

Using Internet of Things Technology to Improve Patient Safety in Surgical Instrument Sterilization Control

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Abstract. Medical services influence the people's health and lives. It is a sacred and professional work with the features that do not allow errors and cannot be redone. Therefore, the quality of medical services directly affects the health and safety of patients. In the operating room, the central supply room is responsible for sterilizing surgical instruments. It is also an important place for infection control. Once incompletely sterilized medical devices are used, it may lead to nosocomial infections, thus affecting the safety and quality of the surgical patients. Therefore, to ensure the integrity of the sterilization process and to avoid the use of unsafe surgical instruments. This study uses the sensing technology of the Internet of Things to monitor the sterilization process of surgical instruments sterilization with using the automatic monitoring system to alarm the validity period of surgical instruments pack, and to calculate the required safety stock of surgical instruments packing. With the system, it reduces the additional cost of emergency sterilization when surgical instruments packs are out of supply. Ensure the safety of the patient's use of surgical instruments, so that patients can be treated in a safer medical environment to achieve a win-win benefit.

Keywords: Surgical instrument sterilization · Patient safety · Internet of things

1 Introduction

The purpose of medical services is to alleviate the suffering or injury of patients, but medical services have incredibly complex professional techniques, uncertainties in conditions, and characteristics that do not allow mistakes, so medical services are not as safe as they are supposed to be. Medical services have the characteristics of "no mistakes, no redoing," so the quality of medical services directly affects the health and safety of patients. Patient safety is an important topic that has been concerned by the World Health Organization and the international community in recent years. The research on the frequency of adverse medical events in foreign countries shows that the incidence of adverse medical events is between 2.9% and 16.6% [1]. Moreover, in the ratio of adverse medical events, surgical adverse events are about 40%–50% [2, 3] of

adverse medical events in the hospital and adverse events caused by surgical equipment supply are about 15% [4, 5] of surgical adverse events. In Taiwan, about 8,000 people die directly or indirectly due to nosocomial infections which are causing huge financial losses in hospitals. Therefore, in 2009, the World Health Organization began to advocate "safe surgery, save lives" and called on countries around the world to improve operational safety as an essential medical quality policy [6]. The Joint Commission of Taiwan promotes hospital medical quality and patient safety as the annual target and strategy. Medical institutions will implement infection control and improve operational safety [7].

The hospital supply center is the unit responsible for the sterilization of surgical instruments. It is also an important place for infection control. Once Incompletely sterilized medical devices are used in clinically, it may occur nosocomial infections, which may affect the safety and medicinal quality of surgical patients. Today, with the fierce competition and cost-oriented medical institutions, the service quality and effectiveness of the operating room have received considerable attention. In the operating room, all treatments are invasive. Therefore, the control of surgical infection and the quality assurance of instrument sterilization are important tasks for maintaining patient safety. In [8], the Meyer et al. point out one of the future research areas of medical services is the practice of stock management in hospitals. One of the most significant challenges for clinical care managers is to balance costs and maintain proper stock and immediate patient care. In the pursuit of low-cost, high-efficiency best performance in medical institutions, we must face various uncertainties and risks. Therefore, to ensure the safety of the instruments used by surgical patients and reduce the number of emergency sterilization of the surgical instruments packing, reduce labor costs and improve effectiveness.

In the light of the above arguments, IoT technology is used to improve the sterilization and sterilization process of surgical instruments, to ensure the safety of the sterilization process, and to notify and handle the errors immediately, to improve patient safety and reduce the incidence of errors. Use the wireless temperature sensor with system monitoring to reduce the infection caused by the use of incompletely sterilized instruments and reduce the additional cost of emergency sterilization of the supply center instrument pack by systematic safety stock management and labor cost. It effectively improves the safety of patients, so that patients are in a safer medical environment, to achieve a win-win benefit of medical care.

2 Related Work

2.1 Surgical Instrument Sterilization Safety

Proper sterilization is a significant part of infection control, which affects the infection rate and the length of stays of surgical patients. Infection may be caused by human error or insufficient concept of sterilization of medical devices, so it is necessary to strengthen the standardized operation process and correct sterilization concept [9]. An active sterilization process can prevent the occurrence of surgical infections or other related costs due to surgical infections and It also can improve patient safety.

The monitoring of sterilization quality should be based on the guidelines of the Hospital Infection Control Society and the supply center experts to set up the guidelines for sterilization monitoring, including the load control – it's based on the Process Challenge Device (PCD) to know whether the sterilization conditions meet the sterilization standards, and to issue or recycle the sterilization items [10, 11]. Equipment control – It is mainly divided into mechanical and chemical monitoring to confirm the temperature, permeability, humidity, sterilization cycle time, air removal efficiency. The purpose of equipment control is to ensure the complete function of the sterilize boiler and consistent results of sterilization [12–14]. Pack control: When wrapping the pack, a chemical indicator is placed inside the pack to monitor the sterilization pressure, temperature, humidity, time, etc. during the sterilization process. All of the above four conditions are effective to achieve sterilization standards. When the user opens the sterilization pack, it is visually judged whether the color of the chemical indicator in the pack is changed or whether the color is changed to monitor whether the sterilization succeeds or fails [9, 15]. Exposure control – The chemical indicator outside the pack is mainly in the process of inspection. It can be divided into tape and label type. It can quickly identify the items that have been sterilized or not sterilized by color change [16, 17]. Record keeping control – All the data generated during the sterilization process should be preserved. In the future, as the reference point for the function and maintenance of the sterilizing device flow tracking and sterilize boiler, the above five major controls monitor the sterilization quality to provide patient-safe medical equipment and reduce the risk of infection [15, 16, 18].

The failed of medical device sterilization in medical institutions is an important reason of infection in hospitals. In-hospital infections can cause treatment difficulties and high mortality rates, prolong the hospitalization days and increase the waste of medical resources [19]. Therefore, the quality of medical device sterilization monitoring is critical, and the purpose of the analysis of the monitoring results of sterilization items is to monitor the disinfection and sterilization effect of the disinfected and sterilized items. So as, we can detect the problems in real time, analysis the reason and propose the improvement methods. To ensure the quality of hospital disinfection and sterilization items and it can effectively control hospital infections.

2.2 Medical Service Quality and Patient Safety

The purpose of medical services is to relieve the suffering or injury of patients. Because of the complexity, uncertainty, and refusal to make mistakes, medical services are not as safe as they are supposed to be. Medical services are different from the general industry. Their services are a sacred and professional work because of the health and life of people. They have the characteristics of "no mistakes, no redoing," so the quality of medical services directly affects national health and safety. The people are on demand for medical service quality, with the improvement of knowledge and the rise of consciousness. The demands of the people's self-rights are getting higher and higher, and they are no longer limited to the treatment of diseases. The expectation of medical quality is increasingly emphasized, so the pursuit of medical service quality has become the focus of hospital management. Therefore, how to ensure that patients receive excellent service quality is a top priority for hospitals. Among the various departments of the hospital, the operating room is a highly specialized department with the primary task of performing surgery. The workload of medical staff in the operating room is numerous and high-risk, and the situation of medical disputes in the process of service is also endless. In 2000, Thomas et al. [20] found in 15,000 medical records in Utah and Colorado in the United States that 83.8% of all adverse events occurred in hospitals, of which 39.5% occurred in operating rooms. Compared with other departments, the occurrence of adverse events in the operating room is higher. Research indicates that the operating room is indeed a high-risk service place. To prevent accidental injuries and implement patient safety, it creates a safe medical environment by planning a sound operating system to reduce errors, improve patient safety and promote the quality of medical services.

According to the above literature, the incidence of adverse medical events in the operating room is high, and human error causes many medical errors. The occurrence of adverse events is predictable and avoidable. Therefore, the medical service should have a monitoring design that prevents errors or can immediately detect and effectively handle the control when the error occurs, to minimize the chances of errors and failures in the medical service process, to prevent and reduce medical negligence, and to improve the patient safety.

2.3 Sensing Technology Application Research

The rapid development of Internet technology and applications have changed the way people live and communicate. With the innovation of network and communication technologies and the advancement of Micro-electromechanical Systems (MEMS) technology, perceptual and IoT technologies have enabled sensors and wireless communication chips to be incorporated into physical materials. The sensor is a crucial component for receiving signals or reacting with a variable amount of braking and can convert the physical quantity or chemical quantity to be measured into a data output. Its application function is mainly used to detect human senses and then detect external information, including sight, hearing, touch, smell, taste and so on. Some sensors can also detect messages that humans cannot judge. Through the integration of sensing technology, they can also be applied to the value-added services of smart medical care. In the automatic control of food logistics, it is necessary to monitor factors such as temperature, humidity and time continuously. If the temperature is too high, the humidity is too oppressive, or the delivery time is too long, it may cause the food to deteriorate and produce bacteria, which may affect the consumer. This phenomenon is very similar to the sterilization of surgical instruments. The management of the sterilization process must also control the above factors to avoid sterilization failure or incomplete sterilization process.

Scholars use RFID sensing technology to control food logistics and combine wireless temperature and humidity sensors for wireless monitoring. During the logistics delivery process, various influencing factors in the product storage environment are monitored, and food tracking is performed by RFID sensing technology [21]. However, in the sterilization process of the surgical instrument, the control of the sterilization device can be effectively performed through the application of the sensing device, so

that the hospital can monitor the sterilization process and can immediately handle the error occurrence event.

Through the literature mentioned above, it can be found that the knowledge of the field of Internet of Things technology and medical services is applied to the operating room supply center environment. The supply center with many instruments, limited medical and human resources, can improve the complexity of the sterilization process, and the integrity of the sterilization process can be ensured, and the resources can be maximized, which not only prevents and reduces medical negligence but also enhances the safety of the patient.

3 Methodology

This study aims to improve the safety of surgical patients, ensure the safe sterilization of surgical instruments, optimize the surgical instrument sterilization process, and design the device management information system. The key points include the pairing of the sensor and the pack, and the sterilization in the sterilization boiler to monitor the sterilization process; the automatic monitoring validity period of the pack after sterilization and the calculation of the safety stock of the pack. As mentioned above, the system will be divided into three functions: sterilization error monitoring function, validity monitoring function, and safety stock calculation function. The system will be described in detail below.

The system architecture will be divided into the base layer, the sensing layer, the transport layer, the backend data layer and the application layer as a discussion, as shown in Fig. 1. The base layer and the sensory layer collect information from device sterilization. The transport layer will sent/transmit data and transmit the information in wireless transmission mode. The data layer converts and stores the received

Data Application	Application Layer Stock Management System
Data Processing	Data Layer Middleware Sterilization Monitoring Validity Monitoring Safety Stock Calculation
Data Transmission	Transport Layer Wireless Ethernet Network Network
	Sensing Layer Reader
Data Collection	Base Layer Instrument Tray with Tag

Fig. 1. System architecture

information. The sterilization error monitoring function, the validity monitoring function and the safety stock calculation function will read the information in the database for the judgment of sterilization standards, to determine whether it has expired, and calculate the quantity of the safety stock before storing it to the database. The application layer is responsible for providing different users to view different screens. The system will present different screens according to different user rights.

As shown in Fig. 2, the sterilization stock control assistance mechanism will be divided into three parts: the sensor end that sends the information, the core program that performs the information calculation and processing judgment, and the web end show the results. The sensor at the sensor end collects information on the time and temperature changes of the instrument pack in the sterilizing boiler and transmits the information stored in the memory to the reader using the 2.4 GHz wireless transmission technology, and the reader transmits the received information to the system via Ethernet transmission. The relay software in the core program converts the received information such as the sterilization time and temperature information of each sensor, the pack barcode and the ID number corresponding to the sensor, and the expiration date of the pack.



Fig. 2. Application design

The sterilization monitoring function is determined by the system reading the sterilization time and temperature information of each pack in the database. Whether the sterilization temperature of the pack meets the sterilization standard, if the standard is not reached, an alarm is issued, indicating that the sterilization of the pack is incomplete and it needs to be resterilized. The validity monitoring function is determined by the system reading database when the label of each pack is made. According to the selected packaging method, the system automatically brings out the set expiration date and the date of the day, if the expiration date is less than the date of the day.

Then it issues an expired alarm. The safety stock calculation function reads the information in the database that the status is expired and the sterilization fails, calculates the average incidence rate of the two, and brings it into the safety stock calculation formula. It is more appropriate to calculate the safety stock quantity. When the safety stock is less than the safety stock, the system will issue an alarm that the inventory quantity is too small and it needs to be sterilized. System alarms and quantity of stock are presented in the form of web browsers. Monitor the sterilization process through the Internet of Things technology, match the system monitoring alarm reminder pack expiration, and optimize the safety stock calculation, reduce the sterilization error rate and expiration rate found only when the pack is in use, and calculate the clinical safety stock amount to avoid the lack of supply of the pack cause the operation time is delayed. The following describes each system function in detail.

4 Results

This study optimizes the surgical instrument sterilization process and combines the system background judgment. When the sterilization failure, the pack expires, and the stock is insufficient, an alarm will be issued to remind the supply center medical staff that the condition of the instrument pack is up to standard. The system usage features are described in detail below.

4.1 Pack Sterilization Error Alarm Interface

The following Fig. 3 shows the alarm interface of the pack sterilization error. The system reads the information of the sterilization process of the pack stored in the database, and judges whether the pack is successfully sterilized according to the sterilization standard of the pack. If it is found that the sterilization of the pack is a failure, an alarm will be issued to remind the supply center medical staff which tray pack sterilization failure and failure reasons, and the pack must be resterilized.



Fig. 3. Pack sterilization error alarm

4.2 Pack Expiration Alarm Interface

The following Fig. 4 shows the alarm interface for the expiration of the pack. When the pack is in the warehousing operation, the system will automatically read the validity

period of all the packs in the database and compare the date of the day. If the pack is overdue after the comparison, the medical staff will be reminded which pack has expired and need to be re-sterilized.



Fig. 4. Pack expired alarm

The system will also start a warning reminder two days before the expiration date of the pack, to inform the medical staff that the time limit for the pack is close. The pack should be used as soon as possible within the service period. As shown below (Fig. 5).



Fig. 5. Nearly expired alarm

4.3 The Insufficient Stock Alarm Interface

The following Fig. 6 shows the alarm interface for the shortage of the stock of the pack. When the system is in the warehousing operation, the amount of the existing stock and the safety stock calculated by the system is compared, and judges whether the existing stock quantity has less than the safety stock quantity. If the existing stock quantity is small, it will remind the medical staff which packs insufficient stock, it



Fig. 6. Insufficient stock of the pack alarm

needs to be sterilized again, and it will reduce the existing stock according to the calculated safety stock. It shows how many packs need to be sterilized, which is enough to supply the pack requirements.

5 Conclusion

Medical services have characteristics that do not allow errors and cannot be redone. Therefore, delays in surgery or the use of surgical instruments that are not thoroughly sterilized may affect the treatment of the disease. Severe cases are more likely to cause worsening of the condition and even death. The anxiety caused by the patients and their families due to long waits also affects their satisfaction with hospital satisfaction and trust. Therefore, in the supply of surgical instruments, the appropriate stock should be maintained to meet the needs of patients, and When using the pack, it can make sure that the pack is fully sterilized.

This study uses the Internet of Things sensing technology to improve the disinfection and sterilization process of surgical instruments to ensure the integrity and safety of the sterilization process, and to achieve instant notification and handling when an error occurs, to improve the safety of the devices used by patients, and to reduce the error rate of sterilization equipment. Moreover, with the system monitoring, whether the alarm device pack has expired and coming soon to expire. It reduces infections caused by patients using expired or incompletely sterilized instruments. At the same time, through the system's safety stock management, the additional cost and labor cost incurred in the emergency sterilization of the supply center equipment pack are reduced, and the patient's safety is effectively improved. So that it effectively improves the safety of patients, patients are in a safer medical environment, and achieve a winwin benefit.

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