Elective Subject

(Academic Course 2026-2027)

Subject title: RESEARCH ON HEALTH CARE QUALITY

Code: 609361
Subject: Elective
Responsibility Center: Faculty of Nursing, Physiotherapy and Podiatry
Credits: 3 ECTS
Number of places offered: 20

	Total (32% attendance)	Theory	Seminars	Practices	Others
Classroom activities	24	24			

Course schedule: (semester, day and schedule): Second semester (Thursdays, 4:00 p.m. to 8:00 p.m.)

STUDENT PROFILE (University degrees for which they are offered, if applicable)

Graduates in degrees in the area of health sciences or related, and especially recommended for graduates in Nursing, Physiotherapy or Podiatry.

BRIEF DESCRIPTOR

The subject covers the fundamental principles and advanced quality practices in biomedical research. It starts with understanding integrity and total quality management, including quality frameworks and ISO standards. It focuses on how to conduct research with a conscious focus on quality, applying standard guidelines such as the PMBOK® and considering gender equality and effective data management. Additionally, quality is examined at all stages of the research, from planning to communication of results, emphasizing ethics and legal compliance. The subject also explores the application of artificial intelligence through the prompting methodology and its ethical implications in health. Finally, it highlights the importance of patient safety, health risk management and safety culture within healthcare environments.

OBJECTIVES

- Develop a deep understanding of ethical and quality principles, and their critical application in advanced scientific research and professional practice.
- Acquire specialized skills to apply and adapt quality management models in the planning and execution of biomedical research projects.
- Achieve expert management of the tools and methods to ensure and improve quality in all stages of biomedical research, from design to dissemination of results.
- Expertly integrate knowledge of national and international legislation and codes of ethics, applying them to decision-making in biomedical research.
- Train in the design and application of artificial intelligence technologies to solve complex problems in health research, with an understanding of the ethical and practical implications.
- Promote patient safety as a critical element in research and clinical practice, leading the implementation of effective strategies to minimize risks and improve the quality of health care.

KNOWLEDGE, SKILLS AND COMPETENCES

Knowledge:

- Gain a thorough understanding of integrity principles, quality management methodologies such as TQM and the PDCA cycle, and the ISO regulatory framework to ensure excellence in research and development.
- Possess in-depth knowledge of project management models such as PMBOK®, the role of funding agencies and the use of tools for risk management and the promotion of gender equality.

• Understand the phases and procedures of scientific research with an emphasis on quality, including planning, development of protocols and the use of standardized guidelines for scientific communication.
• Know in detail the applicable legislation and the fundamental ethical principles that govern biomedical research at the national and international level.
• Understand the fundamentals of the prompting methodology in AI, evaluating its quality and ethical applications in health.
• Have a deep understanding of the patient safety culture, including incident reporting, health risk management and the implementation of safety rounds.

Skills:

• Ability to carry out a critical analysis of quality in scientific studies.
• Evaluation of the quality and internal, external and construct validity of the research.
• Ability to manage biomedical research projects, including data management.
• Application of risk management techniques in health projects.
• Ability to communicate research results clearly and effectively.
• Writing scientific documents following standards such as those of the EQUATOR Network.
• Ability to apply ethical and conduct principles in research.
• Interpretation and application of current legislation in biomedical research.
• Ability to design and optimize AI prompts for health applications.
• Evaluation of AI applications to ensure an ethical and quality response.
• Ability to perform reactive and proactive analysis of safety incidents, learning from errors to improve care.
• Ability to develop and implement effective strategies to prevent safety incidents and medication errors.
• Ability to effectively communicate patient safety principles and practices to interdisciplinary teams.

Competences:

• Competence to integrate and apply the principles of quality and total management in research projects.
• Competence in the direction and conscious management of biomedical research projects.
• Competence to develop and execute research protocols that meet high standards of quality and ethics.
• Competence to navigate and adhere to ethical and legal frameworks in biomedical research.
• Competence to innovate in the field of health through the ethical and effective application of AI.
• Competence to foster a safety culture that prioritizes patient-centered care and transparency in incident reporting.
• Competence to continually evaluate safety procedures and promote evidence-based improvement.
• Ability to lead and educate other professionals in the implementation of safe practices and risk management in healthcare settings.

LEARNING OUTCOMES

Knowledge:

• Demonstrate a comprehensive understanding of ethical and quality principles in research, applying methodologies such as TQM and PDCA, and adhere to ISO regulations to guarantee excellence in all stages of the investigative process.
• Apply advanced knowledge in biomedical project management models, including PMBOK®, and effectively manage the expectations of funding agencies, risks and promotion of gender equality.
• Plan and execute research protocols, ensuring effective communication and compliance with international scientific standards for quality.
• Interpret and apply national and international legislation, as well as ethical principles, in the design and execution of biomedical research.
• Evaluate and apply the fundamentals of the AI prompting methodology to improve the quality of AI responses and their ethical impact in the field of health.
• Identify and manage patient safety incidents and health risks proactively, applying preventive and educational strategies for continuous improvement in health care.

Specific Skills:

• Conduct critical analyses and evaluate the internal, external and construct validity of scientific research to drive improvements in research quality.
• Manage biomedical research projects, including data management and application of risk management techniques.
• Communicate results and write scientific documentation with clarity, precision and in accordance with international standards such as those of the EQUATOR Network.
• Apply ethical principles and current regulations in the conception and conduct of biomedical research.
• Design and optimize AI prompts, ensuring that applications are ethically sound and of quality in health contexts.
• Implement proactive and reactive analyses for the identification and prevention of safety incidents, promoting a culture of continuous improvement based on patient safety.

Professional Skills:
• Integrate principles of quality and total management in the direction and execution of research projects, achieving results that meet the highest standards of quality and ethics.
• Direct biomedical research projects consciously and effectively, showing leadership and decision-making skills based on evidence and ethical practices.
• Innovate in the field of health through the implementation of AI-based solutions that respect ethical and legal frameworks, and that improve the quality of health care.
• Promote and lead the implementation of a safety culture that focuses on patients and transparency, guaranteeing safe and effective practices in the healthcare field.

TEACHING ACTIVITIES (theoretical, practical, seminars, workshops, etc.)

- Master classes: 15 face-to-face hours.
- Group work / seminars / presentations: 7 face-to-face hours + 25 hours of autonomous work.
- Evaluation: 2 face-to-face hours.
- Tutoring: 6 hours.
- Study: 20 hours of individual learning.
- Total: 75 hours (3 ECTS × 25 hours).

CONTENT TOPICS

TOPIC 1. DEFINITIONS AND CONCEPTS
- Principles of integrity and quality in research
- Total Quality Management (TQM)
- Process-based approach
- PDCA cycle
- Quality certification and accreditation processes
- ISO standards 9000, 17025, 166002 on quality management and R&D

TOPIC 2. QUALITY IN BIOMEDICAL RESEARCH CENTERED ON PROJECTS
- Introduction and concepts
- Mindful management
- Research project management model
- Project management through the PMBOK® Guide to improve quality
- Funding agencies
- Tools for risk management
- Gender equality plan
- Data management plan

TOPIC 3. QUALITY IN THE STAGES OF RESEARCH
- Principles of scientific quality
- Process and stages of research from a quality perspective
- Planning and protocols: quality of the research report
- Critical reading: CASPe
- Evidence of clinical practice: GRADE system
- Guide for writing clinical studies: EQUATOR Network
- Quality in research execution: internal, external and construct validity
- Quality in research communication

TOPIC 4. ETHICS AND LEGISLATION
- Ethical principles and legislation
- Importance of the ethical and legal framework: components and benefits
- National laws: Law 14/2007 on Biomedical Research and other regulations
- Code of Conduct for research in the EU: ALLEA
- Ethics in biomedical research

TOPIC 5. PROMPTING METHODOLOGY: ARTIFICIAL INTELLIGENCE
- Fundamentals of prompting in AI
- Design and optimization techniques for prompts
- Applications of prompting in the health field
- Evaluation and analysis of the quality of AI responses
- Ethics of AI in health

TOPIC 6. PATIENT SAFETY

- Culture of safety and key concepts (definitions, taxonomy...)
- Reporting of safety incidents (SI) and medication errors (ME)
- Concept, identification and management tools for health risks: reactive and proactive analysis
- Basic principles of safety rounds

EVALUATION

REGULAR CONVOCATION			
EVALUATION ACTIVITY	**WEIGHTING**	**REMARKS**	**MAXIMUM SCORE**
Final exam	50%	Written test on the theoretical contents. As the final exam carries 50% of the grade, failure to sit it results in a 'Not Presented' grade (Art. 8). A final grade equal to or higher than 5.0 out of 10 is required to pass the subject.	5
Group and/or individual work	50%	Seminars, assignments and presentations developed during the course. Graded on the Art. 8 scale: Fail (0-4.9), Pass (5.0-6.9), Good/Notable (7.0-8.9), Outstanding (9.0-10); 'Matricula de Honor' (Honours) for grades >= 9.0, max. 5% of those enrolled.	5
EXTRAORDINARY CALL			
EVALUATION ACTIVITY	**WEIGHTING**	**REMARKS**	**MAXIMUM SCORE**
Final exam	100%	Written test on all the contents of the subject. Any fraudulent conduct (copying, plagiarism, impersonation or submitting work not produced by the student) results in a grade of zero, and 'Not Presented' may never be recorded. Grades published within 8 calendar days; review within 4 working days and appeal within 10 days (Arts. 9-11). Governed by the Assessment and Disciplinary Regulations of the Faculty of Nursing, Physiotherapy and Podiatry (UCM).	10

BIBLIOGRAPHY - INTERNET Resources

Quality management in research

- Alonso Miguel P. Calidad en Investigación (1ª parte). De qué trata la gestión de calidad en investigación. Revista de Investigación en Gestión de la Innovación y Tecnología. MADRI+D, N.º 32, octubre 2005. Available at: https://www.madrimasd.org/revista/revista32/aula/aula1.asp
- Alonso Miguel P. Calidad en Investigación (2ª parte). Aproximación metodológica a la mejora de las actividades de investigación. MADRI+D, N.º 33, diciembre 2005. Available at: https://www.madrimasd.org/revista/revista33/tribuna/tribuna3.asp
- Casado M, Patrao MdC, de Lecuona I, Carvalho AS, Araujo J. Declaración sobre integridad científica en investigación e innovación responsable. Barcelona: Edicions de la Universitat de Barcelona; 2016.
- Lamas S, Ayuso C. La integridad científica como fundamento esencial de la investigación clínica. En: Dal-Ré R, Carné X, Gracia D. Luces y sombras en la investigación clínica. Madrid: Triacastela; 2013.
- Sánchez Alfaro LA. Integridad Científica: elemento esencial en el progreso de la ciencia. Movimiento Científico. 2017;11(1):1-4.
- Universidad Complutense de Madrid. Código de buenas prácticas en investigación. Madrid: UCM; 2020.
- UNE 166000:2006 – Gestión de la I+D+i: terminología y definiciones de las actividades de I+D+i.
- UNE 166001:2006 – Gestión de la I+D+i: requisitos de un proyecto de I+D+i.
- UNE 166002:2021 – Gestión de la I+D+i: requisitos del Sistema de Gestión de I+D+i.
- Cobos-Carbó A, Augustovski F. Declaración CONSORT 2010. Med Clin (Barc). 2011;137(5):213-215. doi:10.1016/j.medcli.2010.09.034
- von Elm E, Altman DG, Egger M, et al. Declaración de la Iniciativa STROBE. Gac Sanit. 2008;22(2):144-150. doi:10.1157/13119325

• Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ). Int J Qual Health Care. 2007;19(6):349-357. doi:10.1093/intqhc/mzm042
• Estarli M, Aguilar Barrera ES, Martínez-Rodríguez R, et al. Declaración PRISMA-P 2015. Rev Esp Nutr Hum Diet. 2016;20(2):148-160. doi:10.14306/renhyd.20.2.223
• Brouwers MC, Kerkvliet K, Spithoff K, on behalf of the AGREE Next Steps Consortium. The AGREE Reporting Checklist. BMJ. 2016;352:i1152. doi:10.1136/bmj.i1152
• Saiz A, Blasco JA y Grupo GEVIEC. Evaluación de la calidad de Estudios Cualitativos. Madrid: Plan de Calidad para el SNS del MSSSI, Agencia Laín Entralgo; 2011. UETS 2010/01.

Quality of care and patient safety

• Mompart García MP, Almazán González S. Calidad y seguridad del paciente. En: Mompart García MP, Durán Escribano M. Administración y gestión. 3ª ed. Colección Enfermería S21. Madrid: DAE; 2018. p. 413-40.
• Davins Miralles JP. Comparativa de 3 modelos de gestión de calidad: EFQM, ISO, JCAHO. FMC. 2007;14(6):304-8.
• Almazán González S, Mompart García MP. Seguridad del paciente: eventos adversos relacionados con la atención sanitaria. En: Mompart García MP (coord.). Actualizaciones año 2010. Madrid: DAE; 2010. p. 49-65.
• Forcada Segarra JA. Conceptos de seguridad del paciente. En: Actualización y formación continuada en prevención de riesgo biológico para enfermer@s. Madrid: DAE; 2014. p. 145-52.
• Aranaz Andrés JM. La seguridad en la práctica clínica, una dimensión de la calidad asistencial. En: Cabo Salvador J. Gestión de la calidad en las organizaciones sanitarias. Madrid: Díaz de Santos; 2014. p. 1285-1309.
• Ministerio de Sanidad, Servicios Sociales e Igualdad. Estrategia de Seguridad del Paciente del Sistema Nacional de Salud 2015-2020. MSSSI; 2016. Available at: https://www.seguridaddelpaciente.es/resources/documentos/2015/Estrategia%20Seguridad%20del%20Paciente%202015-2020.pdf

Internet Resources

• Red EQUATOR. https://www.equator-network.org/
• Consorcio AGREE. https://www.agreetrust.org/
• Programa de Habilidades en Lectura Crítica Español (CASPe). http://www.redcaspe.org/
• Sociedad Española de Calidad Asistencial (SECA). http://calidadasistencial.es/
• Ministerio de Sanidad: Seguridad del Paciente. https://www.seguridaddelpaciente.es/es/
• Fundación Avedis Donabedian. https://www.fadq.org/
• Asociación Española de Normalización y Certificación (AENOR). https://www.aenor.com/
• Club Excelencia en Gestión. https://clubexcelencia.org/
• Asociación Española para la Calidad (AEC). https://www.aec.es/
• Modelo EFQM de Calidad y Excelencia. https://www.efqm.org/
• Joint Commission International. https://www.jointcommissioninternational.org/
• Formación en metodología de la investigación (Fisterra). http://www.fisterra.com/mbe/investiga/index.asp

TEACHING STAFF *(It should be indicated whether teachers have completed all their teaching dedication or not)

Teacher Responsible (coordinator): Francisco José García González
Department: Nursing
Teaching dedication: 80%

Teachers:
Name: Andrés Sebastián Santiago Sáez
Department: Legal Medicine, Psychiatry and Pathology
Teaching dedication: 20 %