Using Internet of Things to Improve the Sterilization Process for Surgical Instruments in Healthcare

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Abstract

The concept of the Internet of Things (IoT) brings information advances. Such technological innovations are affecting the world with amazing speed and giving rise to the Internet of Medical Things. The supply center within a hospital is responsible for sterilizing surgical instruments to ensure that medical instruments are fully sterilized and free from infections. Incompletely sterilized or expired surgical instruments will directly compromise the safety of the patients. In the current management of surgical instruments, the control of sterilization temperature and time is completely dependent on manual operation and independent sterilization boiler machines, so it is difficult to detect the failure or error of sterilization equipment immediately. This study is mainly aimed at optimizing the process of surgical instrument sterilization in the hospital by monitoring the completeness of the process of surgical instrument sterilization with IoT sensors. In order to determine whether the sterilization is up to the standard, a high-temperature pressure sensor is placed in the packaging of hand instruments to collect the changes of sterilization temperature and time. As a result, medical equipment managers in the hospital can supply materials and renew expired products from time to time, maintain appropriate surgical instruments and improve the quality of medical services.

Keywords: Internet of Things, Instrument package, Quality of sterilization, Expiration rate, Safety stocks

1 Introduction

The operating room is a highly specialized department in the hospital, and its main function is to perform surgical operations. Therefore, compared with ordinary nurses, the medical staff who manage the operating room have a large workload, high risk and relatively high rate of medical disputes complaints. According to the survey, the incidence of adverse events occurred in medical practice was 2.9%-16.6% [1], of which the adverse events occurred during surgery account for about 40%-50% of the adverse events [2-3] and the supply of surgical instruments accounts for 15% of the adverse events occurred during surgery [4-5] indicating that patient safety and nosocomial infections cannot be ignored. The World Health Organization has also advocated "Safe Surgery, Save Lives" calling on all countries in the world to make surgical safety a key medical quality policy [6]. Surgery is a kind of invasive medical treatment, which involves the direct contact between medical devices, surgical instruments and patients. Therefore, the sterilization quality of surgical instruments has become an important evaluation index of infection management and patient safety.

As the unit in charge of sterilization of surgical instruments, the supply center within a hospital is also a place where surgical infections are controlled with the quality assurance of instrument sterilization. If patients use incompletely sterilized or expired medical instruments, or there is a shortage of packs, it may cause delays in operations or nosocomial infections, which will directly compromise the safety of the patients and operations and the reputation of the hospital. At present, the surgical instruments in the supply center are manifold and expensive. The sterilization, inventory checks, deployment, and management of surgical instruments take a lot of time and manpower. When packs are expired, surgical instruments are frequently not sterilized due to human negligence, which leads to an excessive number of expired packs and the increased costs of repacking. The complexity of sterilization, inventory checks, deployment, and management of the packs thus increases, thereby causing a shortage or an oversupply of the packs.

Therefore, the management of a hospital should establish a comprehensive operating room information system to improve the quality and efficiency of medical service. According to the research of Bates and Gawarde et al., IT intervention can improve patient

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safety by reducing errors caused by adverse events, responding quickly to adverse events, tracking adverse events and providing feedback [7]. To keep patients from accidental injuries, a sound operating system is implemented to ensure the safety of surgical instruments and reduce errors. In this study, the IoT was used, along with the inventory management system, where the automatic monitoring mechanism for the safe sterilization of packs, automatic control over the expiration date of packs, and safety stock formula were used to determine the clinically required safety stock, to control the safety of surgical instruments used by patients, address potential risks in traditional workflows, such as human errors, and improve the quality of medical services. The specific goals of this study are as follows:

- Monitor the safety of sterilization of the packs using IoT sensors to make sure that the packs are fully sterilized.
- Monitor the expiration date of the packs automatically to avoid using expired packs due to human errors.
- Calculate the safety stock to assist managers in adjusting the stock of the packs, replenish the reserves appropriately, and save the costs of sterilization and hospital resources.

2 Literature Review

This section will explore the sterilization of surgical instruments, nosocomial infections and patient safety, and literature on applications of sensors for the IoT in sequence in hopes of optimizing the surgical instrument inventory management system with sensors for the IoT to make it more clinically compatible and safer to patient.

2.1 Sterilization of Surgical Instrument

The supply center within a hospital is mainly responsible for the sterilization of medical instruments, including standard operating procedures such as repacking, cleaning, drying, maintenance, packaging, sterilization, storage, and picking. Whether medical instruments are clean and fully sterilized is one of the major causes of nosocomial infections. If an infection occurs, it will increase the number of hospital stays and the waste of medical resources; therefore, the supply center is an important part of nosocomial infection control [8].

2.1.1 Sterilization

Different medical instruments are set up according to clinical needs. Circulating nurses and supply center staff are responsible to check whether the quantity of used packs is correct; after confirming that the quantity is correct, they soak the medical instruments in an enzyme cleaner that can decompose human secretions such as proteins, saliva, and cell membranes to speed up the cleaning of the instruments and reduce the contact between medical staff and pollutants, and then place the instruments in the washing machine; then, supply center staff apply the chemical indicators (including the names, bar codes, and expiration date of the packs and packers) to the packs, allowing the users to visually determine whether the medical instruments have been sterilized; next, medical instruments to be sterilized are placed in a sterilization cart and sent to a sterilizer for sterilization; after the sterilization, packs are placed in the sterile storage. Before use, supply center staff collect the packs required for surgery according to the manifest, place them in the case cart, and distribute them after checking the items and quantities requested by the users. The sterilization flowchart is shown in Figure 1.

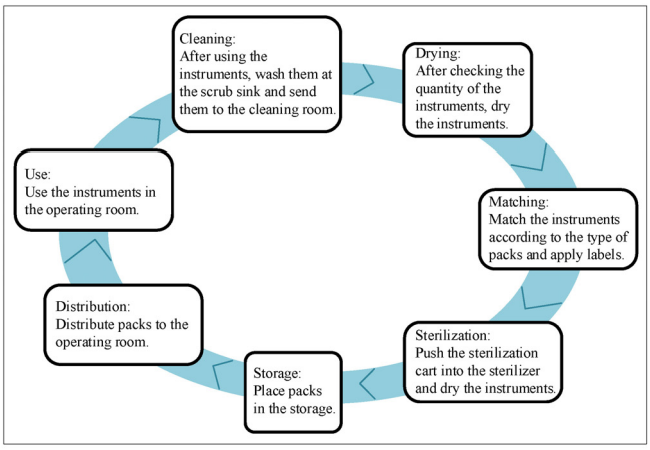

Figure 1. Sterilization flowchart

The sterilization of surgical instruments is complicated. Different types of sterilization are required according to instruments, materials, and applicable surgical sites. After exploring the sterilization of surgical instruments, this study concluded that there were five statuses of packs shown in the system, namely "Ready for Sterilization, Ready for Storage, Distributed, Used, and Returned" and that the records of packs, which were kept manually, contained the bar codes, types, and statuses of packs, sterilization dates, expiration date, and sterilization staff, as shown in Table 1 below.

At present, all records are kept manually. To avoid manual omissions and erroneous values displayed due to system failures, sensors for the IoT was introduced in this study for monitoring. The accuracy of sterilization was double checked and recorded electronically in the back-end system for infection follow-up and improvement. This helps nurses and supply center staff speed up the accuracy and setting of sterilization.

Table 1. Setting of high-temperature, high-pressure sterilizer

Basic Information	Date
	Start Time
	End Time
	Sterilization Method
	Sterilizer Type
	Sterilizer Load
Test Data	Air Removal Frequency
	Air Removal Test
	Highest Temperature
	Lowest Temperature
	Pressure
	Sterilization Time
	Drying Time
	Circulation Time
	External Indicator
	Interior Indicator
	Biological Indicator
	Class 5 Indicator

2.1.2 Quality Monitoring

Effective sterilization prevents the occurrence of surgical infections and improves patient safety. According to the international sterilization standards, the quality of sterilization should be monitored in accordance with the monitoring guidelines developed by experts from the infection control committee and the supply center. The guidelines should cover the standards for equipment control, exposure control, load control, pack control, and record control, as described below [9].

- **Equipment control.** Equipment control is mainly divided into two categories: mechanical monitoring and chemical monitoring, where the sterilizer's temperature, permeability, humidity, and circulation time, as well as the efficiency and function of air removal, is controlled. The purpose of equipment control is to ensure the complete functions of the sterilizer and the consistency of the sterilization results. Staff use the consistent color change of the chemical indicator daily to check the capacity of the vacuum pressure device [10].
- **Exposure control.** Chemical indicators outside the packs, which are divided into tapes and labels, are mainly used to check for errors. Whether the packs are properly sterilized can be quickly confirmed by changes in colors; therefore, each sterilization pack, sterile drape pack, and instrument case, as well as the exterior of the pack, should be applied with a chemical indicator label or sticker.
- **Load control.** At present, whether the sterilization is complete is directly confirmed by microbial culture. In biological cultivation, strains with strong survivability and a certain quantity of microbial shoots were selected to determine whether the sterilization standards are met based on extremely low spore mortality [11].
- **Pack control.** When medical instruments are packed, chemical indicators are placed inside to check whether four sterilization standards, namely pressure, temperature, humidity, and time, are met during the sterilization. Each chemical indicator reacts differently to express the sterilization results. The reason for the incomplete discoloration of the chemical indicators inside the packs may be that the packs are not fully sterilized and penetrated; therefore, when chemical indicators react incorrectly, it indicates that there is an abnormal condition during the sterilization, which should be carefully checked and identified [11].
- **Record control.** All data generated during the sterilization should be retained and used as a reference for equipment tracing and the functionality and maintenance of the sterilizer.

2.2 Nosocomial Infections and Patient Safety

According to the findings of Thomas et al. based on 15,000 medical records in the U.S. states of Utah and Colorado, 83.8% of the adverse events occurred in the hospitals, of which 39.5% were in the operating rooms. Compared to other departments, the incidence of adverse events in the operating room was higher. The research indicated that the operating room was a high-risk theater.

Kanamori et al. pointed out that most of the medical infections were caused by improper disinfection, highlighting the importance of infection control and effective sterilization of medical instruments. They felt the necessity of ensuring the proper cleaning and disinfection or sterilization of medical instruments to prevent nosocomial infections [12]. Four types of nosocomial infections, namely catheter-related urinary tract infections, surgical site infections, blood infections, and pneumonia, accounted for more than 80% of nosocomial infections. Among the most common infections, surgical site infections were ranked second, accounting for about 20% [13]. To protect patients from infections in the process of medical treatment, ensuring that reusable medical instruments are fully sterilized is of vital importance in medical institutions.

To sum up, many medical errors in patient safety and nosocomial infections resulted from the improper sterilization of medical instruments, highlighting the importance of sterilization control. To keep patients safe during medical care, an information monitoring model was designed with sensors for the IoT and wireless transmission in hopes of preventing medical errors and detecting abnormalities during the sterilization.

2.3 Literature on Applications of Sensors for the IoT

As the key technology of the IoT, sensors detect external signals and physical conditions (such as light, heat, and humidity) or chemical composition (such as smoke and carbon monoxide) and send the detected information to other devices. With integrated sensing technology, the quality and convenience of life can be improved [14].

Applying the IoT to healthcare brings multiple opportunities to the medical industry and facilitates system innovation in large-scale medical services. In terms of automated control over food logistics, factors such as temperature, humidity and time need to be continuously monitored. Once the temperature or humidity is too high, or the transportation time is too long, it may cause food deterioration or produce bacteria, which is very similar to the sterilization of surgical instruments. During the sterilization, the aforesaid factors should also be controlled to avoid ineffective or incomplete sterilization.

Radio-frequency identification (RFID) has many advantages such as long-distance reading, bulk reading, and reuse. It is often used in logistics management to improve efficiency. With the IoT, some scholars used RFID, coupled with temperature and humidity sensors, to manage food logistics. During the shipping, RFID was used to monitor the factors in the environment where products are stored and track food. During the sterilization of surgical instruments, sensors for the IoT can be used to effectively control the sterilization and address errors immediately.

However, RFID has some technical challenges that cannot be overcome. For example, signal transmission is easily affected by factors such as metal, moisture and angle, resulting in poor reading. During the sterilization of surgical instruments, high temperature and pressure and steam interfere with RFID reading as surgical instruments are mostly made of metal, making it difficult to develop. Currently, it is not put in use.

To sum up, the IoT and medical expertise were used in the supply center for the operating room. High temperature pressure sensors were placed in the packs to transmit signals that indicated whether the sterilization standards were met and visualized the temperature curve. This allowed the supply center with limited medical and human resources to enhance the completeness of sterilization, prevent and reduce medical errors, and improve patient safety.

3 Methodology

This study is aimed at ensuring the safe sterilization of surgical instruments and the expected quantity of packs used in consideration of the error rate and expiration rate of packs. The instrument management information system was designed and was divided into high temperature sensors, relay software, database, sterilization monitoring system, expiration date monitoring system, and safety stock calculation system, as shown in Figure 2.

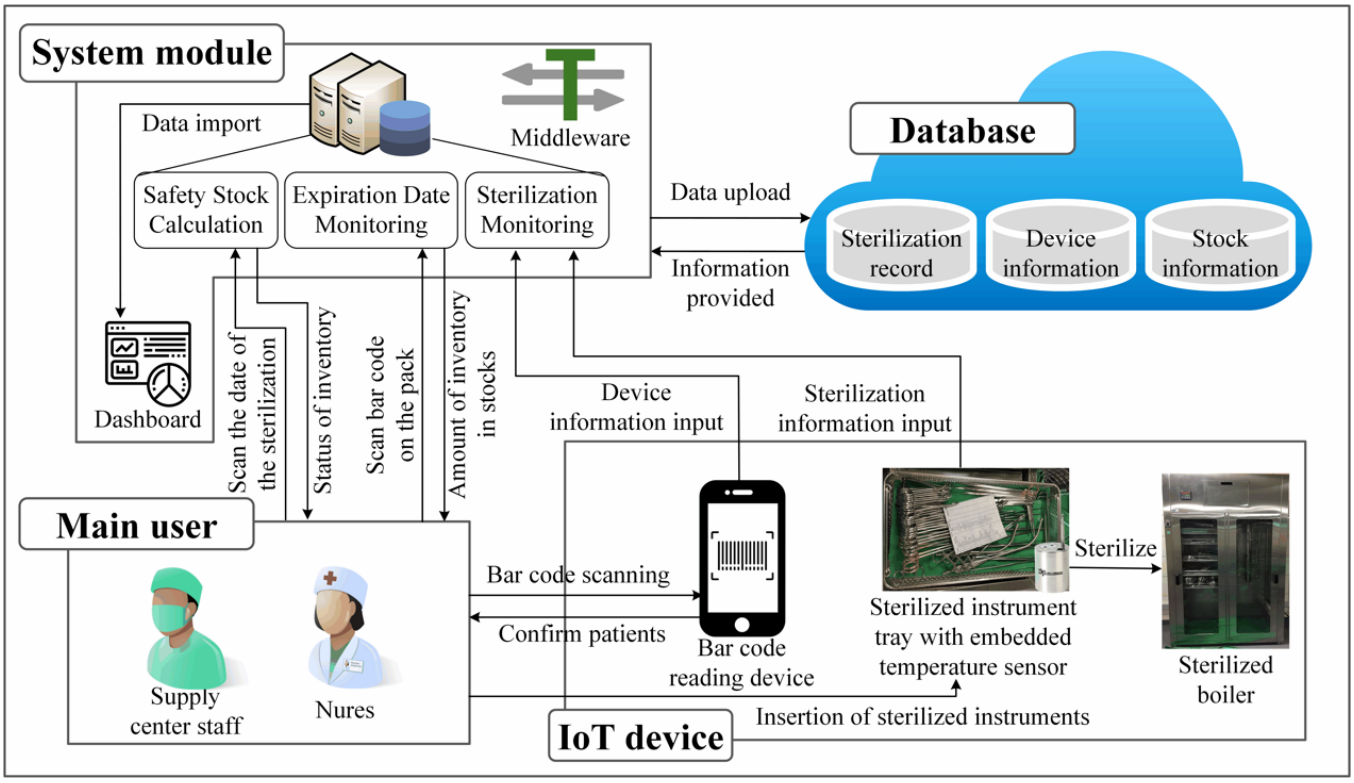

Figure 2. System environment

The system reads the sterilization time and temperature of each pack in the database to determine whether the sterilization standards are met according to regulations. If the sterilization standards are not met, the system will issue a warning of incomplete sterilization. After the completion of sterilization, the date of the sterilization is shown on the label of the pack and the system calculates the expiration date of each pack based on the type of the packing method. The time length of valid pack is set and different for each packing method. If the expiration date is earlier than the date of reading, the system will issue a warning. The system reads the information in the database showing "Expired" and "Failed", calculates the average incidence of these two types of packs, applies it to the safety stock formula to calculate the optimal value of the safety stock, and finally displays data according to users' limits of authority. Three major functions are described below.

3.1 Sterilization Monitoring

This study adopted NanoVACQ as the front-end sensor. The sensor is mainly placed inside a pack for sterilization to record changes in time and temperature of the pack in the sterilizer and transmits such information to the back-end system; then, the system determines whether the sterilization is successful according to the sterilization standards. The sterilization of surgical instruments is a method to kill all microorganisms, including pathogenic and non-pathogenic bacteria. This study delved into the sterilization of surgical instruments with a vacuum pressure device. A vacuum sterilizer sucks out the air in the boiler by vacuum and sprays steam into the boiler to replace the air, which can effectively prevent the formation of an air chamber. The temperatures and times of the vacuum sterilizer are 131 to 134°C with at least 3 to 4 minutes exposure time [15].

In the existing supply center system, errors in the sterilization of packs are not monitored. Whether the sterilization of packs is successful is manually determined by the changes in colors and locations of the indicators. After many years of practice, human errors are unavoidable, resulting in the use of incompletely sterilized surgical instruments. To reduce such human errors, high temperature pressure sensors are placed in the packs to collect changes in times and temperatures of the packs in the sterilizer and transmit the information stored in the sensors to the reader via 2.4GHz wireless transmission; the reader then sends the received information to the system through a USB.

The sterilization monitoring function reads the sterilization time and temperature of each pack in the database and determine whether the sterilization standards, that is temperature up to 140°C with 4 minutes exposure time, are met; if the sterilization standards are not met, the system will issue a warning of ineffective sterilization to supply center staff, requesting the second sterilization of the pack, and override the status of the pack in the database from "Fed" to "Failed," to protect patients from using incompletely sterilized surgical instruments.

3.2 Expiration Date Monitoring

In the existing supply center system, medical staff access the system to check information such as the date of manufacture, expiration date, and bar code of each pack. There is no warning of packs that are expired or about to expire; therefore, packs may expire due to the order of picking or inaction by the expiration dates.

When producing the labels of the packs, the system automatically populates the default expiration dates based on the selected packing method, and the timer program in the system automatically reads the expiration date of each pack in the database and compares it with the date of reading; if the expiration date is earlier than the date of reading, the system will issue a warning, requesting the second sterilization of the pack, and override the status of the pack in the database from "Normal" to "Expired." The system will also remind medical staff of the expiration date of the pack two days in advance and change the status of the pack in the database from "Normal" to "Warning."

3.3 Safety Stock Calculation

The concept of safety stock calculation in the existing supply center system is not mature. The approximate quantity of safety stock is manually set based on the past statistics. This study explored the safety stock formula for the general business environment to effectively manage the stock and satisfy customers' needs with a low level of inventory. The safety stock formula was optimized to calculate the safety stock based on the clinical needs. The size of the safety stock is mainly determined by the customer service level. Customer service level refers to the service level of satisfaction with customers' needs. The higher the service level of satisfaction is, the larger the safety stock is and the fewer the shortages are; the lower the service level of satisfaction is, the smaller the safety stock is and the more the shortages are [16].

Assume that a customer's need is a random variable with normal distribution, and the inventory level of the manufacturer is 95% (that is, the probability of acceptable shortage is 5%). The Z value in the cumulative normal distribution probability table can be used as the safety factor [17]. For example, when the manufacturer's inventory level is set at 95%, the safety factor is equal to 1.64, as shown in Table 2.

Table 2. Customer service level and safety factor

Customer Service Level (%)	Safety Factor (z)	Customer Service Level (%)	Safety Factor (z)
100.00	3.09	96.00	1.75
99.99	3.08	95.00	1.65
99.87	3.00	90.00	1.29
99.20	2.40	85.00	1.04
99.00	2.33	84.00	1.00
98.00	2.05	80.00	0.84
97.70	2.00	75.00	0.68

From the customer's point of view, lead time is the time from when an order is placed to when the goods are received; from the supplier's point of view, lead time is the time from when an order is accepted to when the cash is collected, that is, the time from the purchase of raw materials to the receipt of payment from the customer [18]. The safety stock formula is described as follows: First, the basic safety stock formula commonly uses two parameters: the average demand and the standard deviation. The average demand ($\bar{D}$) is shown in Formula (1), where T is the number of days during the study and D(i) is the demand required on the i-th day. The standard deviation (σ) of the samples is shown in Formula (2).

$$\bar{D} = \frac{1}{T}\sum_{i=1}^{T} D(i) \quad \textbf{(1)}$$

$$\sigma = \sqrt{\frac{1}{T-1}\sum_{i=1}^{T}(D(i)-\bar{D})^2} \quad \textbf{(2)}$$

To accurately calculate the safety stock, it is necessary to add the lead time ($\sqrt{LT}$) and service level (Z) that affect the stock. The safety stock (SS) is presented in Formula (3).

$$SS = Z \times \sqrt{LT} \times \sqrt{\frac{1}{T-1}\sum_{i=1}^{T}(D(i)-\bar{D})^2} \quad \textbf{(3)}$$

In the structured business management, most enterprises adopted Formula (3) as their safety stock formula. In clinical practices, however, there were more uncertainties and unexpected conditions, especially in the supply center, where the error rate of the sterilizer and the expiration rate of sterilization equipment are key factors in inventory management. Given the clinical restrictions on the stock of packs, parameters were added to optimize the safety stock formula for business practices. In business practices, lead time refers to the time from when an order is accepted to when the cash is collected; in clinical practices, however, lead time refers to the time where surgical instruments are cleaned and sterilized to when the instruments are stored. In both business and clinical practices, a probability of acceptable shortage and a safety factor are selected based on the severity of loss caused by the shortage of supplies. Given the current status, two major factors in inventory management, namely sterilization error rate (SER) and package tray error rate (PTER), were considered to produce the safety stock based on the clinical needs. The optimized safety stock formula is shown in Formula (4).

$$SS = Z \times \sqrt{LT} \times \bar{D} \times (1 + SER + PTER) \quad \textbf{(4)}$$

When receiving instruments, the system compares the existing inventory with the safety stock in the database to check for any shortage. When the existing inventory is less than the safety stock in the database, the system will pop up a warning, indicating the number of packs that need to be sterilized to meet the demand. This function can reduce the temporary increase in the demand for packs due to uncertainties and prevent patients from delaying medical treatment.

4 Experimental Result

The optimized flowchart for the supply of packs is shown in Figure 3. The main difference, as described below, is the addition of a temperature sensor which can determine whether the sterilization is successful, monitoring of the expiration date and safety stock, and a warning mechanism in the system that can reduce human errors.

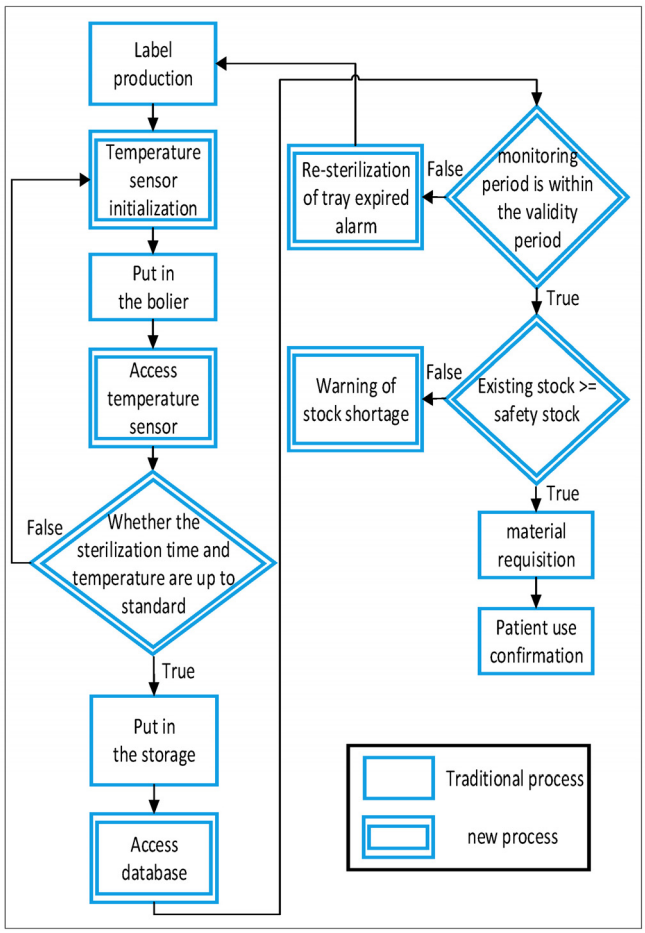

Figure 3. Optimized flowchart for supply of packs

4.1 Sterilization Error Prompt

The system reads the information on the sterilization of packs in the database and determines whether the packs are fully sterilized based on the sterilization standards, that is, temperature up to 140°C with 4 minutes exposure time. As shown in Figure 4, the left Y axis is the sterilization time, the right Y axis is the average sterilization temperature, and the X axis is the sterilization date. According to Figure 4, the sterilization standards were not met for 5 times. In these cases, the system would determine that the sterilization of packs failed and issue a warning to supply center staff, indicating the reason for the failure and requesting the second sterilization of the packs. The sterilization error prompt window is shown in Figure 6.

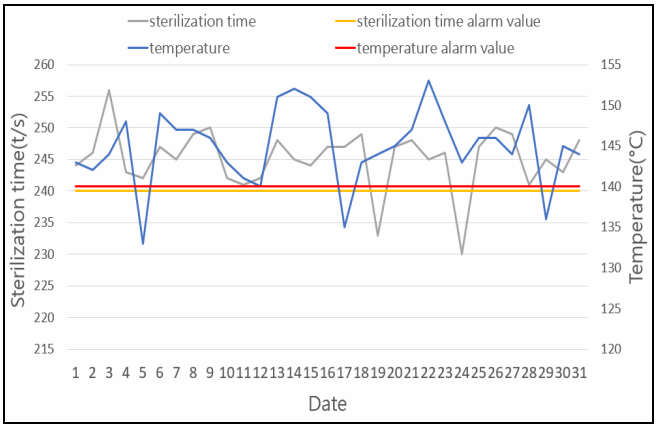

Figure 4. Sterilization data

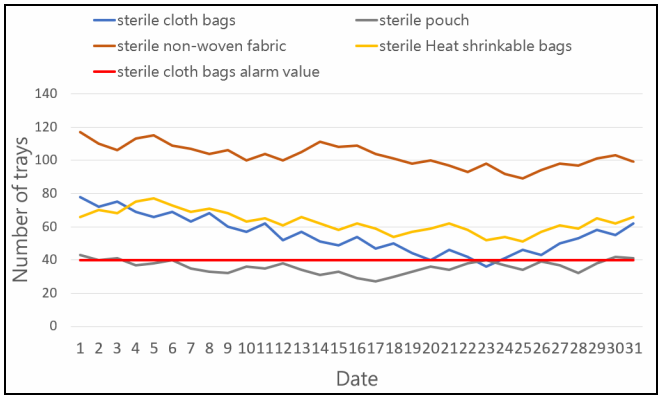

Figure 5. Stock of packs

4.2 Expiry Prompt

The expiry prompt window is shown in Figure 7. The timer within the system continuously reads the expiration dates of all packs in the database and compare them with the date of reading. If the packs are expired, the system will issue a warning to medical staff, requesting the second sterilization of the packs. As shown in Figure 8, the system will also remind medical staff of the expiration date of the pack two days in advance.

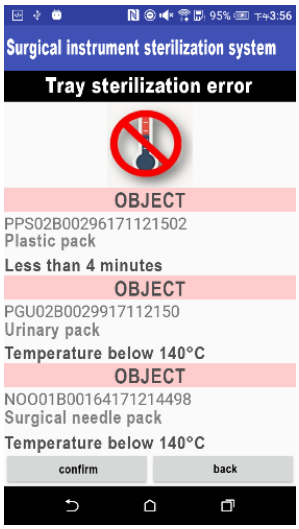

Figure 6. Sterilization Error Prompt Window

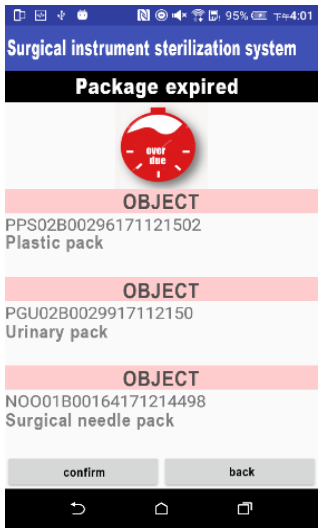

Figure 7. Expiry prompt Window

4.3 Insufficient Stock Prompt

When receiving instruments, the system compares the existing inventory with the calculated safety stock to check for any shortage. As shown in Figure 5, the Y axis is the quantity of packs in stock, and the X axis is the date when the quantity of packs is calculated. Through the visual display, medical staff can quickly check for the shortage of packs (calculated safety stock minus existing inventory), as shown in Figure 9.

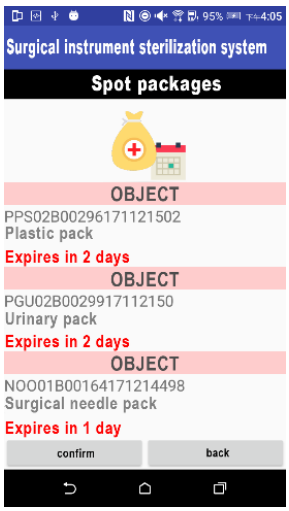

Figure 8. Expiration date prompt window

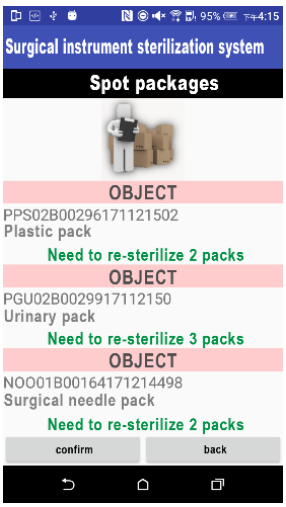

Figure 9. Insufficient stock prompt window

5 Conclusion

This study adopted sensors for the IoT to improve the sterilization process of surgical instruments. As sensors detected the changes in the sterilization time and temperature of the packs in the sterilizer, the system could determine whether the packs were fully sterilized based on the sterilization standards. Compared to the manual identification of discoloration of

indicator tapes, the use of sensors was more accurate and can avoid the increase of the error rates caused by human errors and can improve patient safety as well. In terms of control over expiration dates, the system emphasizes the warning mechanism, so it automatically reads the expiration dates of all packs in the database. When the packs have expired or are about to expire, the system will immediately pop out a warning of the expiration dates to prevent patients from using expired packs and causing nosocomial infections. As to inventory management, the system can calculate the safety stock based on the clinical needs. When there is insufficient stock, a warning of pack sterilization will be issued to medical staff, which can keep the safety stock at the optimal level. Thus, the unexpected increase in the demand for packs due to uncertainties can be met and patients can also receive proper medical care at the hospital.

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