

Medication Safety Efforts and Challenges

Portuguese Example

Paulo Almeida and Catarina Luz Oliveira, Portugal



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IMSN 2021 Annual Meeting Program

November 8 – 9, 2021



november 2021



EXECUTIVE SUMMARY

- ✓ PORTUGUESE PATIENT SAFETY NACIONAL PLAN 2015-2020
- ✓ PORTUGUESE PATIENT SAFETY NACIONAL PLAN 2021-2026
- ✓ FALSIFIED MEDICINES DIRECTIVE - MEDICINES VERIFICATION SYSTEM (MVO)
- ✓ HEALTH EVENT RISK MANAGEMENT
- ✓ MEDICATION ERRORS
- ✓ CLINICAL PHARMACIST SUPPORT

PORTUGUESE PATIENT SAFETY NACIONAL PLAN



According to the National Health Plan, access to quality health care, all the time and in all levels of provision, it is a fundamental right of the citizen, who is recognized all legitimacy to demand quality in care that provided, and safety is one of the fundamental elements of quality in health. Security is essential data for the trust of citizens in the health system and in the National Health Service. (SNS)

This Plan respects the Recommendation of the Council of the European Union, of June 9, 2009.

It should be noted that the occurrence of security incidents during the provision of health care is closely linked to the of safety culture existing in the institutions that provide this care, either to their organization, with evidence that demonstrates that the risk of occurring increases ten fold in institutions that neglect investment in good health care safety practices.

The National Plan for Patient Safety aims, through transversal actions, such as safety culture, sharing of knowledge and information and actions aimed at problem specific, improve the safe provision of health care for all the levels of care, in an integrated way and in a process of continuous quality improvement of the National Health Service.

PORTUGUESE PATIENT SAFETY NACIONAL PLAN



Strategic goals:

1. Improve safety policy of internal environment
2. Improve communication safety
3. Improve surgical safety
- 4. Improve safety in medication use**
5. Ensure unambiguous patient identification
6. Prevent the occurrence of falls
7. Prevent the occurrence of pressure ulcers
8. Ensure systematic practice of incident reporting, analysis and prevention
9. Prevent and control antimicrobial infections and resistance

PORTUGUESE PATIENT SAFETY NACIONAL PLAN



The World Health Organization estimates that between 8% and 10% of patients admitted to intensive care and about 13% of out patients are victims of incidents due to unsafe practices in the use of medication.

The international approach to safe use of the drug requires a decrease in the prevalence of incidents, through the adoption of structural and procedural preventive measures, implying organizational and behavioral changes by the professionals involved and the population in general, or institutions.

Institutions must specifically implement strategies that ensure the safe use of high-risk drugs as well as medicines with orthographic and/or phonetic name and/or similar appearance, known as “Look-alike” and “Sound-alike” medications or simply LASA medications.

PORTUGUESE PATIENT SAFETY NACIONAL PLAN

| | 2015 | 2016 | 2017 | 2018 | 2019 | 2020 | |
|---|------|------|------|------|------|------|---------------------|
| publish guidelines about safe medication use | X | X | | | | | DGS |
| develop information systems regarding med rec in SNS | X | X | X | | | | DGS, SPMS |
| implement intercommunication between ADR portal and Notific@ | X | X | | | | | DGS, SPMS, INFARMED |
| implement safety practices regarding LASA medicines | X | X | X | X | X | X | Hospitals, ULS |
| implement safety practices regarding high risk medicines | | X | X | X | X | X | Hospitals, ULS |
| implement safety practices regarding med rec | | | | X | X | X | Hospitals, ULS |
| ensure electronic ADR warning systems | X | | X | | X | | SPMS, INFARMED |
| audit safe medication practices every six months | | X | X | X | X | X | Hospitals, ULS |

**High risk
medicines**

NORMA |
da Direção-Geral da Saúde

Maria da Graça
Gregório de
Freitas

Digitally signed by Maria da Graça
Gregório de Freitas
DN: cn=PT, ou=Ministério da Saúde,
ou=Direção-Geral da Saúde,
cn=Maria da Graça Gregório de
Freitas
Date: 2015.08.06 14:16:42 +01'00'

NÚMERO: 014/2015
DATA: 06/08/2015

ASSUNTO: Medicamentos de alerta máximo
PALAVRAS-CHAVE: Segurança do doente; segurança na medicação; medicamentos de alerta máximo
PARA: Instituições prestadoras de cuidados de saúde do Sistema de Saúde
CONTACTOS: Departamento da Qualidade na Saúde (dqs@dgs.pt)



**LASA
medicines**

NORMA |
da Direção-Geral da Saúde

Francisco
Henrique
Moura George

Digitally signed by Francisco
Henrique Moura George
DN: cn=PT, ou=Ministério da
Saúde, ou=Direção-Geral da
Saúde, cn=Francisco Henrique
Moura George
Date: 2015.12.14 15:46:45 Z

NÚMERO: 020/2014
DATA: 30/12/2014
ATUALIZAÇÃO 14/12/2015

ASSUNTO: Medicamentos com nome ortográfico, fonético ou aspeto semelhantes
PALAVRAS-CHAVE: Segurança do doente; segurança na medicação; medicamentos LASA
PARA: Instituições prestadoras de cuidados de saúde do Sistema de Saúde
CONTACTOS: Departamento da Qualidade na Saúde (dqs@dgs.pt)



Pillar 1: Safety Culture

- Promote the training of health professionals in the field of patient safety
- Assess the Safety Culture
- Increase the literacy and participation of the patient, family, caregiver and society in the safety of care provision



Pillar 2: Leadership and Governance

- Ensure the involvement of management and leadership of institutions in the implementation of the plan
- Consolidate the articulation of the security governance structures national, regional and locally

Pillar 3: Communication



- Optimize intra and inter-institutional communication with particular emphasis for transition care moments.
- Adapt the communication of clinical information to the patient, family and caregiver.

Pillar 4: Prevention and management of patient safety incidents



- Increase culture and transparency of the incident notification of patient safety in the NOTIFICA
- Promote the monitoring and evaluation of security incidents of the patient in the NOTIFICA

Pillar 5: Safe practices in safe environments

- Implement and consolidate safe practices in an environment providing health care by promoting the use of digital tools
- Monitor the implementation of safe practices
- Reduce infections associated with healthcare and antimicrobial resistance
- Promote safe digital health



MEDICINES VERIFICATION SYSTEM (MVO)



The medicines verification system is a pan-European system which aims to prevent falsified medicines from entering into the legal supply chain and to detect potential falsifications.

The system consists of a central information and data router (designated as “hub”) and of repositories which serve the territories of each Member State (designated as «national repositories»)

<https://mvoportugal.pt/en/>

MEDICINES VERIFICATION SYSTEM (MVO)



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FARMACÊUTICOS HOSPITALARES



Medicines verification system

The verification system will help secure the legal supply chain from falsified medicines and detect potential falsifications.



Safety features

The safety features will enable to verify the authenticity and integrity of the medicinal product before it is supplied to the Patient.

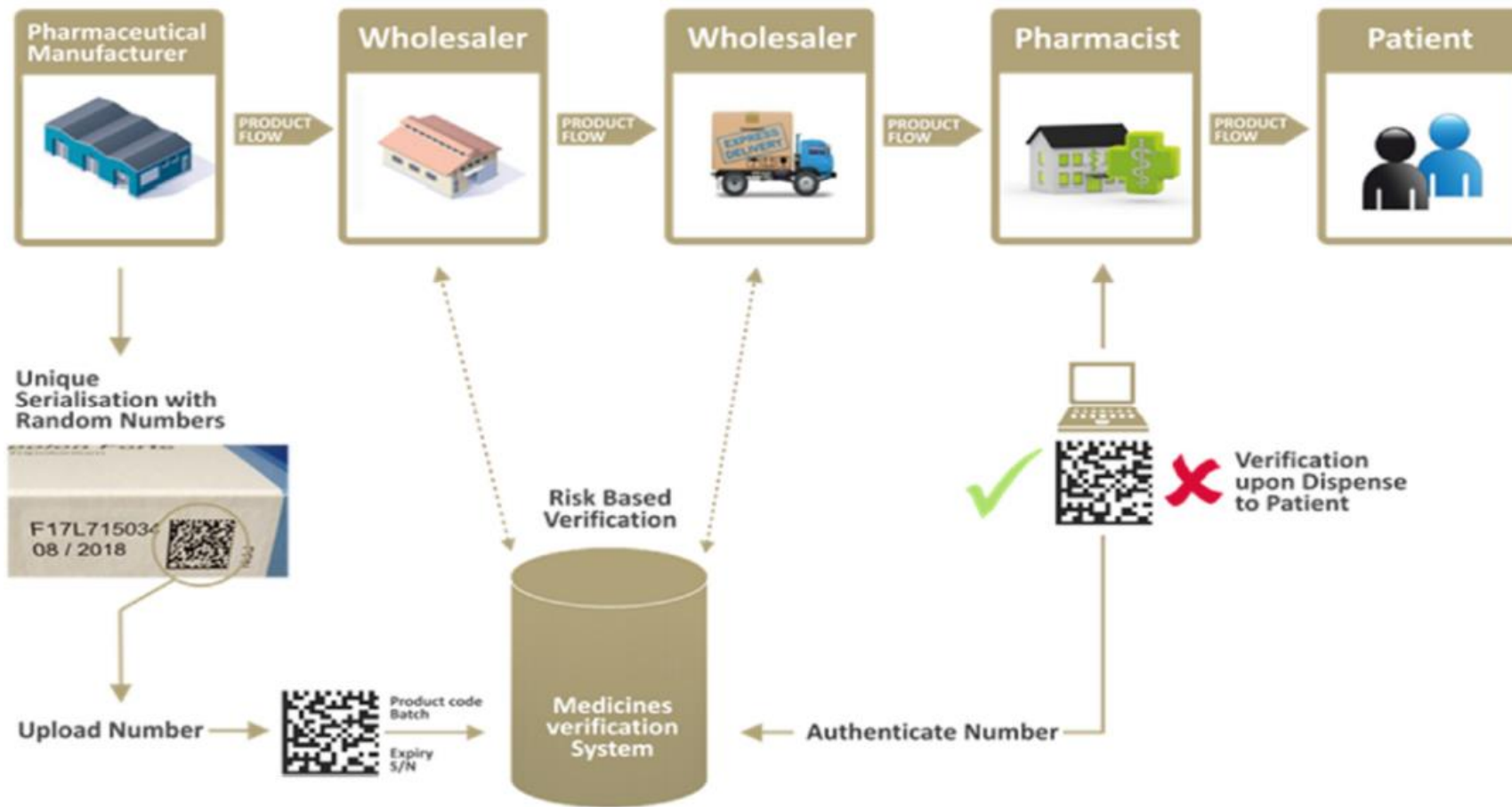
The national medicines verification system is an integral part of the European medicines verification system and consists of the national repository, where the information regarding the packs that circulate in Portuguese territory will be stored. The users of the national system (wholesalers, pharmacies and healthcare institutions) will establish a connection with it in order to be able to execute their obligations of verification and decommissioning of the unique identifier.

<https://mvoportugal.pt/en/>

MEDICINES VERIFICATION SYSTEM (MVO)



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HEALTH EVENT RISK MANAGEMENT



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NOTIFICA is one of the pillars PATIENT SAFETY NACIONAL PLAN

- National Incident Notification System;
- Provided free of charge by the Ministry of Health;
- Covers all levels and areas of health care delivery;
- Notification through this platform is voluntary, confidential, anonymous and non-punitive;
- Notification can be done by health professionals and citizens.



SNS SERVIÇO NACIONAL DE SAÚDE



DGS desde 1899
Direção-Geral da Saúde

A DGS SAÚDE A a Z PNS e PROGRAMAS SAÚDE PÚBLICA QUALIDADE e SEGURANÇA INTERNACIONAL

Início

Sistema Nacional de Notificação de Incidentes - NOTIFICA

O NOTIFICA é uma plataforma destinada à gestão de incidentes ocorridos no Sistema de Saúde, na qual o cidadão ou o profissional de saúde podem reportar três tipos diferentes de incidentes:

- Relacionado com a prestação de cuidados de saúde;
- Relacionado com a violência contra profissionais de saúde ocorrida no local de trabalho;
- Relacionado com a utilização de dispositivos médicos corto-perfurantes.

notifiQ@

<https://www.dgs.pt/servicos-on-line1/notific-sistema-nacional-de-notificacoes-de-incidentes-e-de-eventos-adversos.aspx>

notifiQ@

Goals:

- Increase patient safety;
- Health incident management;
- Learn from the incident/error;
- Avoid future occurrences;

Monitoring and progress **reports are issued** within the scope of health care provision in general and to the institutions involved in the incidents.

Limitation: the system is not designed to investigate individual cases.

HEALTH EVENT RISK MANAGEMENT



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HER +

- Hospital Risk Management Platform;
- Notification system for adverse events that could cause problems for the hospital.
- Most Portuguese hospitals to manage their incidents use the HER + software.

<http://www.risi.pt/>



HEALTH EVENT RISK MANAGEMENT



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Goals:

- Implement a patient safety culture;
- Improve processes to mitigate adverse hospital events;
- Centralize and track incidents;
- Improve the hospital's credibility and image by reducing the occurrence of adverse events;
- Develop real-time indicators to measure and improve the quality of healthcare services at each hospital.



<http://www.risi.pt/>

HEALTH EVENT RISK MANAGEMENT



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Sair
Utilizador: **Ana Marta Jorge**
Empresa: **HVFX**

- Registo de Incidentes
- Lista de Incidentes
- Análise

REGISTO DE INCIDENTES

- TIPO DE INCIDENTE:
- 1 - Gestão do Percurso do Doente
 - 2 - Processo/Procedimento Clínico
 - 3 - Documentação
 - 4 - Infecção Associada aos Cuidados de Saúde
 - 5 - Medicação/Fluidos Intra-venosos
 - 6 - Sangue e Derivados
 - 7 - Alimentação e Dieta
 - 8 - Gases Medicinais
 - 9 - Dispositivo/Equipamento Médico
 - 10 - Comportamento
 - 11 - Acidente do doente
 - 12 - Queda do Doente
 - 13 - Úlceras Por Pressão
 - 14 - Infra-estrutura/Edifício/Instalações
 - 15 - Gestão Organizacional/Recursos
 - 16 - Segurança Geral
 - 17 - Segurança e Higiene no Trabalho
 - 18 - Outros

5. Medication / Intravenous Fluids

N.º de Incidente: **Novo** Estado: **Aberto** Tipo de Incidente: **5 - Medicação/Fluidos Intra-venosos** Data de Criação: **30-10-2021** Data de Comunicação:

DADOS DO INCIDENTE

Dia: 30 | Mês: Outubro | Ano: 2021 | Hora:

Declarante: Ana Marta Jorge

Local de Detecção: Local Ocorrência:

Incident Data
Notifier Data

DADOS DO LESADO (PREENCHIMENTO OBRIGATÓRIO)

Nome: N.º Processo: Data de Nasc.: Género:

| TIPO | NOME | DATA DE NASCIMENTO | IDADE | GÉNERO | IDENTIFICAÇÃO |
|------|------|--------------------|-------|--------|---------------|
|------|------|--------------------|-------|--------|---------------|

Não existem dados para visualizar

Injured Patient Data

HEALTH EVENT RISK MANAGEMENT



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DESCRIÇÃO

Categoria Profissional do Declarante

...

Descrição dos Factos (Descreva o que aconteceu, como e o quê)

A medicação/fluido envolvido (nome genérico, nome de marca, lote e prazo de validade)

...

Selecione a fase do processo

...

Selecione o tipo de dano



- **Description incident problem**
- **Drug reported**
- **Process phase**
- **Type of damage (Physicist; Social/ Economic; Psychological)**



HEALTH EVENT RISK MANAGEMENT



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Nº. de Incidente: **Novo** Estado: **Aberto** Tipo de Incidente: **5 - Medicação/Fluidos Intra-venosos** Data de Criação: **30-10-2021** Data de Comunicação:

AÇÕES DE MELHORIA IMEDIATAS

Descreva (medidas imediatas para minimizar as consequências deste incidente):

AÇÕES DE MELHORIA PREVENTIVAS

Descreva (medidas que na sua opinião, deverão ser planeadas para prevenir este incidente):

EVIDÊNCIAS (FOTOS, DOCUMENTOS)

📁 📄 📷

| DESCRIÇÃO | DATA DE CRIAÇÃO | UTILIZADOR DE CRIAÇÃO | DATA DE MODIFICAÇÃO | UTILIZADOR DE MODIFICAÇÃO |
|-----------|-----------------|-----------------------|---------------------|---------------------------|
|-----------|-----------------|-----------------------|---------------------|---------------------------|



- **Immediate improvement actions to minimize the incident;**
- **Preventive improvement actions to avoid the incident;**
- **Incident Evidence (photos; documents).**



HEALTH EVENT RISK MANAGEMENT



ASSOCIAÇÃO PORTUGUESA DE FARMACÊUTICOS HOSPITALARES



HER+ also allows access to the **QUALITY** and **SAFETY REPORTS** issued by the National Medicines Authority **INFARMED**



| CÓDIGO ALERTA | TIPO ALERTA | ASSUNTO | LINK | DATA PUBLICAÇÃO | DATA REGISTO |
|---------------|-------------|--|---|-----------------|--------------|
| 1109 | SEGURANÇA | Medicamentos contendo fosfomicina: alteração e suspensão de Autorizações de Introdução no Mercado | https://www.infarmed.pt/web/infarmed/infarmed/-/journal_content/56/15786/3749988 | 17-07-2020 | 18-07-2020 |
| 1108 | QUALIDADE | Recolha voluntária de lotes do medicamento Tamiflu, oseltamivir, 75 mg, cápsula | https://www.infarmed.pt/web/infarmed/infarmed/-/journal_content/56/15786/3749988 | | |
| 1107 | QUALIDADE | Informação adicional para utilização do teste "GeneFinder COVID-19 Plus RealAmp Kit" | https://www.infarmed.pt/web/infarmed/infarmed/-/journal_content/56/15786/3749988 | | |
| 1106 | QUALIDADE | Comercialização descontinuada do teste "BIOEASY 2019 - Novel Coronavirus (2019-nCoV) Ag GICA Rapid Test" | https://www.infarmed.pt/web/infarmed/infarmed/-/journal_content/56/15786/3749988 | | |
| 1105 | SEGURANÇA | Retificação - Recolha voluntária de lote do teste Tell Me Fast Rapid Diagnostic Test Coronavirus (COVID-19) IgG/IgM Antibody Test (S/P/WB) - fabricante Biocan Diagnostics Inc | https://www.infarmed.pt/web/infarmed/infarmed/-/journal_content/56/15786/3749988 | | |
| 1104 | SEGURANÇA | Recolha voluntária de lote do teste Tell Me Fast Rapid Diagnostic Test Coronavirus (COVID-19) IgG/IgM Antibody Test (S/P/WB) - fabricante Biocan Diagnostics Inc - Retificação | https://www.infarmed.pt/web/infarmed/infarmed/-/journal_content/56/15786/3749988 | | |
| 1103 | QUALIDADE | Recolha voluntária de lote do medicamento Cetorolac Baxter, solução injetável, 30 mg/1 ml | https://www.infarmed.pt/web/infarmed/infarmed/-/journal_content/56/15786/3749988 | | |
| 1102 | SEGURANÇA | Recolha voluntária de lote do teste "Tell Me Fast Rapid Diagnostic Test Coronavirus (COVID-19)" | https://www.infarmed.pt/web/infarmed/infarmed/-/journal_content/56/15786/3749988 | | |
| 1101 | QUALIDADE | Recolha voluntária de três lotes do medicamento Ciclosporina Generis | https://www.infarmed.pt/web/infarmed/infarmed/-/journal_content/56/15786/3749988 | | |
| 1100 | QUALIDADE | Recolha voluntária de lotes do medicamento Duavive | https://www.infarmed.pt/web/infarmed/infarmed/-/journal_content/56/15786/3749988 | | |
| 1099 | QUALIDADE | Recolha voluntária de lote do medicamento Lisaspin 1000, pó para solução oral | https://www.infarmed.pt/web/infarmed/infarmed/-/journal_content/56/15786/3749988 | | |
| 1098 | SEGURANÇA | Novas medidas para evitar erros de administração de medicamentos contendo leuprorelina | https://www.infarmed.pt/web/infarmed/infarmed/-/journal_content/56/15786/3749988 | | |

Medicamentos contendo fosfomicina: alteração e suspensão de Autorizações de Introdução no Mercado

Circular Informativa N.º 111/CD/100.20.200 Data: 29/06/2020

Para: Divulgação geral

CONTACTE-NOS



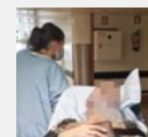
Pólicia mata 25 membros de gang responsável por assaltos com explosivos a bancos no Brasil



Advogado de família de homem morto por carro de Cabrita nega tese de que vítima não estava a trabalhar



Bolsonaro insulta jornalistas que acabam agredidos por seguranças do presidente brasileiro. Veja as imagens



Médica d salva vid: em centr no Porto

Cegos de Santa Maria: Técnica diz que usou medicamento certo

A técnica de farmácia do Hospital de Santa Maria, Sónia Baptista, afirmou esta quinta-feira, no julgamento do caso das seis pessoas que cegaram em 2009, ter a certeza de que pegou no medicamento certo, o Avastin, para preparar a solução que foi injectada nos olhos dos seis doentes.

Farmacêutico e Técnica são acusados de seis crimes de ofensa à integridade física por negligência.

MENU 🔍 ☁️ 18

Diário de Notícias

TSF 👤

INÍCIO

Relatório do Garcia de Orta não explica remédio no local errado

ANA MAIA
13 Outubro 2010 — 01:00

TÓPICOS

- Portugal
- Sul

O Hospital Garcia de Orta, em Almada, não consegue explicar como é que o ácido usado por engano em duas crianças foi arrumado no frigorífico em vez de no armário da sala da urgência. Um dado que faz parte da conclusão do inquérito interno, conhecido ontem, ao incidente que queimou duas crianças a 17 de Junho. O hospital vai negociar compensações com os pais e a médica foi punida com uma repreensão escrita.

PUBLICIDADE

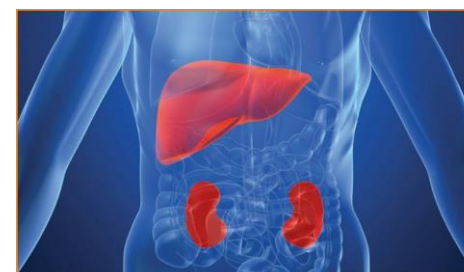
Não Perca

 **DINHEIRO**
Argélia fecha hoje gasoduto do Magrebe que serve Espanha e Portugal

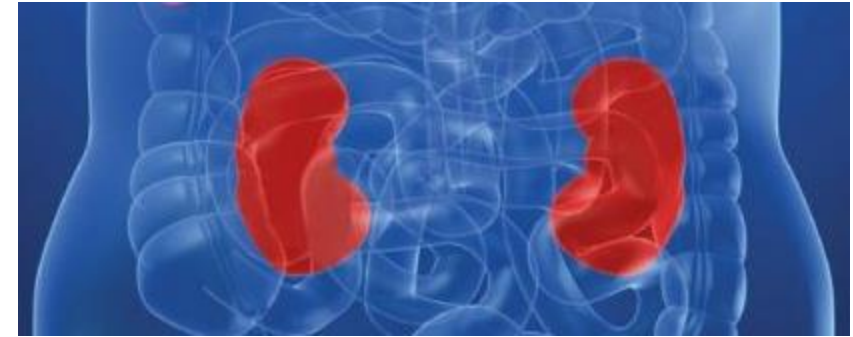
 **SOCIEDADE**

<https://www.dn.pt/portugal/sul/relatorio-do-garcia-de-orta-nao-explica-remedio-no-local-errado--1684372.html>

- **Ensure the implementation of the National Patient Safety Plan**
- **Improve safety in the use of medications**
- **Ensure safe practices**
- **Focus priorities**
 - ✓ **Patient's Clinical Conditions**
 - ✓ **Special Populations**
 - ✓ **High-Alert Medications**
 - ✓ **Nephrotoxic and Hepatotoxic Drugs**

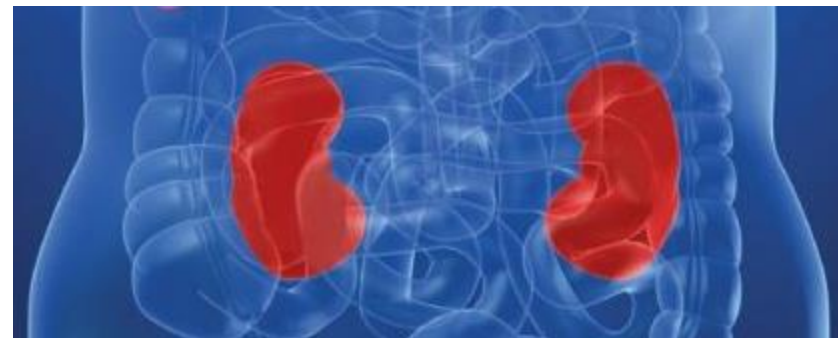


Identifying Determinants And Consequences of Drug-induced Acute Kidney Injury (AKI)



AKI is a common syndrome in hospitalized patients and associated with short and long-term morbidity and mortality, often induced by exposure to AKI-inducing drugs. A possible consequence of the use of nephrotoxic drugs is an increased risk of progression to chronic renal failure. The absence of specific treatment calls for the need for prompt clinical identification of creatinine changes.

Identifying Determinants And Consequences of Drug-induced Acute Kidney Injury (AKI)

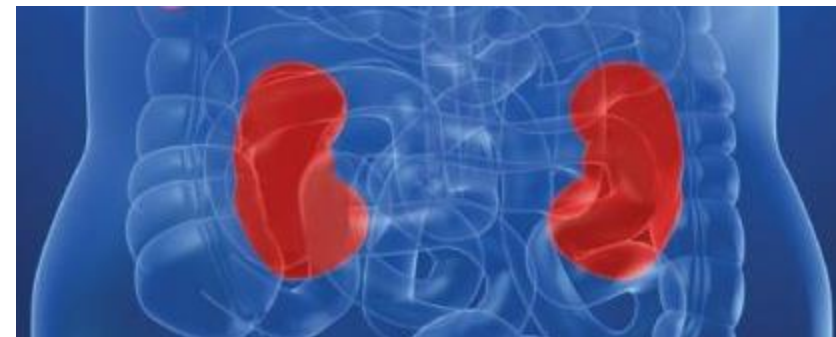


To contribute to the development of a clinical pharmacist intervention program to minimize drug-induced AKI.

The intermediate goals are:

- to evaluate the evolution of the glomerular filtration rate (GFR), as a marker of prognosis of kidney injury, in patients admitted to the Vila Franca de Xira Hospital (HVFX) and treated with drugs with nephrotoxic potential;
- and to estimate the prevalence of Acute Renal Insufficiency as ADRs reported to the Portuguese national pharmacovigilance database and describe drugs more frequently involved.

Identifying Determinants And Consequences of Drug-induced Acute Kidney Injury (AKI)



The results of this work are expected to contribute to a deeper understanding of the AKI-inducing drugs and how other factors may change the odds of occurrence of AKI in real-world.

This will thus lead to the development of clinical pharmacy evidence-based interventions to be implemented in future work and ideally to creating AKI Adverse Event Trigger Tool Worksheet.

