Healthcare and Medical Devices, Vol. 130, 2024, 8–18
https://doi.org/10.54941/ahfe1004832

A Structured Approach to Clinical Pathway Mapping (CPM): A Case Study of a Postoperative Patient Controlled Analgesia (PCA) Pump

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ABSTRACT

This study describes an evidence-based Clinical Pathway Mapping (CPM) visualisation method that can be used to enhance healthcare quality in the face of complex systems and constrained resources. The CPM visualisation method we are proposing highlights the connection among the key components of the healthcare work system – individuals, tasks, tools, technology, physical environment, and organisational conditions. When seeking to innovate a clinical pathway by adding or changing a (technological or procedural) component, practitioners need to consider that changes in one component will affect the others, so being able to map and visualise the relationship among the components is essential to patient safety and care delivery. We present the CPM method using a case study focused on a new Patient-Controlled Analgesia (PCA) pump in the postoperative sector. Feedback was gained through semi-structured interviews with stakeholders from four NHS Trusts in the UK. By evaluating the device's effect on post-operative procedures, the research produced a thorough picture of the postoperative environment as it exists today. We identified the two most likely scenarios of use and carried out a work system analysis to investigate these scenarios in detail and implications for the healthcare work system's components. This analysis facilitated the identification of new criteria necessary for the device's effective integration into NHS Hospitals. The study emphasises the benefits of utilizing a human and system centred process for visualisation, identifying areas for development, and improving the security and effective application of emerging medical technologies.

Keywords: Clinical pathway mapping, Process mapping, Healthcare implementation

INTRODUCTION

Process mapping (PM) is a tool that focuses on systems and processes to gain a better understanding of existing processes and practices and provide context for considering the potential impact of new interventions (Jun et al., 2009; Jun, Ward and Clarkson, 2010; Kalman, 2002). This approach entails constructing a macro-map, identifying, and prioritizing bottlenecks in the existing process, constructing a micro-map to identify the root causes of the bottlenecks, and informing iterative redesign (Borsci et al., 2018).

The use of PM in healthcare is gaining attention to improve quality and safety by breaking down medical procedures into consecutive steps; it is primarily a qualitative process which models a given clinical context in which a new device is likely to be used (Kinsman et al., 2010) and it enables the identification of integration barriers and downstream consequences of a new technological intervention (Borsci et al., 2018). It could be argued that PM can be considered a healthcare intervention itself when it facilitates the structured implementation of care plans, guidelines, or treatment protocols, and aims to standardize care for specific clinical issues within a targeted population (Kinsman et al., 2010). PM methods have helped to minimise risks associated with healthcare delivery (Buckle et al., 2010) and to simplify the process of documenting, monitoring, and evaluating variances in a multidisciplinary clinical team (De Bleser et al., 2006). Moreover, such approaches have been used to implement evidence-based clinical practices (Vanhaecht et al., 2006), guide care management, through representing the patient's journey (De Bleser et al., 2006), and simplify the translation and communication of national guidelines (Campbell et al., 1998). In line with the SEIPS model - Systems Engineering Initiative for Patient Safety - (Carayon et al., 2014; Carayon et al., 2006; Holden and Carayon, 2021), which considers the entire work system and its interrelationships with processes, PM methods have been utilized to facilitate human factors studies for the evaluation of point-of-care tests for diagnostics (Borsci et al., 2017; Micocci et al., 2020a).

While PM has the potential to support the integration of novel technologies and to assess their potential value, it is unable to predict with absolute certainty how a system will react following the introduction of a new technology. This is due to the presence of unknown factors that may bring about unpredictable changes to the system. This makes it challenging to specify the potential benefits that the technology will make. Factors such as patient outcomes and implications for decision-making are components of an "improved" pathway, inferred by mapping and modelling activities, and encouraged by communication between levels of care (Aspland, Gartner and Harper, 2021).

Integrating New Technologies in Healthcare Through a Structured Approach to Clinical Pathway Mapping

To fully understand the impact of a new intervention, it's essential to consider the broader organizational context in which it will be used. Patient journeys are not isolated but are influenced by external factors such as regulatory entities, healthcare workforces (Carayon et al., 2014) and individual's tasks and responsibilities. When a care journey starts, the work system interacts and responds to changes in external environments, (e.g. a patient portal or any technology intervention to support care) and in the way work is organized (Carayon et al., 2020). The Work System Model (Carayon, 2009) highlights the interconnectedness of five critical elements - individual, task, tools and technologies, physical environment, and organizational conditions - which work together to achieve the desired outcomes. Changes made to any of these elements will have a ripple effect on the others. A qualitative comprehensive approach for data collection and visualisation is required when mapping out the integration of a new technological intervention in healthcare. By doing so, we can assess the implications for the healthcare system as a whole and evaluate its implementation. Importantly, we can develop scenarios about how a particular technology is likely to impact the care. However, to identify the factors that make up clinical pathways and to assess how they may be affected by an innovation, it is beneficial to use a more structured and standardized data collection and visualization tool to ensure that relevant factors are considered and that the potential impact of the technology is understood.

A Case Study of a Postoperative Patient Controlled Analgesia (PCA) Pump

Patient Controlled Analgesia (PCA) allows patients to self-administer small intravenous opioid doses, like morphine. PCA devices are set up by healthcare professionals to administer specific medication amounts per patient request. Some provide continuous infusions alongside patient-controlled boluses; bolus requests can be limited for safety. We conducted an evaluation of AmyPCA by DAIKEN Medical Co. Ltd., an innovative infusion pump that has been successfully implemented in Japan's healthcare system, but whose integration into the UK's National Health Service (NHS) remains unexplored. The device comprises a main unit (drive pump - pump), a Smartphone application (Amy's Window), a dedicated communication module (Comm Touch) connecting the pump to the smart phone, and a PCA switch (remote bolus button). This compact pump is portable for patients, while healthcare professionals set up the infusion via a mobile app on a dedicated smart phone. The app also tracks pain assessment and infusion history.

The management of AmyPCA via a smartphone app differs from traditional devices which have built-in displays placed on bedside poles. The pump lacks a direct display; instead, nurses control it via the mobile app once connected to the pump. AmyPCA connects to smart phones using the magnetic Comm Touch, which is detached post-setup. This design promotes patient mobility and offers enhanced infusion control, however, innovations in this standardized setting need rigorous Human Factors studies for patient safety and overall system implementation. Anchored in the foundational principles of the Work System Model, we present a structured, evidence-based data collection and visualisation method for Clinical Pathway Mapping (CPM) using the AmyPCA case study. This approach not only enhances existing process mapping tools but also offers an enriched data visualization chart spotlighting key element of a clinical pathway.

Aim and Objectives

The aim of this study was to improve process mapping techniques by integrating real-world data collection into a cohesive approach for CPM. This approach requires the creation of detailed maps of the existing processes to identify and address bottlenecks, visualise the interrelations among tasks and processes, prioritise scenarios of use and enabling the efficient integration of new technologies and interventions.

METHOD

The Components of a Clinical Pathway Map

Based on the five critical elements highlighted in the Work System Model (Carayon, 2009) we have identified and defined the components that shape the existing clinical pathways and the improved clinical pathways for future healthcare delivery. This exploration is crucial for understanding how each element within the Work System Model not only functions in isolation but also interacts with others, thereby impacting the clinical pathway as a whole.

Individual

Understanding the stakeholders involved in each stage of the clinical pathway, how tasks are allocated, and their roles within a given clinical setting is fundamental when considering adoption of new technologies.

Tasks

Examining the specific tasks involved in patient care helps in identifying potential areas for improvement and efficiency. Defining the clinical workflow and its tasks, and emphasizing elements that enhance its efficiency, are part of what is called 'anatomy of the process' (Nelson, Batalden and Godfrey, 2011).

Tools and Equipment

In a clinical setting, understanding the use, connectivity, and physical environment of tools and equipment is paramount. These devices often have intricate operations, and their effectiveness can be influenced by their surrounding environment. Equally crucial is recognising the skill set required for their proper use.

Physical Environment

Medical devices are typically situated in hospitals, clinics, doctors' surgeries, and patients' homes. However, some are also designed for non-traditional locations like ambulances or community settings, especially if they are portable. Each environment presents its own unique challenges. These varying environments directly influence how a device is utilised, its efficiency, and its safety (Micocci et al., 2021; Micocci et al., 2020b).

Organisational Conditions

Such conditions encompass the necessary information required for operation, including guidance, standards, and decision-making processes. Familiarity with these guidelines and policies not only optimises device utilisation but also upholds the standard of patient care.

Data Collection

The CPM data visualisation method consists of two-phase data collection protocol (Table 1) covering elements from both process and system aspects (phase 1) and how these will be affected by the integration of a new technology (phase 2). We conducted semi-structured interviews with key stakeholders (n = 2 Consultant Anaesthetists, n = 1 Consultant in Intensive Care Medicine, n = 1 Anaesthetic trainee, n = 3 Pain Nurse Specialists) involved in the management of post-operative patients in the postoperative sector in 4 NHS Trusts in the UK. We used a purposeful sampling strategy to identify and recruit relevant specialists (Bryman, 2016). After details of pathways and processes were elicited, participants were presented with information regarding the AmyPCA, including its basic features and the basic process of use. The components of AmyPCA, drive unit, control unit, Comm Touch and giving sets were shown to participants. Participants were presented with a live demonstration of the device and asked a series of open questions regarding how AmyPCA might be best utilised in clinical practice. Questions were asked to reflect the key elements of the Work System Model (Carayon, 2009).

Table 1. Framework for data collection methods and analysis.

Phases of data collection for CPM	Aims	Methods	Data Analysis
Phase 1	To understand current process and system workflow, work systems elements and bottlenecks	Semi-structured interviews	Process Mapping techniques
Technology presentation	To introduce key elements of the new technology, explaining when and how it will be used.	Simulation-base activity	/
Phase 2	To identify how the new technology will be integrated and to identify scenarios of use and to prioritise scenarios of use.	Semi-structured interviews	Framework Analysis Method and Scenario-based Analysis

Data Analysis

Three main analysis techniques were used. Process mapping was used to map out the clinical pathway described by clinicians during interviews (Lim et al., 2014). Process data are visually represented through flow charts whilst additional systems elements integrated in a swim-lane diagram. Framework Analysis Method (Ritchie et al., 2013) was used to organise the data and to support thematic analysis to appreciate key components of the post-operative sector that might impact the adoption of the new pump. A scenario-based analysis (Vollmar, Ostermann and Redaèlli, 2015) was used to prioritise scenarios of use against elements of the Work System Model.

FINDINGS

As a result of the data analysis, figure 1 [Appendix I] presents a simplified clinical pathway flowchart detailing the key tasks, integrated with a swim-lane diagram that illustrates the five elements of the Work System Model. We identified 5 existing gaps in the current workflow and a discrepancy between the current healthcare setting and the one required to effectively integrate the features of the new pump. Notably, the new device's design presents unique challenges: it is portable and operated via a smart phone, which complicates the management of the equipment by healthcare professionals, especially when moving patients without misplacing any components. Additionally, maintaining the phone in a constantly charged, connected, and available state poses practical difficulties.

Therefore, we have identified the two most likely scenarios of use (Table 2) that were analysed against their implications for the 5 elements of the Work System model:

Scenario 1: only one smart phone, used to set up the pump and operate it, accompanies the patient from the recovery unit to the medical ward;

Scenario 2: the pump alone moves with the patient to various units and reconnects to various local mobile phones capable of controlling it.

Pros and cons of each scenario were analysed under the lens of the 5 key elements of the work system and through their ability to bridge the current gaps in the pathway.

The number of smartphones required for the entire pain team to use the device is a concern in both scenarios, especially considering the limited number of smartphones available and the need to allocate staff to set up the device and maintain it. A primary concern is the pump's battery life, as it often requires being plugged in to a charger for continuous treatment, which may not always be feasible due to the unavailability of charging points. Connectivity issues pose another challenge, as some of AmyPCA features require an internet connection, which might not be reliable on NHS premises. Lastly, the visibility of the infused volume is a concern. In emergency situations, it may not be easy to quickly access the mobile device that displays treatment information, complicating the process of turning off the pump or troubleshooting. These issues highlight the need for careful considerations and potential redesign to ensure the AmyPCA pump's effective integration into NHS Hospitals. However, the pump's primary advantage lies in its portability and handheld design, facilitating early patient mobilization and compatibility with existing hospital devices. The integration of smartphone technology offers significant advantages in this regard. Amy's Window, the dedicated smartphone application, for instance, can display patient statistics, such as the number of successful medication administrations, which could be downloaded and attached to electronic patient records. This feature provides valuable insights into patient pain thresholds and treatment efficacy.

Table 2. Scenario-based analysis against elements of the work system model.

Work System Model elements	Gaps in the current pathway	Scenario 1	Scenario 2
Individual	Lack of training. Bedside nurses are not adequately trained to troubleshoot PCA pumps	Pros: The smartphone app could benefit from a customizable interface with helpful videos Cons: Less accessible to those unfamiliar with mobile phones or unable to use management software. Only trained users are allowed to use the phone	
Task	Disrupting workload due to availability of the equipment, maintenance and shelf-life	Pros: Only one smartphone to manage. Cons: Smartphone not always available	Cons: Many handovers of expensive equipment; unclear task allocation (e.g., responsibility of charging the battery)
Tools and Technologies	Pumps are steady and bulky devices that affect early mobilisation of patients	Pros: Portability Cons: The bolus button is wirelessly connected and may get lost easily	
Physical environment	Pumps are easily tampered	Cons: Need for a lockbox to secure the pump	
Organisational conditions	Lack of good patient management	Pros: Graphically enhanced pain assessment	Pros: Graphically enhanced pain assessment Cons: Nurses need to retrieve the smart phone to get access to patient data

DISCUSSION

The aim of the research was to enhance healthcare quality and safety by developing a structured approach to CPM for integrating new technologies into healthcare systems. The aim was addressed by using process mapping techniques and semi-structured interviews with key stakeholders, enabling the identification and analysis of gaps in current workflows and the potential impacts of integrating new technologies like the AmyPCA pump.

The research provided us with detailed insights, enabling a thorough evaluation of the pros and cons of two hypothetical scenarios for the use of a new infusion pump. Scenario 1 is the one that would align better with the requirements of the postoperative setting in the UK National Health Service, given a better management of the equipment and minimisation of risks. However, this scenario has several limitations, such as connectivity, battery life and staff allocation, that should be addressed with further R&D. This comprehensive view is pivotal in identifying and understanding the interplay between various components of the healthcare system, from technological tools to human factors and organizational processes.

Limitations

This methodology is not without its limitations. It relies heavily on participant feedback, making the diversity and number of participants crucial. Factors such as experience with legacy devices, familiarity with similar technologies, and trust in technology significantly influence the quality of the data collected. Additionally, it is hard to cover the full range in potential clinical settings and the research described herein did not attempt to be exhaustive in that regard. Another challenge is the time-consuming nature of semi-structured interviews, which can be a barrier for healthcare professionals whose availability and commitment are often limited.

CONCLUSION

In this paper, we demonstrated how a structured approach to CPM helps visualising elements of a clinical setting that could affect or facilitate the integration of new technologies, like the AmyPCA pump, into healthcare systems. This method has supported the identification of technology-related challenges, suggesting the potential for further research and development to optimize their integration and effectiveness in clinical settings.

ACKNOWLEDGMENT

This research has been funded by DAIKEN Medical Co. Ltd. and supported by the NIHR, London In-Vitro Diagnostics Cooperative (LIVD), Imperial College London.

ETHICS

Ethics approval was sought, and obtained, from the Imperial College Research Ethics Committee (ICREC reference: 21lC6730).

APPENDIX I

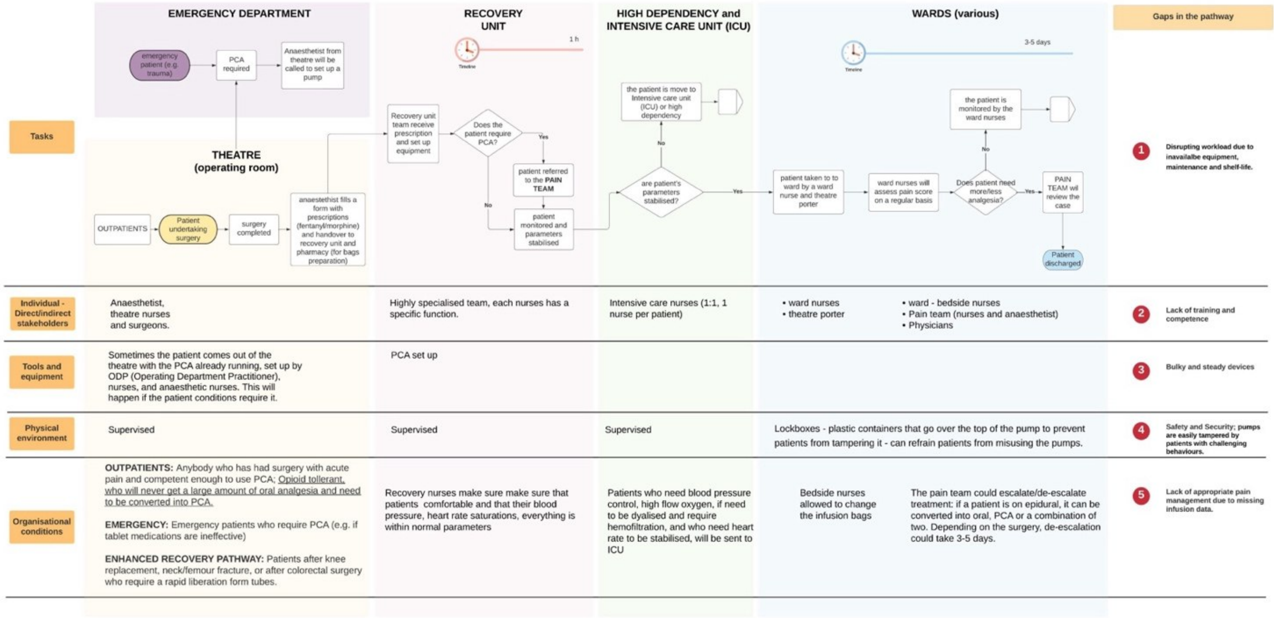

Figure 1. Clinical Pathway Map of the postoperative setting including current gaps and key elements of the Work System Model.

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