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＜Practice Report＞

Current status of local network system for patient safety in Japan

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Abstract

Since the 'Patient Safety Promotion Comprehensive Measures' report in 2002, Japan's medical safety system has been established utilizing financial incentives based on medical fee additions. In addition to audits based on the Medical Care Act, the system incorporates third-party evaluations and certifications related to hospital functions. Furthermore, since 2006, the implementation of the Preferential Patient Safety Countermeasure (PPSCF) Fee 1 and 2, and since 2018, Additional Fee for the Local Network (AFLN) 1 and 2, which include peer-to-peer assessments, have contributed to building a patient safety system of international caliber. However, comprehensive reports on the overview of this system and the current situation in Japan have been scarce. This study aims to provide an overview of Japan's patient safety measures, with a specific focus on local network sheets, peer reviews, and third-party evaluations, highlighting the features of these initiatives in Japan.

keywords: patient safety, Additional Fee for the Local Network, peer review

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I. Japanese patient safety System and Third-Party Evaluation

Patient safety constitutes a foundational and critical element within the healthcare system in Japan. Since 1999, the incidence of patient safety accidents in Japan has garnered attention, mirroring a global rise in awareness and concern for medical and patient safety during the same period[1]. In 2002, the National Council for Patient Safety convened to deliberate on strategies for patient safety, culminating in the 'Patient Safety Promotion Comprehensive Measures' report[2]. Coordinated by the council, this report outlined various aspects: safety measures at medical facilities, enhancements in the safety of medication and medical equipment, education and training focused on patient safety, systemic improvements like the development of patient consultation services, dissemination of patient safety information, and scientific research in the field of patient safety. Based on the 'Patient Safety Promotion Comprehensive Measures' report, numerous patient safety initiatives have been implemented. However, within the framework of ensuring patient safety, specifically in Chapter 2, titled 'Challenges and Solutions for Ensuring patient safety,' and more precisely in Section 2-4, known as 'Environmental Development for Promoting patient safety,' the promotion of third-party evaluations has emerged as a unique development in Japan. Despite its significance, there has been limited reporting on Japan's distinct third-party evaluation system.

II. Regarding the patient safety Regional Collaboration

In the context of third-party evaluations in Japan, the Medical Care Act Article 25, Section 1 mandates that all hospitals under the jurisdiction of the prefectures, and Section 3 of the same article requires that advanced treatment hospitals undergo inspection and audits. Additionally, while not obligatory for all hospitals, third-party evaluations and

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Table 1　Detailed Comparison of Requirements for PPSCF and AFLN Fee Applications in Patient Safety

PPSCF 1	PPSCF 2	AFLN1	AFLN2
A trained pharmacist, nurse, or equivalent professional is appointed as a ***full-time*** medical safety manager, having undergone specific training in healthcare safety	A trained pharmacist, nurse, or equivalent professional is appointed as a safety manager, having undergone specific training in healthcare safety	(1) Must be a medical institution covered by insurance, other than a designated function hospital.	(1) Must be a medical institution covered by insurance, other than a designated function hospital.
The medical institution establishes a dedicated department for medical safety management, ensuring a structured approach to implementing healthcare safety measures.	The medical institution establishes a dedicated department for medical safety management, ensuring a structured approach to implementing healthcare safety measures.	(2) Must have filed for PPSCF 1	(2) Must have filed for PPSCF 2
The institution includes a patient consultation office focused on medical safety.	The institution includes a patient consultation office focused on medical safety.	(3) Must have a dedicated doctor with over three years of experience in medical safety measures, or a dedicated doctor who has completed appropriate training in medical safety measures, assigned to the medical safety management department.	(3) Must have received an evaluation on medical safety measures from an institution that has filed for PPSCF1.
		(4) Must conduct evaluations regarding medical safety measures for ***BOTH*** institutions that have filed for PPSCF1 and those that have filed for PPSCF2, and the institution itself must also have received an evaluation regarding medical safety measures from an institution that has filed for	

PPSCF, Preferential Patient Safety Countermeasure Fee; AFLN, Additional Fee for the Local Network
This table is based on "中央社会保険医療協議会 総会（第576回）個別事項（その22）について." [Online]. Available: https://www.mhlw.go.jp/content/12404000/001184896.pdf. [Accessed: 21-Jan-2024].

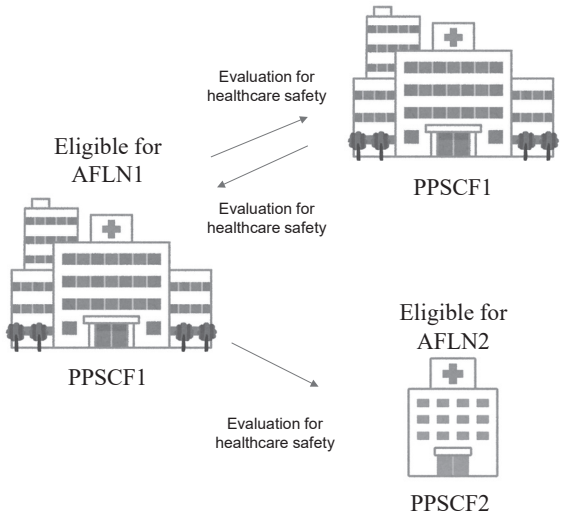

Figure 1　Inter-hospital peer-to-peer assessment in PPCSF1 and PPSCF2
PPCSF1, patient safety countermeasure fee1;
PPCSF2, patient safety countermeasure fee2

accreditation as per the legal text include those conducted by the Japan Council for Quality Health Care (JQ), the International Organization for Standardization (ISO), and the Joint Commission International (JCI)[3]. These evaluations serve as part of the requirements for certain medical fee and as indicators of a hospital's function. Furthermore, since 2018, a new financial incentive scheme, the local network for patient safety, has been introduced to create a framework for patient safety through regional collaboration. Hospitals can receive better reimbursement if they establish local networks to improve patient safety, which involves organizing regular meetings and site visits to share patient safety practices.

The requirements for claiming additional medical fees in the field of patient safety are complex[4]. Initially, the preferential patient safety countermeasure fee (PPSCF) was established in 2006, with levels varying based on whether a trained pharmacist or nurse is appointed as a full-time safety manager, and whether an organizational system for patient safety measures is in place (Table 1)[5]. In 2018, the Additional Fee for the Local Network (AFLN) was added to this. Similar to the PPSCF, it is classified into two types: AFLN1 and AFLN2. The AFLN1 requires facilities that are already classified as PPSCF1 to have a dedicated physician with over three years of experience in patient safety or who has completed relevant training. Additionally, AFLN1 necessitates that facilities evaluate hospitals in both the PPSCF1 and PPSCF2 categories and also be evaluated by hospitals in the PPSCF1 category, ensuring a comprehensive evaluation of patient safety practices. Furthermore, AFLN2 requires evaluation from a PPSCF1 facility (Figure 1). This represents a unique Japanese system where, in addition to internal patient safety management, inter-hospital peer-to-peer assessment and peer review system are established. This is a different framework from the aforementioned inspections and audits, and is considered analogous to the peer review system of advanced treatment hospitals, which also necessitates mutual peer reviews among hospitals.

III. The History of patient safety regional collaboration sheet and Peer Review

In Japan, several organizations, such as the Council of Heads of National and Public Dental Schools and Hospitals of Japan, the Private University Hospital Liaison Council, the Japan Organization of Occupational Health and Safety, and the National Hospital Organization, began mutual checks on patient safety and the formation of networks within communities in the early 2000s. Each organization has been conducting these activities independently and voluntarily. While many of their initiatives contain common

Table 2　Examples of seven processes for achieving healthcare safety regional collaboration.

1. Meeting 1 (Schedule, Evaluation Method, Consideration of specific themes)
Initial meeting of the year, including introductions.
Discussion on schedule, evaluation method (evaluation forms to be used), and consideration of individual themes.
Exchange of documents detailing facility overview (number of beds, departments, staff numbers, etc.).
Consideration of continuing collaboration with facilities from the previous year, including a review of the last year's summary.
2. Self-Evaluation (Use of Evaluation Forms and Preparation at Own Facility)　: 2 MONTHS before Evaluation
Start about two months before the evaluation and aim to complete one month prior.
Conduct self-evaluation at own facility and prepare (targets for facility tours, preparation of questions, confirmation of moderator, etc.).
3. Meeting 2 (Final Confirmation of Evaluation Implementation Date) : 1 MONTHS before evaluation
Conducted one month before the evaluation.
Confirm the schedule for the day, attendees, and whether there are pre-questions.
Confirm attendees (participation of dedicated doctors, department heads, etc. is desirable).
4. Evaluation (Actual Evaluation Process)
Final confirmation before starting, introduction of attendees, implementation of evaluation following the Medical Safety Regional Collaboration Sheet.
Conduct facility tours, concluding remarks at the end of the evaluation.
Confirmation of the deadline for the report submission at the end of the evaluation.
5. Report Submission (Submission of Evaluation Results Report) : 1 MONTHS after evaluation
Send the report of evaluation results to the evaluated facility by the deadline.
6. Improvement Plan Submission (Creation and Submission of Improvement Plan Within the Fiscal Year) : 2 MONTHS after evaluation
Create and send an improvement plan within the fiscal year, based on the report of evaluation results.
7. Sharing and Summarization of Improvement Results (Consideration for Next Year's Regional Collaboration)
Sharing of the results of improvement efforts, summarization of regional collaboration for the fiscal year.
Consideration for the next fiscal year's regional collaboration.

*This table is based on "2019 Masahiko I, Kenkyu daihyosha. Research on Health, Labour and Welfare Policy Research Grants. [Iryoanzen ni okeru iryokikan no rennkei niyoru hyouka nokenkyu.] (H30-Tokubetsu-Shitei-001) Report on Fiscal Year Heisei 2019. (in Japanese)."

Table 3　Distribution of Medical Safety Checklists Usage

Checklist	Percentage (%)
National Hospital Organization's Mutual Medical Safety Check Sheet	38.5
Ministry of Health, Labour and Welfare's Regional Medical Safety Collaboration Sheet	28.6
Hospital (Hospital Group)'s Own Survey Form	17
Japanese Hospital Association's Standard Safety Management Checklist	11
Worker's Health and Safety Organization's Medical Safety Checklist	2.2
Council of Private Medical University Hospitals' Mutual Round Site Visit Evaluation Form	2.2
Meeting of Directors of National University Hospitals' Mutual Check Items for Medical Safety and Quality Improvement	1.6
Others	8.1

This table is based on "飯田修平, 研究代表者. 厚生労働科学研究費補助金 健康安全確保総合研究分野 地域医療基盤開発推進研究「医療機関の医療安全の連携の現状把握及び促進する手法の開発に関する研究」令和４年度 総括研究報告書 (21IA1001) P69-73 . 2022 Syuhei I, Kenkyu daihyosha. Research on Region Medical Grants. [Iryokikan no iryoanzen no rennkei no genjyo haaku oyobi shuhou no kaihatsu ni kansuru kenkyu] (21IA1001) 2022 (in Japanese). P69. (Modified)

elements, there has been no uniform sheet or methodology established across the board. Building on the background where various organizations were independently conducting mutual checks, Ishikawa and others conducted interviews and surveys to investigate the actual situation[6]. Based on these findings, they developed the 'Patient safety Regional Collaboration Sheet' in 2018. In addition, to facilitate its use, they also created the 'Practical Guide for Utilizing the Patient safety Regional Collaboration Sheet', which explains the specific methods of using the collaboration sheet. According to their studies, the patient safety regional collaboration involves seven processes, which requires over approximately three hours, following a timetable exemplified in the Table.2[6]. The peer-to-peer assessment and review system has evolved at the local network level based on such circumstances. In regional collaboration, the specifics are typically left to the discretion of each medical institution. According to a study by Iida et al. in 2020, despite a low response rate of 20%, it was found that 38.5% of respondents were still using the National Hospital Organization's mutual check sheet, and 28.6% were utilizing the Patient safety Regional Collaboration Sheet (Table.3) [7].

Globally, peer review has evolved through a process that includes pressuring clinicians to improve performance, implementing quality improvement efforts[8], conducting internal physician peer reviews, and requiring regulatory accreditation. Following this, organizational peer-to-peer assessment, as seen in the nuclear industry's history, was exemplified by the Institute of Nuclear Power Operators (INPO), which established industry norms and normative pressures to enhance nuclear safety. INPO, driven internally, played a pivotal role in shaping an industrial culture with a defined industrial morality, ultimately leading to improvements in safety[9]. This peer-review program continues today, involving independent international teams of experts assessing plant operations. Such a model could potentially benefit the healthcare industry in enhancing patient safety through structured clinician-led peer reviews and hazard

identification, supplementing existing quality improvement approaches[10]. Indeed, the aforementioned seven steps in Japan overlap with the Peer-to-Peer Protocol used at Massachusetts General Hospital and Johns Hopkins Hospital, as reported by Mort et al., which includes planning, team selection, document review, organizational assessment, harm reduction assessment, evaluation and report dissemination, and improvement planning.

While peer-to-peer assessment has evolved within the framework of patient safety, there are few reports demonstrating its effectiveness in enhancing patient safety. In countries like Japan, where audits and inspections are supplemented by peer-to-peer assessment and peer review in the context of medical remuneration, and to some extent voluntarily, it is necessary to examine how these practices influence patient safety. Additionally, in terms of third-party certifications, frameworks for patient safety provided by organizations such as the Joint Commission and AHRQ in the United States have concretized the concept of a patient safety culture over time [11]. Globally, while document review is acknowledged, there is no scientifically validated regional-level checklist like Japan's 'Patient Safety Regional Collaboration Sheet'. Against the historical backdrop of the development of checklists in surgical settings, Japan has developed the 'Patient Safety Regional Collaboration Sheet' as a unique cultural adaptation.

IV. Insights into Japan's Patient Safety Local Networks

The overview of medical fee applications by medical facilities entails submissions to the regional bureaus of the Ministry of Health, Labour and Welfare (MHLW), with this data being publicly accessible. As of December 11, 2023, information was collected from the websites of health bureaus across eight regions: Hokkaido, Tohoku, Kanto, Tokai-Hokuriku, Kinki, Chugoku, Shikoku, and Kyushu. From these datasets, we can categorize each medical facility's eligibility for PPSCF1, PPSCF2, and whether they are advanced treatment hospitals. While we intended to include AFLN data, it must be noted that such data is not openly available. Zip code data for each municipality was sourced from the official website of Japan Post. The comprehensive postal code information, essential for the geographical aspects of our analysis, was obtained from the publicly accessible online platform provided by Japan Post at https://www.post.japanpost.jp/zipcode/download.html. This resource offered detailed and up-to-date ZIP code information. By leveraging these datasets and employing the leaflet library in R[12], we successfully created an interactive map that visualizes the geographical distribution and categorization of medical facilities.

Among available hospital data including 113345 hospitals and clinics according to the May 2023 Healthcare Facility Survey, 1705 (1.5%) have filed for PPSCF1, 2292 (2.0%) have filed for PPSCF2, and 88 (0.1%) are advance treatment hospitals. However, given the large number of clinics without inpatient facilities, the proportion based on hospitals that have some form of inpatient care or are eligible for inpatient additions is more relevant. According to the Regional Health Bureau data, 10.4% of the 16455 hospitals have filed for PPSCF1, 13.9% have filed for PPSCF2, and 0.5% are advance treatment hospitals (Table4).

The geospatial map provides valuable insights into the patient safety hospitals in Japan (https://atsushi-mizuno.github.io/Patient_safety_20240218/, Figure.2). It illustrates how categories such as PPSCF1, PPSCF2, and advanced treatment hospitals are distributed across the country (Figure 2.A-C). However, in a peer-to-peer assessment, hospitals required for AFLN1 (necessitating PPSCF1) and AFLN2 (requiring PPSCF2) are responsible for evaluating patient safety. Yet, their distribution poses challenges, especially in regions like Tohoku (Figure 2.D). The considerable distances between these hospitals in Tohoku, compared to other regions, suggest a potentially higher burden when conducting peer reviews and assessments. This geographic dispersion, clearly visible on the map, could impact the effectiveness and efficiency of patient safety evaluations in more isolated or less populated areas. Incorporating further data, including currently unavailable AFLN, would enhance future research.

V. Current and future perspective of safety management system in Japan

In conclusion, as we have observed, a significant number

Table.4 Number and Proportion of Hospitals by Medical Safety Fee Categories

Hospital category	PPSCF1	PPSCF2	Advance treatment hospital
Number of hospitals	1705	2292	88
Proportion of hospitals based on the total number (n = 16455) from Regional Health Bureau data*	10.4%	13.9%	0.5%
Proportion of hospitals based on the total number (n = 113345) from May 2023 Healthcare Facility Survey†	1.5%	2.0%	0.1%

PPSCF, Preferential Patient Safety Countermeasure Fee;
*Note: The data from the Regional Health Bureau includes facilities that potentially qualify for the Preferential Patient Safety Countermeasure Fee upon hospitalization (refer to the main text). † Note: This data is derived from the May 2023 Healthcare Facility Survey, combining the total number of hospitals (8132) and general clinics (105213). Accessed on 2024-06-02.

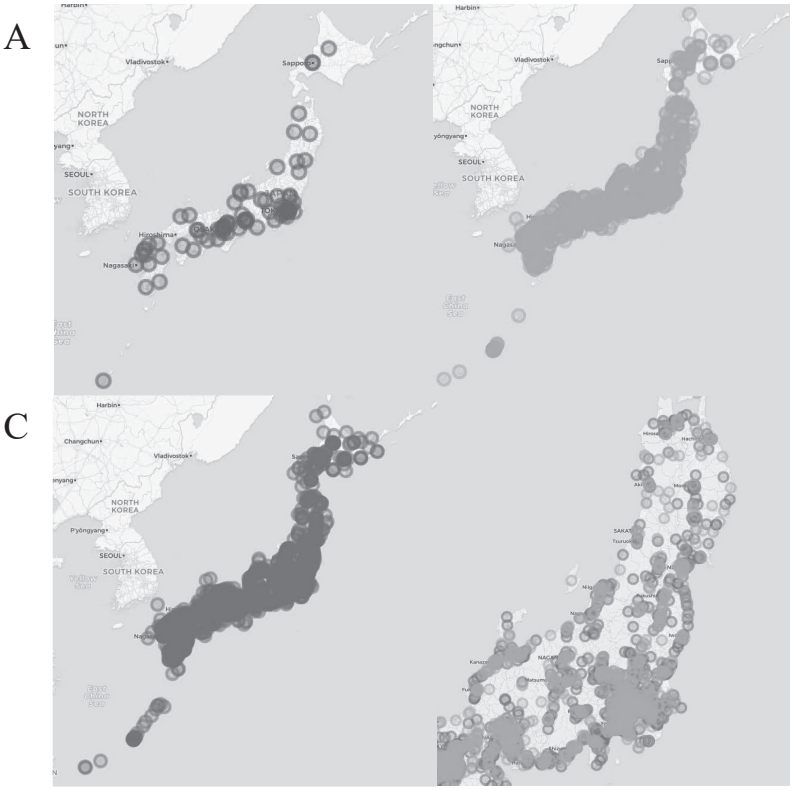

Figure.2 PPCSF1, PPCSF2, and advanced tratment hospitals

of hospitals across Japan have been utilizing the medical fee-for-service system to establish a patient safety infrastructure. The audits mandated by the Medical Care Act, combined with voluntary third-party evaluations and accreditations, and peer reviews including peer-to-peer assessments, are believed to be cultivating a unique culture of patient safety in Japan.

However, there are challenges to consider. Apart from the mandatory audits under the Medical Service Law, the third-party certifications and peer-to-peer assessments, though reimbursed, impose substantial costs on hospitals, including consultancy fees and the logistics of visiting other hospitals and scheduling. The efficiency and contribution of audits, third-party evaluations, and peer-to-peer assessments to patient safety are not yet clear, and further research is needed to evaluate their effectiveness. Currently, these network-related initiatives are voluntary. In Japan, every prefecture is mandated to create a "Medical Care Plan" based on the Medical Care Act Article 30 section 4, in order to build effective and efficient medical service systems in its constituent regions. Starting from 2024, the eighth Medical Care Plan will include 'the proportion of hospitals that are evaluated by other hospitals or undergo third-party evaluation regarding patient safety measures relative to the total number of hospitals'. This addition will enable prefectural-level consideration of how these proportions impact the patient safety system.

Given the limitless nature of costs associated with patient safety in hospitals, it is essential to continue developing systems that can provide high-quality care to patients more effectively and efficiently. This development must be guided by policy direction and evidence-based research, with careful consideration of cost-effectiveness.

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Conflicts of Interest

The author declares that there are no conflicts of interest regarding the publication of this article.

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＜報告＞

日本の医療安全地域連携体制について

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抄録

日本における医療安全体制は，2002 年の医療安全対策検討会議以降，診療報酬加算に基づく金銭的インセンティブを活用しながら体制を構築してきた．医療法に基づく監査に加えて，病院機能に関わる第三者評価，第三者認証，さらには2006 年からの医療安全対策加算 1,2 の設定，2018 年からの医療安全対策地域連携加算 1,2 の設定に基づく他医療機関からの評価により国際的にも高度な医療安全体制を構築している．しかしながら，これまで医療安全地域連携制度の全体像と日本の現状についての報告は少ない．本研究では，日本における医療安全対策，特に地域連携シートと，ピアレビューなどの相互評価および第三者評価に焦点を当て，その全体像と取り組みの特徴について報告する．

キーワード：医療安全，医療安全対策地域連携加算，ピアレビュー