

Title Page

- The Design and Optimization of a Scalable National Product Information Management System for the NHS
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Abstract

- Concise summary of the thesis objectives, methods, findings, and conclusions.

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Chapter 1

Introduction

1.1 Introduction to research

This chapter contains an introduction to the area of focus of this thesis project. It focuses on the main research problem, the motivation for embarking on this research,, research aims and

objectives, and the research questions that guide this study. The final section of this chapter presents the overall organizational structure of the thesis.

1.2 Overview of the research problem

In modern day healthcare systems, efficient and standardized procurement and supply chain processes are necessary in ensuring availability of medical supplies, medicines, devices, and equipment essential for the delivery of high-quality care (Steer-Stephenson, 2022). It is important to accurately manage healthcare product data because these products have a direct impact on patient health and safety. It is critical to enable the supply chain to deliver the right products to the right place at the right time (Department of Health & Social Care, 2023).

The primary healthcare provider in the United Kingdom, the National Health Service (NHS), serving millions of patients across the UK, is plagued with challenges in effectively managing the product information sharing process between its suppliers and its vast network of trusts, hospitals, clinics, and healthcare facilities. Due to the absence of a unified and scalable system, product information management within the NHS is characterized by lack of standardization, inconsistency, inefficiency, and fragmentation, with disparate infrastructure and processes essentially leading to difficulties accessing accurate and up-to-date product information (Procurement, Investment & Commercial Division, DHSC, 2014). This leads to delays in procurement, disruptions in the supply chain, and poor decision-making, ultimately affecting patient care and outcomes. Hence, it is imperative to address these pressing challenges and improve the management of product information and data sharing within the NHS' procurement ecosystem.

1.4 Problem Statement

The NHS is faced with challenges in managing medical product information across its supply chain. These challenges include but are not limited to, a glaring inefficient data sharing process between manufacturers/suppliers and NHS trusts, a lack of standardized data formats and identifiers, disparate information scattered across repositories in different departments and healthcare trusts, manual processes for accessing and updating product information.

Consequently, healthcare practitioners face difficulties in finding the right products at the right time, causing delays in care and inefficient resource allocation.

The absence of a centralized and scalable system for managing product information poses an obstruction to interoperability and efficient exchange of data with external stakeholders e.g. suppliers, regulatory bodies, patients, and other healthcare organizations. This lack of integration and interoperability brings to fore, the challenges the NHS faces in maintaining accurate and reliable product information throughout its procurement lifecycle.

1.5 Motivation for research

This research is primarily motivated by the pressing need to address the challenges the NHS faces in product information management within its procurement process and inventory management system. Efficient management of the procurement process is essential for an effective and functioning healthcare system. For a healthcare system such as the NHS, where resources are stretched thin, optimizing the procurement system is essential for ensuring access to products, medical supplies, and equipment.

The implementation of a scalable national product information management system will enhance procurement efficiency, ensure patient safety, and care quality, meet regulatory requirements, foster collaboration, and drive innovation within the UK's health system.

1.6 Aims and Objectives of research.

1.6.1 Research Aims

The primary aim of this research is:

1. To design and optimize a scalable national product information management system for the NHS.

1.6.2 Research Objectives

To achieve the project's aim, the following objectives were set:

1. To analyse the existing product information management practices within the National Health Service (NHS) procurement ecosystem, identifying key challenges and assessing the needs and requirements of stakeholders.
2. To design the conceptual, logical, and physical database frameworks for a scalable national product information management (PIM) system tailored to the needs and requirements of the NHS.

3. To develop a prototype of the proposed PIM system, leveraging advanced relational database management technologies and methodologies to ensure scalability, optimization, and usability in a real-world NHS setting.
4. To evaluate the effectiveness and impact of the PIM system in improving procurement processes, supply chain management, and patient care outcomes within the NHS through testing and user feedback.
5. To provide recommendations and guidelines for the implementation, adoption and improvement of the national product information management system within the NHS.

1.7 Research Questions

This research will be guided by the following questions:

1. What are the key challenges faced by the NHS in managing product information within its procurement processes?
 - ANS- data fragmentation, disparate systems, inconsistent data
2. How can the implementation of a national product information management system improve procurement efficiency within the NHS?
 - ANS- improved uniformity informs correct decision making and hence improve patient care outcomes. also, reduction of manual interphases and workload leads to more accuracy and efficiency.
3. What are the essential features and functionalities required in a scalable product information management system tailored to the needs of the NHS?

1.8 Significance of the study.

The significance of a study on the design and optimization of a scalable national product information management (PIM) system for the NHS cannot be overemphasized. By streamlining procurement and hospital catalogue management systems through the implementation of a national PIM system, the NHS can increase its efficiency, minimize administrative burdens, and improve the overall procurement process. A centralized and up-to-date product information management system will provide healthcare practitioners with reliable information about medical devices and products thereby minimizing the risk of errors, and further ensuring patient safety.

Furthermore, a scalable national product information system has the potential to ensure optimization of the supply chain by enhancing interoperability and collaboration between healthcare providers, suppliers, and other stakeholders critical to ensuring the delivery of service within the NHS. A seamless data exchange and real-time access to accurate product information will foster transparency and accountability across the procurement ecosystem.

Additionally, embracing the implementation of innovative technologies and digital solutions such as a product information management system can help the NHS leverage opportunities in advanced analytics, artificial intelligence, and automation to optimize the procurement process, identify cost saving opportunities, and position itself at the forefront of healthcare innovation. Overall, this study has the potential to revolutionize the healthcare supply chain and information management process, improve patient outcomes, and advance healthcare delivery not just within the NHS but globally.

1.9 Structure of the Thesis

This section explains the organizational structure of this thesis. This thesis is organized into 7 chapters, each one serving a specific purpose to providing an overall understanding of the work. Chapter 1 introduces the study. It serves as a foundational framework for the study, by providing context, outlining the background, the research problem, aims & objectives, significance of study and structure.

Chapter 2 presents a comprehensive review of relevant literature to healthcare procurement, and product information management. It discusses key concepts, methodologies, and findings in this field, highlighting existing gaps in the literature which this research seeks to address.

Chapter 3 outlines the research methodology employed for the design, development, and evaluation of the proposed system.

Chapter 4 presents a thorough assessment of the needs and requirements for the design of a product information management system for the NHS. It employs the mixed-methods approach to collecting data from primary and secondary sources on the information needs of the relevant stakeholders within the NHS procurement ecosystem.

Chapter 5 discusses the design and modelling of a conceptual framework for the proposed product information management system, including the discussion of relevant entities, database the normalization process, optimization strategies employed, and design of the user interface.

Chapter 6 focuses on the implementation and development of the system. It discusses the implementation of the database system, the user interface, and the integration with external systems. It also discusses the process of testing and quality assessment.

Chapter 7 discusses the evaluation of the developed product information management system. Specifically, it discusses the evaluation criteria employed, and the evaluation of the system in comparison with set objectives.

In conclusion, chapter 8 discusses the result of the research, draws conclusion based on the results, and presents recommendations for future research.

Chapter 2

Literature Review

2.1 Introduction to literature review

In today's dynamic healthcare landscape, efficient information management systems and procurement practices are essential for ensuring access to medical products, optimizing resource allocation, and improving care outcomes. Though there is limited literature in recent times on the design and implementation of a product information management system especially for a healthcare organization such as the NHS, this literature review aims to explore existing literature on the design, optimization and application of Product Information Management (PIM) systems, the As-Is To-Be Analysis of the PIM system scoping framework, which is a gap analysis activity which aims to provide an understanding and assessment of the processes and systems currently in place in the organization including challenges, and the proposed future systems and processes (Battistello, 2020). This chapter aims to inform the research objectives of this study by providing a thorough understanding of the current state of knowledge by synthesizing key concepts, methodologies, and findings from relevant sources.

2.2 Product Information Management

2.2.1 What is Product information?

Product Information is any information about a product which a client or customer uses to make an informed decision about purchasing a product. (Palmer, 2024)

2.2.2 Product Information management

The concept of Product Information Management (PIM) began relatively circa 2003 (Abraham, 2014). Product information management is sometimes referred to as Product Data Management (Vedapudi, 2000).

So, what is Product Information Management (PIM)? To put it simply, PIM is the management of Product information. To further expatiate on this definition, PIM may be defined as the processes and technologies set up to manage product information in one shared place – “a single source of truth”, to further distribute that information into different systems without having to manually re-enter it. (Abraham, 2014).

2.3 Background of Product Information Management in the NHS: As-Is

Prior to the set-up of the new NHS Supply Chain in 2019, NHS procurement activities were done through a fully outsourced operating model also called NHS Supply Chain. The new NHS Supply Chain was set up following the Lord Carter report which cited wide variations in products and supplier data across NHS trusts (Carter, 2016). There are several ways for NHS trusts to buy its products as expressed by (Davies, 2024) in Figure 1 below.

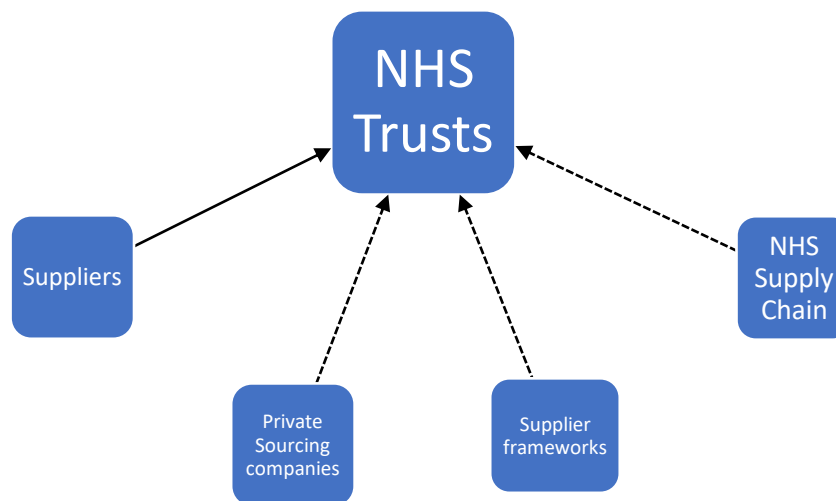


Figure 1: How Trusts can buy products

Under the new operating model, NHS trusts may buy medical products through the NHS Supply Chain, or directly from suppliers. Although nearly all trusts buy at least some specialized high-value products through the NHS Supply Chain.

The use of master data across the supply chain is necessary for effective supply chain management, especially in long and complex supply chains such as the NHS'. In addition to accurate analysis of expenditure, hospital catalogue management, and requisition exchange, the

use of master product data is critical for patient care management in terms of decision making, and product traceability (Procurement, Investment & Commercial Division, DHSC, 2014).

Unfortunately, the use of master product data is very limited within the NHS, from manufacturer to patient. Suppliers of products and medical supplies to the NHS respond to multiple requests for master product data by several NHS providers who use their supplied products as shown in Figure 2 below (Commercial Division, DHSC, 2017). This information is often shared manually (e.g. emailing Excel files) which means it can easily become wrong, out-of-date, or inconsistent with other sources. This means that the same medical items are described and coded differently by NHS providers and suppliers (Procurement, Investment & Commercial Division, DHSC, 2014). The application of NHS eClass, the primary classification standard currently used by teams within the NHS, is inconsistent across the NHS and is not up to the global standards of product classification. (Procurement, Investment & Commercial Division, DHSC, 2014)

Historically, product information management within trusts has been plagued with several issues. These issues are outlined in a report by (Department of Health & Social Care, 2018):

- i. Out-of-date pricing.
- ii. Manual data entry at trust level.
- iii. Product descriptions being designed by trusts and not recognized by suppliers.
- iv. Instances of incorrect data including product codes.
- v. Product data being held in various systems within a given trust, thus creating several versions of the 'truth'.

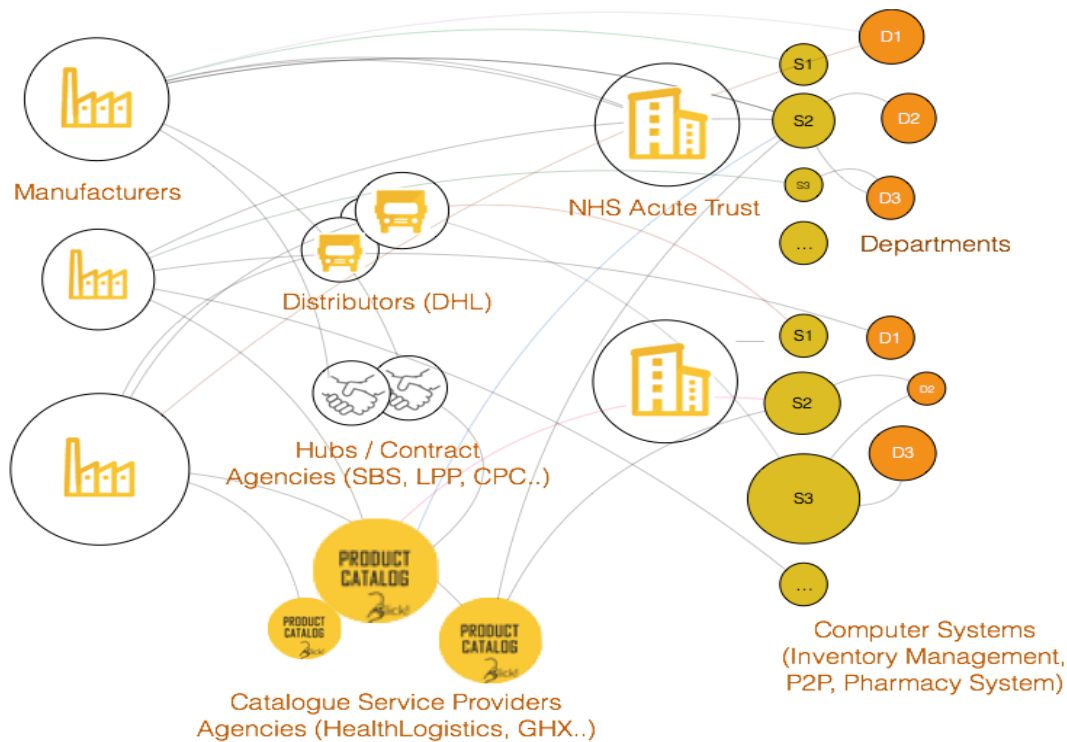


Figure 2: Typical product data management process in the NHS.

Source: Department of Health & Social Care

This inefficient product data management and exchange across the NHS results in duplication of efforts, increased costs, delays, and compromised data quality (Commercial Division, DHSC, 2017).

Furthermore, in a study done by (Boulding & Hinrichs-Krapels, 2021), some major challenges affecting the procurement decision-making process include:

- i. Variations in procurement processes and systems within and across NHS trusts. In fact, certain trusts still have paper-based system of generating orders for medical supplies.
- ii. Inefficient IT procurement systems: the stakeholders involved in procurement of supplies for the NHS trusts cited that the systems have major shortcomings which affect their decision making. The systems have poor search capabilities, they are bad at providing images of products, and they contain obsolete products which have yet to be taken off the system, causing more challenges for procurement decision-making. According to subjects

of the study, the systems can be greatly improved by providing images of products, improving its search functionality, optimization of product lifecycle information etc.

Introduction of a new product information management system is desperately needed in the NHS, and it is necessary to involve the end users of that technology in its development process. Stakeholder involvement is key to the successful development and implementation of any technology within the NHS (Ahmad, et al., 2012).

2.4 Centralization of Product Information Management in the NHS: To-Be

There are 3 sequential phases for the centralization of product information management (Battistello, 2020):

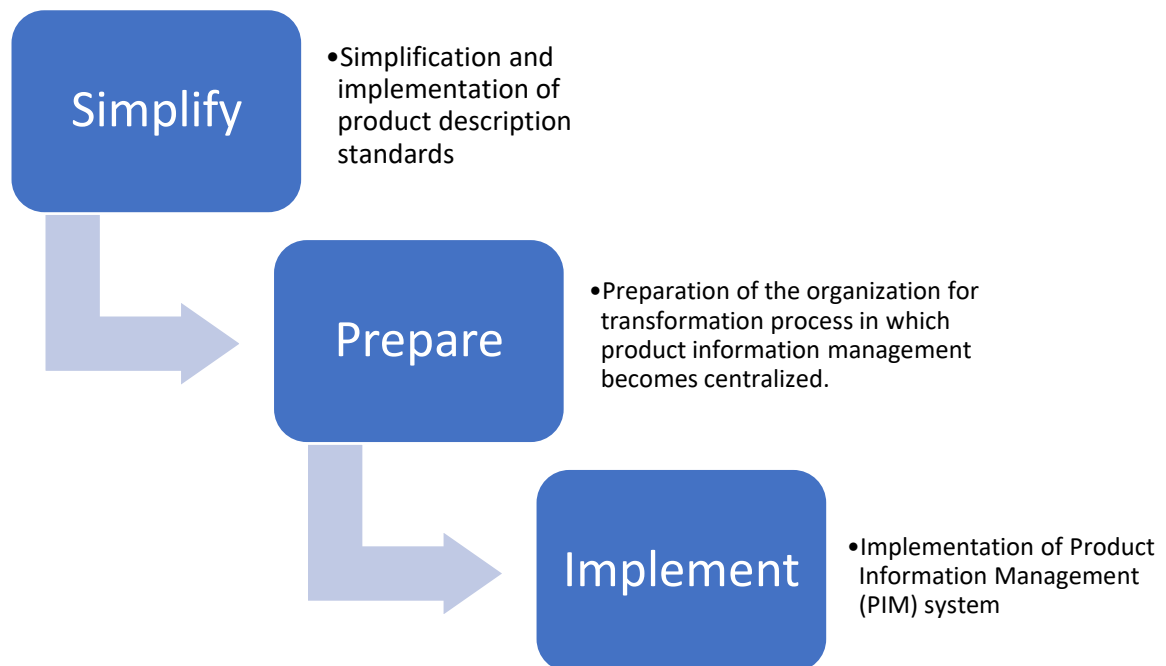


Figure 3: Framework for centralization of Product Information

In this section, the progress of the NHS towards the centralization of product information management is analyzed against these phases.

As the author (Battistello, 2020) proposed, the NHS has begun the sequential phases for the centralization of product information management.

1. Phase 1: Simplification and implementation of product description standards

Upon recognizing the need for, and benefits of improving its systems to improve data quality and data-sharing processes, the NHS launched the *NHS eProcurement Strategy*, to guide the adoption of GS1 standards as the supply chain coding standard by the NHS and its supplier base (Department of Health, 2013). GS1 standards are global coding standards used for the unique identification of products and locations, to enable data synchronisation and end-to-end traceability from manufacturer to patient.

The NHS recognized the adoption of GS1 coding standards by NHS providers and suppliers as the building block for improving data quality and enable interoperability between NHS provider and supplier systems (Procurement, Investment & Commercial Division, DHSC, 2014).

The NHS mandated both NHS providers and suppliers to adopt GS1 standards, including a requirement to place master product data in a GS1-certified data pool, through conditions of contract such as:

- i. the NHS Terms and Conditions for the Supply of Goods and the Provision of Services,
- ii. the 2014/2015 NHS Standard Contract between healthcare commissioners and NHS providers.

This adoption plan was mandated to encompass all goods supplied to the NHS providers, except for medicines which already had an established management system in place.

2. Phase 2: Preparation of the organization for transformation process

The preparation phase involves the organization preparing for the transformation process by establishing an understanding of the benefits of the project. The NHS embarked on a *Demonstration of Technology (DoT)* project to show how the adoption of GS1 can solve the problems of the NHS (Commercial Division, DHSC, 2017).

The main purpose of the DoT was to use the GS1 & Global Data Synchronization Network (GDSN) in a live environment to show the ability to seamlessly facilitate the exchange of master product data and understand the impact of adopting GS1 standards on interoperability

between NHS trusts systems and supplier systems, data quality assurance, operating process, scalability from the DoT to an NHS-wide implementation.

DoT methodology

The DoT involved the participation of 6 medical device suppliers, 6 NHS Trusts and their catalogue service providers (CSP), the Department of Health, and GS1. The demonstration followed the following methodology (Commercial Division, DHSC, 2017):

- i. creating a product data dictionary,
- ii. sourcing data for 20 products from select suppliers,
- iii. the suppliers loading the data into a GS1-certified GDSN data pool of their choice,
- iv. publishing the supplier data on the 20 products to an NHS GS1 data pool - *this is done by subscribing to the suppliers' data pools using their GS1 Global Location Number (GLN)*,
- v. data validation,
- vi. maintenance updates, and finally,
- vii. providing the output from the master product data to the catalogues of the participating NHS organizations.

The DoT was successful in showing that the adoption of GS1 & GDSN for implementation of a PIM system for the exchange of master product data between suppliers and NHS providers would result in a more efficient and effective health care and ultimately improve patient safety.

3. Phase 3: Implementation of PIM system

The success of the DoT informed the decision to fully implement an NHS-wide product information management system for the seamless exchange of master product data between suppliers and NHS providers. Figure 4 below shows the proposed framework for the near real-time exchange of master product data between suppliers and NHS providers using the Global Data Synchronization Network (GDSN). The GDSN is a set of global data pools created in compliance with GS1 standards to share structured product data (GS1 UK, 2021).

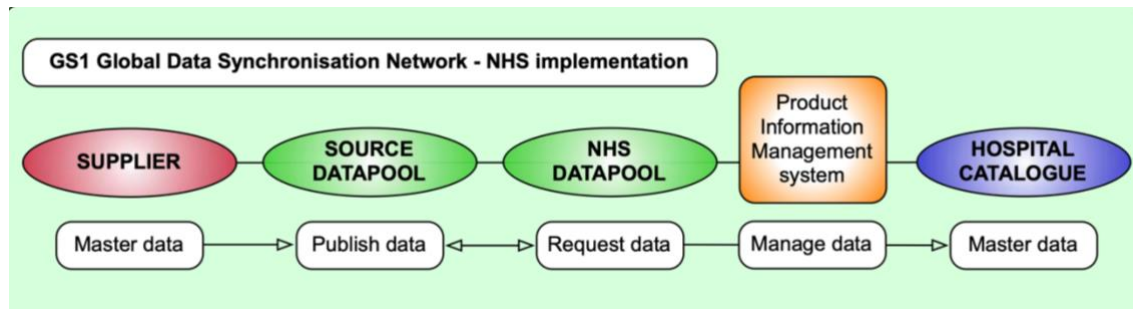


Figure 4: Proposed NHS GS1 master data exchange network.

Source: Department of Health & Social Care

The department of health establishes a GS1-certified data pool for the NHS which will take product data from suppliers' GS1-certified data pools to become the master product data repository for all medical devices and products supplied to the NHS (Procurement, Investment & Commercial Division, DHSC, 2014).

A National Product Information Management (PIM) system will then serve as the national infrastructure for the integration of the NHS data pool with NHS providers, where NHS providers can access master product data, thereby ensuring data integrity, quality, and accuracy across multiple systems.

The use of GS1 standards will also facilitate the use of Automatic Identification and Data Capture (AIDC) technology, which is used to identify a product at the point of use.

Research Gap 1: *The lack of a national infrastructure for the management of master product data constitutes the gap for my research.*

Research Gap 2: *Lack of understanding of the difference between Product Information Management System and Product Master Data Management System within the NHS.*

2.5 Product Information Management (PIM) Systems

A Product Information Management (PIM) system is an information system used to centrally store, enrich, manage, and distribute product information across several different units of an organization, thus alleviating the need to manually re-enter the data in a different system.

(Battistello, et al., 2021). Product Information management systems are necessary for the unification and synchronization of disparate product information.

2.5.1 Benefits of a PIM System

A Product Information Management (PIM) System offers several benefits across various industries. The following are some of the benefits of a PIM system as identified by the authors (Abraham, 2014; Battistello, 2020):

1. Centralized Data Management: a PIM system provides a centralized repository for storing, organizing, and managing product information. This ensures data consistency and accuracy by eliminating errors, duplicates, and/or redundancy.
2. Data Quality Improvement: a PIM system ensures the maintenance of a high data quality, by enforcing standardized data formats and data validation rules. Good quality data ensures reliability and compliance with regulatory requirements.
3. Enhanced Operational Efficiency: a PIM system helps to streamline product information management processes by removing manual workloads, minimizing errors, and improving data accuracy.
4. Increased Productivity: implementing role-based access controls and workflow management capabilities in PIM systems lead to improved productivity and faster decision-making.
5. Legal & Regulatory Compliance: a PIM system helps to ensure compliance with regulations on data privacy protections, standardization, and other data security measures.
6. Scalability: PIM systems offer the ability for organizations to expand product catalogs and support large volumes of product data.

2.5.2 Benefits of a PIM System to the NHS

- a. traceability of medical devices, especially for field safety corrective actions,
- b. adequate identification of medical devices through distribution and use,
- c. identification of medical devices in adverse events,
- d. reduction of medical errors,
- e. documenting and longitudinal capture of data on medical devices.

f. Effective data retrieval systems

(IMDRF UDI Working Group, 2013)

2.5.3 Product Information Management (PIM) vs similar Information Systems

A Product Information Management (PIM) system is comparable to several other information systems that manage product data (Battistello, 2020). These systems include Product Data Management (PDM), Product Lifecycle Management (PLM) and Master Data Management (MDM).

Product Lifecycle Management (PLM) and Product Data Management (PDM) systems are internal-facing systems which focus on the manufacturing and developmental lifecycle of a product from ideation till after the product is no longer being sold (for example, product not yet on the market, product discontinued etc.). (Abraham, 2014)

Master Data Management is the comprehensive management and maintenance of master data within an organization. A Master Data Management (MDM) system focuses on providing solutions to problems of data fragmentation, incoherent processes, and disparate systems (Nurminen, 2022).

Master data is the definitive single source of truth for all information which an organization holds about its core entities such as its products, employees, suppliers, accounts etc. (Nurminen, 2022). Master data serves as the foundational data which may be shared and reused by different information systems and business process applications in an organization as a source for accurate reporting, and for reduction of errors and redundancy (Edel & Sutedja, 2023; Pansara, 2021). This is further supported by (Nurminen, 2022) who posited that Master data must be accurate, relevant (proper data attribute selection), timely (data synchronization), complete, and accessible.

Master Data Management (MDM) may be said to be the first step in a Product Information Management (PIM) process (Abraham, 2014). Product Information Management (PIM) is a subset of Master Data Management that deals with product-related information for sales and marketing purposes (Battistello, 2020). In essence, a Master Data Management process must first

be implemented to be able to implement an outward-facing Product Information Management system.

Both PIM and MDM systems, to some extent, aim to solve the same product data management challenges. However, where a Product Information Management system focuses on the outward view of Product information for sales & marketing activity, a PMDM focuses on the management of product data and leveraging it to improve business process and decisions that are dependent on product data (Sheldon & Goetz, 2014).

In the context of the NHS, the product data as supplied to the GS1 certified data pools by the suppliers of medical device products forms the basis of **Product Information Management** for sales and marketing from the perspective of the suppliers, while the product data as received by the NHS Providers through the GDSN forms the basis of **Product Master Data Management** within the NHS.

2.6 Information Management System Development Life Cycle

The lifecycle of an information or database system includes all the steps necessary for the design and implementation of the system. According to (Langer, 2008) , system developments projects must include the following steps, regardless of which design methodology is used:

1. Identifying the need for a business process improvement/support system e.g. a Product Information management system
2. Defining the goals for that system
3. Gathering the business requirements
4. Converting the business requirements to system requirements
5. Designing the system
6. Building, testing, and deploying the system.

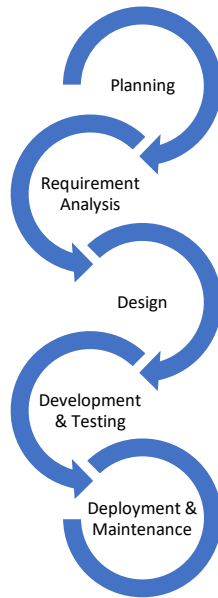


Figure 5: Information System Development lifecycle

These outlined steps will serve as a guide for the execution of this research project in achieving its outlined research objectives.

2.7 Information Management System Design Tools and Technologies

2.7.1 Databases and Database Management Systems

A Database Management System (DBMS) is a software which manages and controls access to a collection of logically related data called a *database*, designed to meet the information needs of an organization. (Connolly & Begg, 2015). A database is said to resemble a well-organized electronic filing cabinet whose content is managed by a powerful software known as the database management system (Coronel & Morris, 2016).

The DBMS is used to define and manipulate the database using Data Definition Language (DDL) and Data Manipulation Language (DML) respectively (Connolly & Begg, 2015). The interaction between a relational DBMS and a database is facilitated by a query language called **Structured Query Language (SQL)**.

An application program is a computer program written in a programming language which is used for interacting with the database by issuing SQL statement requests to the DBMS. An application program could be produced by designing a software application or by using an **application generator** instead (Connolly & Begg, 2015).

The relationship between an application program, a DBMS, a database, and users of the database system is shown in Figure 6 below.

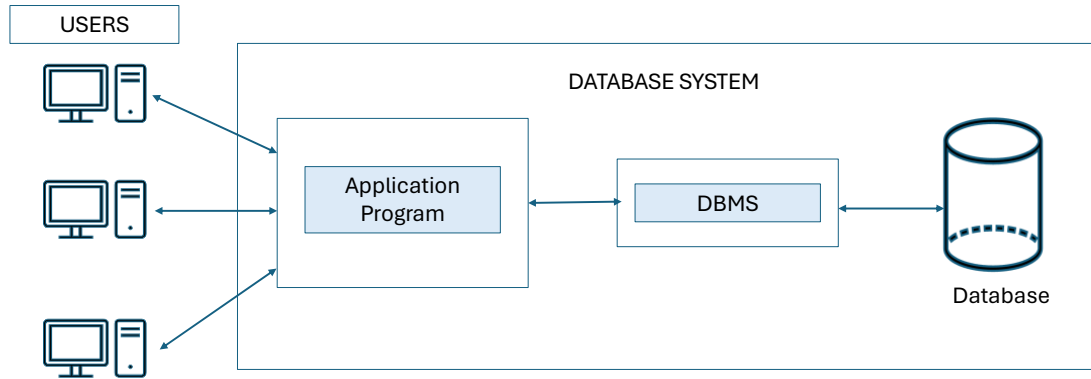


Figure 6: Database System Application Processing

2.7.2 Advantages and Disadvantages of Database Management Systems

The advantages and disadvantages of a database management system are listed in the tables below:

Table 1: Advantages of a DBMS

ADVANTAGES	
i.	Improved data sharing
ii.	Improved data security
iii.	Minimized data inconsistency.
iv.	Improved data integration
v.	Improved data access
vi.	Improved decision making
vii.	Increased productivity

Table 2: Disadvantages of a DBMS

DISADVANTAGES	
i.	Complexity of DBMS software
ii.	Size
iii.	Cost of DBMSs
iv.	Additional hardware costs
v.	Cost of conversion
vi.	Performance
vii.	Greater impact of a failure

2.7.3 Types of Databases

There are several methods of classifying databases such as by the number of users, location of data, data type, data usage and data structure. They are summarized by (Coronel & Morris, 2016) as follows:

- i. A **single-user database** (desktop database) supports only one user at a time while a **multiuser database** supports multiple users at the same time.
- ii. A **centralized database** supports data located at a single site while a **distributed database** supports data distributed across different sites.
- iii. A **general-purpose database** contains a variety of data used across several disciplines while a **discipline-specific database** contains data focused on a particular subject area.
- iv. An **operational database** primarily supports a company's day-to-day operations such as sales, payments, purchases, etc., while an **analytical database** focuses on maintaining historical data used for strategic decision making.
- v. A **SQL database** supports the management of structured data while a **NoSQL (Not-only-SQL) database** has emerged in recent years for the management of vast amounts of data with varying structures (semi-structured, unstructured, structured) and velocity. The choice between SQL and NoSQL databases depends on the needs of the organization and the type of data being managed. Organizations with a need for structured and consistent data will find SQL databases more preferable while organizations with large amounts of unstructured data will prefer NoSQL (Dhasmana, et al., 2023).

Adequate infrastructure is required to support the implementation and operation of databases.

The organization typically maintains this infrastructure, but the use of cloud databases has grown in recent years. (Coronel & Morris, 2016). A cloud database is a database created and maintained using cloud data services which provide defined performance measures for the database like speed, scalability, storage capacity (Google Cloud, 2024).

The product information needs of the NHS are structured, relational data, most of which are stored on spreadsheets across different parts of the supply chain. Hence, a **centralized discipline-specific multiuser cloud relational database system (Cloud SQL)** would be best utilized.

2.7.4 Database System environment

A typical database system environment comprises 5 major components. According to (Connolly & Begg, 2015) and (Coronel & Morris, 2016), the major components of the DBMS environment are:

- i. **Hardware:** this refers to all the physical device components of the system such as computers, storage devices, servers, printers, network devices and other devices which the DBMS and its applications require to run.
- ii. **Software:** this consists of the DBMS software itself, the application program(s), and the operating system software on which the hardware components function, allowing all other software to run. Examples of DBMS software include Microsoft SQL Server, Oracle MySQL, and IBM's DB2 while examples of operating system software include Microsoft Windows, Linux, Mac OS etc.
- iii. **Data:** This is the bridge between the machine components and the human components of the DBMS environment. The database contains both the data stored in the database and the metadata.
- iv. **Procedures:** these are the instructions and guidelines that govern the design and use of the database system.
- v. **People:** This includes all the users of the database system. Database users may include database administrators, system analysts, database designers, and end users of the system.

2.8 Scalability in PIM Systems

Scalability is the ability of a system to handle growing amounts of work or changing demands (Wikipedia, 2023). In essence, it is the ability of a system to grow to accommodate larger volumes of data and users.

- SQL db (scale vertically), NoSQL (Scale horizontally) (Dhasmana, et al., 2023)
-
- prerequisites for scalability
 - Data storage should be sufficiently large to store and process all the incoming data.
 - Data writing, searching, and retrieval for a single patient's data have to be very fast and independent of the number of patients in the system.

- Data will be written once and read several times. In fact, most of the data that is stored will never be modified or deleted; hence we can exploit this property of this data.
-
- how to implement scalable DBMS?
 - Replication: ensures scalability and stability by making sure application continues to be accessible in the case of server failure. you can replicate data across many servers (Šušter & Ranisavljević, 2023)

2.9 Optimization strategies for relational database systems

Explain what optimization is in the context of databases and information systems.

- Physical programming (partitioning, indexing, data compression and data clustering) page 144 (Šušter & Ranisavljević, 2023)
 - data types e.g use TINYINT instead of INT or BIGINT
 - storage engines
 - index design
 - field optimization-based method (Györödi, et al., 2021)
 - [Indexing strategies for performance optimization of rel db](#) (Praveena & Chikkamannur, 2021)
 - Indexing results in a higher performance and energy efficiency. (Mahajan, et al., 2019)
- Data Tuning (also known as performance optimization) to locate and get rid of bottle necks. page 146 (Šušter & Ranisavljević, 2023)
 - Query optimization is a critical part of data tuning, for ensuring that SQL queries perform better.
 - improving joins, indexing frequently queried columns (suster and ranislav). (Maesaroh, et al., 2022)
 - avoid using select *, callout the column names (Mahajan, et al., 2019)
 - use EXISTS instead of IN

- server configuration, size of buffer pool be changed to optimize memory utilization and boost query performance. max_connections parameter increase to manage high number of concurrent users (suster and ranislav)
- normalization: reduction of data redundancy and duplication can enhance query performance and lower storage costs. (find reference on normalization)
- Caching and replication: caching saves frequently accessed data in memory for easy retrieval.

○

2.10 Case studies and best practices – application of PIM in healthcare, and in other industries

<https://www.gs1.org/industries/healthcare/udi> -UDI implementation around the world

UDI database (UDID)- EU and FDA

European database on medical devices EUDAMED

ACCESS GUDID

The work also aligns with the 'collect once, use often' approach to data as recommended by the Independent Medicines and Medical Devices Safety Review (<https://www.immdsreview.org.uk/Report.html>) and will help bring the UK MedTech system in line with international efforts, as both the USA (<https://accessgudid.nlm.nih.gov/>) and the EU (<https://ec.europa.eu/tools/eudamed/#/screen/search-device>) have launched similar solutions

<https://www.federalregister.gov/documents/2013/09/24/2013-23059/unique-device-identification-system>

2.11 Summary of key findings and gaps in the literature.

INSERT TABLE OF RELEVANT PAPERS AND THEIR CONTRIBUTION. IDENTIFY GAP in literature

empirical review

- domain
- database management system/database infrastructure

- optimization techniques
- user interface

Author(s)	Methodology	Finding(s)	Gap
			Cant download query results
			Not specific to the uk health system which is different
			Cannot easily trace the location of the recipient as its not provided in the system.

There is a dearth of literature on the design of product information management systems especially in the UK healthcare space, hence the need for this project to fill that gap.

Chapter 3

Methodology

3.1 Introduction to Methodology

This chapter outlines the methodology employed in this project for the design, development, and evaluation of the National Product Information Management (PIM) System for the NHS. It encompasses the information system development lifecycle stages as outlined in the previous chapter, in addition to ethical considerations.

3.2 Research Design

This study leverages existing research findings and data collected by the NHS and the Department of Health & Social Care (DHSC) to inform the design and optimization of the PIM system, ensuring alignment with user needs and requirements while maximizing the utilization of available resources.

A sequential mixed-methods approach is adopted, combining qualitative and quantitative methods, to address the research problems and objectives appropriately (Office for Health Improvement and Disparities, 2020). The qualitative approach involves the research and review of literature, documents, and publications to understand the research problem, and goals of the intended PIM system using secondary data collected by the NHS through interviews, surveys, and stakeholder engagement sessions. The quantitative approach involves the performance testing and evaluation of the PIM system after its design and implementation to evaluate how the system meets defined requirements through statistical analysis of primary quantitative data from user survey responses.

3.3 Planning Phase

The planning phase of the development lifecycle involves an organization reaching a high-level understanding of their current situation, assessment of improvements needed, and a plan for reaching the improvement goals (Oppel, 2009). This phase forms the basis from which the project is launched. Once a business improvement need is identified, a feasibility study is done to evaluate how the project meets the organizations set goals.

The Department of Health & Social Care embarked on an in-house discovery phase which involved interactions (interviews, site visits, focus group sessions, resource sharing etc.) with

over 25 internal and external stakeholders from NHS trusts, the Medicines and Healthcare products Regulatory Agency (MHRA), NHS Supply Chain, NHS England, Medical Device Outcome Registry, manufacturers, and medical device data bodies (Crown Commercial Service, 2024).

The findings of this planning and discovery phase forms a foundational basis for this project, its scope, and requirements analysis. The primary data source for this consists of research reports, publications and documentations produced to this effect by the NHS, DHSC and other major players within the UK health system.

3.4 Requirements Analysis

In the requirements gathering and analysis phase, a high-level description of what the project must accomplish are gathered and documented. It focuses on the *what* rather than the *how*, which is developed in the design phase. The requirements analysis phase captures the existing and expected proposed system, business rules, and entities (Oppel, 2009).

It involves an identification of the stakeholders, and their needs, forming the basis of the analysis of the user views. A user view is a method for presenting a set of data to the user of a system in a way which meets the identified needs of that user (Oppel, 2009).

The requirements analysis of this study builds upon the insights gathered during the planning phase to define and refine users' needs, and system functionalities. It also establishes non-functional and the legal requirements which the system must meet.

3.5 Design Phase

The design phase involves translating the findings from the requirement analysis into a comprehensive design framework for the PIM system. This framework encompasses data model, system components and its user interface (UI).

The design phase may be broken down into the following 3 frameworks:

1. **Conceptual Design:** this involves the design of the externals of the system i.e., the layout of reports, screens, and web pages etc. This may be documented in the form of flowcharts or screen diagrams, providing an understanding of the logical flow of the system (Savelios, 2021). This phase involves the integration of the user views, entities, and business rules into an entity-relationship diagram (ERD).

2. **Logical Design:** this is the technical design phase. It involves the design of the internals of the system, a blueprint for the design of the relational database. The major task in this phase is *Normalization*, a technique for producing a set of relations with desirable properties, given the data requirements of an organization. The main purpose of normalization is to remove data redundancy, and eliminate *Insert*, *Update*, and *Deletion* anomalies (Olagunju, 2023).
3. **Physical Design:** in this phase, the logical design is converted into the hardware and system software which will be used for the implementation of the PIM system (Oppel, 2009). The normalized relations from the logical design phase are implemented in the Database Management System (DBMS) using Data Definition Language (DDL).

3.6 Development and Evaluation

This phase builds on the system design specifications to develop, test and evaluate the PIM system. It follows the process of system development, testing and evaluation procedures to ensure the system's functionality, performance, and usability align with the defined user needs and objectives.

3.6.1 System Development

The system is developed using the appropriate tools and technologies, while adhering to best practices and coding standards. The tools and technologies used are discussed briefly in subsections 3.6.2 Hardware Requirements and 3.6.3 Software Requirements.

3.6.2 Hardware Requirements

The following machine features were used to build and implement the frontend and backend of the prototype PIM system:

Table 3: Hardware Requirements

Chip:	Apple M1
CPU:	8-core CPU (4 performance and 4 efficiency)
Memory:	8 GB
Storage Capacity:	256 GB SSD
Operating System:	MacOS Sonoma Version 14.2.1

The following hardware features will be sufficient to build and implement this PIM system: at least 8GB RAM, 256 GB Solid-State Drive (SSD) storage, Windows 10, and an intel core i5 processor or higher.

3.6.3 Software Requirements

The backend of the PIM system is built using the following software tools and technologies:

- i. **Oracle SQL Developer Data Modeler:** this is a free graphical tool by Oracle which facilitates efficient data modelling, ensuring the integrity and consistency of the database structure. This tool is used in this study for designing and creating the conceptual Entity-Relationship Diagram (ERD) for the PIM system.
- ii. **MySQL:** one of the world's most advanced open-source object-relational database system, MySQL will serve as the relational database management system for storing and managing all the entities, fields, and data within the PIM system. Its extensibility, fault tolerance, and advanced features make it an ideal choice for a PIM system handling a large volume of structured data.
- iii. **MySQL Workbench:** this is the most popular and advanced open-source administration and development platform for MySQL. It is used in this study as the user interface tool for administration and interaction with the MySQL database.
- iv. **Aiven for MySQL:** this is an open-source cloud data platform for hosting, managing, and deploying MySQL databases. It is used in this study as the cloud data service for deploying the MySQL database to the cloud.
- v. **Python:** Python is a free high-level, powerful, and easy-to-use object-oriented programming language. Python is used in this study to generate dummy data for the PIM system and to develop the backend logic and data processing scripts due to its versatility, extensive library, and ecosystem of frameworks.
- vi. **GitHub:** this is a web-based software development platform used for storing and tracking software projects. GitHub is used in this study as a version control system and platform for storing, managing, and documenting SQL and python scripts used in the development of this PIM system.

The software requirement for building and designing the front-end of the PIM system is:

- i. **Streamlit:** this is an open-source Python framework for building and deploying dynamic web-based data applications. It is used in this study as the application generator for

producing the front end of the prototype PIM system, for implementing the functional requirements and interacting with the backend SQL database.

3.6.4 System Evaluation

The process of evaluating the developed system to ensure its functionality, usability and alignment with requirements was structured as follows:

1. **Functionality Evaluation:** The PIM system's functionality is evaluated against the system requirements to ensure the system was correctly implemented.
2. **Performance evaluation:** performance testing is done to evaluate the system's performance in terms of its responsiveness, and efficiency under varying loads. The system's response time is the major performance metric measured and analyzed.
3. **Usability evaluation:** usability testing is conducted to evaluate the effectiveness and efficiency of the user interface and experience. Feedback is collected to identify any usability issues, and areas of improvement.
4. **Alignment with User Requirements:** deviations between the developed system and the documented user requirements are identified and evaluated. This is also done through feedback from users.

3.7 Data Collection Methods

Data collection for this study is done through review and thematic analysis of secondary data sources like research publications, and documentations, and through analysis of system evaluation survey responses.

The system evaluation involved distribution of a questionnaire to individuals identified as potential users of the system. The potential users were required to respond to the questionnaire after they had used the prototyped PIM system, to gain insights into their perception of the system's performance and to identify areas of improvement.

The questionnaire was designed using the online questionnaire tool, **Google Forms**. The survey employs **close-ended and open**-ended questions to receive responses from users on their perception of the system.

Survey: 10 respondents participated in the system evaluation survey and responded to the following questions:

1. vfcdgyhjhbxcjdkmd ?
2. dfghujncdhkmvcv l,?
3. vghyuwcDJNDVJKMC ?

The data collected is categorized into qualitative and quantitative data.

3.7.1 Qualitative data

The qualitative data collection method was employed initially to understand the business problem, and requirements of the PIM system as defined by the NHS, and to evaluate the performance of the PIM system after development.

- *Thematic analysis findings: qualitative findings from thematic analysis of secondary data sources like research publications, and documentation produced by the NHS, and the department of health.*
- *Open-ended survey response: Qualitative feedback provided by survey respondents through open-ended questions. Open-ended responses offer detailed insights into user perceptions, suggestions, and areas for improvement regarding the PIM system.*

3.7.2 Quantitative data

- *Close-ended survey responses: quantitative data obtained through surveys. responses provide numerical metrics and ratings on aspects such as usability, satisfaction levels and perceived performance.*
- *System performance metrics: Quantitative measures of the PIM system's performance, including response times, data processing speeds, and system uptime. These metrics are collected using monitoring tools and performance testing methodologies.*

3.8 Ethical Considerations

Ethical considerations were of paramount importance throughout this research process. Measures were taken to ensure data privacy, confidentiality, and informed consent of participants in the user testing and evaluation of the system.

Appropriate ethical considerations in relation to the use of secondary data were also carefully considered. The research contributions of secondary sources such as the NHS, Department of Health & Social Care, and all other relevant sources were properly cited and acknowledged to maintain the integrity of this research work.

In general, this study complied with all ethical guidelines and principles by respecting the rights of participants involved in the data collection and system evaluation process.

3.9 Limitations and Assumptions

This study adopts a transparent approach to address potential bias and mitigate risks by acknowledging the limitations associated with the methodology, including resource, time, and data access constraints.

The use of secondary data for analysis of requirements is subject to limitations such as a potential bias in the original data collection, limited control over data quality, and constraints on scope and depth of analysis & insights.

These limitations are acknowledged and addressed in the interpretation and discussion of research findings.

3.10 Summary of research methodology

The chart below summarizes the methodology employed in this study.

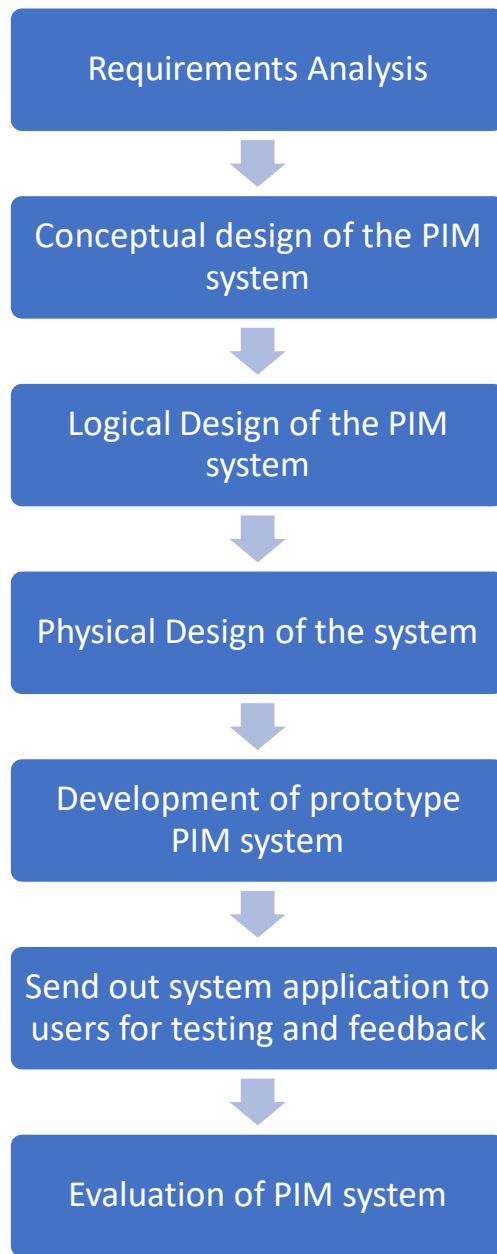


Figure 7: Summary of Research Methodology

Chapter 4

Requirements Analysis

4.1 Introduction to Requirements Analysis

This chapter covers the requirements analysis section of this information system design project. This is a foundational step in the system development lifecycle of a National Product Information Management (PIM) system for the NHS.

This phase is necessary to capture all the business needs in relation to the proposed PIM system (Langer, 2008).

4.2 Identification of Stakeholders and Information Needs Assessment

Stakeholder identification is the first step in the Requirements analysis phase (Simplilearn, 2023). Identifying the key stakeholders whose interests must be considered in the design and implementation of this national PIM system is crucial.

This section builds on the findings of the in-house planning and discovery phase for this project, done by the Department of Health as the foundational basis for identifying the problem, and business improvement need. As discussed earlier, this phase involved interviews, focus group sessions, resource sharing and site visits with internal and external stakeholders.

The main question asked during this phase was:

"How can we make basic information about medical products more available and of better quality?" (Crown Commercial Service, 2024)

This section presents a comprehensive overview of insights gained in this discovery phase as reported by (Crown Commercial Service, 2024), providing a foundational understanding of major stakeholders and an assessment of their information needs in relation to this PIM system.

1. Stakeholder: Suppliers/Manufacturers

- Information Need(s): Suppliers and manufacturers of medical devices and products in the UK need to share information about their product with the NHS for the trusts to

have accurate, consistent information about them. The product information provided by suppliers is used as the basis of the Product master data management system within the NHS. This data forms the basis of the PIM system.

2. Stakeholder: Data Systems Leads

- Information Need(s): Data systems leads in NHS trusts need to have accurate product information so that this information may be used in other systems within the trust e.g. financial records, electronic health records etc.

3. Stakeholder: Procurement Leads

- Information Need(s): Procurement Leads in NHS trusts need to have adequate, accurate information about medical products or devices to fully understand the characteristics of different products and be able to make the right decision on which products to buy, and/or alternatives.

4. Stakeholder: Patient Safety Leads

- Information Need(s): Patient Safety leads in NHS trusts are responsible for ensuring products and devices being used in patients' care are safe. They need to have accurate and up-to-date information about products to facilitate product traceability in case of recalls, and to meet other national safety initiatives like the Scan4Safety.

5. Stakeholder: Data Analysts

- Information Need(s): Data analysts in core sectors of the UK Health System like the NHS England, the MHRA, and the Department of Health & Social Care (DHSC), need to have information about products being used in patient care for easy export and joining with product information with other datasets, to analyse the market and understand patient safety trends.

6. Stakeholder: Patients

- Information Need(s): Patients need to have information about products or devices being used on them to ensure their confidence in the safety of the products.

4.4 System Requirements Analysis

The system requirements analysis builds on the findings of the needs assessment to define the specific requirements which the proposed PIM system must meet. The problem which the PIM system aims to solve is the inefficient data sharing process and inconsistent product information management throughout the supply chain from supplier to patient. This system aims to improve accessibility and quality of medical product data distributed across the UK healthcare system.

4.4.1 Functional Requirements

The following functions are required from the national PIM infrastructure according to analysis of findings from (Boulding & Hinrichs-Krapels, 2021) and (Procurement, Investment & Commercial Division, DHSC, 2014):

1. Users must be able to access to the existing dataset of medical device products supplied to NHS Trusts.
2. Users must be able to use the system to view product data,
3. Users must be able to search for product information,
4. Users must be able to apply appropriate filters,
5. Users must be able to export product information from the system,
6. Users must be able to identify obsolete items.

4.4.2 Non-functional Requirements

Non-functional requirements of the national PIM system are as follows, as outlined in a report by (Commercial Division, DHSC, 2017):

1. **Scalability:** The system must be scalable i.e. it must be able to accommodate increasing volumes of data and users.
2. **Quality assurance:** The system must provide consistent, standardized data to ensure the quality of information gotten from it.
3. **Interoperability:** The system must ensure interoperability between systems used by NHS providers, suppliers, and other relevant bodies.

This national PIM system will act as a shared reference point for exchanging information about medical products for NHS stakeholders. It will make data sharing more efficient, and the use of accurate, consistent data is going to improve the decision-making process, thus improving patient care outcomes.

4.5 Legal and Regulatory Frameworks

The design and implementation of a national PIM system for a healthcare organization like the NHS requires strict adherence to legal and regulatory requirements. This section provides an examination of the standards, guidelines and regulations governing healthcare product data management in the UK.

4.5.1 Relevant legal and regulatory compliance standards and obligations

The NHS operates within complex legal & regulatory frameworks which are aimed at ensuring data privacy and security across all information management systems. It is necessary to comply with the legal and regulatory requirements to avoid litigation and ensure trust and reliability among all stakeholders.

The following are some legal and regulatory standards which the UK health system must comply with in the development of a product information management infrastructure:

1. **International Medical Device Regulators Forum (IMDRF) guidance for Unique Device Identification (UDI) of Medical Devices:** this is a supporting guidance for the unique identification of medical devices (GMDN, 2023). It is a framework for developing a UDI system which achieves harmony with the global standard (IMDRF UDI Working Group, 2013).
2. **European Commission (EC) framework for a unique identification system of medical devices in the union:** This framework applies to medical devices, implantable medical devices, and in-vitro diagnostic medical devices. The rationale for which is improving incident reporting, facilitating actions by national bodies, enabling queries in several data systems, reducing medical errors (European Commission, 2013).
3. **The Medical Devices Regulations 2002:** information provided by manufacturers and suppliers of medical device products to the NHS are subject to data validation and scrutiny

by the MHRA in accordance with the Medical Device Regulation of 2002 (Medicines and Healthcare products Regulatory Agency, 2020). Global Medical Device Nomenclature (GMDN) terms and codes must be implemented by suppliers/manufacturers as part of the regulations for registering devices for the UK market (GMDN, 2023).

- 4. Data Protection Act (DPA 2018):** since the UK's exit from the European Union, the DPA 2018 has replaced the EU General Data Protection Regulation (GDPR) for operations inside the UK. The provisions of the GDPR have been directly incorporated into the UK law (Spencer & Patel, 2019). This law imposes rules on the collection, storage, and processing of personal data in the UK, ensuring the protection of rights of individuals, and the responsible handling of data. Personal data in this context includes information about any persons associated with products e.g., suppliers or employees.

4.5.2 Influence of legal and regulatory considerations on the design and implementation of the NHS PIM system.

All the requirements set out by the Department of Health for the NHS' National Product Information Management System align with the GDSN standard for healthcare across Europe, based on a common European data dictionary (Commercial Division, DHSC, 2017), which also aligns with the standard set internationally by the IMDRF (European Commission, 2013). This ensures interoperability, not only within the NHS, but across global healthcare organizations.

The internationally agreed standards for unique device identification management which have influenced the UK Department of Health's Product Information Management system requirements outlined by (European Commission, 2013) and (IMDRF UDI Working Group, 2013), are summarized as follows:

Product Information

- i. A Unique Device Identifier (UDI) will be assigned to a medical device/trade item or its package. Higher levels of packaging will be assigned their own UDI;
- ii. the UDI will contain 2 parts: a UDI Device Identifier (UDI-DI) and a UDI-Production Identifier (UDI-PI);
 - a. a UDI-DI is a globally unique identifier specific to a device trade item which is represented by the Global Trade Item Number (GTIN)

- b. a UDI-PI is a unique identifier which identifies the unit of production. It comprises a device's serial number, lot/batch number, manufacturing and/or expiry date.
- iii. A new UDI-DI must be assigned if any of the following data attributes change; brand name, device model/version, size, labelled as single use, sterilization, quantity per package, warnings, and contraindications etc.;

Product Information Management System

- iv. the system must incorporate all core data attributes; the minimum required to identify and describe a product throughout the supply chain;
- v. the system will contain no commercially sensitive or confidential information.
- vi. the core data attributes must be publicly accessible;
- vii. Product lifecycle information e.g., information about product discontinuation or suspension, must be included in the system.

Based on these guidelines, the following are the core data attribute requirements for the design and implementation of a National PIM database system as recommended by the EC and the IMDRF:

- a) Product brand/trade name;
- b) UDI-Device Identifier – GTIN
- c) Unit of Issue e.g. each, case, pallet
- d) Quantity per package configuration e.g. 1 each, 10 each(es)
- e) Manufacturer's name, address, and customer service contact information;
- f) Authorized representative's name, details and contact information;
- g) Global Medical Device Nomenclature (GMDN) code and description;
- h) UDI-Production Identifier
- i) Global Model Number (GMN) - Device model or version;
- j) Manufacturer Reference and/or Catalogue number (if applicable)
- k) Clinical size (volume, length, diameter, gauge);
- l) additional product description or information;
- m) Storage and/or handling conditions;
- n) License or Registration number

- o) Is device labelled as Single Use? (Yes/No)
- p) If reusable, restricted number of reuse(s);
- q) Is device packaged sterile? (Yes/No)
- r) Does device need to be sterilized before use? (Yes/No)
- s) Sterilization method – if device needs to be sterilized;
- t) Critical warnings or contraindications associated with device use:
 - i. Is device labelled as containing latex? (Yes/No)
 - ii. Is device labelled as containing DEHP? (Yes/No)
 - iii. Is device compatible with MRI? (Yes/No)
- u) Product lifecycle information and date

These core data elements will be incorporated into the design of the proposed NHS Product Information Management System.

4.6 Summary of Requirements Analysis

It has been established that the product information management ecosystem within the NHS suffers from major burdens such as manual data requests resulting in outdated, inconsistent, and even incorrect product information. Hence, there is need for a new system to collect standardized and consistent data once and use often, leading to improved accessibility and data quality for all stakeholders and initiatives.

The major stakeholders and users of the system have been identified as suppliers and manufacturers, data analysts, data systems leads, procurement leads, patient safety leads, and patients. The goal is for them to have access to accurate product data and information. The system must be accessible, accurate, secure etc. ensuring quality of product data, interoperability, and scalability.

The work complies with EC and IMDRF UDI frameworks, MDR 2002 and DPA2018. Minimum data attribute requirements for the NHS PIM system have been established and will be used in the design and modelling of the system in the following chapters.

Finally, this chapter provides adequate answers to my third research question.

Chapter 5

Design and Modelling

5.1 Introduction to system design

This chapter covers all phases of the design of the PIM system including the conceptual, logical, and physical designs. This chapter covers the techniques employed in these phases including the definition of business rules, entity-relationship modelling, normalization, and the conceptual design of the user interface. This is a critical phase in the developmental lifecycle of the PIM system as it lays the foundation for the implementation of the functional and non-functional requirements as discussed in the requirements analysis phase.

5.2 Data Modelling

The data modelling process is the first step in designing the PIM system. It involves creating a data structure representation of the complex, real-world environment to solve a specific problem (Coronel & Morris, 2016). The data model represents the structures of the data involved, their attributes, relationships, and constraints.

5.2.1 Business Rules

The business rules are brief descriptions of the policies or procedures within an organization which govern the use and storage of data (Coronel & Morris, 2016). These rules inform the definition of entities, attributes, relationships and constraints during the design and modelling of an information system for the organization.

In the context of the NHS National Product Information Management System, the following business rules may be defined in accordance with standards established in the requirements analysis:

- Each trade item is supplied by only one supplier, and a supplier may supply many trade items.
- Each trade item is supplied to an NHS provider/trust, and each NHS provider may have many trade items supplied to them.
- A trade item contains a unique medical device, but a medical device may be contained in many trade items (IMDRF UDI Working Group, 2013).

- A Global Medical Device Nomenclature (GMDN) code may be assigned to many medical devices, but a medical device can only have one GMDN code (GMDN, 2023).
- An NHS product classification (eClass) code may be assigned to many medical devices, but a medical device can only have one eClass code. (Procurement, Investment & Commercial Division, DHSC, 2014)
- A medical device may be assigned a Basic UDI-DI, a Global Model Number (GMN) to uniquely identify the model or product family of that medical device, and a GMN may be assigned to multiple medical devices. (GS1, 2024)
- A medical device is manufactured by only one manufacturer, but a manufacturer may manufacture many medical devices.
- A medical device may be assigned a classification reference number by the manufacturer, and a classification number may be assigned to many medical devices of the same family.
- A medical device must have a manufacturer assigned authorized representative, and an authorized representative may be assigned to many medical devices or family of devices.
- A medical device is assigned a regulatory device classification according to its risk class, and a risk class may be assigned to many medical devices or medical device models (Medicines and Healthcare products Regulatory Agency, 2020).

5.2.2 Entities and Attributes

The PIM system is designed to accommodate the information needs of the identified stakeholders while considering the minimum data requirements defined in the requirements analysis, and the business rules defined in the preceding subsection. To meet these needs, the relevant entities and attributes are modelled as follows, with the primary key underlined:

1. Medical Device: This entity provides information about medical devices in the UK market. Attributes include: (GTIN, brand_name, unit_of_use, quantity_of_uou, item_length, item_height, item_width, item_weight, item_volume, unit_of_dimension, product_description, storage_handling, single_use, restricted_no_of_use, sterile, sterilize_before_use, sterilization_method, item_contains_latex, item_contains_dehp, item_mri_compatible, item_model_gmn, gmdn_code, nhs_eclass_code, manufacturer_reference_no)

- Foreign key(s): **item_model_gmn, gmdn_code, nhs_eclass_code, manufacturer_reference_no**

2. Trade Item: This entity provides information about unique trade items supplied to the NHS healthcare providers. Attributes include: (**UDI, gtin, serial_number, batch_number, manufacturing_date, expiry_date, udi_pi, unit_of_issue, unit_of_use_udi, supplier_gln, nhs_provider_gln**)

- Foreign key(s): **gtin, supplier_gln, nhs_provider_gln**

3. Supplier: This entity provides information about the suppliers who trade medical device items with the NHS organization and its healthcare providers. Attributes include: (**supplier_gln, supplier_name, supplier_address, company_registration_no, customer_service_phone, customer_service_email**)

4. Manufacturer: This entity provides information about the manufacturers of the medical devices on the UK market. Attributes include: (**manufacturer_gln, manufacturer_name, manufacturer_address, company_registration_no, customer_service_phone, customer_service_email**)

5. NHS Provider: This entity provides information about the healthcare providers within the NHS organization who are at the receiving end of the medical device trade items supplied by suppliers. Attributes include: (**provider_gln, provider_name, provider_address, provider_registration_no**)

6. Manufacturer Catalog: This entity provides information about products listed in a manufacturers catalog. Attributes include: (**manufacturer_reference_no, product_name, product_model, product_category, market_availability_date, lifecycle_status, last_status_update, manufacturer_gln, authorized_rep_id, risk_class_name**)

- Foreign key(s): **manufacturer_gln, authorized_rep_id, risk_class_name**

7. Risk Class: This entity provides information about the classification of medical devices based on the level of risk they pose to the user. Attributes include: (**class_name**, **class_description**, **regulatory_requirements**)
8. Item Model: This entity provides information about the GS1 identification system of a product model or product family. Attributes include: (**GMN**, **model_name**, **device_type**, **market_availability_date**, **lifecycle_status**, **last_status_update**, **risk_class_name**)
- Foreign key(s): **risk_class_name**
9. Authorized Rep: This entity provides information about the representatives authorized by the manufacturer for their product catalog. Attributes include: (**rep_id**, **rep_name**, **contact_number**, **email**)
10. GMDN: This entity provides information about the global standard for identification and classification of medical devices. Attributes include: (**gmdn_code**, **gmdn_term_name**, **gmdn_term_definition**)
11. NHS Product Classification: This entity provides information about the classification codes used within the NHS. Attributes include: (**eclass_code**, **description**)

A comprehensive data dictionary describing all these terms and attributes is provided in the appendix of this report.

5.2.3 Relationships

A relationship describes the association between entities of a database. The following relationships are identified between entities of this PIM system:

- a) Medical_Device and Trade_Item
- Relationship
 - Cardinality: One-to-Many (1:N)
 - Participation: Source Optional, Target Mandatory

b) Trade_Item and Supplier

- Relationship
- Cardinality: One-to-Many (1:N)
- Participation: Source & Target Mandatory

c) Trade_Item and NHS_Provider

- Relationship
- Cardinality: One-to-Many (1:N)
- Participation: Source & Target Mandatory

d) Medical_Device and Manufacturer_Catalog

- Relationship
- Cardinality: One-to-Many (1:N)
- Participation: Source & Target Mandatory

e) Manufacturer and Manufacturer_Catalog

- Relationship
- Cardinality: One-to-Many (1:N)
- Participation: Source & Target Mandatory

f) Manufacturer_Catalog and Authorized_Rep

- Relationship
- Cardinality: One-to-Many (1:N)
- Participation: Source & Target Mandatory

g) Risk_Class and Manufacturer_Catalog

- Relationship
- Cardinality: One-to-Many (1:N)
- Participation: Source & Target Mandatory

h) Risk_Class and Item_Model

- Relationship
- Cardinality: One-to-Many (1:N)
- Participation: Source & Target Mandatory

i) Item_Model and Medical_Device

- Relationship
- Cardinality: One-to-Many (1:N)
- Participation: Source & Target Mandatory

j) Medical_Device and NHS_product_classification

- Relationship
- Cardinality: One-to-Many (1:N)
- Participation: Source & Target Mandatory

k) Medical_Device and GMDN

- Relationship
- Cardinality: One-to-Many (1:N)
- Participation: Source & Target Mandatory

5.2.4 Entity Relationship Models

Entity-Relationship models are a way of representing data structures graphically, generally accepted to be more effective than describing these structures in text. They are typically represented using entity relationship diagrams (ERD) which use graphical representations to model database components (Coronel & Morris, 2016). This study presents the ERD with logical and relational ER models for the PIM system.

Figure 8 below shows the logical model for the PIM system designed in Oracle SQL Data Modeller by defining the entities, attributes, and relationship between attributes. Figure 9 shows the relational model engineered based on the relations and constraints defined in the logical model. The relationships between the entities are illustrated using the Crow's Foot notation.

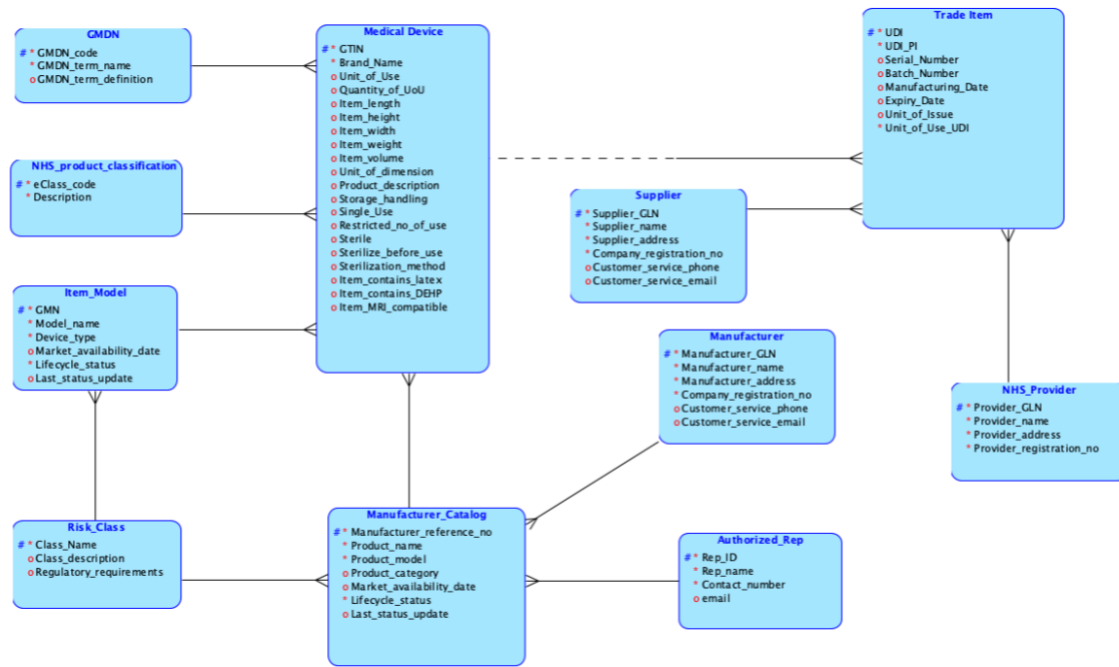


Figure 8: Logical ER model for the PIM system.

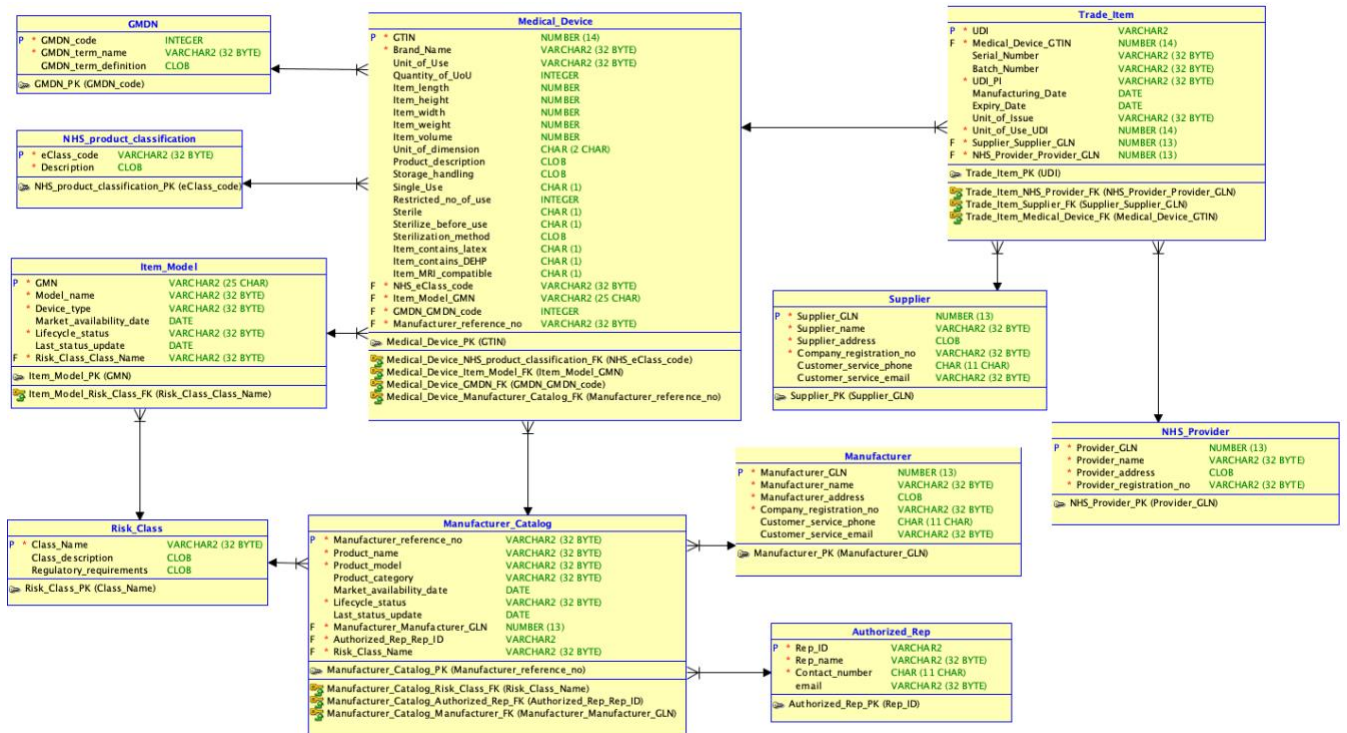


Figure 9: Relational ER model for the PIM system.

5.2.5 Database Normalization chapter 14-15

Normalization is a process of organizing a database according to the requirements and need of an organization, eliminating errors and removing redundancy. From an Unnormalized form, there are 3 main normalization steps to achieve acceptable database normalization.

- i. **Unnormalized Form (UNF):** this is a normalization form where the database entities contain repeating groups. For every row of an identified primary key, there are cells which contain more than one value at the intersection of the row and column. To take a database from UNF to 1NF, values for the repeating groups must be duplicated.
- ii. **First Normal Form (1NF):** This is when a database and its entities contain no repeating groups. At the intersection of a unique row and column, there is only one value representing the mapping of a unique identifier key on the database attribute.
- iii. **Second Normal Form (2NF):** This is when a database and its entities are in first normal form and contain no partial dependencies. A partial dependency exists when a table has a composite key and some of the non-key attributes fully functionally depend on one of the candidate keys.
- iv. **Third Normal Form (3NF):** this is when a database and its entities are in second normal form and contain no transitive dependency.

5.3 User Interface

The PIM system user interface is designed to be easy to use and navigate.

talk about the contextual wireframing first

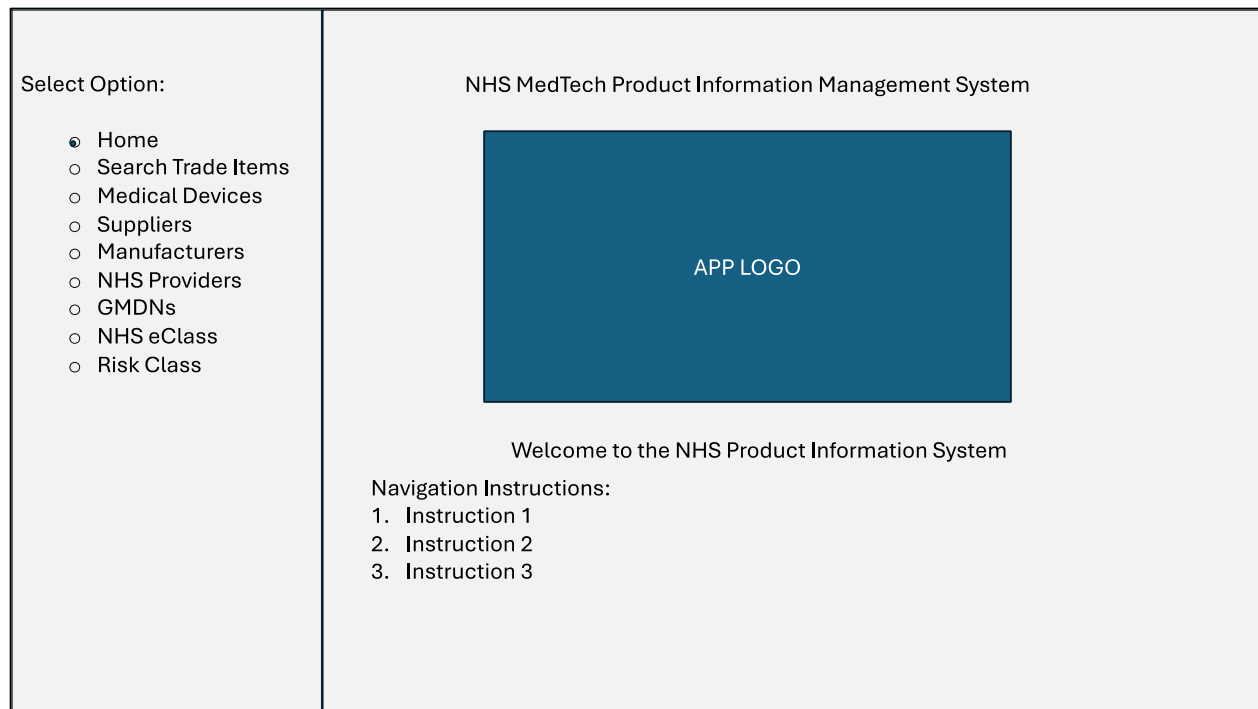


Figure 10: Conceptual Design of the System's Home Page

1.1 discussion on usability principles and best practices in interface design to enhance user experience.

5.4 Summary of System Design

1.2 summary of key design decisions and considerations

1.3 identification of design principles and strategies aimed at meeting stakeholder needs and achieving system objectives

1.4 transitioning to implementation phase, highlighting how the system design will guide the development of the system

Chapter 6

Implementation and Prototyping

6.1 Introduction to Implementation

- Overview of implementation phase and significance in bringing proposed PIM system to life
- Explanation of the objectives and scope of the implementation process

6.2 System Development

- Description of the development lifecycle followed for implementing the PIM system

5.2 Database Architecture

chapter 12 Description of proposed database architecture for the NHS national PIM system

Explanation of the database structure, including tables, fields, and relationships

Discussion of choice of relational Database technology and suitability for managing product information in healthcare

-
- two-tier client-server architecture
- 1. ****Client****: The end user interacts with the system through a client application built in Streamlit. This client application serves as the front end, providing a user-friendly interface for users to input data, retrieve information, and interact with the system's functionalities.
-
- 2. ****Server****: The server-side components include the MySQL database managed through the Aiven for MySQL data platform service. This database server stores and manages the system's data, handling tasks such as data storage, retrieval, and manipulation. Additionally, Streamlit applications typically run on a server environment, where they communicate with the database server to fetch and update data based on user actions.
-
- 3. ****Communication****: The client application (built in Streamlit) communicates with the database server (MySQL managed by Aiven) over a

network connection using connection credentials. User requests from the client application are sent to the server, processed by the server-side components (e.g., database queries), and responses are sent back to the client to be displayed in the user interface.

-

- Overall, this architecture follows the client-server model, where clients (end users) interact with server-side components (database server and Streamlit application) over a network to access and manipulate data stored in the database.

6.3 Database Implementation

- steps involved in implementing database infrastructure
- description of the process i.e. database creation, configuration, and optimization
- Discussion of challenges encountered during implementation

6.5 User Interface development

- **STREAMLIT IS AN APPLICATION GENERATOR**
- Description of the UI development process for the PIM system
- Overview of the design principles, UX considerations and usability testing conducted during interface development
- Discussion on how iterative design process informed the development of the user interface
- <https://docs.streamlit.io/knowledge-base/tutorials/databases/postgresql>
- <https://www.datacamp.com/tutorial/streamlit>
- <https://www.youtube.com/watch?v=ns-Pd-1F4uU>

6.6 Scalability and Optimization

1.5 analysis of scalability requirements

1.6 discussion of scalability challenges and solutions in database design

1.7 description of strategies for ensuring scalability of the database architecture

1.8 Discussion of optimization techniques employed to enhance system performance and scalability. (query optimization, Indexing, Minimizing redundant data retrieval, etc.)

6.6 Data Security and Integrity Measures

- explanation

6.7 Summary of Implementation

- key milestones and successes
- Challenges encountered and solutions adopted during implementation.
- recommendations for future system implementations

Chapter 7: Evaluation and Results

7.1 Introduction to Evaluation

- overview of the evaluation phase and importance in assessing the effectiveness and performance of the developed PIM system
- Explanation of the objectives and scope of the evaluation process

7.2 Evaluation Metrics and Criteria

- description of metrics and criteria used to evaluate the PIM system
- KPI and criteria for assessing system effectiveness, usability and impact

7.3 Evaluation methodology

- Overview of evaluation methods i.e. surveys or interviews employed to collect feedback from stakeholders

7.4 Evaluation of System Scalability

- analysis of the scalability of the PIM system to handle increasing volumes of data and user traffic
- description of tests for assessing system performance
- discussion of scalability challenges and recommendations for enhancing system scalability

7.5 Presentation of Results

- presentation of data collected during evaluation process
- SWOT analysis of the PIM system

7.6 Comparison with objectives and requirements

- comparison of evaluation results with objectives and requirements defined for the PIM system
- Assessment of the extent of the system meeting stakeholder needs, fulfill project goals and addresses identified challenges

-

7.7 Summary of findings

- Summary of key findings, insights and conclusions from evaluation phase
- Summary of recommendations for enhancing system performance, usability and scalability

Chapter 8: Discussion and Conclusion

8.1 Interpretation of the findings in relation to the research objectives.

8.2 Discussion of implications, limitations, and future directions.

Use of relational limits the db to only relational, structured data. future research should look into the implementation of NoSQL databases

These limitations of methodology are acknowledged and addressed in the interpretation and discussion of research findings.

8.3 Summary of key findings and contributions of the thesis.

8.4 Recommendations for practice, policy, or further research.

Evaluating Database Management Systems: A Framework And Application To The Veteran's Administration Hospital <https://dspace.mit.edu/bitstream/handle/1721.1/61034/06564848-MIT.pdf;sequence=2>

Database Management System for Student Admissions

https://soar.suny.edu/bitstream/handle/20.500.12648/10380/Savelios%20Aslanidis%20-%20Thesis%20Project_DBMS%20for%20Student%20Admissions.pdf?sequence=1&isAllowed=y

DESIGN AND IMPLEMENTATION OF SPECIAL EDUCATION APPS INFORMATION MANAGEMENT SYSTEM

https://etd.ohiolink.edu/acprod/odb_etd/ws/send_file/send?accession=kent1492704386514278&disposition=inline

An information management system for a large-scale biological collaboration

https://trace.tennessee.edu/cgi/viewcontent.cgi?article=6723&context=utk_gradthes

Web-based forensic information management system

<https://researchrepository.wvu.edu/cgi/viewcontent.cgi?article=3386&context=etd>

Development of a Database-Driven Management System for Retail Food Packaging Eye Tracking Studies

https://tigerprints.clemson.edu/all_dissertations/2171/

design and development of web based biomed dbms for health services multispecialty

https://web.archive.org/web/20210428045611id_/https://jusst.org/wp-content/uploads/2020/12/Design-and-Development.pdf

Evaluation Of Performance of NoSQL Database Management System: -MongoDB And Relational Database Management System: - PostgreSQL for Efficient Management Of Healthcare Data

<http://sifisheriessciences.com/journal/index.php/journal/article/view/2331>

DESIGN AND IMPLEMENTATION OF A WEB-BASED HEALTH CARE RECORDS MANAGEMENT SYSTEM

[http://ir.mtu.edu.ng/xmlui/bitstream/handle/123456789/178/OIBO%20JOY%20OPEYE MI%20-%20FULL%20PROJECT.pdf?sequence=1&isAllowed=y](http://ir.mtu.edu.ng/xmlui/bitstream/handle/123456789/178/OIBO%20JOY%20OPEYE%20MI%20-%20FULL%20PROJECT.pdf?sequence=1&isAllowed=y)

Database System for Medical Record Keeping and Retrieval

<http://jae-tech.com/index.php/jaet/article/view/101/86>

Implementation of product data management system

<https://oulurepo.oulu.fi/bitstream/handle/10024/15456/nbnfioulu-202009162929.pdf?sequence=1&isAllowed=y>

EVALUATION OF DATABASE MANAGEMENT SYSTEMS – PostgreSQL better than MySQL & SQLite in terms of speed and info retrieval

<https://hh.diva-portal.org/smash/get/diva2:367006/FULLTEXT01.pdf>

Design and Implementation of a Web Shop System

https://www.theseus.fi/bitstream/handle/10024/22377/Shen_Yeyin.pdf?sequence=1&isAllowed=y

Analysis and Design of Information Systems

By Arthur M. Langer

https://books.google.co.uk/books?hl=en&lr=&id=fHZBQZkp-TYC&oi=fnd&pg=PR2&dq=design+of+information+management+system&ots=zsX4RAr&sig=IOBhWdu0FQwBFPce-mknLWjkivw&redir_esc=y#v=onepage&q=design%20of%20information%20management%20system&f=false

<http://ndl.ethernet.edu.et/bitstream/123456789/55870/1/44%202014.pdf> ABRAHAM 2014

[The digitalization journey of PIM](#) (Battistello, 2020)

[https://www.utupub.fi/bitstream/handle/10024/153916/Nurminen_Arttu_opinnayte.pdf?sequence](https://www.utupub.fi/bitstream/handle/10024/153916/Nurminen_Arttu_opinnayte.pdf?sequence=1)

[1](#) NURMINEN, 2022

Classification standards

Classification standards support

- procurement intelligence, by enabling similar items to be grouped together for spend analysis and demand aggregation;
- the traceability requirements of regulatory agencies.
 - Work will be undertaken at the national level to determine the most appropriate procurement classification standards for use by the NHS. The outcome of this work may be to maintain the status quo or to recommend an alternative approach. A likely outcome will be different classification standards for different categories. (eProcurement strategy)
 -
- https://scan4safety.nhs.uk/wp-content/uploads/2022/11/gsl_uk_inventory_management_systems_guidance-1.pdf
inventory management system implementation guidance scan4safety
 -
 -
 -
 - Data/Attribute selection: proper master data management entails an organization identifying and understanding data that is most meaningful to the business. Quality over quantity. (Nurminen, 2022)
 - Master data vs transactional data: master does not change as often as transactional which changes continuously. (Nurminen, 2022) (talk about not using price data since its dynamic i.e. transactional)

Evaluation of existing processes, technologies, and systems within NHS

- Overall, it is a burden for the health system to provide, manage, and use medical product information. The inaccurate and incomplete data collected poses a risk to patient safety and effective procurement and administrative processes There is a risk that manufacturers will not correct or verify the quality of their data which would restrict the usefulness of the proposed solution as trusts would have limited reason to trust and use the data.

- https://www.gs1uk.org/sites/default/files/MDE_Demonstration_of_Technology_Case_Study.pdf master data exchange demonstration of technology -

PREPARATION

- https://scan4safety.nhs.uk/wp-content/uploads/2022/11/Scan4Safety_Product_How_To_Guide-1.pdf
 - scan4safety/ catalogue mgt/product information
- <https://scan4safety.nhs.uk/how-to-get-started/first-steps-for-suppliers/>
- supplier how to get started
- https://www.gs1uk.org/sites/default/files/GS1_UK_Healthcare_Terms_2024.pdf

<file:///Users/ayokunlejames/Downloads/4004202021guidance.pdf>

<https://www.imdrf.org/sites/default/files/docs/imdrf/final/technical/imdrf-tech-131209-udi-guidance-140901.pdf>

([https://eur-](https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:099:0017:0024:EN:PDF)

[lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:099:0017:0024:EN:PDF](https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:099:0017:0024:EN:PDF))

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[study#:~:text=A%20mixed%20methods%20study%20combines,with%20more%20in%20depth](https://www.gov.uk/guidance/mixed-methods-study#:~:text=A%20mixed%20methods%20study%20combines,with%20more%20in%20depth)

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Appendices

- Supplementary materials such as raw data, survey, or technical documentation.
- Evaluation Form
- Data Dictionary??
- link to github