



Navigating Information-Related Risks in Modern Pharmacy Practice: A Patient Safety Perspective

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Abstract

Background: The implementation of pharmacy informatics systems (PhIS) can inadvertently introduce sources of medication risk that may go unnoticed by pharmacists, often exacerbated by high operational demands and insufficient emphasis on data integrity. This investigation aims to identify the specific factors that drive unforeseen outcomes stemming from PhIS use and to analyze how these outcomes compromise information fidelity, thereby jeopardizing patient well-being. **Materials and Methods:** This research utilized a qualitative, explanatory case study methodology, focusing on PhIS deployed in both ambulatory hospital and clinic pharmacy settings. Data was gathered via a multi-faceted approach, including on-site observation, in-depth interviews, and organizational document review. To thoroughly examine the socio-technical dynamics of the systems leading to these consequences, we first applied the Socio-Technical Interactive Analysis (ISTA) framework. Subsequently, the Human–Organization–Process–Technology-fit (HOPT-fit) model was employed to categorize the dominant factors, instances of functional mismatch, and necessary remedial interventions. **Results:** The study cataloged 28 distinct unintended consequences of PhIS, along with their primary determinants and systemic interdependencies. Key causes were determined to include system inflexibility and inherent complexity; deficiencies in staff knowledge, competence, and clarity regarding system functionality; reliance on hybrid paper-electronic records; ambiguous transitional processes; the introduction of redundant or conflicting responsibilities within the workflow; and time constraints leading to cognitive overload and the adoption of informal workarounds. Recommended corrective strategies encompass incorporating human factors engineering principles into system design, enhancing data quality management (especially workspace efficiency), improving training protocols, establishing robust PhIS master data governance, and formalizing communication through the standardization of necessary workarounds. **Conclusion:** Compromises to information quality within PhIS are fundamentally rooted in inadequate system architectural design, a breakdown in aligning system functions with clinical task requirements, and a lack of user proficiency in system operation. Therefore, adopting safety-by-design principles, promoting a culture of information integrity awareness, and ensuring the secure organizational utilization of PhIS are crucial prerequisites for protecting patient safety. The proposed combined evaluation approach offers researchers a practical method to dissect complex socio-technical interactions, identify the causal factors of unintended consequences, and formulate effective mitigation strategies.

Keywords: Human–Organization–Process–Technology-fit (HOPT-fit), pharmacy informatics systems (PhIS), Socio-Technical Interactive Analysis (ISTA), architectural design, interdependencies.

Introduction:

Focus: Health Information Systems (HIS), including **Pharmacy Information Systems (PhIS)**, offer the potential to enhance healthcare quality through improved data accessibility across administrative, inventory, clinical, and medication processes [1], [2], [3], [4]. However, this potential is often undermined by various **socio-technical challenges** within HIS, which can introduce new errors and lead to **unintended consequences (UC)** in healthcare delivery [1], [2], [5], [6], [7].

- **Modification 1 (Focusing on PhIS UC):** Most reported UC related to PhIS (**UC-PhIS**) arise during its adoption, particularly when pharmacists interact with the system or **Computerized Provider Order Entry (CPOE)**. For example, PhIS has changed existing medication management by introducing novel issues, such as errors stemming from users' poor understanding of **system machine rules** [6].
- **Modification 2 (Focusing on reliability and complexity):** While a new dispensing system can help pharmacists safely dispense drugs, **technical issues** can reduce the system's **reliability** and its ability to support current tasks, thereby complicating established work processes [8].
- **Modification 3 (Focusing on error identification):** The incidence of **latent errors** and their unknown causes is rising [9]. The root cause of HIS-related errors often resembles a **black box**, and the use of **workarounds** further complicates efforts to understand this situation [10], [11].
- **Modification 4 (Focusing on complexity):** Understanding **UC-Health Information Technology (HIT)** is complex because it involves the intricate interaction of **people, processes, and technology** across all aspects of healthcare [12], [13].
- **Modification 5 (Focusing on existing literature):** Although the HIS literature has extensively covered basic UC concepts and related frameworks—including system interactions, usability, human factors (cognitive), classification and effects of UC-CPOE, UC-Clinical Decision Support (CDS), UC-Electronic Health Records (EHRs), HIT errors, and UC-workflow-HIT—studies specifically addressing UC in the context of **PhIS remain limited**.
- **Modification 6 (Focusing on the study's proposal):** Therefore, this study proposes an **evaluation approach for UC-PhIS** to facilitate

a structured and comprehensive understanding of the causes and consequences of these unintended outcomes.

- **Modification 7 (Focusing on benefits):** Recognizing **UC-HIS** enables healthcare providers to better understand contributing factors and identify **mitigation mechanisms**. Similarly, developers can design more effective and efficient systems [1], [6], [14], [15].
- **Modification 8 (Focusing on trade-offs):** Evaluators can anticipate future PhIS challenges in improving healthcare quality by converting these UCs into **predictable trade-offs**, thereby reducing the risk of medication errors [14].
- **Modification 9 (Focusing on the proposed approach):** This study proposes an evaluation approach based on **two established, complementary frameworks** that guide the identification of UCs, their dominant factors, effects, and mitigation mechanisms from the user perspective in two pharmacy-based PhIS settings. This proposed approach is intended to guide the understanding of complex **socio-technical interactions** that trigger **UC-HIS** for system improvement and risk mitigation.

Section snippets

Theoretical Background

The concept of **Unintended Consequences (UC)** is often linked with **Clinical Decision Support (CDS)**, which aims to reduce errors by providing targeted warnings, recommendations, and constraints [16], [17]. However, instead of maximizing their potential, these systems frequently generate new UCs and prove to be **inherently error-prone** [18].

The critical finding that **human-technology interaction** is a **dominant factor** in generating UC [19], [20] has pioneered new scholarly approaches. These include employing a **human factors perspective** for assessing UC-HIT [19], [21], evaluating HIT **usability** in relation to **human cognitive load** and the risk of **automation bias** [22], [23], and promoting the principles of **safe HIT use** [24].

Methods and Results

Methods

We employed a **rigorous qualitative, explanatory case study** evaluation to identify the contributing factors to **Unintended Consequences of Pharmacy Information Systems (UC-PhIS)** within two Malaysian ambulatory pharmacy dispensing services: Hospital T and Clinic R. Both facilities had **fully transitioned to and utilized** the Outpatient Pharmacy module in PhIS since 2018. Crucially, while the doctors continued to **prescribe medications manually** (i.e., on paper), pharmacists were responsible for **accurately entering** these orders into PhIS. Author NR systematically collected data in both settings from mid-November to mid-December 2020 through a combination of **direct observations, in-depth interviews, and thorough document analysis**.

Results

The implementation of PhIS at the two settings followed a **structured, staged approach**. Prior to the full rollout, all

participating pharmacists underwent **standardized basic PhIS training**. Following this, the pharmacy unit and the PhIS implementation team successfully provided the **necessary infrastructure** to integrate PhIS hardware into the existing service environment. **However, a critical limitation was encountered: PhIS could not be seamlessly integrated** with patient health records because all wards and clinics still relied on **traditional paper-based documentation**. This **integration failure inadvertently created an unobserved, yet significant, information transfer gap** in the clinical workflow.

Discussion: Frameworks for Analyzing UC-PhIS

The combination of the **Integrated Sociotechnical Analysis (ISTA)** and **Human-Organizational-Technology (HOPT)** components proved highly effective for a comprehensive evaluation of **Unintended Consequences of Pharmacy Information Systems (UC-PhIS)**.

- The **ISTA component** was instrumental in facilitating the **systematic identification** of UC-PhIS within the complex interplay of the **sociotechnical systems** involved in pharmacy practice. This framework allowed for a **detailed mapping** of how people, processes, and technology interact to generate unintended outcomes.
- Conversely, the **HOPT component** provided the **critical lens** necessary to move beyond mere identification, enabling us to focus strategically on the most effective aspects of **mitigating and preventing** future UC-PhIS occurrences.

The most **critical and influential factors** were identified through a meticulous analysis of the **cause-and-effect relationship** for each reported UC-PhIS using the **ISTA framework**. This rigorous analysis was then supplemented by identifying those UCs that served as **primary triggers** or **dominant precursors** leading directly to the occurrence of other subsequent UCs. The evidence illustrating this analytical progression is clearly shown in **Appendix C** (Cause-and-Effect Relationship Analysis) and **Appendix D** (Identification of Dominant Precursors), respectively.

Conclusion: Key Findings and Significance

The **proposed evaluation approach**, which judiciously combined the **Integrated Sociotechnical Analysis (ISTA)** and the **Human-Organizational-Technology (HOPT-fit)** frameworks, provided a **robust and comprehensive methodology** for assessing system impact. This approach successfully assisted us in identifying a significant total of **28 distinct Unintended Consequences (UCs)** directly related to PhIS use across the two studied pharmacies. The evaluation allowed for a detailed analysis of:

- **Complex Socio-technical Factors and Effects:** The ISTA framework was crucial for meticulously mapping the interaction between people, processes, and technology, thereby elucidating the factors contributing to each UC and detailing their immediate effects on the workflow and patient safety.
- **Dominant UCs, Misfits, and Mitigation:** The HOPT-fit framework enabled a deeper focus on identifying the **dominant UCs** (those that trigger others), the resulting **misfits** (e.g., between the

system and the user's task), and the appropriate **mitigation mechanisms** designed to address these fundamental imbalances.

The **primary socio-technical factors** driving UC-PhIS were clearly identified as:

- **System Rigidity and Complexity:** The system's inflexible design and excessive operational complexity often forced users into inefficient workarounds.
- **Users' Lack of Skills and Understanding:** Deficiencies were noted in users' technical skills and, more critically, in their **conceptual understanding** of the system's intended purpose and the flow of information.
- **Paper Persistence:** The **continued reliance on paper documentation** created a problematic **parallel workflow** that directly undermined the system's goal of seamless electronic information transfer.
- **Unclear Tasks and Role Shift:** Ambiguities regarding new electronic tasks and an associated **unplanned shift in professional roles and responsibilities** within the dispensing workflows contributed significantly to confusion and errors.

In essence, the study demonstrates that UC-PhIS are rooted not just in technical flaws but in the deep-seated friction between a rigid digital system and the existing, often messy, reality of human and organizational workflows.

Declaration of Competing Interest : The authors declare that they have no known competing financial interests or personal.

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