

Record Management Practices: A Comparative Systematic Literature Review of the Healthcare and Pharmaceutical Sector

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ABSTRACT

This systematic literature review focuses on record management practices in the healthcare and pharmaceutical sectors. This study aims to compare current practices, key regulatory requirements and challenges in record management practices in both sectors. The review draws upon the results of 27 papers (2016-2026) that were obtained via ScienceDirect, Google Scholar and Scopus. Based on the research questions, the study aims to investigate the current record management practices in the healthcare and pharmaceutical sectors and the key challenges associated with record management within both sectors. The findings reveal that record management serves as the backbone for accountability, transparency and informed decision-making within both sectors. Similarities found in the current practices of record management within these two sectors are that both sectors are currently undergoing a significant shift toward digitization to improve efficiency. However, the pharmaceutical sector shows a more structured implementation compared to the healthcare sector. In addition to this, several distinctions on the current record management practices have been identified involving the type of record created and maintained, the focus, the system as well as the regulatory framework that governs both sectors. In conjunction with challenges, both sectors face similar challenges such as data integrity and accuracy, resources and infrastructure constraints, human factors as well as security and compliance. As for specific-factor challenges, the healthcare sector faces interoperability issues hindering the seamless data flow while the pharmaceutical sector struggles with the underreporting of Adverse Drug Reactions (ADRs). To conclude, while both practice efficient record management practices, the different nature of both businesses leads to variations in record type, focus, systems, regulations and challenges. Effective record management is significant for an organization's performance and compliance.

Keywords: Record management, current practices, regulations, challenges, healthcare, pharmaceutical

INTRODUCTION

Records, regardless of their format, serve as the foundation of every formal organization, providing evidence of transactions, decisions and accountability. In the healthcare sector, records play such an important role in the business operation process and service delivery. Every aspect of healthcare activities requires the creation of records as evidence of daily transactions. The survival of any formal organization, regardless of its type, depends on proper record management practices [23]. In the context of healthcare, records do not mainly provide evidence for business operations, but also for the patient's care. Every diagnostic, treatment plan and patient file must be retained according to the value that the records hold ensuring the information is available when needed and avoiding unnecessary storage of obsolete records. Decision-making in the healthcare sector is complex and high-stakes [6]. This justifies that healthcare decision-making relies heavily on evidence, highlighting the importance of continuous and effective record management activities to support informed decisions and accountability within healthcare organizations.

Similarly, robust documentation practices within the pharmaceutical sector refer to the backbone of the development and manufacturing of medicines. The robust documentation ensures the pharmaceutical products

are developed, produced and controlled according to the quality standards [15]. It provides complete documented evidence throughout the process of developing the pharmaceutical products, ensuring transparency, consistency and compliance with the pharmaceutical sector standard. Ensuring data integrity in the pharmaceutical sector involves generating and documenting data accurately [18]. This involves the process of protecting data from modifications, falsification, deletion or destruction. As working in the high-risk sector, developing products related to health, the pharmaceutical sector must ensure that all records are managed effectively and efficiently while protecting the security of the information to ensure transparency, reliability, accountability and uniqueness of the record.

Despite the importance of record management practices in both the healthcare and pharmaceutical sectors, previous studies have primarily examined these sectors as independent studies. Due to the lack of systematic comparison studies on the record management practices, regulatory requirements and implementation challenges, this study aims to synthesize and compare the existing literature to identify similarities and differences between the two sectors in the record management practices.

METHODOLOGY

This study employs a Systematic Literature Review (SLR) approach to synthesize existing scholarly literature on record management in the healthcare and pharmaceutical sectors. The review focuses on three key aspects which include current practices, regulatory frameworks, standards and challenges affecting record management in both sectors. By systematically comparing the findings from previous studies, this study aims to identify the similarities and differences in record management practices between the healthcare and pharmaceutical sectors.

This SLR approach involves three (3) critical phases which include planning, data collection and reporting. The processes involved in each phase are as follows:

1. Phase 1: Planning

- i. Selection of an idea
- ii. Development of research questions
- iii. Identification of search strategy, literature resources and study selection criteria

2. Phase 2: Data Collection

- i. Search process conducted using pre-determined search strings, keyword and databases
- ii. Result filtration based on search selection criteria
- iii. Study selection based on title and abstract
- iv. Screen the literature based on the findings and conduct data extraction
- v. Identify the suitability of the studies based on quality assessment criteria

3. Phase 3: Reporting

- i. Synthesize data and findings aligned with the research questions
- ii. Development of the final report

Research Questions

The research questions were developed based on the overall idea of the study and by applying the PICO formula.

Table 1: PICO Formula and Scope

Criteria	Scope
Population	Healthcare and pharmaceutical sectors
Intervention	Record management practices
Comparison	Differences between healthcare and pharmaceutical record management
Outcomes	Similarities, differences, current practices and challenges

Based on Table 1, the research questions were developed as follows:

1. **RQ1:** What are the current record management practices in the healthcare and pharmaceutical sectors?
2. **RQ2:** What are the key challenges associated with record management in the healthcare and pharmaceutical sectors?

Search Strategy

The scope of the search strategy includes the discussion of the search terms, chosen databases as well as the study selection criteria for this study.

Search terms and techniques

Search terms provide an overview and synthesis of a range of research outcomes [9]. It involves the identification of keywords related to the title of the search. Keywords have been previously determined based on the research questions. Search strings for this SLR are as follows:

("record management") AND ("current practices" OR practices) AND (regulations OR standards) AND (challenges) AND (healthcare OR pharmaceutical)

Search techniques refer to the methods to effectively and efficiently retrieve information from databases. Search techniques are ways or routes to implement the search terms in retrieving the required information and outcome from the search engine [10]. The predetermined search technique ensures that the search results remain relevant and focused on the scope of the study.

1. **Limited field** (Filter by Title and Abstract)
2. **Phrase** (" ")
3. **Boolean** (AND OR)

Literature resources

The main databases utilized for the SLR search process include ScienceDirect, Google Scholar and Scopus. These databases were selected due to their extensive collection of academic literature and broad coverage of studies related to record management practices in the healthcare and pharmaceutical sectors.

Study Selection

The study selection process were conducted systematically to ensure only relevant and high-quality studies were included in the review. The search process began with a predefined search strategies which include keyword, search strings, database as well as the study selection criteria. This process was to ensure identification of all potential eligible studies within the field and maintain the consistency throughout the selection process. In the first stage of study selection process, 1,779 studies were initially retrieved.

The selection process were then proceed with the screening process. The screening process involved two main stages which include screening based on the title and abstract as well as the full-text screening. The first phase of screening based on the title and abstract have identified 34 studies eligible for the inclusion in this review. The 34 studies were then screened based on the study selection criteria (Table 2) which are the inclusion and exclusion criteria and was assessed by using the quality assessment criteria (Table 3) . This is to ensure that the studies were relevant and able to answer the intended research questions.

Study Selection Criteria

The relevancy and scope of the study are pre-determined through the inclusion and exclusion criteria to ensure systematic findings. The inclusion and exclusion criteria of this study are as follows:

Table 2: Inclusion and Exclusion Criteria

Criteria	Scope
Inclusion	- Publication year: 2016-2026 - Databases: ScienceDirect, Google Scholar and Scopus - Keywords: Record management, current practices, regulations, challenges, healthcare, pharmaceutical - Sector: Healthcare, pharmaceutical
Exclusion	- Non-English publications - Outdated publications - Irrelevant topics - Other than the healthcare and pharmaceutical sectors

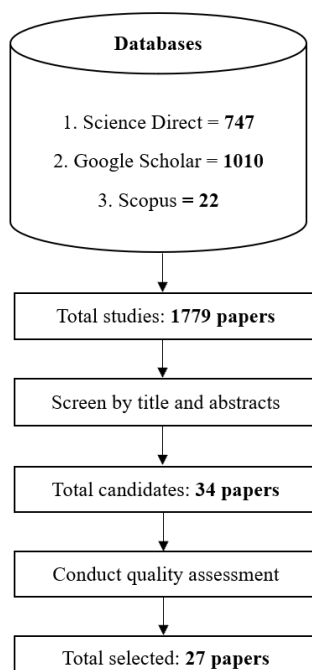
Quality Assessment

Quality assessment criteria was developed in ensuring that all selected studies to be included in this review are top quality and match the area of the discussion, which able to answer the RQ1 and RQ2 comprehensively. The quality assessment was identified based on the questions as follows:

Table 3: Quality Assessment Criteria

Question	Answer
1. Is the aim of the study clearly stated?	Yes = 1 OR No = 2
2. Is the reporting of the papers coherent?	
3. Do the findings of the study relate to RQ1 or RQ2?	
4. Does the study match or provide a meaningful contribution to the field?	
5. Does the paper follows the inclusion and exclusion criteria?	

The process continue with the assessment of 34 studies using the predetermined quality assessment criteria outlined in Table 3. Based on the assessment, 7 out of 34 studies did not meet the quality standards (No=2) such as the study did not relate to the research questions and does not follow the inclusion and exclusion criteria which resulting these 7 studies were excluded. The remaining of 27 studies fulfill all the quality assessment criteria (Yes=1) and were selected for the data extraction and synthesis process.


Figure 1: Study Selection Process

Data Synthesis

Data synthesis involves integrating data extracted from multiple studies to generate a comprehensive and cohesive understanding of the research topics. Data synthesis involves collecting, combining and summarizing findings from the selected papers to provide a comprehensive view of the topic [13]. Results and findings from 27 selected papers were collected, combined and synthesized to carefully answer RQ1 and RQ2. All the findings were reported in the results and discussion section.

RESULT AND DISCUSSION

The results and findings are presented in this section directly to answer the research questions related to record management in both the healthcare and pharmaceutical sectors. The results were synthesized based on the findings from the systematic review of the selected existing literature.

Current Record Management Practices (RQ1)

Based on the selected 27 papers included in the study, record management practices of both sectors can be seen as follows:

a) Healthcare sector

In the healthcare sector, records remain an important asset to support business operations and service delivery, providing evidence for its daily transactions, healthcare dispensation and clinical decision making [26]. In the medico-legal cases, records are the only official and acceptable evidence to be used as a source of facts in the court [5],[6],[26]. Effective record management is particularly important in this field. In the healthcare sector, it is found that it follows a systematic record management lifecycle where it involves the process of creation, capture, use, maintenance, presentation and disposal [5],[6]. Records created within the healthcare were classified by value to ensure they can be used as a guide for the retention and disposal process in the future [22]. A medical record is expected to include records such as patient background, page numbers, physician progress notes, nursing notes, medications, lab or radiology results [4],[5],[6]. These records are particularly important to support the business transactions and they must be complete, authentic and unique where they can be used as evidence. All records created must be dated, time-stamped, readable and signed. The classification of the record within some of the healthcare sectors is based on a centralized filing structure where records are often managed at certain departments such as the Outpatient Department (OPD) [21].

The reviewed study indicate that it is found that healthcare sectors, especially in developing countries, still prominently rely on manual and paper-based record [1],[2],[5],[21]. However, there is progress and significant movement toward the digitization of the medical record and the use of Electronic Health Record (EHR) to improve patient care and make the process more effective and efficient [3],[8]. The EHR system may streamline the healthcare process, enhancing accessibility and retrieval of information, thus reducing the reliance on paper [1],[2],[4],[28]. The integration of this system increases the efficiency of record management by centralizing the monitoring and real-time access to integrated and retrieved patient information across departments involved [28]. The effective record management process within the healthcare sector involve the internal collaboration derives from the efforts of physicians, nurses, administrative staff and IT teams [3]. This is to ensure the records are complete, safe and valid.

Record management practices in the healthcare sector are guided by several national and international regulations, depending on each country. For example, in the United States, the record management practices must adhere to Health Insurance Portability and Accountability Act (HIPAA) [3],[22],[31], the National Health Act (No.61 of 2003) and the Protection of Personal Information Act (No.4 of 2013) in South Africa [21], the National Health Act 2014 and Nigeria Data Protection Act in Nigeria [26], the General Data Protection Regulation (GDPR) in Europe [3], the National Archive Act 2003 in Malaysia [5],[6] and Law Number 44 of 2009 as well as Law Number 36 of 2009 in Indonesia [28]. These are the national standards that govern the record management activities in each country. As for the international standards, the record management practices in the healthcare sector must follow the World Health Organization (WHO) and ISO 15489-1 2016 [1],[2],[4],[23]. Compliance

with these national and international standards are significantly importance as these regulations ensure that records created within the healthcare sector are managed efficiently by reducing cost and errors as well as maintaining the security and confidentiality of the information [22].

b) Pharmaceutical sector

The literature reveals that the pharmaceutical sector employs a comprehensive documentation system across its product lifecycle. The records include quality manual, Standard Operating Procedures (SOPs), master production records, batch production records (BPRs), quality control records, equipment maintenance logs, cleaning validation records, environmental monitoring records, and Corrective and Preventive Action (CAPA) documentation [15],[19],[20],[25],[30]. These records serve as a critical audit trail in the pharmaceutical sector where each step taken must be comprehensively recorded and documented in compliance to the Good Manufacturing Practices (GMP) [15]. The record management within the pharmaceutical sector includes the document lifecycle management, version control, approvals, electronic access and archival or obsolete records within the electronic document management system [24].

The management of records within the pharmaceutical sector indicates the utilization of both methods, manual (paper-based) and electronic record management. There is also a significant shift and progress towards the full utilization of electronic systems through the Manufacturing Execution System (MES) [12]. This system allows the pharmaceutical sector to have real-time recording and automated data capture which enhances its operational efficiency. Besides that, for adverse drug reporting, even though the reporting rates remain low, it is noted that there is an increasing adoption of electronic reporting systems and integration with Electronic Medical Records (EMRs) [27]. This could enhance the reporting practices and thus improve the adverse drug reporting rate in the future. In the pharmaceutical sectors, data integrity is a significant element in ensuring reliability, consistency and accuracy of data throughout the product development [16]. This element involve the completeness of the record, consistency, validity as well as security measures [16],[29].

The pharmaceutical sector is governed by several robust frameworks of regulations and standards related to record management. This includes FDA 21 CFR Part 211, EU GMP (EudraLex Volume 4), ICH Q7, ICH Q9, ICH Q10, World Health Organization's Good Manufacturing Practices (WHO GMP) and ALCOA+ data integrity principles [14],[15],[16],[19],[29]. These standards and regulations guide the pharmaceutical sector in ensuring accurate, traceable and original records to ensure product quality and transparency. Documentation in the pharmaceutical sector must comply with the regulatory requirements to ensure quality assurance, product safety and audit readiness [30].

Challenges Associated with Record Management Practices (Q2)

Based on the selected 27 papers included in the study, challenges affecting the record management practices in both sectors can be seen as follows:

a) Healthcare sector

Several challenges affecting the record management practices in the healthcare sector have been noted by previous researchers. The interoperability challenges were noted as a major challenge as it limits the seamless flow of data across the hospital system and departments [2],[8]. This is due to disparate organizational, incompatible information system, inconsistent data format and standards, lack of internal collaboration and engagement of key stakeholders and many more [11]. In addition, insufficient resources for record keeping often lead to misfiling issues, delayed retrieval, physical deterioration and congestion of records [2],[5],[7],[21],[22],[26]. These issues arise due to the lack of storage facilities and overcrowded filing rooms.

Staffing constraints also hinder the effectiveness of record management in the healthcare sector. This is due to the lack of awareness or knowledge related to software, poor record management knowledge and low computer literacy [26]. The challenges become more complicated due to a shortage of staff, insufficient training and resistance to change among professionals [1],[2],[5],[6],[8],[21]. The insufficient training and shortage of staff

result in the practitioners perceive this process as time-consuming and unrewarding which lead to burnout [3]. These issues support the findings on the lack of management support and limited budget in implementing robust training and systems to improve the record management practices in the healthcare sector [3],[5],[6],[26].

Moreover, resource and infrastructure constraints which include insufficient funding, lack of essential infrastructure, high implementation cost for digital system and limited functionality of electronic record management system further hinder the effectiveness of record management practices [1],[2],[5],[21],[22],[26]. Inadequate resources, resulting in operational issues such as long patient waiting times for record retrieval and delayed disposal of inactive records as well as security and privacy risks [1],[2],[8],[21],[22]. This resulted in the congestion and backlog of records within the healthcare sector. These issues may exposed the system to data breaches, cyber-attacks and unauthorized access [28]. Lastly, data accuracy, completeness and integrity remain as a constant concern due to poor handwriting, missing pages, incomplete charting and duplication of records [2],[5],[6],[21].

b) Pharmaceutical sector

Underreporting of Adverse Drug Reactions is noted as a significant hurdle in the pharmaceutical sector where it happens due to lack of awareness, time constraints, unavailability of reporting forms, uncertainty about suspected drugs, heavy workload and insufficient incentives [27]. In addition, incomplete batch records, undocumented deviations, missing signatures, inconsistencies between records and practice as well as inadequate maintenance of records hinder the effectiveness of record management in the pharmaceutical sector. This is due to the lack of staff training of record management and documentation in the pharmaceutical sectors [17]. This will resulted in the process of documentation and record management will be continuously involving the repeated error and jeopardize the quality of the documentation. It will also lead to data integrity issues, especially within the electronic documentation system [12],[15],[19],[20]. Maintaining document accuracy remains a challenge, as inaccurate or incomplete records may compromise product quality, fail to appropriately record, organized and retain data as well as regulatory compliance [16]. Organizations must also prevent the use of outdated documentation through effective version control to ensure that only current and approved documents are used.

Ensuring traceability is another challenge, requiring complete audit trails that accurately document manufacturing activities [14]. The increasing use of electronic record systems further creates challenges in controlling electronic records, including maintaining data integrity, managing user access and protecting records from unauthorized modification [16]. In addition, organizations must effectively manage document revisions and approvals to ensure that changes are properly authorized and documented, while also maintaining appropriate record retention and retrieval systems to support regulatory inspections and audits [20],[24],[25]. The transition to digital documentation introduces further challenges related to data security, system validation and maintaining compliance with evolving regulatory requirements [12],[30]. Other reported issues include poor documentation practices, non-compliance with Standard Operating Procedures (SOPs), inadequate staff training, limited organizational resources, weak document control systems and insufficient archival and security measures, which may reduce the effectiveness and reliability of record management practices [19],[29].

Discussion

The findings of this review demonstrate that record management within these two sectors plays a significant role in maintaining operational integrity and efficiency. Although both sectors operate within a highly regulated environment, their record management practices differ depending on their operational and regulatory requirements. Both sectors are deeply emphasized on the necessity of documentation to support accountability and evidence in their business transactions. One notable similarity identified in the reviewed studies is that both sectors are undergoing a significant shift towards the digitalization process to improve accessibility, retrieval of information and reduce reliance on paper-based records. This initiative could improve efficiency through centralized monitoring and real-time access to patient data through the integrated system in the healthcare sector and enhance reporting practices in the pharmaceutical sector. Although these significant shifts can be seen on both sectors, the pharmaceutical sector demonstrates a more structured implementation of electronic documentation. This is due to its rigid manufacturing and quality assurance requirements.

The review also emphasized clear differences in the nature of record management within each sector. The differences in the record management practices differ in several aspects such as the record type created and produced, the focus of the record management practices as well as the system utilized in the conduct of record management practices. The differences are significantly influenced by the core functions and operations of each sector. The distinction can be synthesized and compared as follows:

Table 4: Differences in Record Management Practices Between the Healthcare and Pharmaceutical Sectors

Aspect	Healthcare Sector	Pharmaceutical Sector
Record Type	Patient-Centric Record	Product and Process-Centric Record
Focus	Patient Care and Medico-Legal Case	Product Quality and Audit Trail
System	Electronic Health Record (EHR)	Manufacturing Execution System (MES)

Similarly, the key regulations governing the record management practices differ between these two sectors. The healthcare sector primarily complies with regulation in compliance with the patient privacy, confidentiality and medical record retention while the pharmaceutical sector complies with policies related to data integrity, product quality, manufacturing consistency and regulatory compliance. Despite the differences in the key regulations, both sectors conduct record management practices to ensure the records remain authentic, reliable, traceable and accessible throughout their lifecycle. The list among of regulations followed by these two sectors in relation to record management practices is as follows:

Table 5: Differences of Key Regulations Between the Healthcare and Pharmaceutical Sectors

Sector	Regulations
Healthcare	Health Insurance Portability and Accountability Act (HIPAA)
	National Health Act (No.61 of 2003)
	Protective of Personal Information Act (No.4 of 2013)
	National Health Act 2014
	Nigeria Data Protection Act
	General Data Protection Regulation (GDPR)
	National Archive Act 2003
	Law Number 44 of 2009
	Law Number 36 of 2009
	World Health Organization (WHO)
	ISO 15489-1 2016
Pharmaceutical	FDA 21 CFR Part 211
	EU GMP (EudraLex Volume 4)
	ICH Q7
	ICH Q9
	ICH Q10
	World Health Organization's Good Manufacturing Practices (WHO GMP)
	ALCOA+ data integrity principles

The findings further reveal that both sectors encounter challenges in record management, often sharing similar challenges while also facing distinct sector-specific issues. The similarities in the challenges include challenges to data integrity and accuracy, resource and infrastructure constraints, human factors as well as the security and compliance challenges. These findings suggest that technological advancements may improve the efficiency in the record management practices, but they will not be sufficient and effective without adequate organizational support, staff training and compliance with established standards and regulations.

As for the sector-specific challenges, the healthcare sector faces interoperability challenges which hindering the seamless data flow across the hospital system and departments. This leads to operational issues such as long waiting times and delayed disposal of inactive records. In comparison, the pharmaceutical sector faces issues related to the underreporting of Adverse Drug Reactions (ADRs) due to a lack of awareness and time constraints.

These sector-specific challenges reflect the implementation of record management in a distinct operational environment.

RECOMMENDATIONS

Based on the findings, several recommendations can be suggested to improve and strengthen the record management practices within the healthcare and pharmaceutical sectors. Firstly, robust training and continuous learning should be provided by the organization to enhance staff knowledge and competency in record management practices. The training should cover the record management policies, documentation standards and guidelines to use the electronic record management system effectively while maintaining the security and privacy of the data.

In addition to that, organizations may establish a comprehensive document control policy in compliance with regulatory requirements as well as the business operation. The policy should cover the Standard Operating Procedures (SOPs), standardized documentation and record management procedures, version control and more. This document policy should serve as a mechanism to ensure record accuracy, data integrity, authenticity and transparency are maintained throughout the record life cycle.

Finally, the healthcare sector should mitigate the interoperability issues by improving and upgrading the technological infrastructure, ensuring standardized data format and standard, encourage internal collaboration and stakeholder engagement to enable seamless information sharing across departments while reducing the operational delays in the business function. Similarly, the pharmaceutical sector should improve data integrity practices through data validation, a transparent and effective audit trail as well as a secure electronic documentation system to ensure compliance and improve product quality.

CONCLUSION

To conclude, records are the fundamental backbone for both sectors in ensuring accountability, transparency and informed decision-making can be made. The distinction between these two sectors reveals the different types of records created and maintained. While the healthcare sector focuses on records related to clinical evidence, the pharmaceutical sector focuses on documentation related to the manufacturing process and products. Although both sectors are progressively adopting digital record management systems to improve their efficiency, they face common challenges in data integrity, resource and staff limitations as well as security concerns. Effective records management remains significant in supporting organizational performance and compliance within both sectors. In ensuring more comprehensive analysis, future studies may conduct comparative analysis on the record management regulations across different countries for both sectors to identify significant approach in enhancing compliance and data protection.

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