



# Prospects of Hospital Information Systems and Patient Safety in Japan

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**Objectives:** Approximately 20 years have passed since hospital information systems (HISs) featuring full-scale electronic medical records were first implemented in Japan. Patient safety is one of the most important of the several “safety” roles that HISs are expected to fulfill. However, insufficient research has analyzed the contribution of HISs to patient safety. This paper reviews the history of HISs in connection with patient safety in Japan and discusses the future of the patient safety function of HISs in a favorable environment for digitization. **Methods:** A review on the history of HISs with functions that contribute to patient safety was conducted, analyzing evidence from reports published by the Japanese government and papers on patient safety and HISs published in various countries. **Results:** Patient safety has become a concern, and initiatives to promote patient safety have progressed simultaneously with the spread of HISs. To address the problem of patient safety, most large hospitals prioritize patients’ welfare when building HISs. However, no HIS-associated reduction in adverse events due to medical treatment could be confirmed. **Conclusions:** HISs are expected to help prevent medical accidents, such as patient- and drug-related errors. It is hoped that the patient safety functions of HISs will become generalized and contribute to patient safety in the future. To achieve this, the government and academic societies should provide regulations and guidelines on HISs and patient safety to the medical community and medical-device vendors. Furthermore, departments responsible for HISs and patient safety should collaborate to gather evidence for the effectiveness of HISs.

**Keywords:** Hospital Information Systems, Electronic Medical Records, Electronic Health Records, Patient Safety, Safety Management

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## I. Introduction

Approximately 20 years have passed since hospital information systems (HISs) featuring comprehensive electronic medical records were first implemented in Japan. In recent years, such HISs have become widespread both in large hospitals and in small and medium-sized hospitals and clinics [1]. Junior doctors’ first exposure to HISs no longer occurs during clinical practice. Instead, training on HISs is a core part of the medical education curriculum established by the Ministry of Education, Culture, Sports, Science, and Technology of Japan [2].

Safety is a core element of HISs. To help healthcare profes-

sionals provide safe and appropriate medical care to patients, HISs must operate accurately, stably, and smoothly; in addition, patient information entered into the system must be managed safely and securely. “Safety” in the HIS context is classified into several categories, some of which are regulated by the government [3,4]. One of these categories is patient safety, which refers to the expectation that HISs will help prevent medical accidents, such as mistakes concerning patients (e.g., wrong-site surgery) and medication-dispensing errors. Indeed, hospitals that have proactively customized HISs have developed functions that contribute to patient safety through collaboration with contracted vendors, referring to incident report analyses from the institutions themselves.

However, to date, insufficient research has analyzed the contribution of HIS patient safety functions in real-world medical practice in Japan, despite their widespread use [5,6]. This paper reviews the history of HISs in connection with patient safety in Japan and discusses future prospects for the introduction of HIS patient safety functions based on their value. As research materials, the reports and official documents related to HISs and patient safety were comprehensively collected from websites operated by the Japanese government.

## II. Review

### 1. Development of Hospital Information Systems

HISs, which store medical records, can reduce the workload for medical staff by improving the readability of key information, allowing the staff to easily check patients’ medical history and share information with other medical staff. HISs may also contribute to improving the efficiency and quality of medical care by making it possible to accurately grasp the medical workflow using records of healthcare workers who order treatment and receive treatment materials and patients who undergo treatment. At large hospitals, over the past 20 years, HISs have gradually moved from conventional order entry systems to electronic medical record-equipped systems [1].

According to the “Status of HIS Diffusion” report released by the Ministry of Health, Labour and Welfare (MHLW) in 2017, the penetration rate of HISs featuring Electronic Medical Records was 85.4% for medical institutions with over 400 beds and 64.9% for those with 200–399 beds [1]. Since junior doctors use HISs in almost every university and clinical training hospital, it is extremely difficult for them to provide medical care without using their institution’s familiar HIS.

Furthermore, in recent years, HISs have become increasingly common at small and medium-sized hospitals and clinics [1].

In 1999, HISs featuring Electronic Medical Records were legally recognized in Japan. According to the Medical Care Act, files on an HIS are recognized as medical records if the system satisfies three principles set by the MHLW: authenticity (the HIS cannot be rewritten, erased, or misrecognized), readability (the data are visible and can be documented), and preservability (as required by law) [3]. Since 1999, a notification regarding the external storage of medical records (2002), the Act on the Protection of Personal Information (2005), and the Law Governing the Use of Information and Communications Technology in the Preservation of Documents that Private Businesses Perform (2005; the so-called “e-Document Act”) have been enforced. Based on these regulations, The MHLW, the Ministry of Internal Affairs and Communications, and the Ministry of Economy, Trade, and Industry have created security guidelines for the storage of patient medical records and provided them to the medical community and the medical information industry. These guidelines have occasionally been revised in accordance with legislative changes and technological advances in HISs [4].

### 2. Relationship between Hospital Information Systems and Safety

HISs feature multiple safety-promotion elements that can be broadly classified into the following four types:

- 1) HIS security: As outlined above, hospitals and HIS vendors are required to comply with government guidelines regarding the protection of personal information and adherence to the three principles set by the MHLW.
- 2) Safety in the operation of medical equipment connected to the HIS (ensuring the safety of medical devices, as stipulated in the Act on Securing Quality, Efficacy, and Safety of Products Including Pharmaceuticals and Medical Devices): Since HISs are not used to treat patients directly, they are not subject to this law; however, medical software installed on the HIS and connected devices may be subject to this law, and system administrators are required to manage such software and devices appropriately.
- 3) Support for hospitals’ patient safety management departments: In Japan, the first articles on patient safety were introduced in the enforcement rules of the Medical Care Act (2003) and the revision of the Medical Care Act (2006). Large hospitals, such as special functioning hospitals and hospitals designated for clinical training, are now required to collect and analyze information

concerning incidents or accidents that occur within the hospital [7]. Thus, these hospitals' patient safety management departments spend large amounts of time collecting information on medical accidents and incidents. Several operations of these departments are now computerized, and HISs are very helpful for collecting and analyzing patient safety-related information. In addition, patient safety management departments commonly use HISs to manage and implement training for hospital staff.

4) HIS functions that contribute to patient safety: This is the focus of the present study. When HISs were first implemented, their functions concerning patient safety quickly attracted attention [8]. Hospitals, through their patient safety management departments, medical information departments, and HIS vendors, have continued working to enhance the safety measures related to these four categories, parallel to the continued development of HISs.

In 2021, a research group investigating measures to disseminate the functions of HISs that contribute to patient safety, supported by Health, Labour, and Welfare Policy Research Grants, conducted a survey on HISs and patient safety at 10 hospitals in Japan [9]. The results of a survey concerning the above four categories showed that most hospitals had implemented relatively effective measures for all areas. As HISs have been refined, safety measures also seem to have made steady progress.

### 3. Health Information System Functions that Contribute to Patient Safety

Around 1999, a series of serious medical accidents caused by simple miscommunication occurred at medical institutions that were highly trusted by the public, such as special functioning hospitals and large public hospitals; these events caused the government to recognize that patient safety represents a national issue [10]. In response, the Medical Safety Promotion Office was established in the MHLW in 2001, and in 2003, the enforcement rules of the Medical Care Act were amended to require that special functioning hospitals establish patient safety systems. Furthermore, the 2006 revision of the Medical Care Act mandated that all medical institutions must seek to improve patient safety [7].

Before 2000, medical institutions appropriately implemented patient safety, with each hospital employing procedures for preventing medical accidents and manuals for emergency responses to medical accidents [11]. The first Japanese Model Core Curriculum for Medical Education, published in 2001, covered "safety care and crisis management in healthcare" [12]. The generalization of HISs featuring electronic

medical records and the increased prioritization of patient safety occurred at approximately the same time [13,14].

The contributions of HISs to patient safety have been debated since their inception. According to the "Comprehensive Measures for Medical Safety Promotion" document, published by the MHLW in 2002, information systems can feature errors not only when transmitting information but also regarding instructions, preparations, and the implementation of medical practices across all stages of the care process [8]. The document also emphasized that HISs could play a major role in improving the quality and safety of medical care in the future [8]. Furthermore, the final report of the Standard HIS Promotion Committee (2005) highlighted the patient safety functions of "preventing misunderstandings concerning patients," "preventing mistakes regarding medicine dosage and usage," "preventing mistakes concerning prescription and test/treatment instructions," and "preventing misidentification of test results" and emphasized the importance of incorporating these goals into HISs as basic functions [15].

That report also mentioned the risk of incidents caused by HISs, such as the possibility of mistakes by medical staff who concurrently operate different HISs at different levels of operability, and of incidents caused by defects that are difficult for users to discover, such as the incorrect installation of common master files (e.g., the diagnostic classification master file or pharmaceutical master file) and computational logic on HISs. Hospitals and vendors have continued to address these risks while developing HISs. Specific examples of HIS functions that contribute to patient safety are listed in Table 1 [16].

At the 3rd Global Ministerial Summit on Patient Safety, which was held in Tokyo in 2018, a panel discussion entitled "ICT and Patient Safety" was conducted [17]. This summit featured presentations concerning HISs' contribution to patient safety, one of which was the detection of adverse events through HISs using a "Global Trigger Tool" invented by the Institute for Healthcare Improvement in the United States, which can identify adverse events (harms) and measure the rate of adverse events over time [18], as well as the risks associated with the introduction of HISs. Qualitative and quantitative data on the link between HISs and patient safety have been collected from countries throughout the world, and new technologies to further improve patient safety continue to be developed [19–27]. In Japan, a report from a study group on standard HISs (2019) prepared by the Cabinet Secretariat stated that improving the quality and safety of medical care is a major issue that HISs should address in the

**Table 1. Hospital information system functions that contribute to patient safety**


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**1. Authentication, double-checks, and approval**

(A) Patient authentication using name bands, barcodes, etc.

- 1) When administering oral medication
- 2) When administering an injection/drip
- 3) When administering a blood transfusion
- 4) When providing an invasive treatment
- 5) During radiation/physiological examination
- 6) When entering the operating room
- 7) During outpatient chemotherapy

(B) Functions for instructors and others to approve decisions made by junior residents

- 1) When writing oral prescriptions
- 2) When administering injections/drips
- 3) When administering blood transfusions
- 4) When ordering an invasive treatment
- 5) When making recommendations for clinical pathways
- 6) When making recommendations for chemotherapy regimens

**2. Information regarding drugs, prescriptions, and allergies**

(C) Drug prescription systems

- 1) Single-dose prescriptions for internal medicine (printing with the daily dose)
- 2) Adoption of master files for standard usage in prescription ordering systems
- 3) Identifying high-risk drugs and managing them using system support
- 4) Overdose check/alert function
- 5) Dosing contraindication check/alert function
- 6) Function for printing an ingredient amount corresponding to a prescribed medicine
- 7) Off-label prescription check/alert function
- 8) Interaction/contraindicated drug check/alert function
- 9) Function for checking consistency among prescriptions from multiple clinical departments
- 10) Preventive measures for selecting wrong medicines with a similar name (three-character input, etc.)
- 11) Function for checking agreement between drug allergy information and drug orders
- 12) Function for checking agreement between food allergy information and meal orders
- 13) Calendar-format display function
- 14) Management and prescription system for medicines taken by patients

(D) Transmission of allergy-related information from the core system to departmental systems

- 1) Integration with the pharmaceutical department
- 2) Integration with the radiation department
- 3) Integration with the endoscopy department
- 4) Integration with the nutrition-management department

**3. Addition of safety functions**

(E) Introduction of other systems (equipment) and functions

- 1) Function for checking for double registration of patients
- 2) Introduction of electronic clinical pathways
- 3) Introduction of a management system for chemotherapy regimens
- 4) Function for notifying the attending physician (the doctor responsible for orders) about abnormal test results
- 5) Function for notifying the attending physician (the doctor responsible for orders) about unread pathology/imaging test reports
- 6) Function for confirmation messages regarding implants before magnetic resonance imaging examinations
- 7) Function for checking blood type when ordering blood transfusions
- 8) Function for recording the blood type of a patient
- 9) Function for checking whether the plasma type matches the blood type of a patient when ordering plasma products
- 10) Traceability of blood transfusion/biopharmaceuticals and biological, medical materials
- 11) Function for retrospective investigation of infections after blood transfusions
- 12) Standardization of the insulin sliding scale format
- 13) Preventive measures for hepatitis B reactivation due to receiving anticancer drugs, etc.

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Based on Ohara and Kusuoka [16].

future [28]. Thus, in many countries, including Japan, HISs and patient safety have progressed concomitantly.

### III. Analysis

#### 1. Have HISs Contributed to Patient Safety?

Has the widespread use of HISs reduced medical incidents? According to the Project to Collect Medical Near-Miss/Adverse Event Information operated by the Japan Council for Quality Health Care, the number of medical adverse event reports from the medical institutions (about 270) subject to the reporting requirement was 1,114 in 2005, but increased to 4,321 in 2020 [29]. During this time, the scope of events reported as adverse medical events has not changed, so it would seem that the incidence of these events has increased. However, the most widely accepted explanation is that this increase was driven by fostering a patient safety culture in the medical community, thereby encouraging accident or incident reporting to prevent accidents [29].

Many studies confirming the effects of patient safety functions introduced in specific hospitals have been conducted, but it has not been possible to verify these effects within the entire medical community [19,20,24,26]. A reason for this may be that incident statistics cannot be integrated because of heterogeneity among medical institutions in definitions of particular patient safety functions and specific incidents.

#### 2. Future of Functions that Contribute to Patient Safety

History shows that hospitals and HIS vendors have supported advances in HIS patient safety functions. However, most of these functions were developed based on the needs of individual hospitals and were not intended to be shared with other medical institutions. Furthermore, sharing technology across institutions may not proceed smoothly, even among platforms developed and deployed by the same vendors, if the hospitals in question have different requirements. It is also possible that developments to date have had limited effects because only a few of these functions involve universally accepted categorizations, and there is a lack of demand for these functions among vendors and hospitals. Nonetheless, it is hoped that in the future, HIS patient safety functions will become generalized and an environment in which many hospitals actively consider introducing such functions will be created. To achieve this goal, the government and academic societies should provide regulations and guidelines on HISs and patient safety for the medical community and medical-device vendors.

However, specific regulations and guidelines have not yet

been established in this regard. To date, the Japanese government has made few attempts to generalize safety functions. There have been no developments in this regard since 2019, when a research group organized by the MHLW developed a specification for a function ensuring that diagnostic imaging reports are read [30]. It is hoped that related parties, including the MHLW, will continue to make efforts to create guidelines and specifications regarding patient safety functions.

Some other factors may explain the somewhat subdued interest in the association between HISs and patient safety. In particular, due to the short history of HISs and patient safety, there is insufficient evidence regarding the degree to which patient safety functions contribute to reducing medical accidents. The authors believe that it is vital for highly rigorous research to be conducted to clarify these issues; such studies should include comparisons of the number of medical accidents before and after the introduction of patient safety functions, estimations of the potential cost reductions secured by preventing medical accidents, and comparisons of the usability of various safety-promoting technologies.

### IV. Discussion

This study reviewed the history of HIS patient safety functions in Japan. HISs featuring electronic medical records have become increasingly popular since the beginning of the 21st century and contribute to patient safety. In many countries, including Japan, HISs and patient safety initiatives continue to progress concomitantly.

However, concerns exist regarding the possibility that existing developments have had limited effects because only a few of these functions involve universal categorizations and because there is a lack of demand for those functions among vendors and hospitals. Inadequate communication between patient safety and HIS personnel may also be a barrier to improving patient safety by refining HISs. A pervasive problem is the lack of sufficient evidence on whether patient safety functions contribute to reducing medical accidents; therefore, it is unclear whether investing in them is cost-effective.

The authors hope for a future in which patient safety functions will become generalized, and many hospitals will be willing to adopt them. Achieving this goal will require improvements in three areas. First, there is a need to develop regulations and guidelines on HISs and patient safety that can be referenced by the medical community and medical-device vendors. Second, concrete discussions should be held to establish methods to verify the effectiveness of patient safety functions. Finally, hospital information systems and

patient safety staff should understand and collaborate with each other.

It is expected that future research will yield further knowledge on HISs and patient safety.

## Conflict of Interest

No potential conflict of interest relevant to this article was reported.

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