

IOT-BASED BUSINESS PROCESS MANAGEMENT FOR TEMPERATURE-CONTROLLED LOGISTICS SYSTEM OF LABORATORY SPECIMENS

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ABSTRACT

The transportation of laboratory specimens and raw materials for advanced therapy medicinal products (ATMP) is challenging due to the need for strict temperature control and limited delivery periods. Such transportation must be conducted with care to prevent damage or compression, which may compromise the viability and stability of the specimens. Unlike other types of materials, transportation of specimens requires more complex control measures to ensure their usefulness in laboratory examinations and biological processes. Any damage or deterioration during transportation could significantly affect patient diagnosis and treatment. The transportation logistics system for these specimens contains sensitive personal information related to patient safety and life preservation. Hence, good control, tracking, and traceability are crucial to ensure safe transportation. This research recommends an IoT-based temperature-controlled logistics system for laboratory specimens, using Business Process Model and Notation (BPMN) to efficiently manage the transportation process. This system aims to maintain specimen stability and viability, thus ensuring the safety and quality of patient treatment. Thai transport and logistics service providers can implement this system to enhance transportation safety and quality.

INTRODUCTION

The effective management of logistics for specimens, including laboratory testing samples and raw materials for the production of ATMPs such as blood, urine, bone marrow, and tissue, requires precise temperature control, limited transportation times, and measures to prevent physical damage during transport. The temperature control and transportation time limitations vary for each type of specimen (Sánchez-Romero et al., 2017). The measures for controlling specimen transportation are crucial to maintaining their stability and viability, which

is more complex than for general material transportation. If specimens are damaged during transport, their quality may deteriorate, making them unusable for laboratory testing or biological processes, thereby significantly impacting the treatment of patients awaiting diagnosis or those requiring treatment (Palmer, et al., 2017; Kung et al., 2021). Furthermore, the logistics system for specimens has specific concerns related to personal data protection and safety, as well as legal and ethical considerations.

Therefore, it is crucial to ensure appropriate control when transporting specimens from the origin to the destination. This can be accomplished by precisely identifying the specimen's owner, donor, or recipient and monitoring and verifying its journey. These measures are necessary to guarantee patient safety.

The objective of this study was to propose an IoT-based temperature-controlled logistics system for laboratory specimens using BPMN. The proposed system integrates an IoT temperature control smart packaging for transporting specimens with a transportation management system for real-time monitoring and control. The aim was to create opportunities for logistics and transportation operators in Thailand to expand the market for temperature-controlled shipping of healthcare products and related medical logistics systems that meet high standards. This initiative also seeks to improve patient safety by mitigating the risks of damage or errors during specimen transportation, in terms of both data and product quality. Additionally, the proposed system offers more transportation options for hospitals and medical service providers, increasing the potential for saving human lives.

The paper is organised as follows. In Section 2, the current challenges in the supply chain and logistics system for laboratory specimens are outlined. Section 3 details the proposed business process management for an IoT-based temperature-controlled logistics system for laboratory specimens, using BPMN. This includes the implementation of an IoT temperature control smart packaging for transporting specimens with a specimen transportation management system for real-time monitoring and control. Section 4 briefly presents the implementation of this system. Finally, the paper is discussed and concluded in Section 5.

BACKGROUND

AS-IS Supply Chain and Logistics System for Laboratory Specimens

Logistics and transportation management for specimens covers laboratory specimens and raw materials for advanced therapy medicinal products (ATMP), such as cells, tissues, blood, and bones of living things.

The main stakeholders involved in the logistics and supply chain of laboratory specimens include hospitals, private laboratories, and various institutions that provide analysis and testing services, both in the provinces and in Bangkok. In cases where the analysis cannot be performed in-house, hospitals store and prepare the specimens for transport to external private laboratories or other institutions that provide analysis and testing services, such as the Institute of Dermatology or the Institute of Pathology, by hiring regular private transport vehicles or utilizing transport vehicles from nearby private laboratories.

Transporting specimens for use as raw materials for advanced medical products (ATMPs) such as stem cells and bone marrow for the treatment of certain diseases. Specimens used for the purpose of ATMPs include primary origin cells donated by individuals, which are transported to destination hospitals for use in treating other patients who are not the owners of those specimens

(allogeneic). Specimens may also be transported from the general public, such as cord blood and placenta from new-borns, for storage and cultivation of stem cells in stem cell banks for future use in treating their own diseases (autologous). Temperature-controlled logistics system for specimen is shown in Figure 1.

AS-IS Business Process for Transporting Laboratory Specimens

The logistics system and supply chain for the transport of specimens encompasses three primary stakeholders as follows.

- 1) healthcare service providers such as clinics, hospitals, etc.
- 2) temperature-controlled transport service provider
- 3) laboratory service provider

The current process for transporting specimens in the healthcare industry was analysed through in-depth interviews, and the results were depicted in Figure 2 using BPMN, which is a graphical notation language commonly used for modelling business processes. BPMN is widely used for designing and implementing process improvements, as well as for facilitating communication between business analysts, process designers, and IT professionals (Chanpuyetch and Kritchanchai, 2020; van der Aalst, 2009)

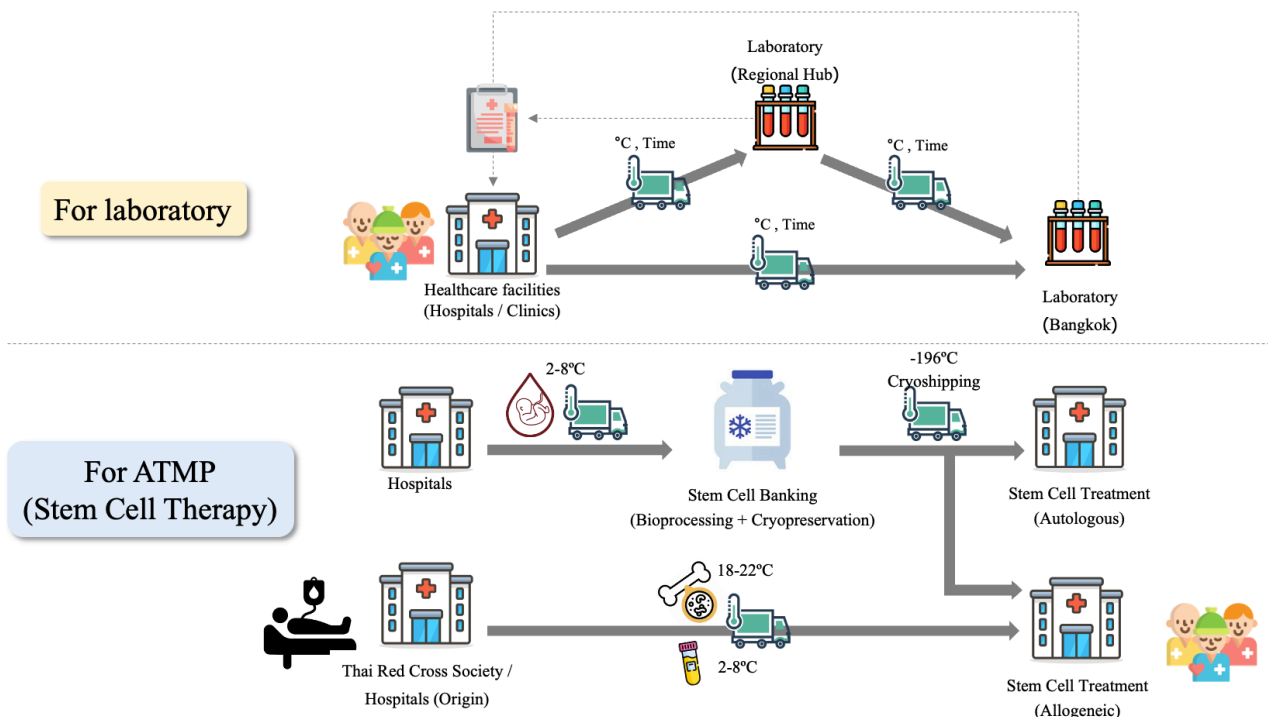


Figure 1: Temperature-controlled logistics system for laboratory specimen.

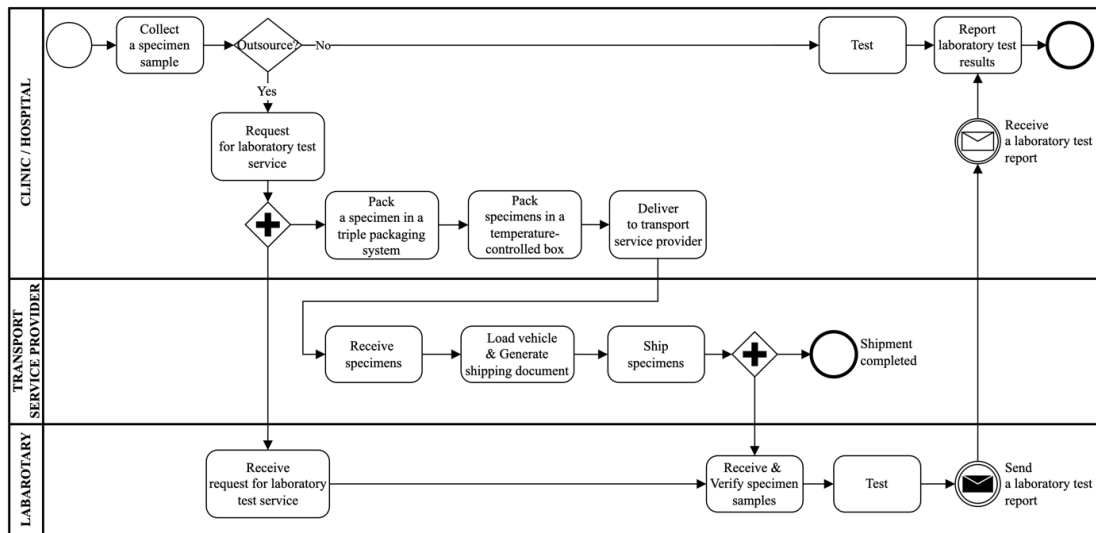


Figure 2: AS-IS business process for transporting laboratory specimens.

Figure 2 illustrates the current business process, obtained through in-depth interviews with laboratory service providers and hospitals. In some instances, a healthcare facility sends specimens to an external laboratory by contacting them through line, telephone, or email to schedule an appointment for a specific day and time. Subsequently, the healthcare facility collects the specimen samples, packs them into specimen packaging, and place them in temperature-controlled packaging, which is typically a foam box containing a cold gel. The packaging is then sealed and accompanied by necessary transportation documents, before being delivered to the transport service provider. The specimens are transported to the destination laboratory through either an ambient vehicle or aircraft.

Logistics Management Challenges for Laboratory Specimens

The inefficiencies in specimen logistics management as perceived by stakeholders within the supply chain, including the transport service provider, patient, hospital, or healthcare service provider, are depicted in Table 1.

Table 1: The inefficiencies in laboratory specimen logistics management

Stakeholders	Challenges
Transport service provider	<ul style="list-style-type: none"> The management of specimen transportation is complex due to the diversity of specimen types, as the arrangements and conditions required for transport depend on the intended purpose of examination or use. As a result, the packaging for transporting specimens is also diverse. In particular, samples of infected specimens require a triple packaging system to ensure safety during transport. The features of the packaging must consider various factors, including size, temperature control range, temperature maintenance duration, and the possibility of reuse. Research by UPS found that packaging errors accounted for as much as 41% of errors in the

Stakeholders	Challenges
	<ul style="list-style-type: none"> transportation of specimens (Arnold, 2020). When transporting multiple specimens, the transport service provider must be aware of the appropriate conditions, time constraints, and specific restrictions for each specimen. Human error can be a challenge to avoid in such circumstances.
Patient	<ul style="list-style-type: none"> Patients may incur additional expenses if specimens are damaged or become inaccurate during storage and transportation, which can result in delayed or incorrect treatment.
Hospital / Healthcare service provider	<ul style="list-style-type: none"> A small number of certified specimen carrier alternatives. Re-work is necessitated if specimens are damaged or faulty during storage and transportation, which results in wasted time that could have been spent treating other patients.

ANALYSIS OF THE KEY REQUIREMENTS FOR TRANSPORTING LABORATORY SPECIMENS

A thorough review of relevant literature on laboratory analysis and synthesis was conducted to achieve optimal conditions for the transportation of specimens. This was done with the aim of designing temperature-controlled packaging innovations. The resultant synthesis process is presented in Figure 3.

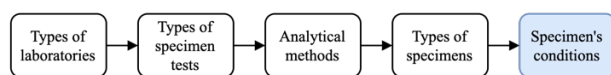


Figure 3: Synthesis process

Laboratory analysis and testing are classified into different types of laboratory rooms that offer testing services based on the principles of laboratory analysis. The selection of the analysis approach depends on the type of testing services required. Different specimen preparation methods are used for each testing type, and

certain testing services necessitate specific precautions to be taken (Jain, 2011).

Based on the data synthesis, it was found that some test items require the immediate or short-term transportation of specimens, while others can be stored for longer periods, ranging from 4 to 72 hours, or stored at the appropriate temperature until they can be tested. The specimens that can be stored for a certain period can be transported to external laboratories for analysis, which requires control during transportation to ensure that the specimens meet the specifications of each testing procedure and can lead to accurate and reliable test results.

Therefore, there are several key considerations that must be taken into account during the transportation of specimens when designing IoT-based temperature-controlled packaging and the transportation management system for specimen transportation. These include:

- The temperature range required for specimen transportation is typically between 2-8 °C and room temperature at 25 °C.
- Some specimens are not allowed to be refrigerated or frozen (Geneva: WHO, 2012).
- The storage time for specimens depends on the type of specimen, the test, and the appropriate temperature, typically ranging from 4-72 hours.
- Specimens must not be exposed to light.
- Specimen containers must be stored upright and not tilted.
- Blood specimens cannot tolerate strong impacts or high-frequency vibrations, as this can cause red blood cells to hemolysis (Johannessen et al., 2021; Wan Azman et al., 2019).

BUSINESS PROCESS MODEL OF IOT-BASED TEMPERATURE-CONTROLLED LOGISTICS SYSTEM FOR LABORATORY SPECIMENS USING BPMN

In response to the challenges and data synthesis of the requirements for managing specimen transportation, this study has developed a novel business process to manage a temperature-controlled logistics system for specimens, based on IoT. The system incorporates IoT smart packaging technology and an information system, named the Specimen Pick-up and Delivery Order Management System: SPD-OMS, which is designed as a web-based application to manage pick-up and delivery orders with temperature control. This system facilitates the transportation of specimens from medical service providers, such as clinics or hospitals, to medical laboratories.

According to the gathering requirement through in-depth interviews, document analysis, and participation in the requirement generation process, two type of requirements can be identified as follows.

- 1) Medical service providers who need to send specimens for analysis to external laboratories or other hospitals, are responsible for delivery by themselves, and
- 2) Medical laboratories that offer services for their customers to pick-up and delivery specimens to their

laboratory, covering the transportation costs for delivering the specimens from the origin to the destination.

The SPD-OMS system encompasses four primary user groups as follows.

1. Healthcare professionals from clinics or hospitals who require medical laboratory analysis of specimen samples at an external laboratory. They can use the SPD-OMS system to request analysis service and, if they are responsible for delivering the specimens, they can also request pick-up and delivery services from a logistics service provider via the SPD-OMS system.
2. Medical laboratory staff who provide analysis services to various organisations. They can use the SPD-OMS system to receive service requests and confirm those requests. If the laboratory is responsible for delivering the specimens, they can also request for pick-up and delivery services from a logistics service provider through the SPD-OMS system.
3. Logistics service providers who offer pick-up and delivery services for specimens from the originating healthcare service facilities to the destination laboratories. They can use the SPD-OMS system to receive service requests, monitor specimen transport status, and track the temperature-controlled transportation process.
4. The SPD-OMS system administrator, who has user authorization to modify and manage user data, change system settings that impact service delivery, and monitor the system's operation status.

Table 2 displays the specific authorizations for each user group within the SPD-OMS system. The BPMN diagram in Figure 4 represents the newly redesigned business process model of IoT-based temperature-controlled logistics system for laboratory specimens.

Table 2: The specific authorizations for each user group within the SPD-OMS system.

Levels of user authorization	User groups			
	Healthcare professionals	Medical laboratory staff	Logistics service provider	SPD-OMS system administrator
Request pick-up and delivery services for laboratory specimens	●	●	-	●
Receive and confirm pick-up and delivery service requests for laboratory specimens	-	-	●	●
Monitor and track the transport status of the specimens using the business intelligence (BI) report, which retrieves information from IoT sensors embedded in temperature-controlled smart packaging.	●	●	●	●
Access the historical data recorded by the IoT sensors embedded in the temperature-controlled smart packaging, which are store on the cloud for future reference.	-	-	●	●

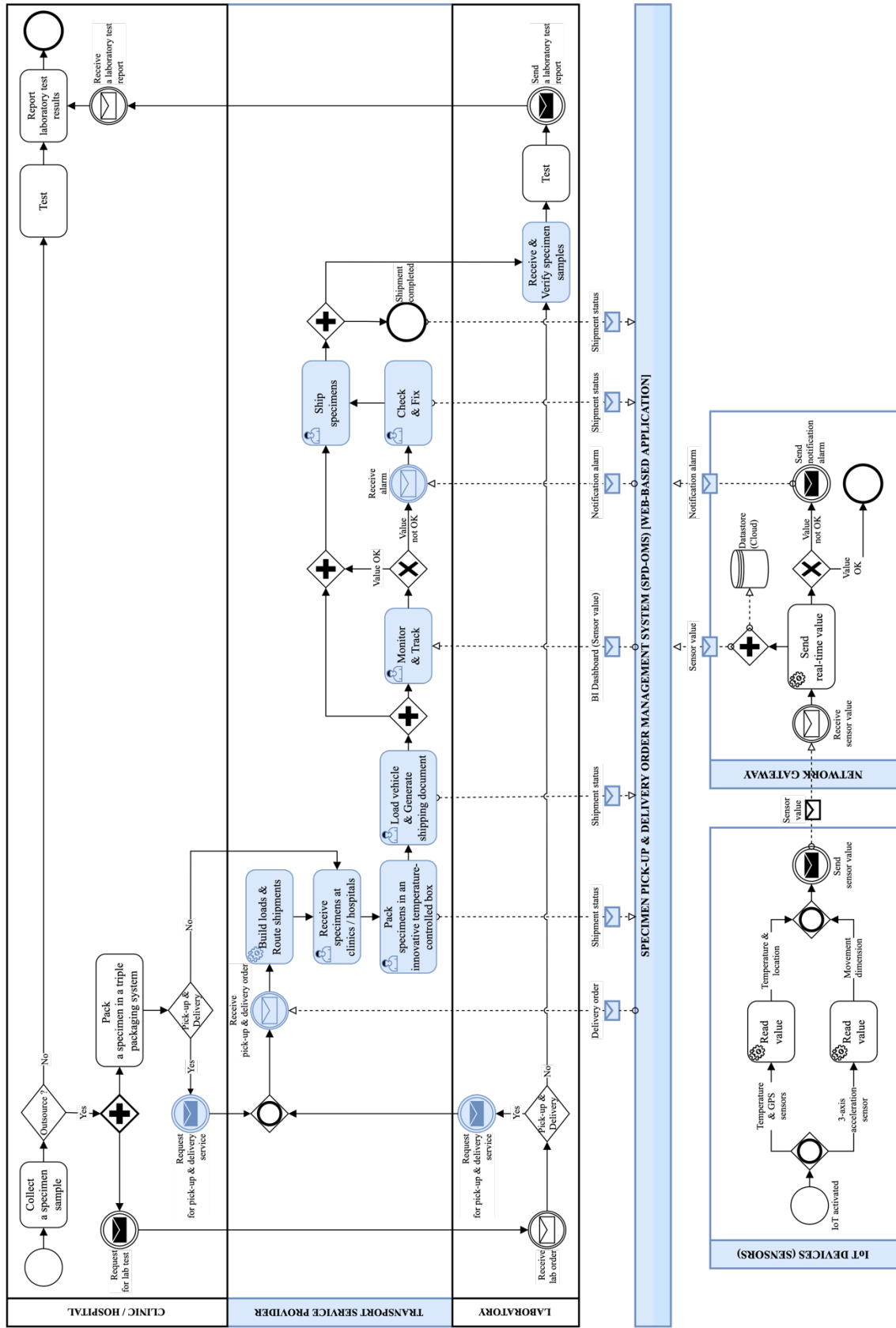


Figure 4: The redesigned business process model of IoT-based temperature-controlled logistics system for laboratory specimens using BPMN

TECHNOLOGIES DEVELOPMENT

The Prototype of IoT-Based Temperature-Controlled Smart Packaging for Laboratory Specimen Transportation

The analysis of both primary and secondary data has revealed several crucial considerations when designing IoT-based temperature controlled smart packaging for laboratory specimens transportation. These include the dimensions of the packaging, temperature control range, IoT sensor type, data protection mechanism, packaging material properties, internal packaging features, and marking for identifying biohazards on the packaging. The requisite specifications for developing temperature-controlled packaging are outlined in Table 3.

Table 3: The specifications of the temperature-controlled smart packaging for laboratory specimen transportation

Specifications	Description
Dimensions of the packaging	<ul style="list-style-type: none"> The packaging is compatible with common specimen containers such as blood tubes, racks, and bag containing tissue samples. The packaging can accommodate approximately 40 RT-PCR blood tubes, placed on a rack or three bags of tissue samples.
Temperature control range	<ul style="list-style-type: none"> The packaging is capable of maintaining temperatures of 2-8 °C and 25 °C and can support transportation for approximately 6-8 hours.
IoT sensor types	<p>There are sensors that measure the following values:</p> <ul style="list-style-type: none"> Temperature Global Positioning System (GPS) Motion of the transported laboratory specimens, such as embryos, where transportation should avoid vibration and tipping Exclusively equipped with 3-axis acceleration sensor
Data protection mechanism	<ul style="list-style-type: none"> The packaging must limit access to authorized personnel only in situations where there is a risk of unauthorized access due to accidents during transportation or loss of packaging. Unauthorized access may result in the leakage of sensitive patient data.
Packaging material properties	<ul style="list-style-type: none"> The packaging material must be able to withstand cleaning and disinfection using heat or various disinfectants. The packaging must be cleaned thoroughly after each use to avoid the risk of incorrect laboratory testing results and misdiagnosis due to contamination. The absence of seams and corners in the packaging allows for easy cleaning and prevents leaks from the biological specimen package. The material must be opaque. The packaging should be lightweight.
Internal packaging features	<ul style="list-style-type: none"> The packaging should accommodate the placement of temperature-controlled gel packs. The packaging should support the placement of a 40-tube rack.
Marking for identifying biohazards	<ul style="list-style-type: none"> The packaging must be labelled with a biohazard warning symbol to indicate the presence of potentially hazardous biological materials.

The Specimen Pick-up and Delivery Order Management System (SPD-OMS)

In order to manage the transportation of laboratory specimens with controlled temperature, this study proposes the development of the Specimen Pick-up and Delivery Order Management System (SPD-OMS) in collaboration with an IoT-based temperature-controlled smart packaging. The SPD-OMS system aims to act as a central hub for managing and tracking temperature-controlled specimen transportation. It is responsible for managing and tracking information related to temperature-controlled specimen transportation, with a notification system that alerts users to any errors or problems during transport, such as incorrect temperature control or failure to adhere to delivery schedules.

Healthcare professionals who desire to transport specimens for analysis can submit a request for transportation services through the SPD-OMS system, as depicted in Figure 5.

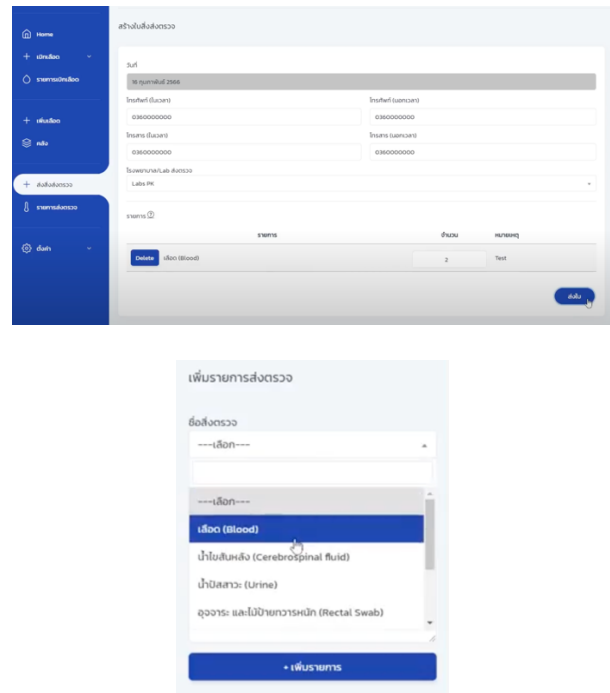


Figure 5: The SPD-OMS system: Request pick-up and delivery services for specimens

The transportation service provider will then collect the specimen from the origin and transport it to the destination using the IoT-based smart packaging embedded with various sensors. These sensors are as follows.

- A temperature sensor for measuring the temperature within the packaging and the environmental temperature during transportation in Celsius (°C).
- An accelerometer sensor for measuring acceleration in 3-axis as a multiple of g (9.81 m/s²).

- A gyroscope sensor for measuring the angular velocity (rad/s) of rotation in 3-axis, namely yaw (horizontal rotation), pitch (vertical rotation), and roll (tilting).

The data collected by these sensors are transmitted to the SPD-OMS system via a 4G communication module to enable tracking of the operation of the specimen packaging during transportation.

CONCLUSIONS

The present study introduces an IoT-based logistics system for the temperature-controlled transportation of laboratory specimens utilizing BPMN to achieve efficient management of the process. The proposed solution incorporates IoT smart packaging technology and the Specimen Pick-up and Delivery Order Management System (SPD-OMS), which is a web-based application designed for managing temperature-controlled pick-up and delivery orders. The system is aimed at ensuring specimen stability and viability, thereby improving patient treatment safety and quality. The authors suggest that the implementation of this system by transport and logistics service providers in Thailand could significantly enhance transportation safety and quality.

ETHICAL APPROVAL

This study was performed in accordance with the declarations of Helsinki. The research design and ethical considerations were reviewed and approved by the Ethics Committee of Institute for the Development of Human Research Protections (IHRP) (Certificate of Approval (COA) number: HIRP2022060).

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