

Course Unit	Patient Safety and Risk Management	Field of study	Health
Master in	Applied Health Sciences - Community Intervention	School	School of Health
Academic Year	2023/2024	Year of study	1
Type	Semestral	Semester	2
Workload (hours)	121,5	Contact hours	T - TP - PL - TC - S - E - OT - O 56
		Level	2-1
		ECTS credits	4.5
		Code	5055-668-1207-00-23

T - Lectures; TP - Lectures and problem-solving; PL - Problem-solving, project or laboratory; TC - Fieldwork; S - Seminar; E - Placement; OT - Tutorial; O - Other

Name(s) of lecturer(s) Emanuel Onofre Serra Lameiras

### Learning outcomes and competences

At the end of the course unit the learner is expected to be able to:

1. Learn to discuss and evaluate error;
2. Improve the effectiveness of communication among health professionals;
3. Improve safety in the use of medicine, medical devices and other health products;
4. Develop a safety culture;
5. Be aware of the development of drug risk minimization plans, including the development of systems and procedures for reporting errors;
6. Understand the importance of the pharmacovigilance system and its role as health professionals and citizens;
7. Identify and classify adverse reactions taking into account their seriousness;
8. Properly fill out the adverse reaction notification forms;
9. Research, analyze and interpret epidemiological studies and data on pharmacovigilance.

### Prerequisites

Not applicable

### Course contents

1. National Plan for Patient Safety
2. Detection, recording and error control systems.
3. Good practices during health care
4. The National and European Pharmacovigilance System
5. Surveillance of Medical Devices and Other Health Products
6. Risk Management Plans

### Course contents (extended version)

1. National Plan for Patient Safety
  - Assessment of Patient Safety Culture in Hospitals and Primary Health Care
  - Optimize intra and inter-institutional communication, in the transition of care and with the patient
  - Mechanisms and Procedures for the Unequivocal Identification of Patients
  - Safe practices related to surgical safety, occurrence of falls and pressure ulcers
  - Medication safety and therapeutic reconciliation
2. Detection, recording and error control systems
3. Error detection, recording and control systems. Prevention and management of patient safety incident
4. The National and European Pharmacovigilance System
  - Mechanisms of Adverse Drug Reactions (ADRs) and risk factors
  - Classification and notification of ADRs
  - Good Pharmacovigilance Practices
5. Surveillance of Medical Devices and Other Health Products
6. Risk Management Plans

### Recommended reading

1. Despacho n.º 9390/2021. Plano Nacional para a Segurança dos Doentes 2021 -2026 (PNSD 2021 -2026). | Normas DGS. | WHO 2021. Global Patient Safety Action Plan 2021–2030 -T. eliminat. avoid. harm in HC
2. Edwards, L. D. & Fox, A. W. & Stonier, P. D. (2010). Principles and Practice of Pharmaceutical Medicine (3rd Ed). New Jersey: Wiley-Blackwell
3. EFP, (2012). The new EU pharmacovigilance legislation: Directive 2010/84/EU and Regulation No. 1235/2010, Guidance for Patient Organisations | Relatório Infecções e Resistência a antimicrobianos 2018
4. EMA (2013). Guideline on good pharmacovigilance practices. London, United Kingdom: European Medicines Agency and Heads of Medicines Agencies; 2013
5. Herdeiro, M. T. & Ferreira, M. & Ribeiro-Vaz, I. & Junqueira Polónia, J. & Costa-Pereira, A. (2012). O Sistema Português de Farmacovigilância. Acta Med Port, 25(4): 241-249

### Teaching and learning methods

T-classes: systematization of concepts, knowledge for the discussion of case studies, publications, NF filling, elaboration of PSR or CIOMs with oral presentation and discussion in TP classes. TC and OT for research and data analysis - for self-learning, planning and implementation capacity of Risk Management and Pharmacovigilance programs. Teachers Emanuel Lamiras (IPB) and Sandra Ventura (IPG).

### Assessment methods

- Single alternative - (Regular, Student Worker) (Final, Supplementary, Special)
  - Final Written Exam - 70%
  - Practical Work - 30%

### Language of instruction

Portuguese, with additional English support for foreign students.

### Electronic validation

Emanuel Onofre Serra Lameiras	Luis Migue Fernandes Nascimento	Ana Maria Nunes Português Galvão	Adília Maria Pires da Silva Fernandes
14-04-2024	14-04-2024	14-04-2024	14-04-2024