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Safety and Quality Within the Healthcare Supply Chain: A Great Unknown

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> Abstract. Quality and safety in healthcare have emerged as key factors impacting on both clinical effectiveness and clinical outcomes. While improving the healthcare supply chain has been extensively researched, the impact of the healthcare supply chain on clinical safety has received little attention in the literature, largely due to the complexity of such studies and the involvement of multiple stakeholders. This research proposes an evaluation model using key performance measurements for an electronic procurement system that enables digital transformation of the healthcare supply chain. The model will be tested before and after the introduction of an electronic procurement system in the healthcare supply chain for small and medium sized healthcare providers to provide evidence of both the usefulness of the model itself within industry and to further contribute to the knowledge base. Future use of the model may provide benchmarking and important data and insights to enable enhanced clinical safety in the healthcare supply chain.

Keywords. Safety, quality, healthcare supply chain

1. Introduction

The Healthcare Supply Chain (HSC) plays a critical role in the delivery of safe, quality healthcare. After wages, the healthcare supply chain is normally the second highest operating expense for healthcare providers. The importance of the HSC has been addressed from the financial and logistic points of view. However, there is little evidence to suggest that clinical safety and quality are a key consideration when analysing and looking to make improvements (that are increasingly digital) to the HSC.

Globally, healthcare providers and regulators are striving to continually make improvements in safety and quality across healthcare [1, 2]. The emergence of standards, tools and templates has enabled measurable improvement in patient outcomes and service provision [3]. Concurrently, general supply chains have continued to experience improvements in efficiency and accuracy through the use of digital technology and standardisation [4]. Despite these developments, there is minimal literature which looks at the crossover and interdependencies of these two factors, the standards and digital transformation.

The literature does, however, identify some of the reasons that a greater level of integration of safety and quality awareness does not exist in the healthcare supply chain. Previous studies [5, 6] have identified the complex nature of the HSC as being a barrier

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to development and implementation of innovative and progressive management initiatives in the HSC. A global supply chain has both advantages and disadvantages, and the recent Covid-19 pandemic has highlighted some of these shortcomings [7, 8]. Complexity arises from factors such as the broad range of products required by healthcare providers, and the varying levels of clinical safety, regulatory requirements and specific logistic conditions required for some products [9, 10].

A further significant barrier to clinical safety in the HSC is the involvement of a large number of stakeholders compared to supply chains in other industries [11, 12]. The varying needs of these stakeholders may divert the attention required to evaluate safety and quality impacts on healthcare products. The main standards applicable to healthcare providers in Australia are the National Safety and Quality Health Service Standards (NSQHS) [13] which address the clinical governance, communication and overarching clinical standards. While the clinical governance standards will direct quality assurance in some facets of the HSC, there is no specific mention of the HSC in the NSQHS Standards.

One relatively recent development has been the adoption of global supply chain standards into the healthcare supply chain [14, 15]. This has provided a structured method to identify products and locations and a key foundational aspect from a measurement perspective. The unique identification of products enables better tracing of the product through the supply chain from raw materials and manufacturing through to use and environmentally safe disposal. Simultaneously, the unique identification of locations provides greater visibility and environmental control [16].

Given the increasing use of technology within the HSC, the foundational elements such as unique product and location identifiers have emerged to assist in the identification of the impact on clinical safety [17]. As identified by Fonseca and Azevedo [18], the global Covid-19 pandemic has provided the impetus and additional opportunity for organisations to re-visit their supply chains and apply upgrades and improvements.

2. Methods

While limited research has applied a theoretical explanation for the impact of the HSC on clinical safety, several authors have made an attempt, most notably Supeekit, Somboonwiwat [19, 20] to research some related elements from a hospital supply chain perspective. However, these papers still do not drill down and investigate at the clinical safety detail and additionally many variables of interest are considered often at expense of clinical safety.

For the purpose of this research an evaluation model has been developed to target the clinical safety aspects with a specific focus. The Clinical Safety Evaluation Model (CSEM) is based on the theoretical lens of the DeLone and MacLean Information System Success Model [21]. The key aspects of the DeLone & MacLean model have been retained to capture user, process and benefit information; however, the benefits section has been modified to specifically add some key supply chain aspects; Clinical Incidents, Environment, Identifiers and Systems. These specific benefits have been identified through analysis of the Clinical Governance Standard of the NSQHS [13].

The DeLone & MacLean model provides a well-used and proven theoretical approach to the implementation and use of information systems. Importantly, this model has been applied extensively through other applications within healthcare and provides a modifiable framework to address the key elements of HSC [22, 23]. Further

modification of the original DeLone & MacLean model by Zaied [24] have been adapted to create five categories with twenty-six elements and fifty-two statements in total, to measure the impact of digitalization of the HSC on clinical safety.

This research uses a Design Science Research (DSR) methodology to enable iterative improvement of the model as it is tested and applied. A significant number of studies in the literature have identified the usefulness of a DSR approach within healthcare [25-27]. The aim of DSR is to create an artefact which is evaluated and improved with each iteration of use in a real-world setting.

The application of the CSEM enables a scoring system utilising a Likert scale. This provides scores for each statement as well as an overall score to enable a comparison between organisations. This will provide the baseline data for the performance of the HSC and its potential impact on clinical safety in each organisation.

The research entails this initial completion of the CSEM evaluation and interviews prior to a digital intervention in each participating organisation. In this case, the digital intervention is a basic electronic procurement system to enable procurement, visibility and tracking of products through the supply chain. Effectively, the system digitalises the usual procurement and management processes and conforms to the Australian healthcare supply chain standards utilising GS1 identification and messaging components [14, 16, 29, 30].

The participants in the research are small to medium (SME) sized health care providers from both general medical practices and dental clinics. Traditionally, these types of healthcare providers have not had the financial nor technical resources to utilise existing procurement systems embedded in Enterprise Resource Platforms (ERPs) such as SAP and Oracle which require a significant investment beyond the capacity of SME healthcare providers. This has created an environment where large hospital groups and state and territory health departments can access the benefits the Australian healthcare supply chain reform program [14] however the smaller SME healthcare providers have missed out on these systems and benefits.

3. Results

The utility of CSEM will itself be evaluated using the Framework for Evaluation in Design Science Research (FEDS) developed by Venable [31]. The FEDS follows a four step process which examines the goals of the evaluation, the evaluation strategy, and determines the properties to evaluate and design the individual evaluation episodes [31]. The relevance cycle, rigor cycle and the design cycle work together to fine tune the artefact and ensure it is fit for purpose through iteration and evolution. This evaluation will assist in determining the value of the artefact in measuring the impact of a digital intervention, (the electronic procurement system) on clinical safety in the participating organisations.

4. Discussion

Clinical safety reporting in Australia has significantly evolved over time to become more comprehensive. Clinical safety reporting is widely used both voluntarily and increasingly to meet statutory requirements. Incidents such as falls, adverse medication reactions and pressure injuries are now not only measured but also improved through greater knowledge of events [13]. These improvements can be clearly seen when reviewing statistics from organisations such as the Australian Institute of Health and Welfare [32] and comparing the 1st Edition of the NSQHS standards to those of the current 2nd Edition.

Despite these advances, there is still no focus on the HSC within statutory reporting nor clearly articulated in the Clinical Governance Standard. Therefore, an opportunity exists to potentially improve patient safety and clinical outcomes. The use of the CSEM will enable both individual organisation assessment as well as benchmarking against peers.

While the focus of this research is on SME healthcare providers, the CSEM could also be utilised in larger healthcare providers (such as hospitals, residential aged care and procedural facilities). The model utilises universal standards in its structure so there is the opportunity to utilise the model across the healthcare sector both here in Australia and globally across other countries. This provides far greater utility and potential positive impact without being limited to local jurisdictions.

5. Conclusions

The outcomes of this research are expected to expand the knowledge base, provide an industry useable artefact for measuring HSC performance and its impact on clinical safety and provide benchmarking capabilities for the healthcare industry.

The research project field work has commenced with a pilot site to test the main components, that is, the CSEM and the localization of the electronic procurement system with initial interviews of the key participants in the pilot organisation. Following the pilot site, an additional 5 participant organisations will be recruited from general and dental practices. The main data collection is expected to be completed within the first half of 2023. Preliminary findings are expected to be available for further discussion should this paper be accepted for presentation at MEDINFO23.

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