INPLASY

The Clinical Quality Management System (cQMS) of Advanced Therapy Medicinal Products (ATMPs) in the hospital setting: a scoping review protocol

INPLASY202480117

doi: 10.37766/inplasy2024.8.0117

Received: 26 August 2024

Published: 26 August 2024

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ADMINISTRATIVE INFORMATION

Support - University of Macau.

Review Stage at time of this submission - Preliminary searches.

Conflicts of interest - The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

INPLASY registration number: INPLASY202480117

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 26 August 2024 and was last updated on 26 August 2024.

INTRODUCTION

Review question / Objective To identify the quality management guidelines applicable to the use of ATMPs in hospitals, to identify and summarize the quality management experiences of ATMPs in hospital settings, and to analyze the risk management information associated with approved ATMPs.

Background Advanced Therapy Medicinal Products (ATMPs), which include gene therapy, cell therapy, and tissue-engineered products, represent cutting-edge treatments with the potential to address unmet medical needs and improve patient outcomes. However, the complexity of ATMPs introduces specific quality risks, including issues related to manufacturing consistency, product stability, and patient safety. Hospitals that handle ATMPs must ensure rigorous quality management systems (QMS) to mitigate these risks, from production to patient administration. Various regulatory bodies and professional organizations, such as the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA), have issued guidelines to manage the quality risks associated with ATMPs which cover different aspects of the product lifecycle, including nonclinical, manufacturing, and clinical processes. However, there is still a lack of literature systemically exploring the quality management of ATMPs in hospital settings. The research goal is to depict the overall landscape of quality management system for ATMPs in hospital settings to inform best practices and identify areas for improvement.

Rationale This research will contribute to a better understanding of the quality management systems for ATMPs in healthcare settings, informing healthcare providers, regulators, and policymakers. By identifying practical experiences from different levels (system/practice/products), the study aims to depict the overall landscape of quality management system for ATMPs, promoting their safe and effective use in hospitals.

METHODS

Strategy of data synthesis The data synthesis will involve a descriptive analysis of the guidelines, empirical experiences and specific ATMPs information related to quality management of ATMPs. Four databases (PubMed, Web of science, Scopus and Science Direct) will be searched for eligible literature from 1 January, 2004, to 31 July , 2024. The most frequent and relevant terms will be included in the search strategy. Each search will use the following terms:[((quality management) OR (standard*) OR (credential*)) AND (advanced therapy medicinal products) OR (biological therapy) OR (regenerative medicine*)] AND ((hospital*) OR (clinic*) OR (healthcare))]. To ensure an effective search, Medical Subject Headings terms, synonyms and keywords related to the two concepts were used to develop a comprehensive search strategy. Publicly available documents and reports were found from the government and official websites of the corresponding DRAs: National Medical Products Administration (NMPA) in China https://www.nmpa.gov.cn/, Food and Drug Administration (FDA) in the U.S. https://www.fda.gov/, and European Medicines Agency (EMA) in the European Union https://www.ema.europa.eu/en. Additionally, grey literature will be conducted using Google Scholar and citation search.

Eligibility criteria Literature and reports published in English or Chinese will be identified if it directly involving the practical experiences in the quality management of ATMPs within a hospital setting for the purpose of identifying the practical insight and areas for improvement. Articles that did not involve empirical research or quality management practices of ATMPs conducted in a hospital setting will be excluded. In addition, technique guideline and relevant ATMP reports issued by regulatory authorities in the United States, the Europe Union, and China that pertain to quality management will also be included.

Source of evidence screening and selection The review was conducted and reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. Then, two authors will independently screen the titles and abstracts to identify the inclusion literatures. Full texts of potentially relevant articles will be retrieved for detailed assessment. Any discrepancy will be discussed and resolved with 2 other authors.

Data management All records will be submitted to a public reference manager (Zotero® software) to remove the duplications. The data extracted from the included articles, guidelines and reports will be categorized into the Excel table based on the clinical Quality Management System (cQMS) conceptual framework.

Reporting results / Analysis of the evidence For eligible articles, the following items will be extracted into an Excel table: the name of the first author, year of publication, study location, the purposed of studies, the quality management program or model involved (including the name of the program/model, the specific implementation place, type of ATMPs, and the practice content). The types of practices will be classified according to the seven elements of the clinical Quality Management System (cQMS) conceptual framework.

Presentation of the results The results will present the practical experiences of each element according to the cQMS framework, including (1) processes; (2) resources, roles & responsibilities; (3) partnering; (4) risk management; (5) issue management; (6) knowledge management; and (7) documentation supporting achievement of quality.

Language restriction Yes. The language restriction of this scoping review is English and Chinese.

Country(ies) involved Macao SAR, China.

Keywords Quality management system, Risk analysis, Regulatory practices, Advanced therapy medicinal products (ATMP), Hospital, Healthcare settings.

Contributions of each author

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