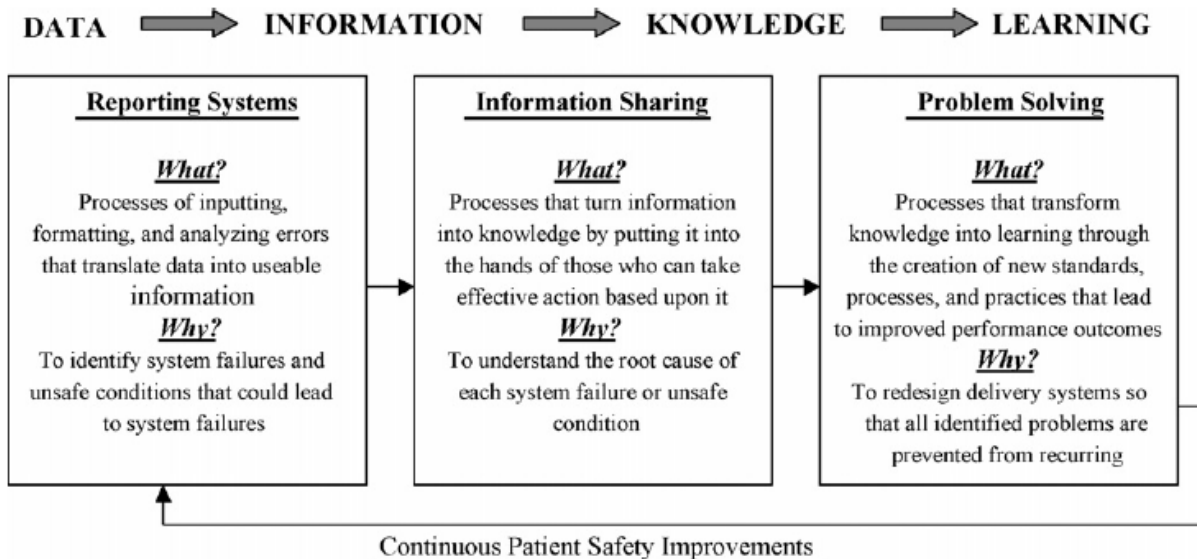
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USP – United States Pharmacopeia

- Disponibiliza o MEDMARX desde 1998 (sistema de notificação de eventos adversos medicamentosos), disponível na intranet, com participação aproximadamente de 775 organizações de saúde.
- Sistema que compartilha informação:
 - Apresentação de relatórios com classificação dos erros.
 - Determinação de ações corretivas.
 - Compartilhamento das ações entre os participantes.

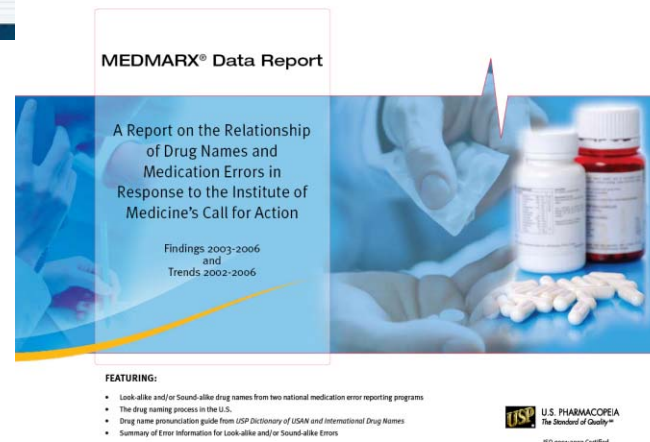
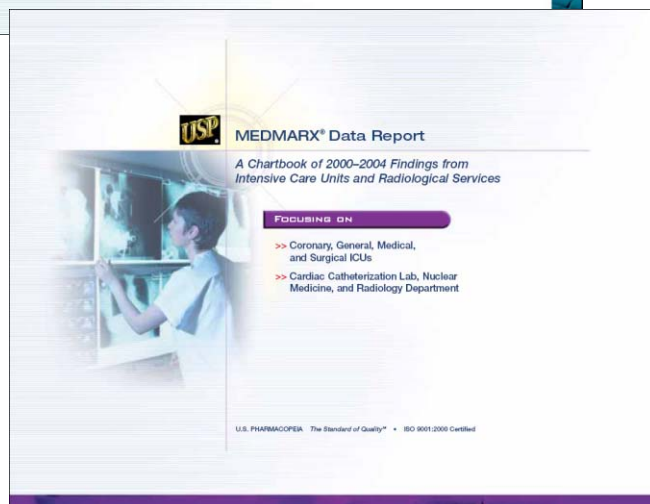
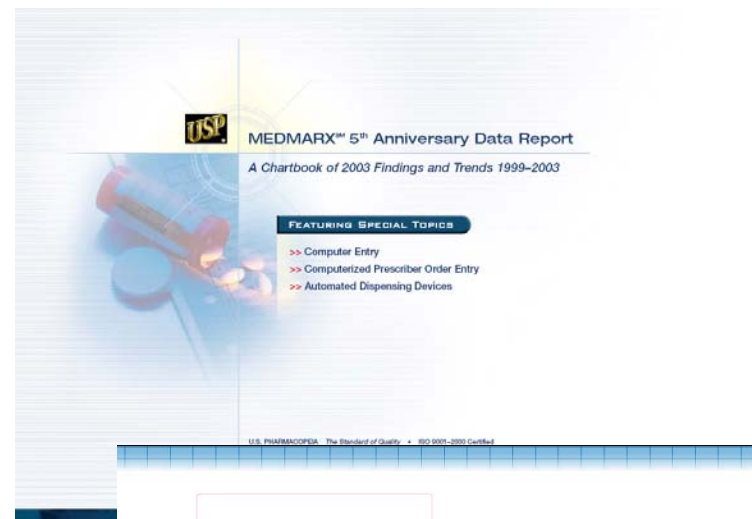
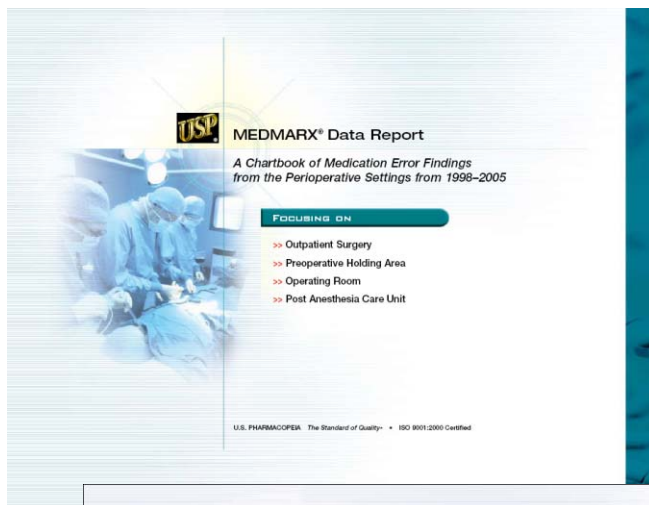


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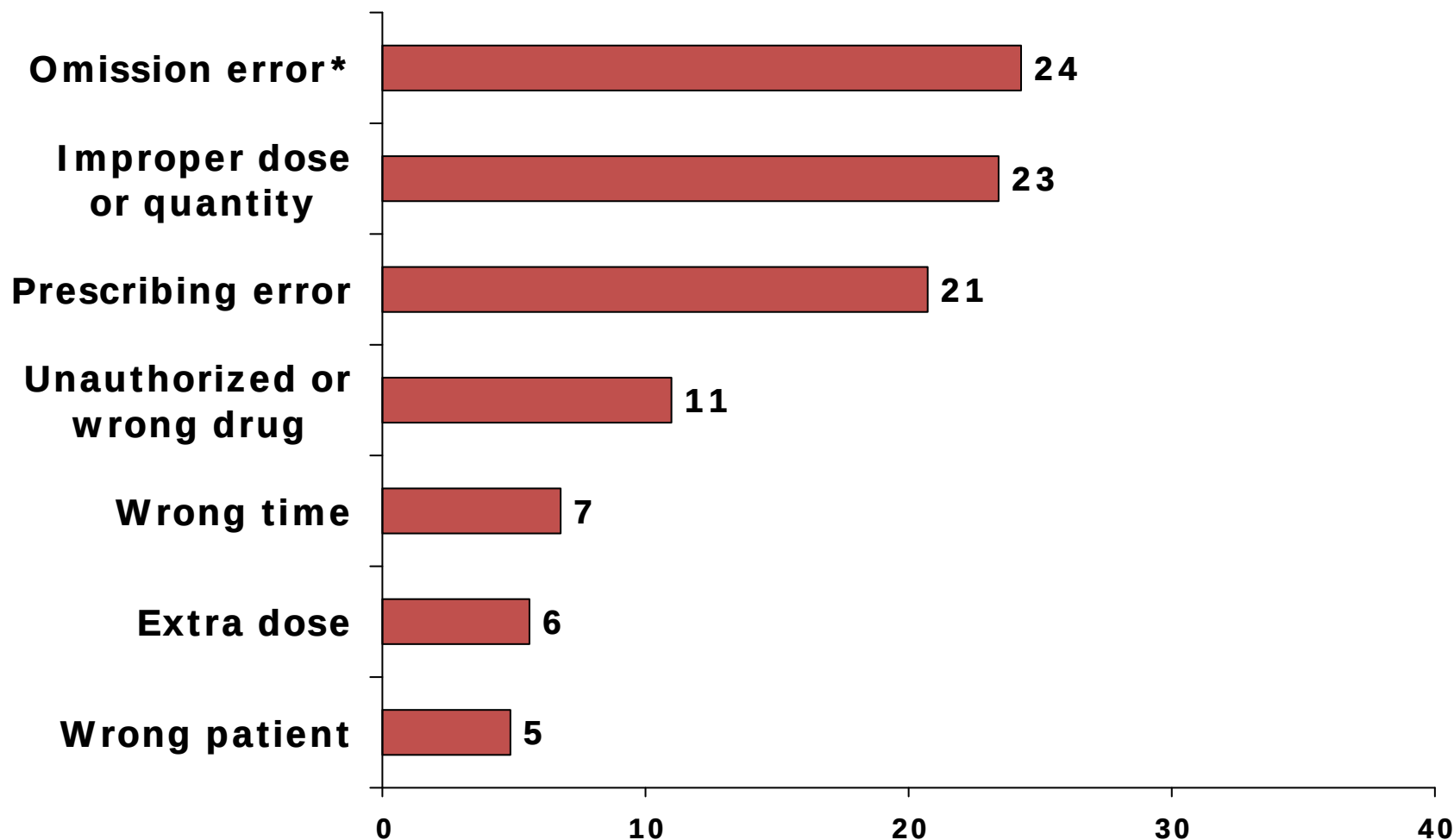
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USP – United States Pharmacopeia



**Most Frequently Reported Types of Medication Errors:
Voluntary Reporting System, 2000–2004
(Percentage of Reports with an Error Type)**



Data: Santell, J.P. et al. 2005. *MedMarx Data Report*. USP Center for the Advancement of Patient Safety. © 2005 The United States Pharmacopeial Convention, Inc. All rights reserved. *Failure to administer an ordered drug dose.

USP – United States Pharmacopeia

- O Tipo de erro de medicação mais comum notificado no MedMARx relacionado a medicamentos não autorizado/medicamento errado – 57.6% (significa que o medicamento errado foi dado por confusão). Relatório 2008

TABLE 4-6. LEADING ADDITIONAL CAUSES ASSOCIATED WITH LOOK-ALIKE AND/OR SOUND-ALIKE ERRORS

TABLE 4-5. LEADING TYPES OF ERROR ASSOCIATED WITH LASA ERRORS

Type of Error	n	%
Unauthorized/wrong drug	15,274	57.6
Drug prepared incorrectly	4,660	17.6
Improper dose/quantity	3,336	12.6
Wrong dosage form	2,664	10.0
Prescribing error	1,659	6.3
Omission error	495	1.9
Mislabeling*	412	1.6

Data based on 29,230 selections associated with 26,508 records.

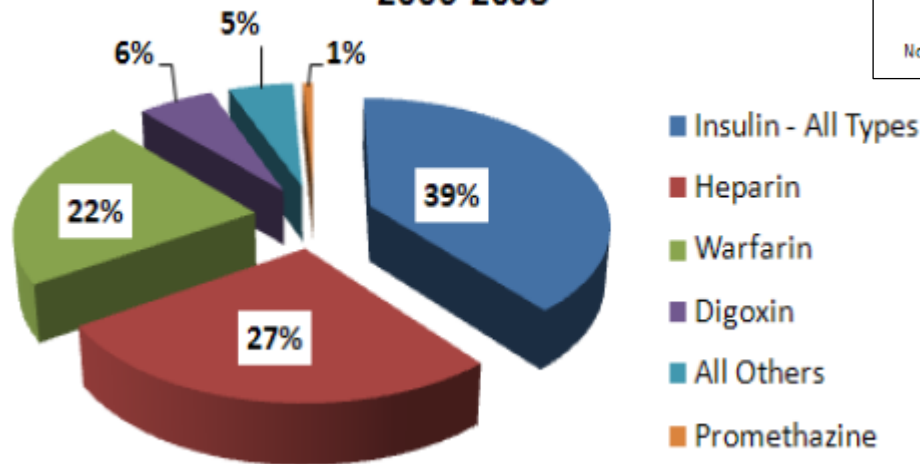
* Selection not available all 4 years

Additional Causes of Medication Error	n	%
Performance deficit	9,170	52.4
Procedure/protocol not followed	2,902	16.6
Computer entry	2,636	15.1
Knowledge deficit	2,316	13.2
Prefix/suffix misinterpreted	1,834	10.5
Transcription inaccurate/omitted	1,656	9.5
Storage proximity	1,632	9.3
Similar packaging/labeling	1,370	7.8
Dispensing device involved	1,328	7.6
Dosage form confusion	1,326	7.6
Documentation	1,294	7.4
Drug distribution system	1,162	6.6
Communication	1,129	6.4
Handwriting illegible/unclear	1,093	6.2
Similar products	1,026	5.9

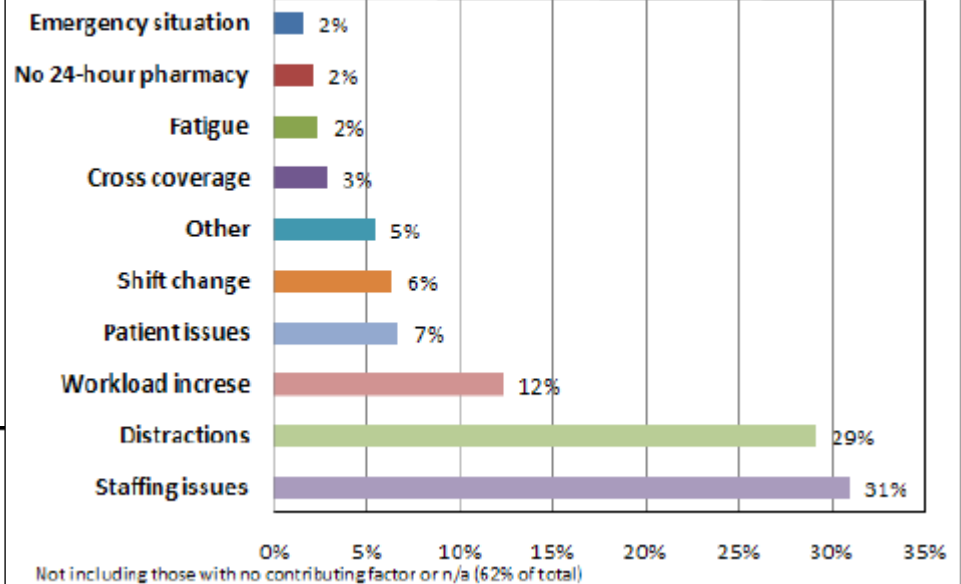
USP – United States Pharmacopeia

Relatório MedMARx 2006-2008 High-Alert Medication

High Alert Med Errors with Harm Only
2006-2008



Contributing Factors Related to High Alert Medication Errors
2006-2008



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Institute for Safe Medication Practices

A Nonprofit Organization Educating the Healthcare Community and Consumers About Safe Medication Practices

A federally certified
Patient Safety Organization



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Here's what's new!

Upcoming ISMP WEBINARS.....click for more info!



ISMP
Medication Safety Intensive

Unique 2-day program
A one-of-a-kind, interactive program that will teach you how to approach medication safety "through the eyes of ISMP." The workshops will be held in Orlando, FL on November 4th and 5th.

UPCOMING ISMP WEBINARS

Beyond "Be Careful": Maximizing Perinatal Medication Safety

Wednesday, October 27, 2010
from 1:30pm - 3:00pm ET
[Click here for more information](#)

On Saturday September 11th the website will be down for a short period of time between about 1:00 and 6:00 PM

Education & Awareness

- [Newsletters](#)
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- [Professional Development](#)
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- [Consumers](#)

Medication Safety Tools & Resources

- [NEW Guidelines for Standard Order Sets](#)
- [NEW tool to assess risk in community pharmacy](#)
- [Quarterly Action Agenda \(Free CE\)](#)
- [High-Alert Medication List](#)
- [Updated Confused Drug Name List](#)
- [Community Pharmacy Medication Safety Tools and Resources](#)
- [Articles of Interest](#)
- [List of Products with Drug Name Suffixes](#)
- [Error-Prone Abbreviation List](#)
- [Pathways for Medication Safety](#)
- [ISMP Guidelines](#)
- ["Do Not Crush" List](#)
- [Improving Medication Safety with Anticoagulant Therapy](#)
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Visit our consumer website
Get customized
Medication Alerts
www.consumermedsafety.org



Report Medication Errors

Report your medication error or safety concern online. Be sure to include all requested information.

[Report Now](#)

ISMP QuarterWatch™
Monitoring MedWatch Reports

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ISMP (Institute for Safe Medication Practices)

- Organização com mais de 30 anos de atuação dedicada à prevenção dos erros de medicação e manejo seguro de medicamentos.
 - Sistema de Notificação (MER): análise e divulgação dos dados.
 - É um sistema de notificação voluntária de erros de medicação criado pelo ISMP em 1975 e administrada hoje pela U. S. Pharmacopeia (USP). Recebe relatórios de profissionais assistenciais através do correio, telefone ou e-mail. A informação é também compartilhada com o FDA e as companhias farmacêuticas citadas nos relatórios (o programa MER recebeu cerca de 3.000 relatórios, desde 1993)
 - Divulgação de alertas: "ISMP Medication Safety Alert!®"
 - Disponibiliza guidelines relacionados ao processo de administração de medicamentos.
 - Orientações relacionadas a pontos críticos dentro do processo de administração de medicamentos com o objetivo de prevenir erros de medicação.

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ISMP (Institute for Safe Medication Practices) - Canada

Browser address bar: https://www.ismp-canada.org/err_report.htm

Navigation bar: Arquivo, Editar, Exibir, Favoritos, Ferramentas, Ajuda

Search bar: ismp canada near miss

ISMP CANADA logo

Institute for Safe Medication Practices Canada
A Key Partner in the Canadian Medication Incident Reporting and Prevention System (CMIRPS)

Web-based Analyze-Err:
Medication Incident and Near Miss Reporting Program

One of the goals of ISMP-Canada is to collect, collate and analyze actual and potential medication errors reported by practitioners so that recommendations and strategies of reducing medication errors can be disseminated to others. We believe in a non-punitive and voluntary approach to medication error reporting and we strongly encourage people to freely report errors so that we may learn from them. Please include as much information about the incident as possible. Thank you for sharing information so that others can learn from the experience.

INFORMATION SUBMITTED WILL BE KEPT STRICTLY CONFIDENTIAL AND PROTECTED. Please do not supply identifying information (e.g., patient name or date of birth, hospital name, or healthcare provider names).

Required fields are titled in **red**, total eight fields. Web ID: [] Assigned by ISMP Canada

1-Incident 2-Outcome 3-Medication(s) 4-Follow Up 5-Patient 6-Reporter 7-Contributing Factors

Date of Incident: dd/mm/yyyy Time of Incident: []

Incident Description/ HowDiscovered: []

Stages Involved:

☐ Prescribing	☐ Order Entry/Transcription
☐ Dispensing/Delivery	☐ Administration
☐ Monitoring	☐ Other

Type of Incident: Select []

Discovered By: Select []

Care Area Type: Select []

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ISMP (Institute for Safe Medication Practices) - Canada

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Required fields are titled in **red**, total eight fields. Web ID: Assigned by ISMP Canada

1-Incident 2-Outcome 3-Medication(s) 4-Follow Up 5-Patient 6-Reporter 7-Contributing Factors

Critical patient information missing
Critical drug information missing
Miscommunication of drug order
Drug name, label, packaging problem
Drug storage or delivery problem
Drug delivery device problem
Environmental, staffing, or workflow problem
Lack of staff education
Patient education problem
Lack of quality control or independent check systems

Select Key Medication Use System Element from each button on the left, then select contributing factor(s) from the window below.

Age
Weight
Allergies
Vital signs
Lab values
Pregnancy
Patient identity
Location
Renal/liver impairment
Diagnosis
Other

Hold down the control key 'Ctrl' to select more than one item, or to remove all choices.

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ISMP (Institute for Safe Medication Practices) - Canada



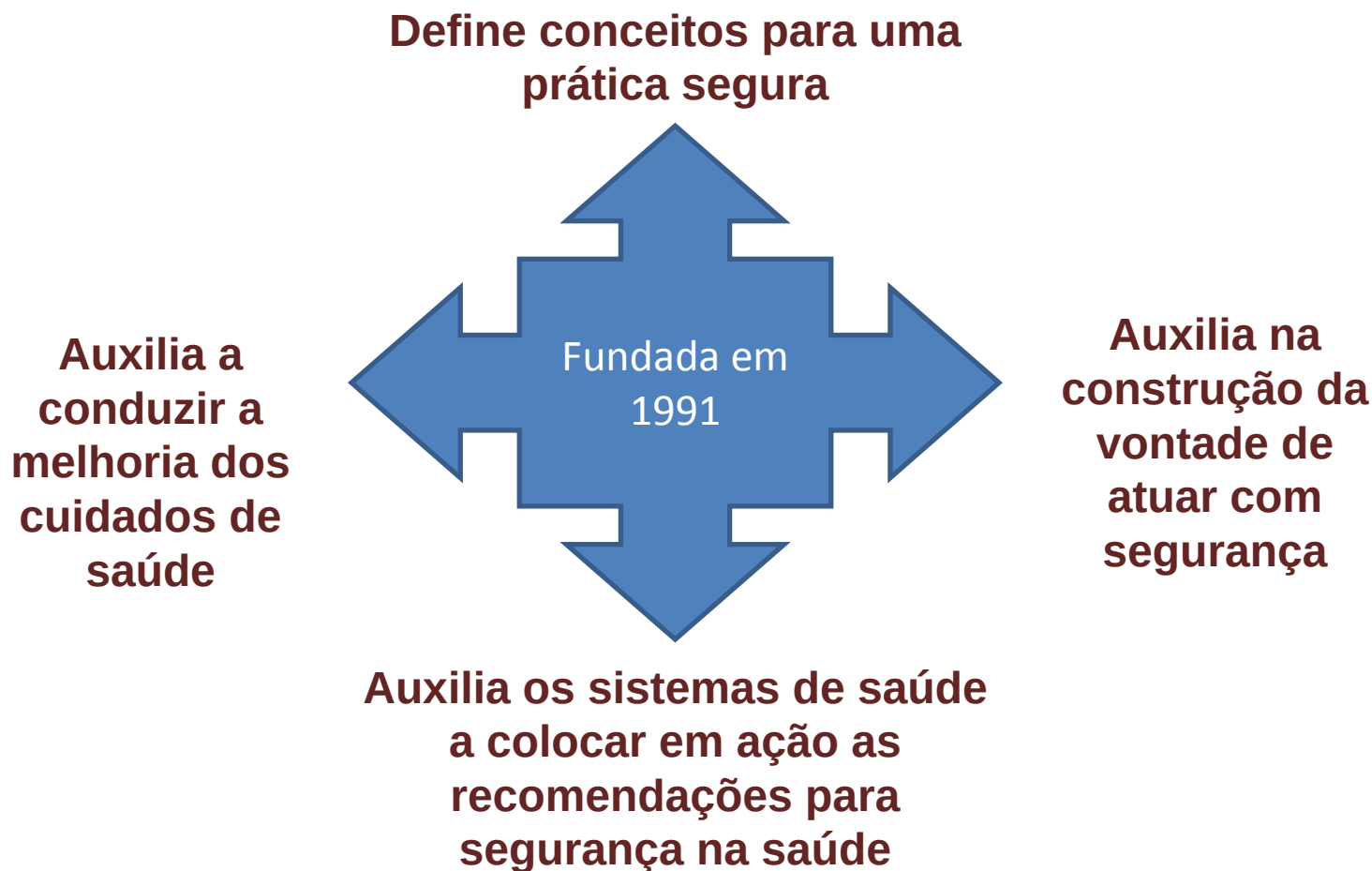
Como se comparar?

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IHI (Institute for Healthcare Improvement)



IHI.org | A resource from the Institute for Healthcare Improvement

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- Strategic Initiatives
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- Workspace
- Results
- Products
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Celebrating ONE Year!

Dedicated to making care:

**Safer
Cost Less
Smoother
Well Led**

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Join the celebration of the IHI Improvement Map's first anniversary!

Access the IHI Improvement Map

IHI improvement map

Home ? click to login

Explore by: Browse All

BROWSE

Cost Time Evidence Difficulty Aim Domain Outcome Services Finance Requirements

73 processes found

L4 Ideas: Scanning
Leaders establish the organizational capability for finding ideas for improvement both within and outside the organization.

L5 Execution: Portfolio of Projects
Leaders build and manage a portfolio of projects that span from prototyping and testing changes, to spreading and sustaining improvement.

L5 Execution: Reliable Processes
Leaders establish processes to ensure highly reliable care through analysis, design or redesign, using a model for improvement and supported by technology and the physical environment.

Laboratory Testing & Reporting
Establish the mechanisms to assure accurate and reliable lab testing.

Medication Administration
Establish safe and reliable medication administration processes to reduce harm.

Medication Ordering
Establish standard processes to prevent errors and harm from the prescribing process.

Medication Reconciliation at All Transitions
Prevent adverse drug events (ADEs) by implementing medication reconciliation at all transitions in care—at admission, transfer, and discharge.

Multidisciplinary Rounding
Multidisciplinary rounds (MDR) enable several members of the team caring for at-risk patients to come together to offer expertise and coordinate patient care.

IHI improvement map

Medication Administration

Details Reasons & Implications Resources

Overview
Establish safe and reliable medication administration processes to reduce harm.

Elements

- Ensure patient information is available in an appropriate literacy level and language
- Ensure that up-to-date medication information is available at point of care
- Minimize the number of medications available on units
- Remove discontinued medications immediately
- Increase frequency of medication delivery
- Use medication dispensing machines
- Standardize doses and concentrations
- Prepare IV medication in pharmacy
- Implement bar code readers
- Use SMART pumps for administration on IV medications

Aims

- Patient Centered
- Safe

Domains

- Processes to Support Care

Process Attributes

- Cost to Implement: \$2
- Time to Implement: 2
- Difficulty to Implement: 3
- Level of Evidence: 1

Improvement Map

Ferramenta que auxilia na implantação de práticas seguras

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VI SIMPÓSIO INTERNACIONAL DE ENFERMAGEM HOSPITAL ISRAELITA ALBERT EINSTEIN



IHI (Institute for Healthcare Improvement)

- Uma das ferramentas sugeridas para a identificação de eventos adversos relacionados ao uso de medicamentos é : **TRIGGER (Trigger Tool for Measuring Adverse Drug Events)**

IHI.org A resource from the Institute for Healthcare Improvement

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Site Map

Home > Workspace > Interactive Tools > Trigger Tool ADEs

Trigger Tool for Measuring ADEs

The Trigger Tool for Measuring Adverse Drug Events (ADEs) provides an easy-to-use method for accurately identifying adverse drug events — harm from medications — and measuring the rate of ADEs over time. Tracking ADEs over time is a useful way to tell if changes a team is making are improving the safety of the medication system. Hundreds of hospitals have used the Trigger Tool to identify ADEs, to measure the level of harm from each ADE, and to identify areas for improvement in their organizations. The Interactive Trigger Tool makes using this method of identifying and tracking ADEs even easier and more accurate.

Using the Trigger Tool (ADEs)

**OSF St. Joseph Medical Center
Bloomington, Illinois, USA**

The team at OSF St. Joseph Medical Center is using the Trigger Tool for Measuring Adverse Drug Events.

Percent of Admissions with an ADE

Adverse Drug Events (ADEs) per 1,000 Doses

[View all Trigger Tools for Measuring ADEs Reports](#)

[Use the Trigger Tool for Measuring ADEs](#)

[Manage my Interactive Tools](#)

[Tour the Trigger Tool \(ADEs\)](#)

Using the Trigger Tool for Measuring Adverse Drug Events (ADEs)

You can use the Trigger Tool for Measuring Adverse Drug Events (ADEs) to conduct a retrospective review of patients records using triggers to identify possible ADEs. This tool includes a list of known ADE triggers — clues that an ADE may have occurred — and instructions for measuring the number and degree of harmful medication events.

Sample Trigger Tool

Trigger Tool for Measuring Adverse Drug Events (ADEs)

Use the Data Manager to keep track of your data over time. Each data point represents the calculated totals for all the ADE Patient Record Review Sheets entered on a specific date. Use multiple series to track ADEs using the same set of triggers.

Manage Tool **Data Manager** **Create Report** **Download Data** **Help**

Series Series 1

To make changes to the series label [Edit](#)

To create multiple series for the same Tool (multiple locations, multiple providers, etc.) [Add Series](#)

To delete this series and all associated data [Delete Series](#)

Data Points for Series 1

To add new data [Add Data](#)

Date (mm/dd/yyyy)	% Adm. with ADE	ADEs / 1,000 Doses	Change or Event	Annotation
12/31/2002	10.00 %	1.98		
11/30/2002	10.00 %	2.04		
10/31/2002	15.00 %	2.26		
09/30/2002	15.00 %	2.65	Change	Clinical Pharmacist added to daily rounds

Triggers: medicações ou resultados laboratoriais - Exemplos:

- Benadril
- Vitamina K
- Antieméticos
- Narcan
- Glicemia < 50
- TTPA > 100 seg

Evento adverso relacionado ao uso de medicamentos (IHI Trigger Tools adaptado)	
¹ Avaliação retrospectiva	² Avaliação retrospectiva
Hospital de grande porte RJ; 2004)	Hospital geral de grande porte (RJ; 2008)
N= 32 prontuários	N= 240 prontuários
Triggers mais frequentes: –Uso antieméticos –Interrupção abrupta de medicação –Sedação excessiva	Triggers mais frequentes –Antagonista de benzodiazepínico –Antidiarréico –Rash cutâneo
Incidência EAM = 16%	Incidência de EAM = 14,6%
	Verificou-se associação positiva entre o número de medicamentos usados e EAM

¹Rozenfeld et al. Drug adverse effect in a public hospital in Rio de Janeiro: pilot study. Revista de Saúde Pública 2009; 43:887-90

²Fabíola Cano. Eventos Adversos a Medicamentos no Ambiente Hospitalar. Tese de doutorado apresentada a Escola Nacional de Saúde Pública Sérgio Arouca. Rio de Janeiro, Janeiro de 2011.

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Campanhas – 5 Milhões de Vidas (2006):

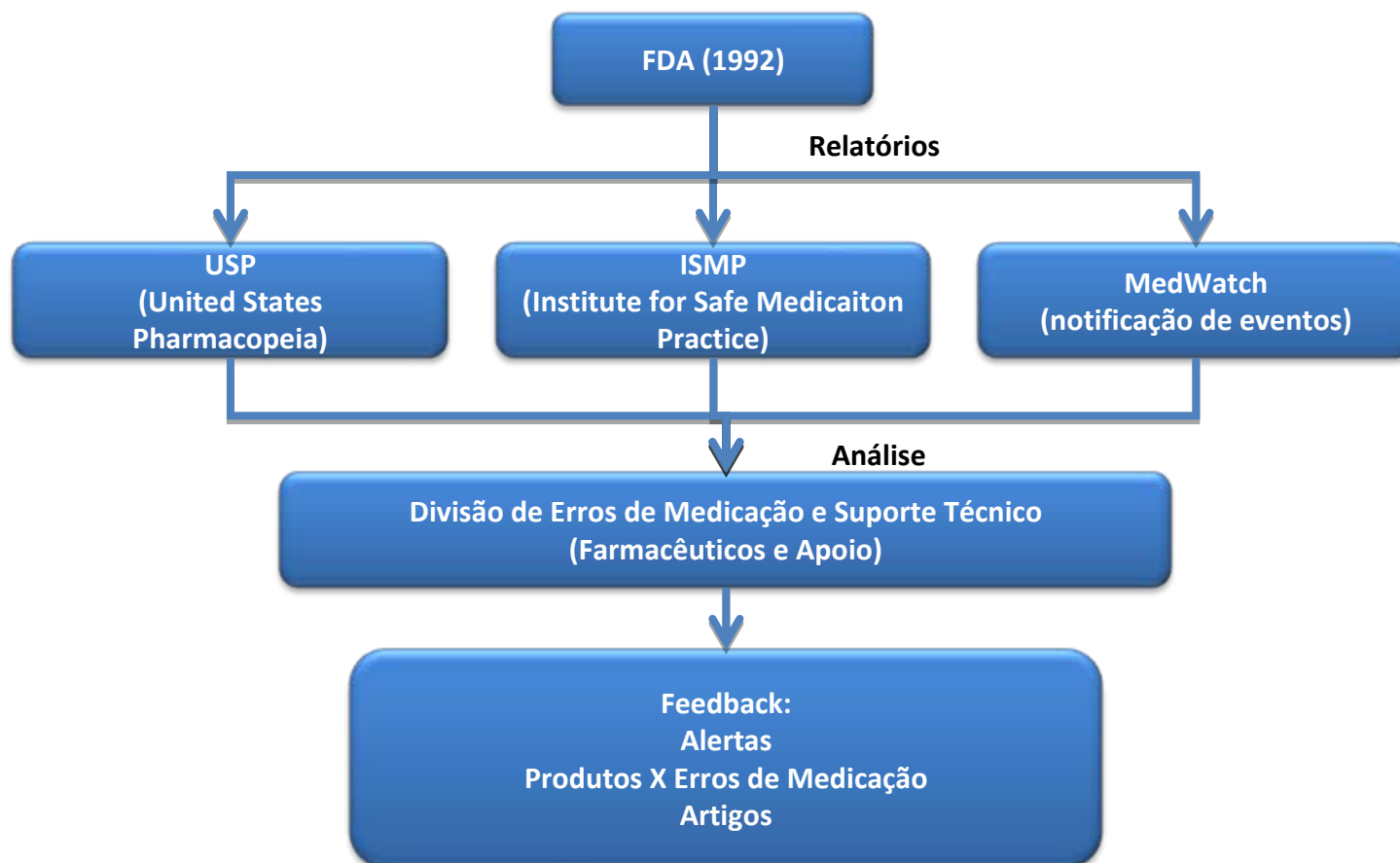
- Prevenção de Úlcera por Pressão
- Redução de resistência a Metacilin em infecções por *Staphylococcus aureus*
- **Prevenir dano decorrente de uso de High-Alert**
- Reduzir complicações cirúrgicas
- Cuidados na Insuficiência Cardíaca Congestiva
- **Prevenção de Eventos Adversos relacionados a reconciliação medicamentosa**
- Melhorar o atendimento ao paciente com Infarto Agudo do Miocárdio
- Prevenção de Infecção do sítio cirúrgico
- Prevenção de Infecção relacionada ao catéter central
- Prevenção de Pneumonia associada a ventilação

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FDA (US Food and Drug Administration)



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FDA (US Food and Drug Administration)



The FDA Safety Information and
Adverse Event Reporting Program

MedWatch Online Voluntary Reporting Form (3500)

Click the BEGIN button to report serious adverse events for human medical products, including potential and actual product use errors and product quality problems associated with the use of:

- FDA-regulated drugs,
- biologics (including human cells, tissues, and cellular and tissue-based products)
- medical devices (including in vitro diagnostics)
- special nutritional products and cosmetics

A Message about Privacy

You can continue to make adverse event reports under the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule. The HIPAA Privacy Rule is not intended to disrupt or discourage adverse event reporting in any way. In fact, the Privacy Rule specifically permits covered entities (such as pharmacists, physicians or hospitals) to report adverse events and other information related to the quality, effectiveness and safety of FDA-regulated products both to the manufacturers and directly to FDA.

For more information, please go to the [Medwatch HIPAA Compliance page](#).

What NOT to Report to MedWatch Using Online Form 3500

- **Vaccines:** Report vaccine events to the Vaccine Adverse Event Reporting System (VAERS) online at <https://secure.vaers.org/VaersDataEntryintro.htm>.
- **Investigational (study) drugs:** Report investigational (study) drug adverse events as required in the study protocol and send to the address and contact person listed in the study protocol.
- **Mandatory reporting:**
[Drugs and Biologics](#)
[Devices](#)

Sistema de Notificação de Eventos Adversos relacionados ao uso de medicamentos:

- É obrigatório aos fabricantes notificar eventos que resultaram em dano grave ou morte;
- É opcional à profissionais da saúde, consumidores, entre outros.

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FDA (US Food and Drug Administration)

Campanhas:

I have been reported to ISMP through the ISMP Medication Error Reporting Program (MERP) as being frequently misinterpreted and involved in harmful medication errors. They should NEVER be used when communicating medical information. This includes internal communications, telephone/verbal prescriptions, computer-generated labels, labels for drug storage bins, medication administration records, as well as pharmacy and prescriber computer order entry screens.

that specifies that certain abbreviations must appear on an accredited organization's "do-not-use" list; we have highlighted these items with a double asterisk (**). However, we hope that you will consider others beyond the minimum Joint Commission requirements. By using and promoting safe practices and by educating one another about hazards, we can better protect our patients.

Abbreviations	Intended Meaning	Misinterpretation	Correction
µg	Microgram	Mistaken as "mg"	Use "mcg"
AD, AS, AU	Right ear, left ear, each ear	Mistaken as OD, OS, OU (right eye, left eye, each eye)	Use "right ear," "left ear," or "each ear"
OD, OS, OU	Right eye, left eye, each eye	Mistaken as AD, AS, AU (right ear, left ear, each ear)	Use "right eye," "left eye," or "each eye"
BT	Bedtime	Mistaken as "BID" (twice daily)	Use "bedtime"
cc	Cubic centimeters	Mistaken as "u" (units)	Use "mL"
D/C	Discharge or discontinue	Premature discontinuation of medications if D/C (intended to mean "discharge") has been misinterpreted as "discontinued" when followed by a list of discharge medications	Use "discharge" and "discontinue"
IJ	Injection	Mistaken as "IV" or "intrajugular"	Use "injection"
IN	Intranasal	Mistaken as "IM" or "IV"	Use "intranasal" or "NAS"
HS	Half-strength	Mistaken as bedtime	Use "half-strength" or "bedtime"
hs	At bedtime, hours of sleep	Mistaken as half-strength	
IU**	International unit	Mistaken as IV (intravenous) or 10 (ten)	Use "units"
o.d. or OD	Once daily	Mistaken as "right eye" (OD-oculus dexter), leading to oral liquid medications administered in the eye	Use "daily"



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U.S. Food and Drug Administration

A-Z Index

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Regulatory Information



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Legislation

Federal Food, Drug, and Cosmetic Act (FD&C Act)

FD&C Act Chapter V: Drugs and Devices

SEC. 502. [21 USC §352] Misbranded Drugs and Devices

Note: revisions were posted to this section in February 2008.

[Note: See prospective amendment notes below.]

A drug or device shall be deemed to be misbranded-- 1

(a) False or misleading label. If its labeling is false or misleading in any particular. Health care economic information provided to a formulary committee, or other similar entity, in the course of the committee or the entity carrying out its responsibilities for the selection of drugs for managed care or other similar organizations, shall not be considered to be false or misleading under this paragraph if the health care economic information directly relates to an indication

Regulamentações Federais e Orientações:

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WHO (World Health Organization)

High 5s Project (2007-2012)

Standard Operating Protocol (SOP)

Objetiva implementar protocolos operacionais inovadores e padronizados para cinco soluções de segurança dos pacientes em cinco anos em 10 Hospitais de 7 Países (Austrália, Canadá, Nova Zelândia, Inglaterra, Estados Unidos, Alemanha e Holanda)

Esta iniciativa visa dinamizar a implementação de soluções que teriam amplos impactos na prevenção de eventos adversos catastróficos evitáveis em hospitais - a morte ou ferimentos graves.

- Comunicação segura: Prevenção de erros relacionados a passagem de plantão;
- Prevenção de erros relacionados a procedimentos cirúrgicos (lado errado/proced errado/paciente errado)
- Assegurar a continuidade do uso das medicações necessárias durante a transição dos cuidados (reconciliação);
- Manejo de Medicamentos injetáveis de alta concentração;
- Aumentar a adesão a higiene das mãos para prevenir infecções associadas ao cuidado da saúde;

The screenshot shows the WHO website's 'Patient safety' section. The left sidebar contains a navigation menu with links like Home, About WHO, Countries, Health topics, Publications, Data and statistics, Programmes and projects, Patient safety (highlighted), Research, Campaigns, Education & training, Implementing change, Patient engagement, Information centre, and News and events. The main content area is titled 'Action on Patient Safety - High 5s' and includes a description of the project's mission, a list of participating countries, and a link to the 'High 5s Overview [pdf 170kb]'. Below this, there is a section for 'Standard Operating Protocols for Implementation' with three sub-sections: 'Managing Concentrated Injectable Medicines', 'Assuring Medication Accuracy at Transitions in Care', and 'Performance of Correct Procedure at Correct Body Site', each with a corresponding image and a link to its SOP document.

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WHO (World Health Organization)

Atuação na formação acadêmica em saúde:

Guia de ensino 2009

Topic 11: Improving medication safety



World Health
Organization

Patient Safety

A World Alliance for Safer Health Care

WHO Patient Safety Curriculum Guide for Medical Schools

Why focus on medications?

1 2

Medicines have proven to be very beneficial for treating illness and preventing disease. This success has resulted in a dramatic increase in medication use in recent times. Unfortunately, this increase in use and expansion of the pharmaceutical industry has also brought with it an increase in hazards, error and adverse events associated with medication use.

Medication has also become increasingly complex:

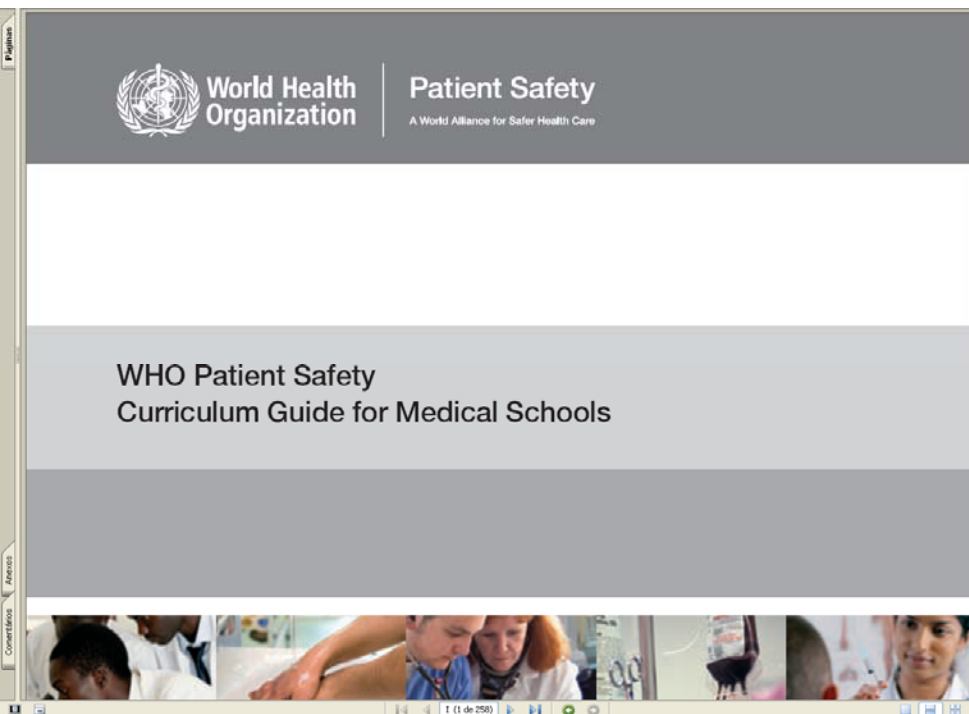
- There has been a massive increase in the number and variety of medications available. These may have different routes of delivery, variable actions (long acting, short acting) and there are drugs with the same action and

and potentially a leadership role in the workplace in relation to medication use and improving patient care.

As future doctors, medical students need to understand the nature of medication error, learn what the hazards are in relation to using medication and what can be done to make medication use safer. All staff involved in the use of medication have a responsibility to work together to minimize patient harm caused by medication use.

Keywords

Side-effect, adverse reaction, error, adverse event, adverse drug event, medication error, prescribing, administration and monitoring.



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WHO (World Health Organization)

Programas e Projetos: SDPF – Patients for Patient Safety

Enfatiza o papel central que pacientes e os consumidores podem desempenhar para melhorar a qualidade e a segurança nos serviços de saúde, em todo o mundo. Trata-se de uma rede global de pacientes, consumidores, prestadores de assistência, e organizações de consumidores que apoiam o envolvimento do paciente nos programas de segurança do paciente



World Health
Organization

Patient Safety
A World Alliance for Safer Health Care

Patients for Patient Safety News July 2010

Welcome to the latest edition of the PFPS Newsletter, featuring news from the PFPS network in Canada, an article on patient safety challenges in India and many other Champion activities around the world.

Patients for Patient Safety Canada

Ryan Sidorchuk, PFPS Champion, Canada

On 5 May, nearly four years after we held the first 'in-country' meeting of Patients for Patient Safety, the group launched as a stand-alone organization, with the aim of increasing our membership roster and

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- Como resultado do desenvolvimento de soluções a OMS publicou em 2007 “**Nove soluções para Segurança do Paciente**”
 - Medicamentos *look alike/sound alike*
 - Identificação do Paciente
 - Comunicação para continuidade do cuidado
 - Procedimento correto e lateralidade
 - Controle de eletrólitos de alta concentração
 - Assegurar a continuidade do uso das medicações necessárias durante a transição dos cuidados;
 - Evitar erros de conexão em cateteres e tubos
 - Uso de dispositivo único para injeção
 - Melhorar a adesão a higienização das mãos para prevenção de infecção associada aos cuidados de saúde



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- Define padrões de cuidados para as instituições de saúde:
 - Padrões com foco no Paciente:
 - Acesso ao cuidado e continuidade do cuidado
 - Direitos dos Pacientes e Familiares
 - Avaliação dos Pacientes
 - Cuidado aos Pacientes
 - Anestesia e Cirurgia
 - Gerenciamento e Uso de Medicamentos
 - Educação de Pacientes e Familiares
 - Padrões de Administração de Instituições de Saúde:
 - Melhoria da Qualidade e Segurança do Paciente
 - Prevenção e Controle de Infecções
 - Governo, Liderança e Direção
 - Gerenciamento e Segurança das Instalações
 - Educação e Qualificação dos Profissionais
 - Gerenciamento da Comunicação e da Informação

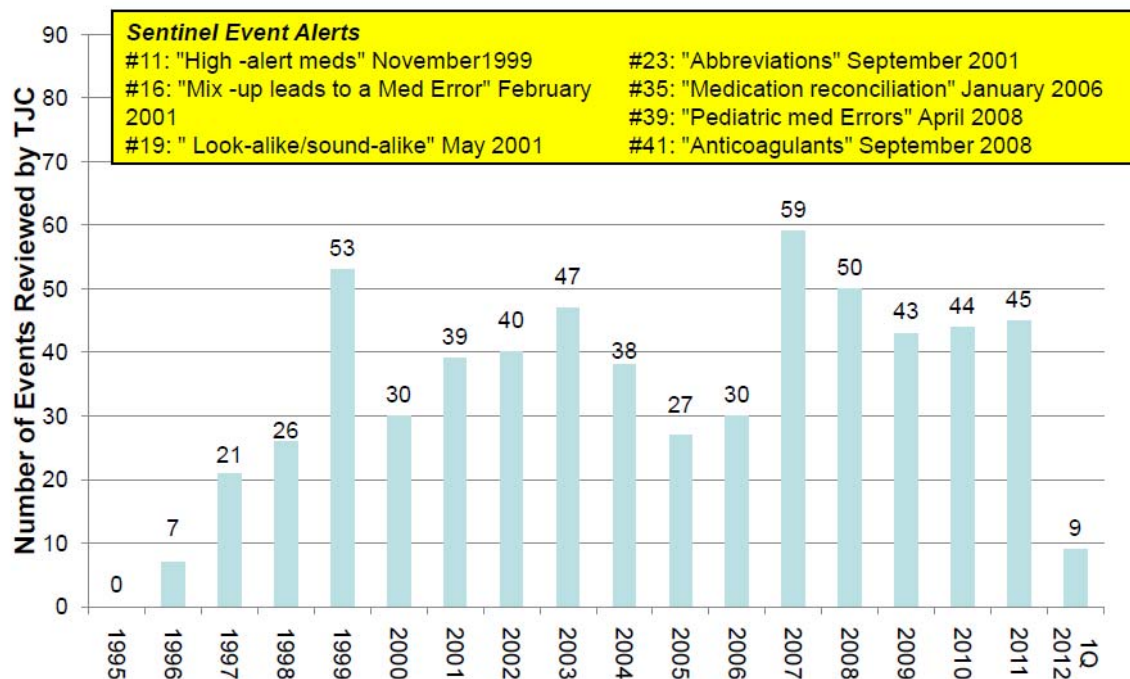
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Medication Error Events Reviewed by The Joint Commission

(Resulting in death or permanent loss of function)



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Most Frequently Reviewed Sentinel Event Categories by Year



2010	2011	1Q 2012
Unintended retention of a Foreign Body	Unintended Retention of a Foreign Body*	Unintended Retention of a Foreign Body*
Delay In Treatment	Wrong-patient, wrong-site, wrong-procedure	Delay In Treatment
Wrong-patient, wrong-site, wrong-procedure	Delay In Treatment	Wrong-patient, wrong-site, wrong-procedure
Op/Post-op Complication	Op/Post-op Complication	Suicide
Suicide	Suicide	Op/Post-op Complication
Fall	Fall	Fall
Medication Error	Other Unanticipated Event****	Other Unanticipated Event****
Other Unanticipated Event	Criminal Event	Criminal Event
Perinatal Death/Injury	Medication Error	Other Unanticipated Event****
Criminal Event	Medical Equipment-Related	Medication Error

*Other includes: Unexpected Additional Care/Extended Care, and Psychological Impact

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Root Cause Information for Medication Error Events Reviewed by The Joint Commission

(Resulting in death or permanent loss of function)



2004 through 1Q 2012 (N=345) <i>The majority of events have multiple root causes</i>	
Medication Use	302
Leadership	255
Communication	246
Human Factors	246
Assessment	141
Information Management	129
Physical Environment	65
Care Planning	33
Continuum of Care	33
Patient Education	10

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Medication Safety – Revisão 2010

Goal 3:

Improve the safety of using medications.

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Medication Safety – Revisão 2010

- NPSG.03.04.01: Label all medications, medication containers, and other solutions on and off the sterile field in perioperative and other procedural settings.
 - *Applies to: Ambulatory, Critical Access Hospital, Hospital, Office-Based Surgery*
- NPSG.03.05.01: Reduce the likelihood of patient harm associated with the use of anticoagulant therapy.
 - *Applies to: Ambulatory, Critical Access Hospital, Hospital, Long Term Care*

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Reconciliação Medicamentosa – Revisão 2010

Goal 8:

Accurately and completely reconcile medications across the continuum of care.

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Joint Commission International

Reconciliação Medicamentosa – Revisão 2010

- NPSG.08.01.01: A process exists for comparing the patient's current medications with those ordered for the patient while under the care of the organization.
- *Applies to: Ambulatory, Behavioral Health Care, Critical Access Hospital, Home Care, Hospital, Long Term Care, Office-Based Surgery*

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No ano de 2002, a ANVISA lançou o Projeto Piloto dos Hospitais Sentinela (Gerenciamento de Risco), que tinha como objetivos:

- (a) atender uma necessidade da própria Agência em obter informações qualificadas sobre reações adversas, agravos e queixas técnicas sobre produtos de saúde e
- (b) criar um meio intrahospitalar favorável ao desenvolvimento de ações de vigilância sanitária em hospitais, com ganhos significativos de qualidade para os serviços e pacientes. O sistema de informação do projeto se compõe de quatro sub-itens: tecnovigilância, hemovigilância, farmacovigilância e queixas técnicas de medicamentos. Com o término do projeto piloto com sucesso, a Agência investiu na criação de um novo projeto, este com a duração de cinco anos (2005-2009). O novo projeto teve seu escopo ampliado, mas o objetivo principal permanece o mesmo (ANVISA, 2005).



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Einstein Sentinela - ANVISA

- Vigilância pós comercialização de produtos por meio da rede sentinela, cada hospital tem a sua estratégia, e notificam não conformidade e evento por meio do NOTVISA:
 - Hemovigilância
 - Tecnovigilância
 - Farmacovigilância

Prevenção, identificação precoce
e manejo de conseqüências
indesejáveis durante uso de
medicamentos

Exemplos de estratégia:

- Centro de Informações de Medicamentos
- Comissão de Farmácia e terapêutica
- Comissão de Padronização de Materiais e Medicamentos
- Busca Ativa de eventos e não conformidades (desvio de qualidade)

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Criação de Congressos para discussão do tema

A PRACTICAL GUIDE TO

Reducing Medication Errors

*Improving Patient Safety:
Towards Zero Tolerance*

Wednesday 14 November 2012
Manchester Conference Centre, Manchester

"Incidents involving medication, such as prescribing errors and failures to review medication after discharge, were the fourth most commonly reported to the National Patient Safety Agency."
<http://www.cqc.org.uk>

This conference will focus on reducing medication errors and improving patient care with a focus on a zero tolerance approach. The day will begin with speakers discussing the issues behind medication errors and how to move forward. Delegates will learn through best practice case studies on developing medication safety indicators and metrics, learning from medication errors and focusing on high risk medicines.

A focus area of the conference is on developing a zero tolerance approach to medication errors - a strategy that has worked effectively for reducing infection rates across the NHS. The panel will discuss the merits of using this approach for medication errors and the appropriateness of setting the goal at zero. This will be followed by case studies on establishing a baseline, monitoring medication errors, and improving accountability if an error does occur. Delegates will learn from the experience of Great Ormond Street in taking a zero tolerance approach to prescribing errors. The final sessions will focus on proactively learning from medication errors and changing practice across the whole patient pathway.

Visit our website www.healthcareconferencesuk.co.uk or tel 01932 429933 fax 01932 680402



IV Fórum

Internacional Sobre Segurança do Paciente

Erros de Medicação

Dia 17 e 18 de Agosto de 2012
MINASCENTRO - BELO HORIZONTE / MINAS GERAIS

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Impacto Financeiro

The Cost of Error

\$79 billion – estimated cost of the 2.6 billion prescriptions filled in the US in 1997¹

\$17 to 29 billion – annual cost of preventable medical errors in hospitals²

2.7 billion prescriptions filled in the US in 1998³

Up to \$5.6 million – estimated annual cost per hospital (depending on hospital size) for ADE-related injuries and deaths⁴

>1,000,000 serious medication errors occur each year in US hospitals⁵

>770,000 hospitalized patients injured or die each year from adverse drug events⁴

44,000 to 98,000 people die each year in hospitals from preventable medical errors²

7,000 – estimated number of medication-error-related deaths annually²

>\$2,000 – added hospitalization cost of a single adverse drug reaction⁶

2:100 to 7:100 – estimated incident rates of adverse drug events per 100 hospital admissions among hospitals performing studies⁴

1:854 inpatient deaths related to medical errors²

1:131 outpatient deaths related to medical errors²

¹Safe Use of Pharmaceuticals as a National Health Priority: Developing a Leadership Agenda. The National Patient Safety Foundation, July 1999.

²Kohn, LT, Corrigan, JM, Donaldson, NS (eds): To Err Is Human: Building a Safer Health System. A report from the Committee on Quality of Healthcare in America, Institute of Medicine, National Academy of Sciences. Washington, DC, National Academy Press, 1999.

³Adverse Drug Events: Substantial Problem but Magnitude Uncertain. United States General Accounting Office, Testimony before the Committee on Health, Education, Labor, and Pensions, U.S. Senate,

February 1, 2000.

⁴Reducing and Preventing Adverse Drug Events To Decrease Hospital Costs. Agency for Health Care Policy and Research, www.ahrp.gov.

⁵Birkmeyer JD, Birkmeyer CM, Wennberg, DE, et al: Leapfrog safety standards: potential benefits of universal adoption. Washington, DC, The Leapfrog Group, 2000.

⁶Classen DC, Pestotnik SL, Evans RS, et al: Adverse drug events in hospitalized patients: excess length of stay, extra costs, and attributable mortality. *JAMA*, 277(4):307-11, 1997.

Ending Extra Payment for “Never Events” — Stronger Incentives for Patients’ Safety

Arnold Milstein, M.D., M.P.H.

On September 1, 2008, Medicare eliminated a long-standing presumption in its payment rules that, since hospitals were doing everything possible to prevent complications of treatment, taxpayers and patients should primarily bear the average cost consequences when complications occurred. A 2006 law, meant to motivate hospitals to accelerate improvement of patients’ safety, constrains hospitals’ ability to bill Medicare for a higher-paid diagnosis-related group when complications occur.¹ The constraint applies only to hospital-acquired

include some “never events,” the National Quality Forum’s label for serious complications that should never occur in a safe hospital. Though the resulting reduction in Medicare payments to hospitals is estimated to be less than 0.01% nationally, some hospital leaders have objected to its “mean-spiritedness” and to the inclusion of some complications that are not wholly preventable by hospitals. They also noted that the policy did not reduce payments to physicians, even when a physician plays a primary causal role. One prominent hospital executive reportedly pounded

listed 18 additional complications it was considering for October 2009. Citing its wish to evaluate the impact of the program to date, the CMS proposed on May 4 that, rather than substantially increase its list, it would add only two additional types of bone fractures to its falls and trauma category. Perhaps partially to address objections from hospitals about physicians’ lack of accountability, the CMS announced in January 2009 that it would cease all payments, including physician payments, in the case of three egregious surgical never events: surgery on the

Existe uma tendência mundial de não pagamento por eventos que poderiam ser evitados.

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2012

VI SIMPÓSIO INTERNACIONAL DE ENFERMAGEM HOSPITAL ISRAELITA ALBERT EINSTEIN



Conclusão

- Preocupação Mundial.
- Impacto na segurança e qualidade da assistência.
- Compartilhamento de informações – Ações Preventivas.
- Maior exposição do tema: Congressos, Fóruns, Campanhas.
- Sistemas de Notificação dos Eventos.
- Dificuldade em comparar resultados (diferentes metodologias)
- Impacto financeiro

Obrigado!

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