DRUG TRACEABILITY AND PATIENT SAFETY

Leonisa Obrusnik

Supply Manager

April 2013

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Hospital Alemão OSWALDO CRUZ

AGENDA

- Institutional
- Risk management and supply chain
- Safe medication practices
- Conclusion

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PROFILE

Hospital Alemão Oswaldo Cruz

- Non-profit private institution
- Beneficient, social and scientific vision
- General hospital of high complexity, mainly surgical

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PROFILE

- General adult hospital
- 263 beds:
  - 34 intensive care beds
  - 29 semi-intensive care beds
  - 13 operating rooms

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Quality Certifications

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SUPPLY CHAIN

Industry

Distributor

Transporter

Hospital Pharmacy

PRODUCT-PROCESS TRACEABILITY

PATIENT

Quality and Safety

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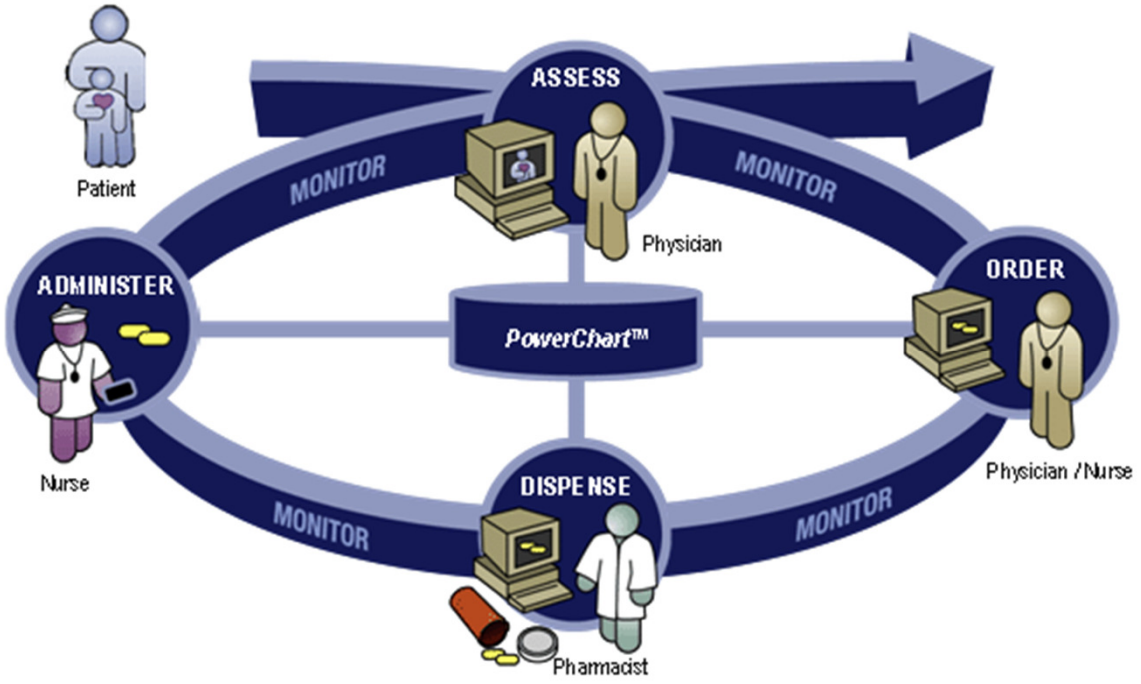
The Medication Process

- Complicated processes
- Many areas and professionals
- Interfaces, processes, knowledge, human resources, technology, training...
- Overview of the medication process and team involvement

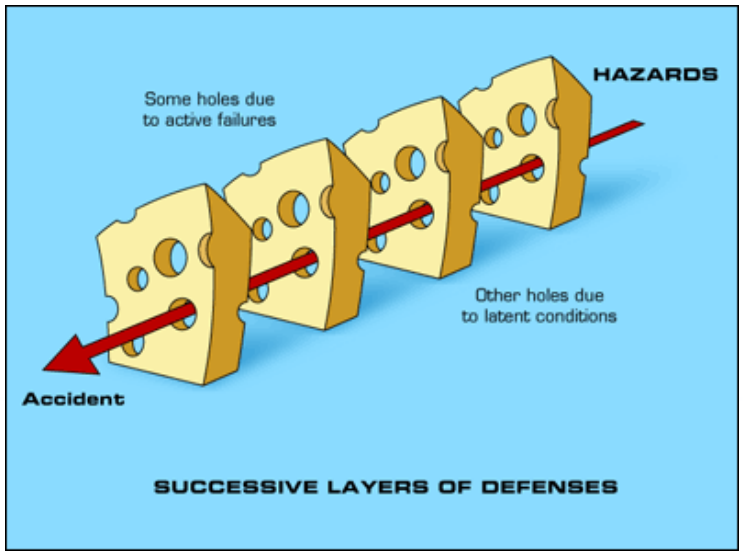


TO ERR IS HUMAN…

Medication error:

Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use."

US National Coordinating Council for Error Reporting and Prevention 2002



International Patient Safety Goals

Relevance:

- "To err is human" - Institute of Medicine (USA) - 1998
  - **44,000 to 98,000 patients died** of **adverse effects**

- World Health Organization (WHO)
  - Patient safety – worldwide politic agenda begining in 2000
  - 2004 - World Alliance for Patient Safety
  - **"First, do no harm"**
    - Socialization of knowledge and solutions

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International Patient Safety Goals

Diagnóstico

A maior parte destas ocorrências poderia ser evitada com medidas para ampliar a segurança do paciente no hospital

País	Incidência (%)	Evitáveis (%)
Brasil	7,6	66,7
Nova Zelândia	11,3	61,6
Austrália	16,6	50
Dinamarca	9	40,4
França	14,5	27,6
Espanha	14,5	42,8
Canadá	7,5	37

**Fonte: Fiocruz - Revisão dos estudos de avaliação da ocorrência de eventos adversos em hospitais - Mendes, W. et al. Rev Bras Epidemiol 2005; 8(4): 393-406*

6-13% hospitalized patients experienced at least **one adverse event**:

- **11-39%** caused by **medications**;

European Medicines Agency in Institute for Safe Medication Practices (ISPM - EMEA) - 2007

1.5 million people are **harmed** by **medication errors** and **7,000 people die** each year in the U.S., costing the country at least **U$3.5 billions/year**

Preventing medication errors IOM 2006

"Errors are caused by systems, faulty processes and conditions that lead people to make mistakes or fail to prevent them."

The Quality of Health Care in America Committee of the Institute of Medicine - IOM

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Potential causes of medication errors

- Problems related to packaging:

  - appearance (tablets, ampoules): look-alike drugs

Sodium Chloride
0,9% x **20%**

Dose **22 times higher**

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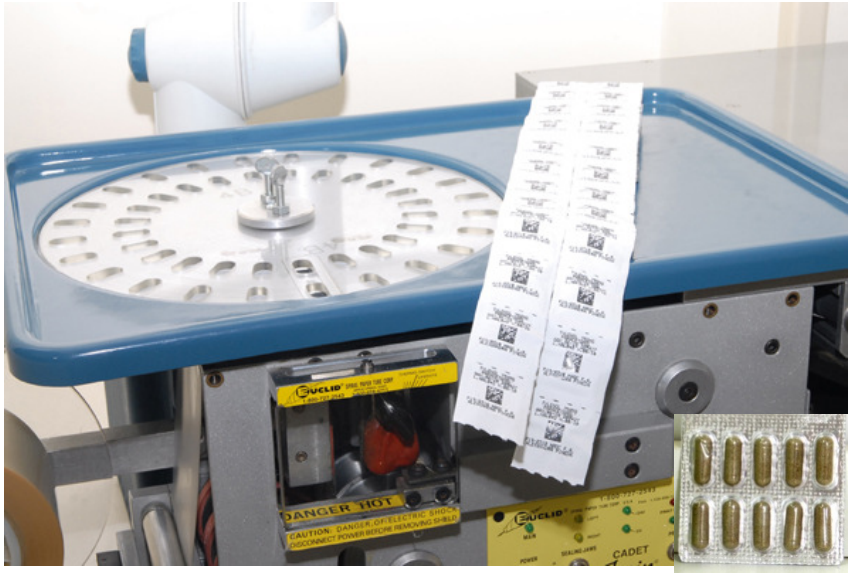
Potential causes of medication errors

- Problems related to packaging:
  - unavailability of products with proper identification: repackaging

Unit dose: ready-to-use

X



Common blisters

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Potential causes of medication errors

- Problems related to packaging:

  - unavailability of products with proper identification: relabeling

Ready-to-use

X

Common vials

Potential causes of medication errors

- Problems related to packaging:

  - unavailability of products with proper identification: relabeling

High damage risk medications:
concentraded electrolytes

High damage risk medications:
chemotherapy

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Potential causes of medication errors

- Problems related to packaging:
  - unavailability of ready-to-use preparations: preparation error
  - impossibility of traceability from manufacturer to bedside

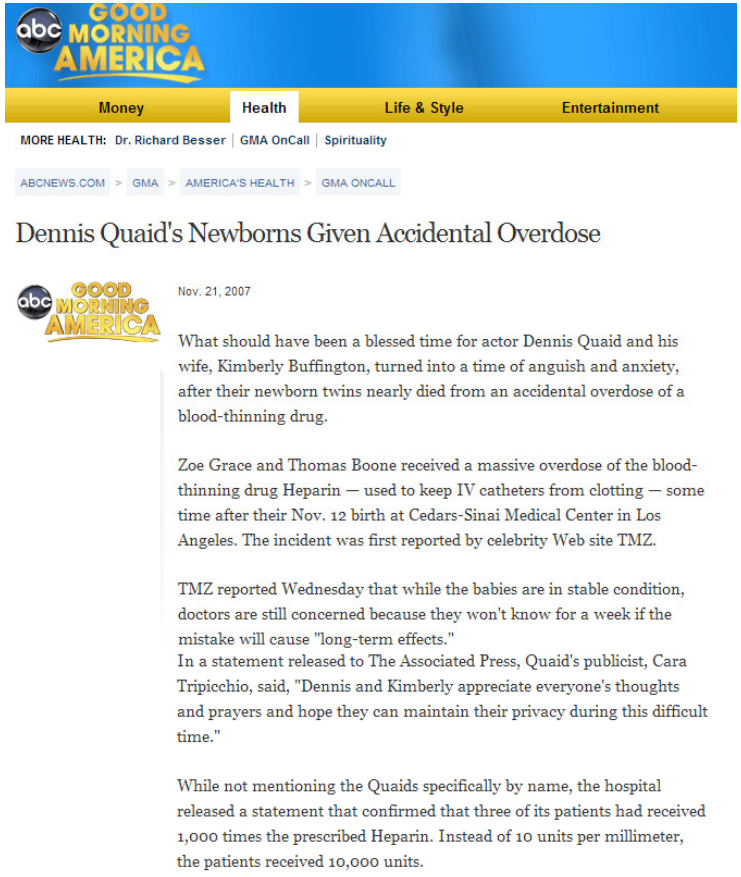
    50-100.000 units/month - ANAHP (Brazil, 2010)

- Exchanges due to identification:
  - Phonetics (Nalbuphine - Nubain® / Cisatracurium - Nimbium®)
  - Graphy (Lamivudine- Epivir ® / Lamotrigine - Lamictal ®)
  - Prefix and Suffix (Manidipine - Manivasc ® / Amlodipine - Norvasc ®)
  - Use of the same lot numbers of different products

Potential causes of medication errors

- Exchanges due to identification:
  - Variety of dosage forms and look alike

Heparin 10,000 units/mL x 10 units/mL



GOOD MORNING AMERICA

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MORE HEALTH: Dr. Richard Besser | GMA OnCall | Spirituality

ABCNEWS.COM > GMA > AMERICA'S HEALTH > GMA ONCALL

Dennis Quaid's Newborns Given Accidental Overdose

GOOD MORNING AMERICA

Nov. 21, 2007

What should have been a blessed time for actor Dennis Quaid and his wife, Kimberly Buffington, turned into a time of anguish and anxiety, after their newborn twins nearly died from an accidental overdose of a blood-thinning drug.

Zoe Grace and Thomas Boone received a massive overdose of the blood-thinning drug Heparin — used to keep IV catheters from clotting — some time after their Nov. 12 birth at Cedars-Sinai Medical Center in Los Angeles. The incident was first reported by celebrity Web site TMZ.

TMZ reported Wednesday that while the babies are in stable condition, doctors are still concerned because they won't know for a week if the mistake will cause "long-term effects."
In a statement released to The Associated Press, Quaid's publicist, Cara Tripicchio, said, "Dennis and Kimberly appreciate everyone's thoughts and prayers and hope they can maintain their privacy during this difficult time."

While not mentioning the Quaids specifically by name, the hospital released a statement that confirmed that three of its patients had received 1,000 times the prescribed Heparin. Instead of 10 units per millimeter, the patients received 10,000 units.

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Packaging and Damage Potencial

Vaseline x Normal Saline

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12/12/2010 20h46 - Atualizado em 12/12/2010 22h47

Auxiliar suspeita de trocar soro por vaselina dá detalhes do atendimento

Stephanie Teixeira, de 12 anos, morreu ao ter vaselina injetada na veia. Ela tinha ido a hospital de SP para se tratar de uma virose.

Licensed practical nurse confuses vaseline with normal saline!

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Regulatory institutions in our favor

July 20, 2010

Planned FDA guidance on drug labeling seeks to help reduce medication errors

By Kathryn Foxhall

FDA is once again tackling the naming, labeling, and packaging practices connected with drugs and biologics, according to a top official.

The agency has made a commitment to publish a draft guidance to reduce medication errors by September 30, the end of fiscal year 2010. To read the FDA notice, log onto www.regulations.gov/ [http://www.regulations.gov/search/regs/home.html#home] and input the docket number "FDA-2010-N-1068." The deadline for comment is July 23.

A third of medication errors, including 30% of fatal errors reported to the Institute for Safe Medication Practices, may be attributed to packaging and labeling, FDA noted.

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Regulatory institutions in our favor

Partial Agreement
in the Social and Public Health Field
Accord Partiel
dans le domaine social et de la santé publique

COUNCIL OF EUROPE CONSEIL DE L'EUROPE

Creation of a better medication safety culture in Europe:
Building up safe medication practices

Expert Group on Safe Medication Practices (P-SP-PH/SAFE)

(2006)

It is recommended that European health care organisations and other related stakeholders take steps to:

- Update the European legislative framework applied by the European Medicines Agency and National Drug Regulatory Authorities to take into account the need for good design with a view to minimising the risks of medication errors when using medicinal products in practice, as well as to include a requirement that packaging and labelling should be subject to specific human factor assessment and **user testing including medicine information in the hospital/ ambulatory setting** by the manufacturers prior to marketing authorisation.
- Update the national and European legislative framework to require pharmacies and other persons authorised for dispensing medicines to ambulatory patients to put a typewritten label on the container of the medicinal product at dispensation. This **dispensing label** is intended to assist patients, carers and health professionals to use the medicines as intended and to minimise errors. Labelling of medicinal products should foresee adequate space for a dispensing label.
- Update the national and European legislative framework to require **complete and unambiguous labelling of every single unit of use** of all licensed medicines products (e.g. tablet, vial and nebules), including the international nonproprietary name (INN), trade name, strength, expiry date, batch number and a data matrix bar code. The data matrix bar code should contain a GS1 Global Trading Index Number (GTIN) identifier in addition to the expiry date and batch number.

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Regulatory institutions in our favor

Agência Nacional
de Vigilância Sanitária

- **Ordinance n° 802, 8th October, 1998 – Brazil** (published in 7th April, 1999)

  - Establishing the Supervision and Control System in the entire supply chain of pharmaceuticals

"The supply chain of pharmaceuticals covers the stages of production, distribution, transportation and dispensing."

"The companies responsible for each of these steps are **jointly responsible** for the **quality and safety of pharmaceuticals** objects of their specific activities."

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Regulatory institutions in our favor

- **Law n° 11.903, 14th January, 2009 – Brazil**

  - Creates the National Drug Control System

  - Regulates each and every product manufactured, sold or dispensed in the country, and regulates the tracking of production and consumption of medications using capture, storage and electronic technology in transmission of data.

- **RDC n° 59, 24th November, 2009 – Brazil**

  - Installs the National Drug Control System

  - Establishes the Data Matrix as the official technology for traceabilitty of pharmaeuticals in Brazil

Brasília , 25 de novembro de 2009 - 15h50

Tecnologia para rastreabilidade de medicamentos está definida

O código de barras bidimensional, também chamado Datamatrix, será a tecnologia usada para garantir a rastreabilidade dos medicamentos comercializados no Brasil. A definição consta da RDC 59, publicada nesta quarta-feira (25), que implanta o Sistema Nacional de Controle de Medicamentos.

A tecnologia será a principal ferramenta para garantir a rastreabilidade desses produtos, ou seja, vai permitir recuperar informações históricas e geográficas sobre o caminho percorrido pelos medicamentos desde sua produção até a entrega ao consumidor.

Ao contrário do código de barras comum, que é visível e contém apenas um número, o bidimensional pode armazenar milhares de informações ao mesmo tempo, como números, letras e outros dados. Todas as informações vão estar reunidas no Identificador Único de Medicamento (IUM), que estará em cada unidade de medicamento comercializada e será impresso em etiquetas de segurança produzidas especificamente para esse fim.

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Automated Dispensing Process

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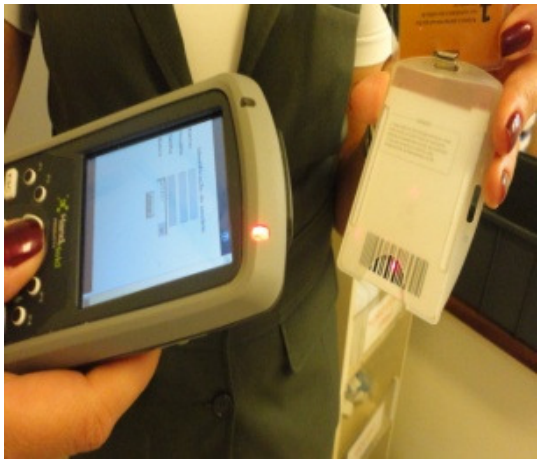
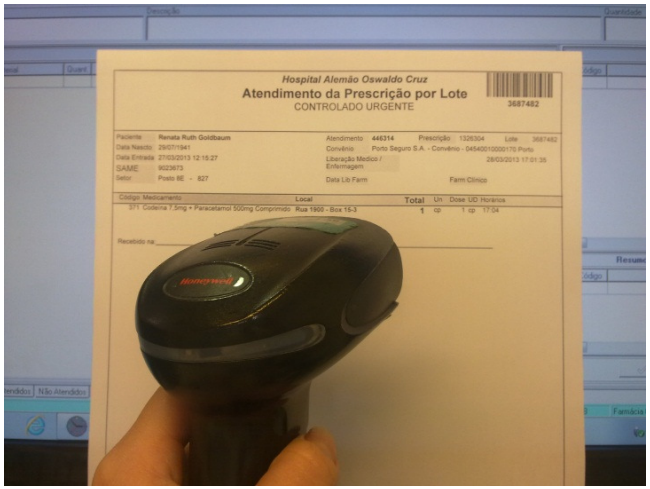
Automated Dispensing Process

User ID:



Identifying medication requisition:



Identifying storage site:

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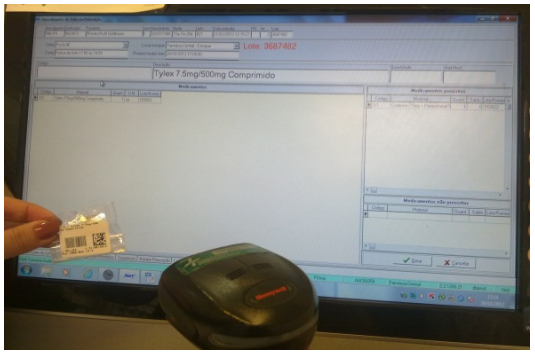
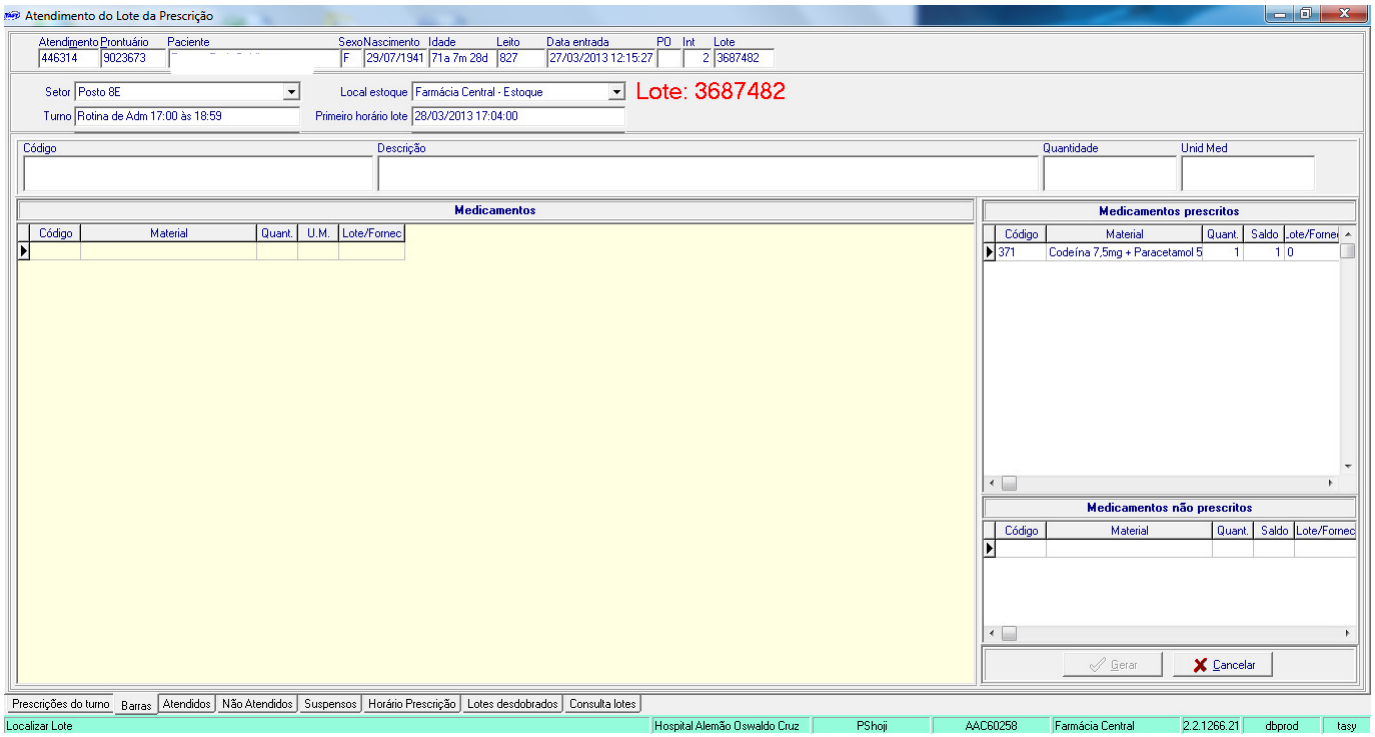
Automated Dispensing Process

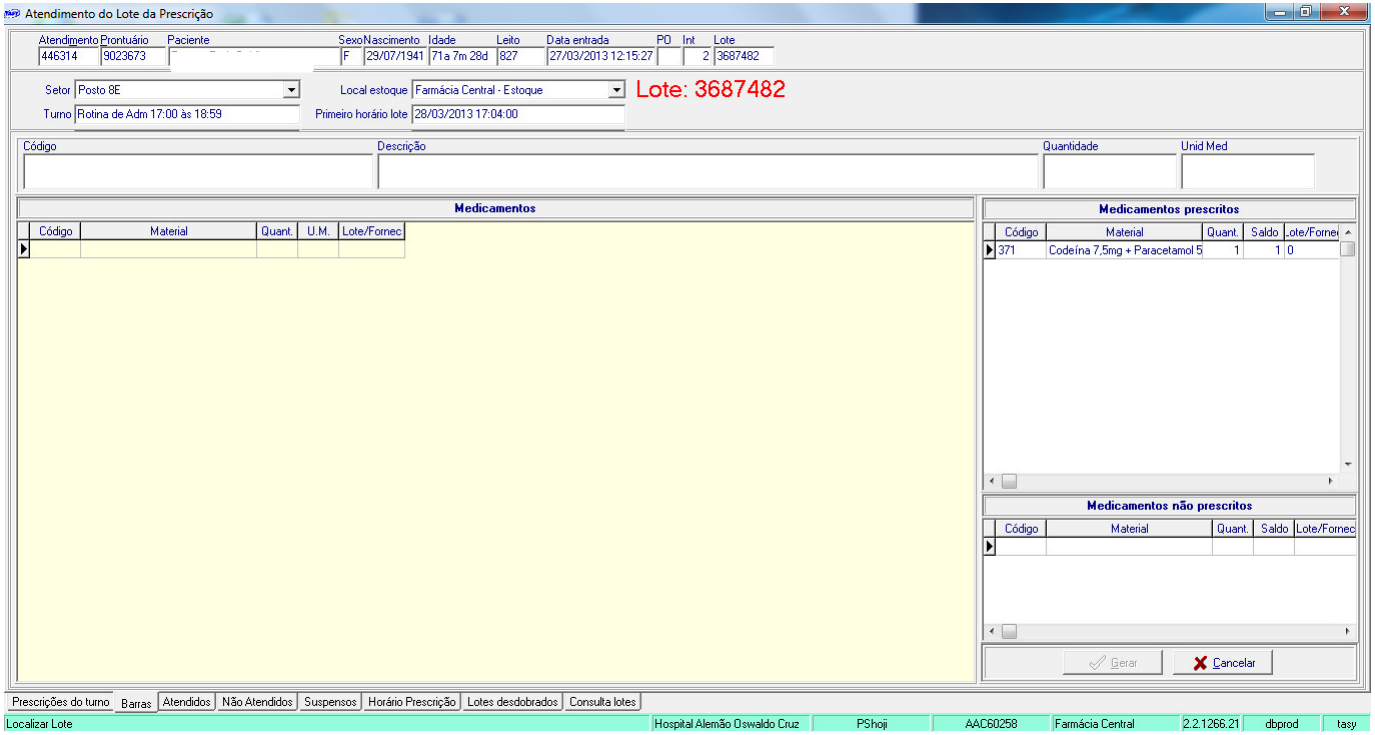
Reading GS1 Datamatrix code





Automated Dispensing Process

Reading GS1 Datamatrix code



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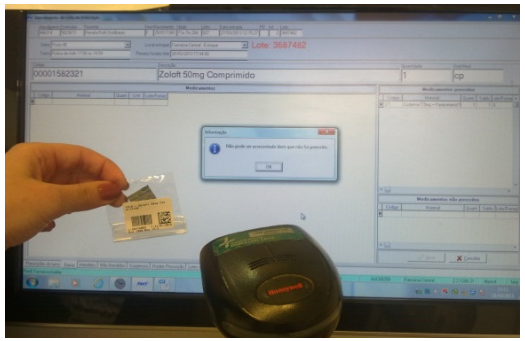
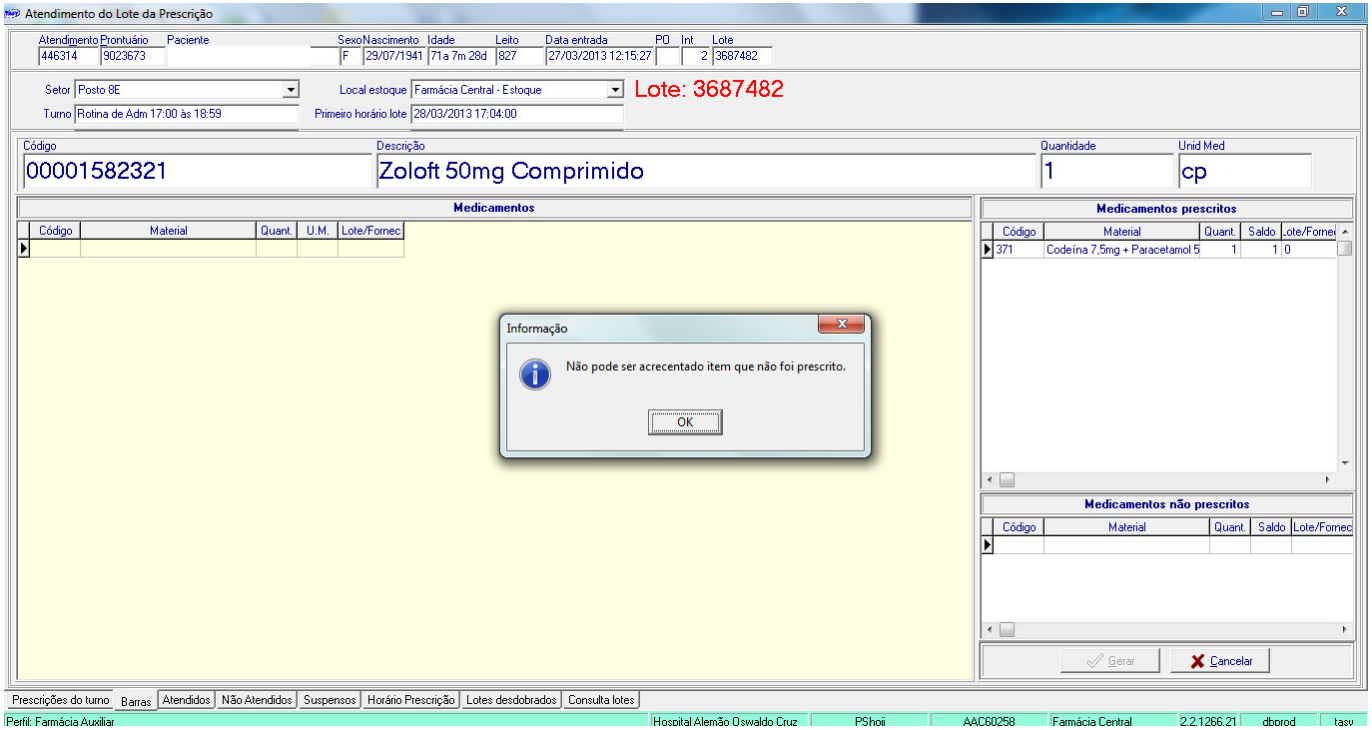
Automated Dispensing Process

Wrong medication:





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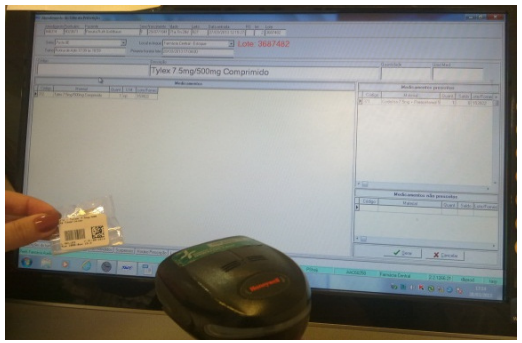
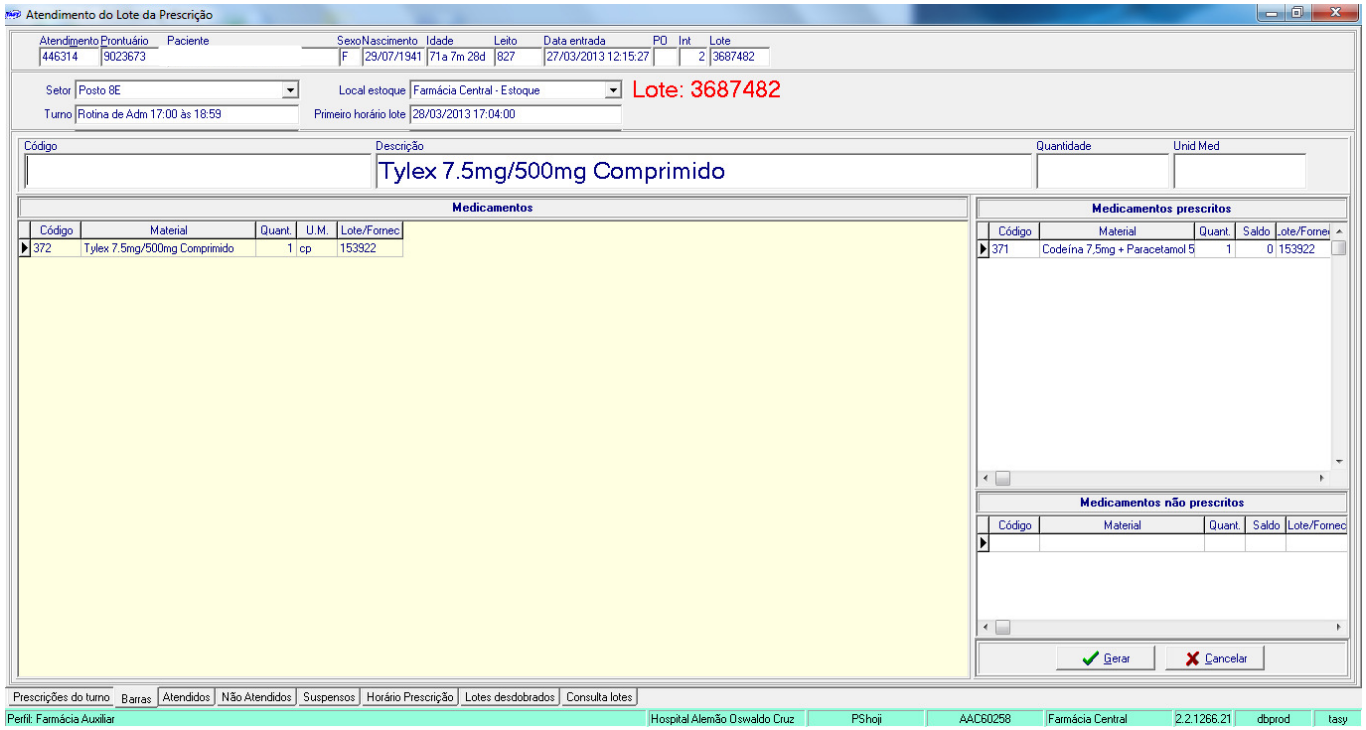
Automated Dispensing Process

Right medication:





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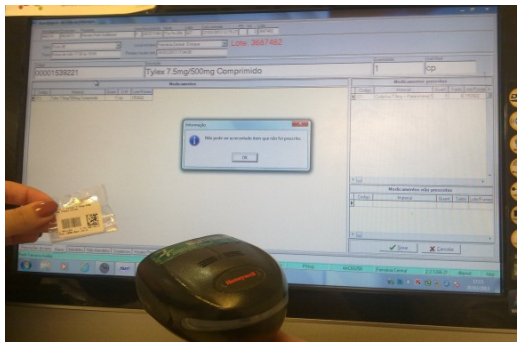
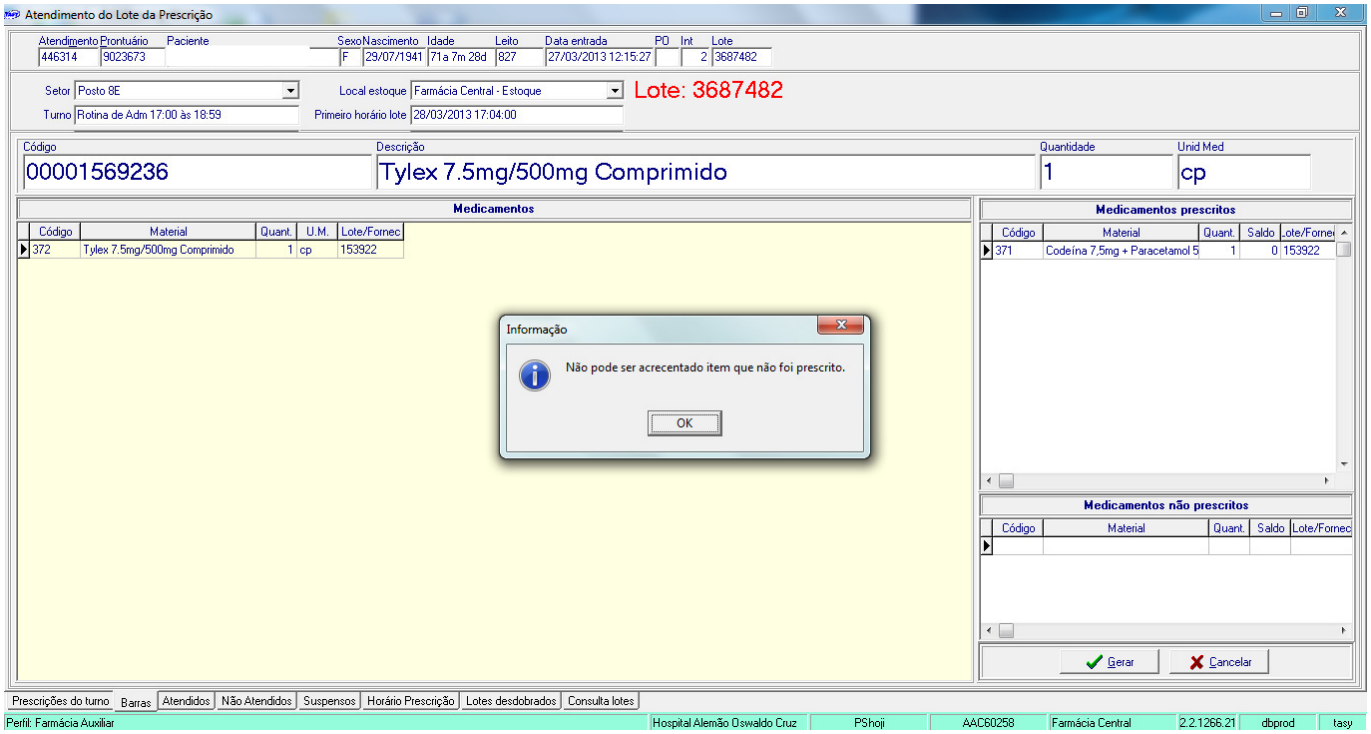
Automated Dispensing Process

Wrong quantity of right medication:





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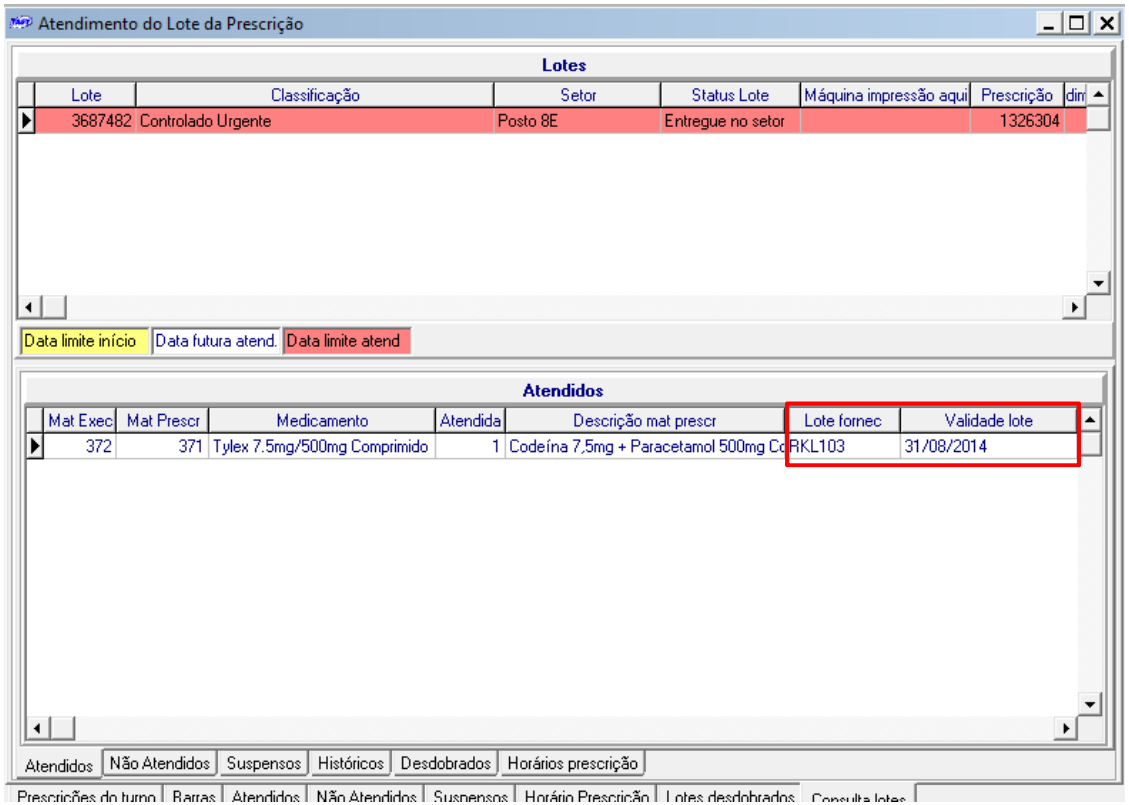
Drug dispensed: lot, expiration date and transport status



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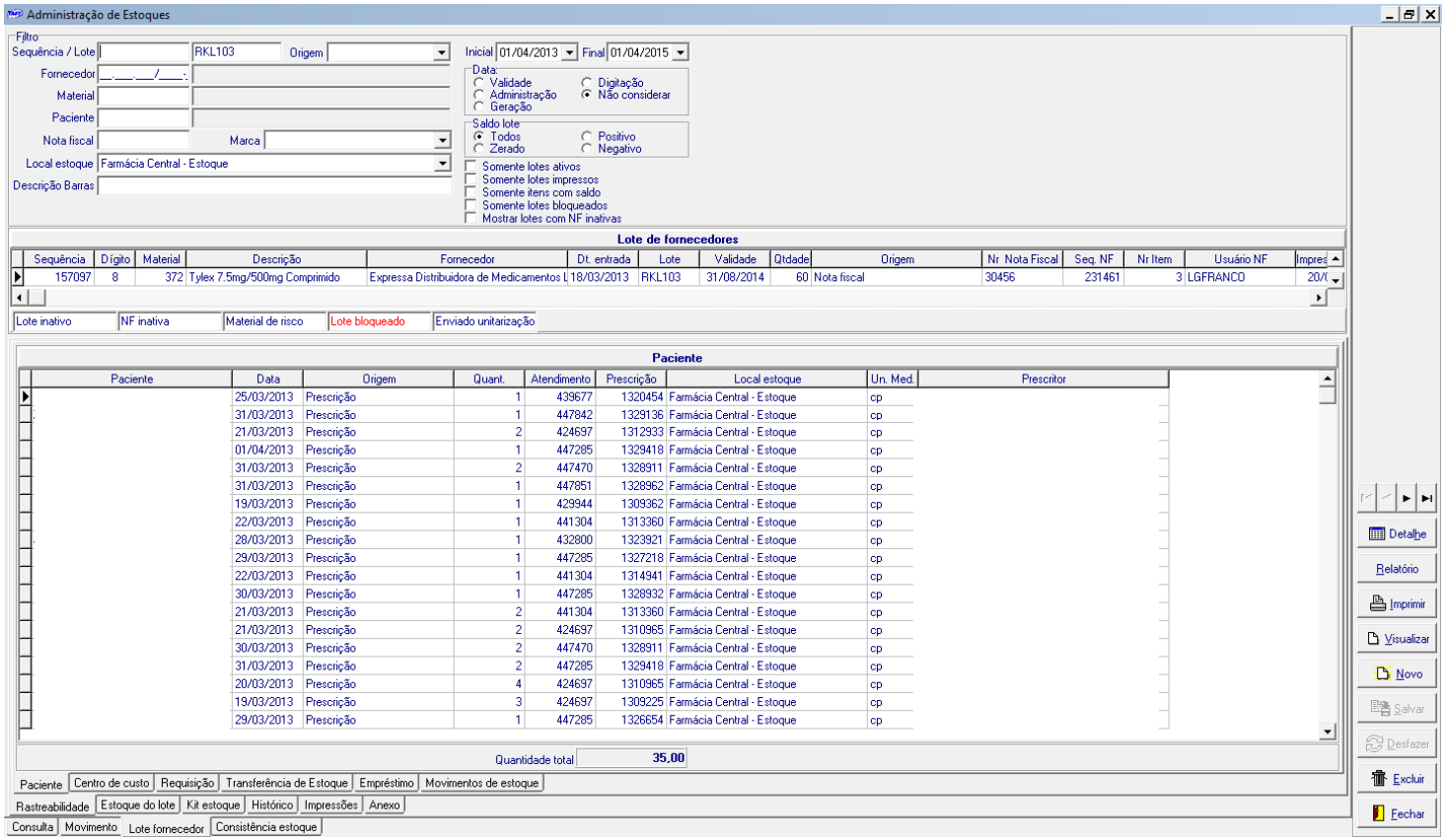

Patients in use of the same lot

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Problems

Relabeling:
- wrong labeling

Relabeling conference:
- wrong conference

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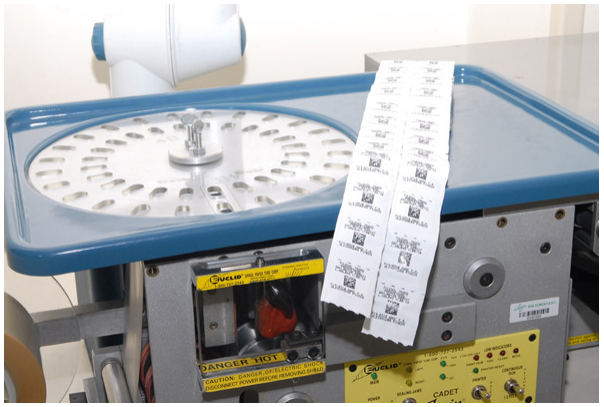
Problems

Repackaging:
- reduced expiration date

Relabeling:
- wrong labeling

Relabeling check:
- wrong check



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Next Steps...

Bedside Bar-Coding

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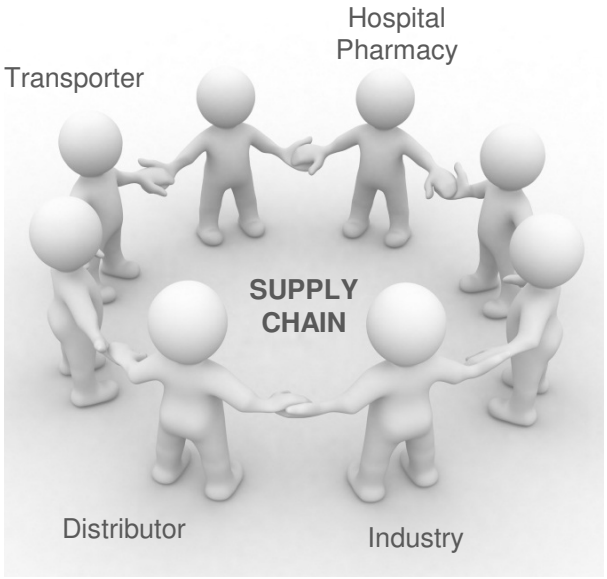
CONCLUSION



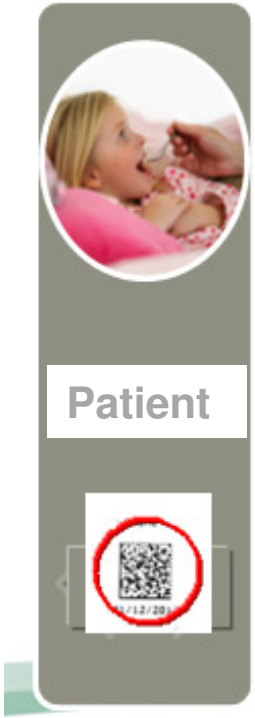
Quality and Safety:

- Origin
- Traceability
- Minimizing errors in medication process

↓40% of administration errors with barcode Bedside

Effect of Bar-Code Technology on the Safety of Medication Administration - *N ENGL J MED 362;18 NEJM.ORG MAY 6, 2010*

Datamatrix GTIN + lot number and expiration date in the smallest unit



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THANK YOU!

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Leonisa Obrusnik

Supply Manager

leonisa.obrusnik@haoc.com.br
+55 11 3549 0100
FAX: + 55 11 3289 9648

Rua João Julião, 331 • Paraíso • CEP: 01323-903 • São Paulo • SP
Tel.: 11 3549 1000 • Fax: 11 3287 8177 • www.hospitalalemao.org.br

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