Original Paper

The Sennen Karte Project for a Sustainable Nationwide Integrated Care Electronic Health Record in Japan: Design and Implementation Study

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Abstract

Background: The need for national-level medical data management is recognized across various areas, such as health care management, drug development, epidemiology, and policymaking. Conventional integrated care electronic health record (EHR) projects in Japan that rely on subsidies are unsustainable and will be restricted over the next 5 years because of the limited duration of the general subsidy period. Therefore, the sustainability of EHR arrangements needs to be discussed not only from the perspective of system implementation but also from that of the legal framework. In response to the demand for the secondary use of medical data, a national-level project called the Sennen Karte Project was launched in Japan in 2015.

Objective: The objective of this project was to establish an integrated care EHR that generates revenue through the secondary use of medical data, enabling a sustainable service that does not require subsidies. System implementation, the maintenance of a nationwide network, and the enactment of a new act are necessary.

Methods: The development of the data extraction function uses a Japanese local standard, the medical markup language. The extracted data are then stored in the integrated care EHR using an XML database and an ISO 13606/OpenEHR–based database. Additionally, EHR services, including mobile apps, web user interfaces, data backup, and statistical reporting, have been implemented. Policy engagement was undertaken to facilitate the introduction of new legislation enabling the monetization of the secondary use of medical data. A government-authorized company was established to collect medical data and facilitate its secondary use.

Results: The project was initiated to promote legislation for a new act that endorses a framework for generating profit from the secondary use of medical data. The new act passed parliamentary scrutiny in 2017 and came into effect in 2018. Since 2015, an EHR has been implemented, and data retrieval from partner hospitals has begun. The project partnered with more than 100 hospitals within the first 4 years. In total, 77 contracted hospitals provide medical records for secondary use. Both system development and regulatory design have achieved a sustainable framework for the proposed project, which has been operational since 2015 and remains ongoing.

Conclusions: This project aims to provide a sustainable, integrated care EHR. Legislation and system implementation have created an environment that supports the secondary use of hospital medical data. The linkage between the for-profit and nonprofit sectors represents the first step toward realizing the proposed medical information circulation model, which aims to provide sustainable EHR services in Japan.

(JMIR Med Inform 2026;14:e85158) doi: 10.2196/85158

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KEYWORDS

electronic health records; standardization; medical markup language; MML; OpenEHR; secondary use; legislation

Introduction

Large-scale medical data integration is expected to achieve high-quality secondary use of medical data in areas such as cooperative health care, clinical research, drug development, public health, and government policymaking. The collaborative use of an electronic health record (EHR) system will ensure data safety and reduce operational costs. With the participation of many medical institutions, EHR and secondary use services will become more valuable.

From a financial perspective, the elimination of medical redundancy is estimated to result in a reduction in public medical insurance expenses of approximately ¥2.5 trillion (US $15.7 billion) across 242 hospitals, with reductions of approximately ¥12.9 billion (US $80.6 million; approximately 0.5%) to 1% of clinical activity costs (including uncovered items), such as those associated with laboratory tests, prescriptions, and treatments [1,2]. Extrapolating this estimate to the current total of approximately 8000 hospitals in Japan in 2026 yields an upper-bound estimate that eliminating medical redundancy could reduce Japanese government spending by approximately US $2.67 billion (0.5% reduction) to US $5.34 billion (1% reduction), based on an exchange rate of 160 JP ¥/US $. With an integrated care EHR system, medical redundancy is expected to decrease. These potential savings could encourage governmental and political decision-makers to invest in EHRs. Several countries worldwide, especially those in Europe and Oceania, have recognized the importance of EHRs. Government-level investments of approximately US $50 per citizen were made in 2012 to develop an EHR system [3,4]. Conventional integrated care EHR systems in Japan face sustainability challenges because they rely on small-scale, temporary subsidies for operation, despite having been introduced in the late 1990s.

In this context, the authors aim to establish an integrated care EHR system with a subsidy-independent cost model. In a previous EHR project, the authors implemented EHR systems separately in different regions [5-7]. The authors established a standard format known as medical markup language (MML), which was first defined in 1995 [8,9]. In September 2015, the authors commenced a project that developed an integrated care EHR. The Sennen Karte Project (meaning “millennial medical record project”; hereinafter referred to as Sennen) involves the large-scale collection and secondary use of health and medical data.

This paper reports on the design, implementation, and operational status of a nationwide EHR infrastructure; it is not intended to provide a comprehensive evaluation of its clinical efficacy. In accordance with the Next-Generation Medical Infrastructure Act (Act Regarding Anonymized Medical Data That are meant to Contribute to Research and Development in the Medical Field), which took effect in fiscal year (FY) 2018, this project sought to commercialize services for the secondary use of medical data by early FY 2019. Within this context, this paper presents an ecosystem model designed to bridge the nonprofit and for-profit sectors to address the critical challenges of the Sennen project.

Methods

Overview

To ensure a sustainable, integrated care EHR system, the authors aim to develop a centralized database that serves as a hub for information circulation across the ecosystem of data generation, retrieval, and use. In addition, the authors aim to establish a legal framework that enables the monetization of medical data in accordance with specific regulations; otherwise, the proposed system would not function as intended. Therefore, the authors proposed an EHR-based medical information circulation model that defines data flow based on use cases and cash flows, representing the dependencies among entities. Figure 1 illustrates the proposed circulation model, which describes the data flow from the hospital to users and from users back to the data source.

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Figure 1. Concept design of the electronic health record (EHR)–centered medical information circulation model for the Sennen Karte Project.

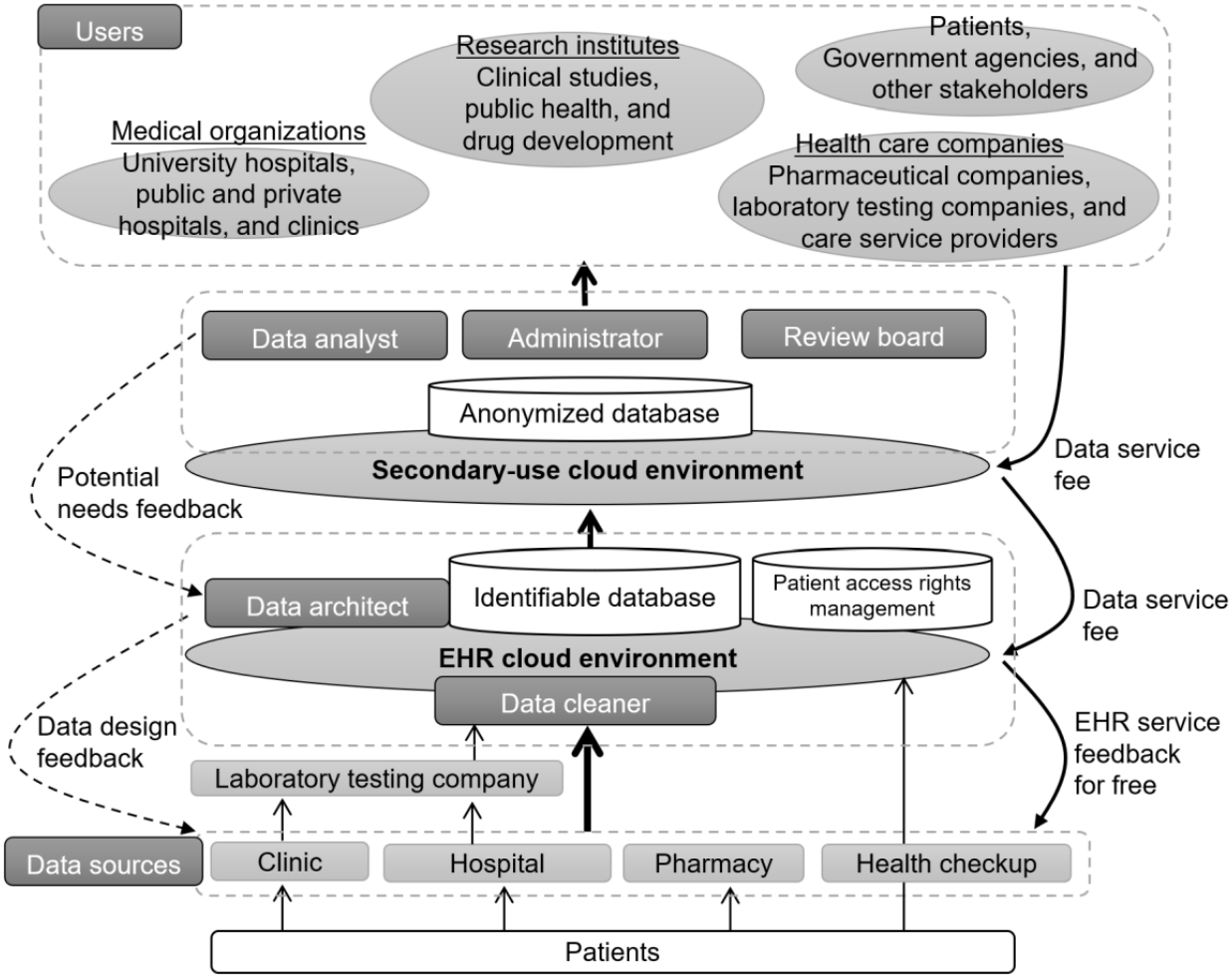


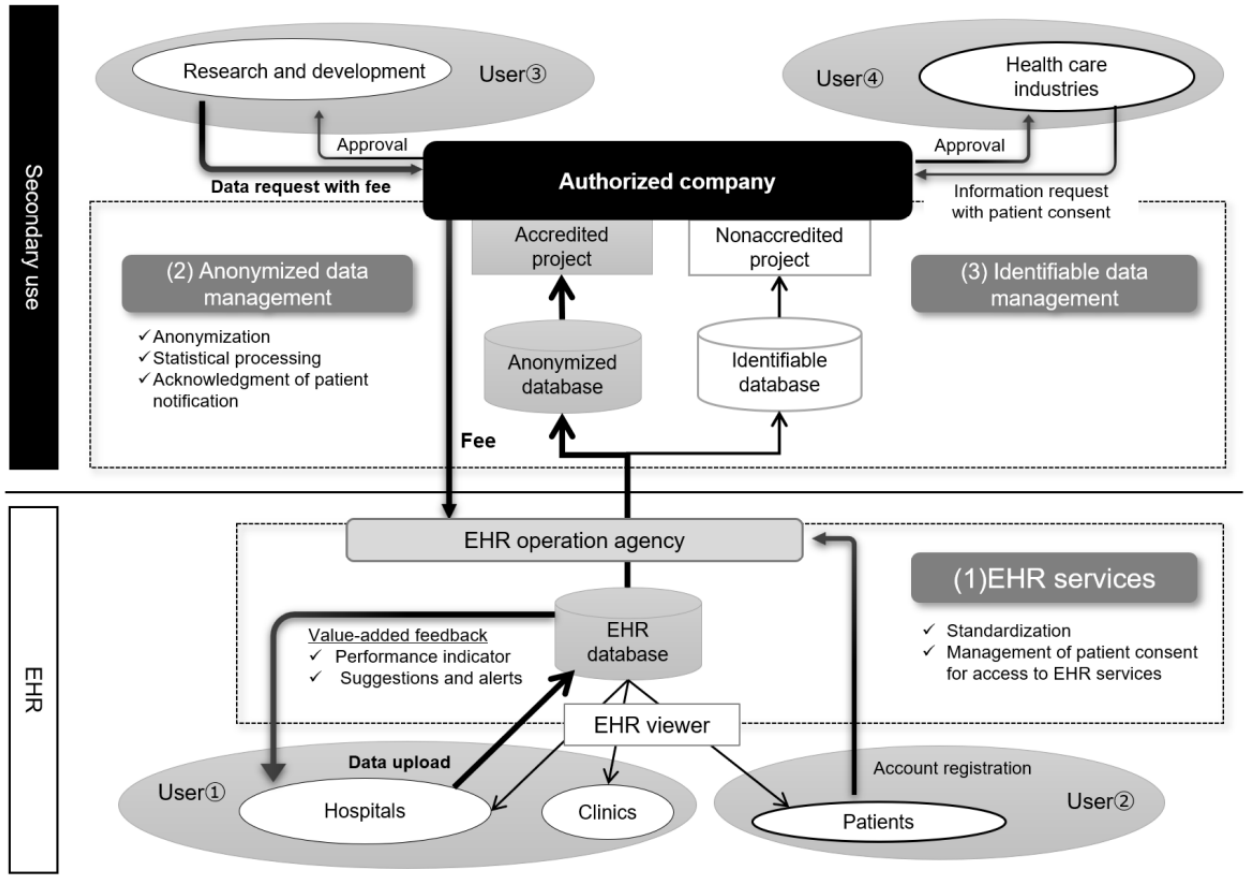
Figure 2 illustrates a system and organizational implementation model for Sennen, designed as a 2-layer model for a sustainable, integrated care EHR system. The first layer is an EHR for clinical use, while the second layer is a regulated database for secondary use.

The primary purpose of the proposed model is to ensure the sustainability of the EHR database, which will serve as a data heritage for future generations. Therefore, the EHR database and EHR services are meant to be operated by a nonprofit organization. To sustain the EHR database, secondary use cases are positioned as the profit-making component, with secondary uses intended to be operated by companies. Here, the secondary use cases are classified into 2 types: the secondary use of anonymized data and the secondary use of identifiable data. The use of identifiable data is covered by the Act on the Protection of Personal Information (APPI). However, the use of anonymized data was not covered by any act in 2015. Hence, a new law was required to facilitate the monetization of secondary use.

In summary, the key issues addressed by Sennen can be summarized into four topics: (1) data extraction from source facilities such as hospitals and clinics, (2) development of an EHR database as a data hub, (3) development of EHR services, and (4) contribution to policy design through active engagement to promote new legislation that enables the monetization of secondary use. Here, the fourth issue is not discussed in this paper.

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Figure 2. Two-layer implementation model of the integrated care electronic health record (EHR) and secondary use of medical data in the Sennen Karte Project.



A 2-Layer Organization Model

The first layer, the clinical EHR, serves as the portal for data collection and service provision to medical institutions as data sources. The second layer for secondary use is the service run by for-profit companies. All identifiable data are stored in the first layer, and selected data, as permitted by the patient, are transferred to the second layer. Permission must be controlled by the source medical institutions and confirmed by both the secondary-layer company and the medical institutions. The first layer is regulated by APPI and serves as a hospital's data backup.

The second layer is governed by the Next-Generation Medical Infrastructure Act, which strictly defines rules for anonymization levels and data distribution controls. The government-authorized company is subject to the act, which defines audits of the organization's operations and contracts, and licenses are evaluated periodically. The contract between the authorized company and the secondary user must specify the period of data use. Therefore, the secondary user must return and delete the provided data after the period has passed, thereby helping to protect patients' rights. Also, the hospital must accept patients' opt-out requests at any time to stop their specific data from being shared with authorized companies. To facilitate this, hospitals must distribute the data-sharing notice on paper to patients, which imposed a huge burden on hospitals participating in the secondary use framework until 2024. Privacy protection details are provided in Multimedia Appendix 1 [10].

Data Extraction From the Data Source

The electronic medical record (EMR) in each facility serves as the primary source of data. Each EMR vendor implements the EMR data extraction function. When a hospital uses a customized EMR, the definition and mapping of a data extraction format, such as MML or Health Level 7 (HL7), must also be customized for each EMR system, even if it uses the same EMR in its original package. Variations in customization increase the burden of system implementation and the associated costs during facility setup.

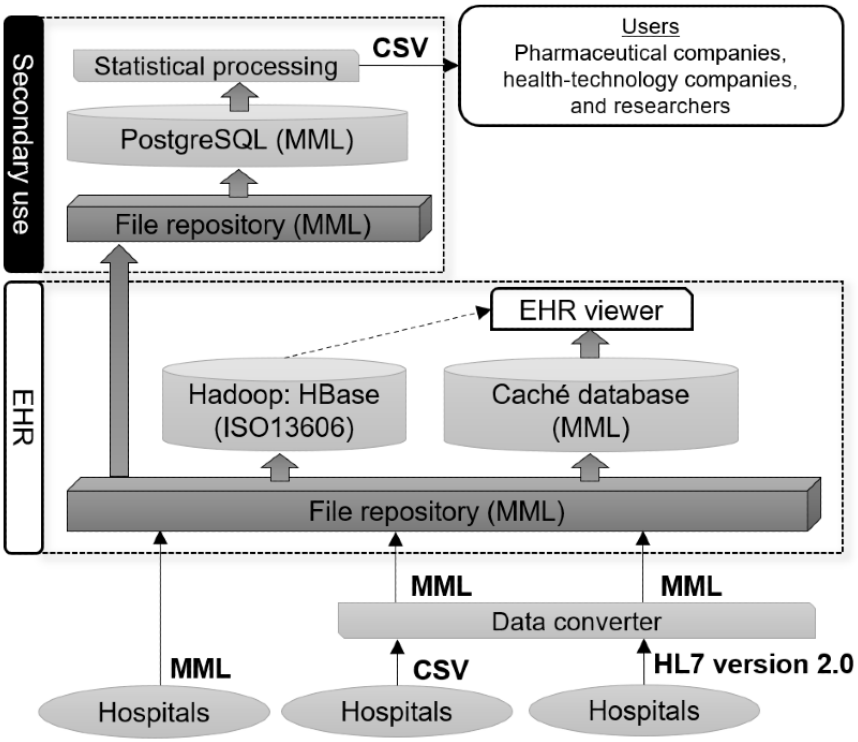
A data uploader is set up in each hospital, and the EMR then generates a new MML instance for the uploader. A daily batch program generates instances each night after the hospital closes.

Development of an EHR Database

Integrating medical data from multiple facilities into a centralized database and standardizing data formats are mandatory. Figure 3 illustrates the applied standards from the viewpoints of "interoperability between systems" and "interoperability within local systems."

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Figure 3. Standards applied to data exchange and database interoperability in the Sennen Karte Project. CSV: comma-separated values; EHR: electronic health record; HL7: Health Level 7; MML: medical markup language.



Interoperability Between Systems

Here, interoperability refers to the exchange of data between systems, including extract, transform, and load (ETL). To achieve interoperability, this project uses MML version 4.1.2 for data exchange. EMR vendors provide an EMR data converter that converts data to the MML format. Sennen originally designed the operational regulations for MML 4.1.2. The regulation provides rules for EMR vendors to generate practical MML instances when an EMR is technically unable to follow the MML 4.1.2 item definition, such as “Implies.” When a data source facility, such as a laboratory test company, provides a special data format, such as company-specific HL7, a data mapping engine converts the specific HL7 format to MML 4.1.2.

Interoperability Within Local Systems

Here, interoperability refers to the database connection between regulated systems. To achieve interoperability, this project uses MML and the ISO 13606 archetype for data storage [9]. Sennen’s primary EHR database stores MML 4.1.2 in an XML structure in the Caché database, enabling a high-performance XML parser. The secondary EHR database uses an archetype model based on ISO 13606 and OpenEHR (openEHR Foundation), which provides a comprehensive dataset [11] for the HBase database’s logical structure. A database relying on the archetype model has the potential to address future extended data retrieval needs, including cross-sectional data. For instance, HL7 Clinical Document Architecture (CDA) rel2, defined by HL7 Japan and widely used for health screenings, is mapped to a new archetype, enabling Sennen to receive data from health screening facilities [12].

Development of EHR Services

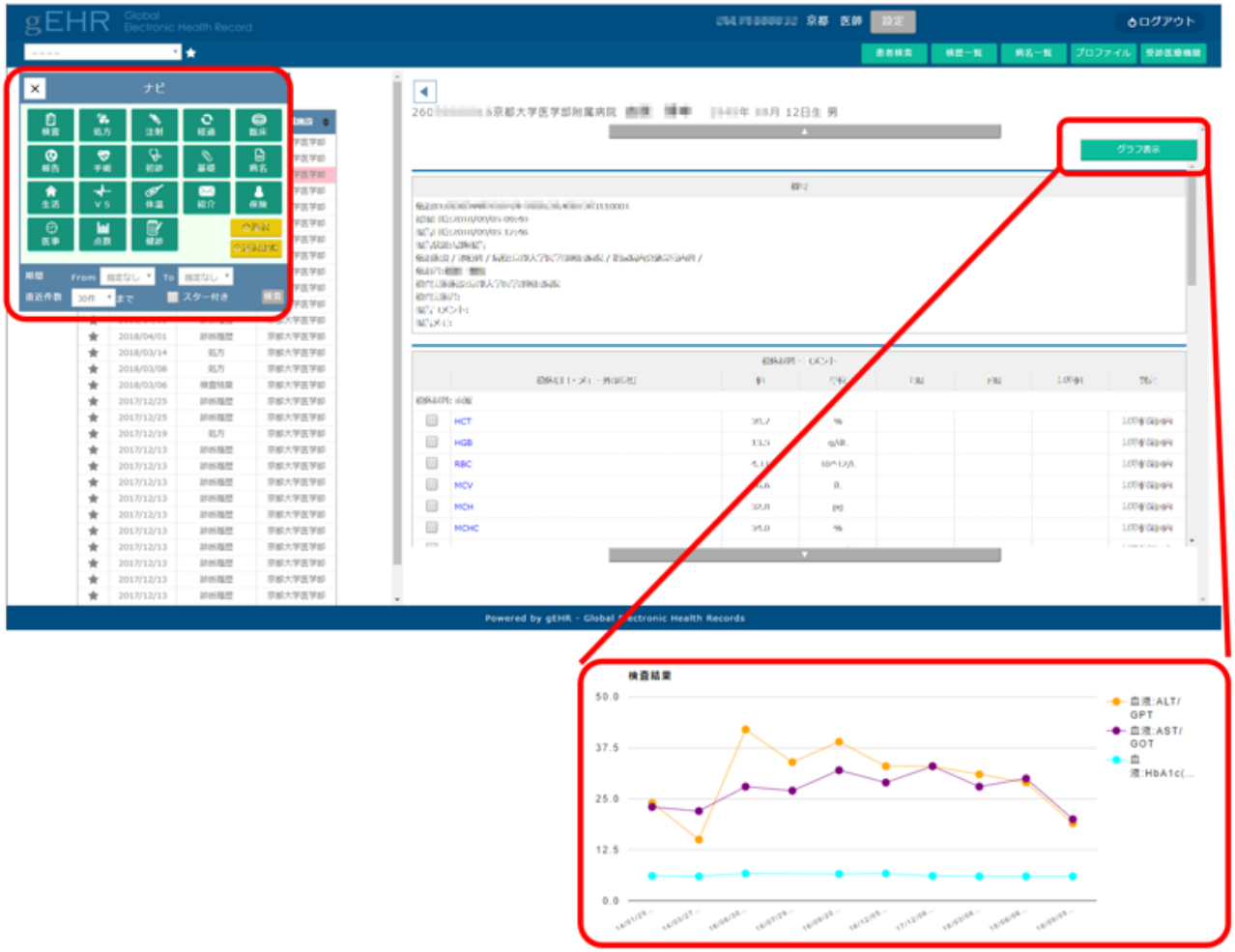
Sennen defines 4 service categories for medical institutions, patients, and others. The first is EMR outcome data backup; the second is information sharing among medical facilities and with patients to promote joint care; the third is value added feedback, such as clinical risk prediction; and the fourth is the secondary use of anonymized and identifiable medical records for research and industry.

The earthquakes that occurred in Japan in 2011 also spurred medical institutions to take countermeasures against catastrophic disasters. This motivated hospitals to participate in Sennen.

Web applications and smartphone apps are implemented for information sharing. Figure 4 shows web application screenshots. Here, laboratory test values are not yet standardized across facilities due to difficulties with item mapping.

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Figure 4. Web interface of the electronic health record (EHR) provided by the Sennen Karte Project. All patient information displayed in the screenshots is entirely synthetic and was created solely for demonstration purposes.



Sennen provides a backup data viewer and management information, such as portfolios and benchmarks, for free to medical institutions that participate in secondary use.

Specifically, Sennen provides statistics from the diagnosis procedure combination (DPC) report data, which are similar to the diagnosis-related group (DRG) dataset. DPC data provide a summary of hospital performance that must be submitted to the Ministry of Health and Welfare. Sennen creates statistics to inform hospital performance rankings using clinical, receipt, and DPC data. Additionally, case finding is a significant topic for which Sennen provides statistics on patients with specific diseases.

Development of a Secondary Use Database

The secondary use database has a structure that duplicates the structure of the EHR database. It stores selected datasets from the EHR based on the terms of the secondary use contract. Also, anonymized databases are separately prepared. A secondary user who provides specifications of the statistical requirements is provided with an exported dataset created by the authorized company staff.

The new act allows patient matching only by the authorized company, and the matching is performed using 4 items: name, sex, date of birth, and address. Japanese surnames are extremely diverse, so mismatches rarely occur. Because the purpose of the data use is secondary, mismatches affecting statistical results have not been observed; therefore, this issue has not been discussed much at this stage. Further quality improvement will be needed.

Ethical Considerations

This article reports on the design and aggregate operational statistics of the Sennen Karte infrastructure. Because no individuals were recruited and no individual-level data were analyzed, this report falls outside the scope of the Japanese Ethical Guidelines for Medical and Biological Research Involving Human Subjects (Part 3, Section 1, C(ii)) [13], and ethics committee review was not sought. Consequently, informed consent, human subject privacy protections, and participant compensation were not applicable. Furthermore, the manuscript contains no images from which individual patients or users can be identified; the patient record displayed in Figure 4 consists entirely of synthetic demonstration data.

Results

Overview

Implementing an EHR system across a region entails significant human and financial costs, including those associated with network infrastructure, customization, user support, and asset

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management. Cost reduction is essential for sustainability. To address this, a large-scale EHR center has been implemented on a cloud server. During the first FY in 2015, Sennen developed an EHR infrastructure using Hadoop (Apache Software Foundation), a scalable framework for distributed data storage. Eleven hospitals were connected by installing an MML extraction function in an EMR and an uploader that redirected connections to the EHR center. A nonprofit organization, the Japan Medical Network Association (JMNA), operated the EHR system.

Table 1 presents the differences in data extraction capabilities across EMR vendors. The capabilities are listed for each medical document type and EMR vendor. Document types are defined in MML. Structured data are extracted as text data based on MML. Some documents cannot be extracted as text data but only as binary data, such as JPG and PDF files. Although the same EMR vendor's product may be used in different hospitals, customization of the EMR can result in different extraction performance across hospitals. In that case, the list indicated that all hospitals using the same EMR vendor support data extraction; supported capabilities are marked as checked. The results suggest that specific reports, such as the operative record, are challenging to extract because the data are managed by a system separate from the EMR in the clinical process. Additionally, conventional systems that provide reports in a human-readable format, such as a PDF file, hinder text data extraction. Information on data extraction and data limitations is provided in Multimedia Appendix 2 [14].

Table 1. Capabilities of data extraction of document types across electronic medical record (EMR) vendors (A to G)[a].

Number	Document types	EMR vender						
		A	B	C	D	E	F	G
1	Patient information	✓	✓	✓	✓	✓	✓	✓
2	Lifestyle information	✓	✓		✓		✓	✓
3	Basic clinical information	✓	✓		✓	✓	✓	✓
4	Diagnosis history	✓	✓	✓	✓	✓	✓	✓
5	Progress notes	✓	✓		✓[b]	✓	✓	✓
6	Health insurance	✓	✓	✓	✓	✓	✓	✓
7	Clinical summary	✓		✓	✓[b]		✓	✓[b]
8	Laboratory test result	✓	✓	✓	✓	✓	✓	✓
9	Injection information	✓	✓	✓	✓	✓	✓	✓
10	Prescription	✓	✓	✓	✓	✓	✓	✓
11	Vital information	✓	✓	✓	✓	✓	✓	✓
12	Temperature chart	✓	✓		✓	✓	✓	
13	Dialysis information	✓	✓		✓	✓	✓	
14	Referral letter	✓		✓	✓[b]	✓	✓	✓[b]
15	Report information	✓		✓	✓[b]		✓[b]	
16	Operative record	✓	✓	✓	✓[b]	✓	✓[b]	
17	Initial visit information	✓	✓		✓[b]	✓	✓	

[a]All check marks represent the availability of data extraction (structured or binary). Empty cells indicate that the extraction is not possible.

[b]These check marks indicate that only binary data (eg, JPEGs and PDFs) can be extracted, not structured text data.

In FY 2026, Sennen EHR has been collecting EMR data daily from 96 hospitals, including several university hospitals, out of the 119 contracted hospitals. The number of unique patients was approximately 12.1 million as of April 2026. Here, the term "unique" indicates that records are strictly deduplicated by patient ID within each individual facility; cross-facility record linkage is not performed because the geographic dispersion of participating hospitals makes patient overlap extremely rare (refer to Multimedia Appendix 2 [14] for details). Among these 12.1 million patients, 77 of the 119 hospitals have agreed to secondary use. This subset covered 3.71 million unique patients as of August 2026. For these 3.71 million patients, the secondary use contract permits the use of their EHR data in parallel with their DPC data. Statistics for the EHR dataset are provided in Multimedia Appendix 3. FY 2015 to FY 2018 constituted the research stage. After that, this project transitioned from research to commercialization in parallel with the establishment of new legislation. The Next-Generation Medical Infrastructure Act, which imposes strict conditions under the opt-out regulation, allows authorized companies to collect identifiable data without patient consent. A company holding national authorization is permitted to receive identifiable data from various stakeholders, including hospitals for health care purposes. Furthermore, companies may provide anonymized medical data to

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stakeholders for a fee. The fee is expected to sustain EHR services. There were 3 authorized companies in FY 2025. One of these companies, Life Data Initiative, was established by Sennen and was the first to be approved in FY 2019 [15].

Use of Identifiable Data for Advanced Clinical Services

The objective of constructing an EHR is to provide diagnostic support based on collected data. In this project, the primary use is defined as use by medical institutions and patients. Advanced medical service use is defined as the use of services for diagnosis, support, and management. For instance, an improved prognosis resulting from an AI application with EHR data for the early detection of acute renal insufficiency has been reported [16,17]. Sennen is also conducting a feasibility study for this purpose.

Secondary Use

After 11 years of data collection, Sennen's stored data are expanding the range of research topics that can be addressed. Notably, both structured data, such as laboratory test results and prescriptions, and unstructured data, including discharge summaries and reports, are collected. Accordingly, research aimed at developing AI-based methods for data analysis and requiring massive amounts of text data can be addressed. The anonymized data may be supplied to secondary users, such as researchers and companies, for activities, including clinical studies and postmarketing surveys. The use cases are listed on the Life Data Initiative website, as the authorized company is required to disclose the cases of secondary use to the public [15].

Discussion

Principal Findings

The project established Japan's largest database of its kind, initially relying on the voluntary participation of medical institutions. The secondary use company has been successfully authorized, securing financial support for the integrated care EHR under the new act. This study developed a medical information circulation model that provides data and an economic ecosystem for a sustainable EHR model without subsidies. However, from a financial perspective, the currently insufficient data volume prevents the sustainability of EHR systems through secondary use fees. Information on scalability and economic sustainability is provided in Multimedia Appendix 4 [18,19]. It is estimated that Sennen requires connections with more than 300 hospitals to achieve business profitability from secondary use. In practice, however, the current number of connected hospitals has nearly reached the limit of voluntary institutional participation, indicating that participation will need to be enforced through public governance. Future sustainability requires robust policy support and institutional incentives to ensure long-term participation.

A key factor in extending the Sennen network is the network effect, which depends on the scale and quality of the data. Detailed and valuable data exist in subsystems such as pathology, radiation, and laboratory test systems. Furthermore, EMR data are formatted according to various standards, including HL7, MML, and industry- and domain-specific original CSV standards. For cost-effectiveness, Sennen integrates these data through data mapping and server-side processing, rather than requesting that EMR vendors provide them in the required format. Even if part of the remaining data are retrieved from the EMR, they are generally in an unstructured or binary format, such as a PDF or JPEG file. Such unstructured data, which are human-readable and intended for clinical use, are unsuitable for secondary use with machine learning. Current generative AI could extend the range of data use to unstructured data. Yet, fundamentally, future EMRs must include a redesigned data output scheme from a secondary use perspective, based on industry-level consensus, such as reliance on OpenEHR.

The secondary use company manages the selection of the hospital that meets the dataset's requirements, according to the secondary user's request. Ongoing projects show the number of hospitals that are available for each specific project. The number never reaches the total number of Sennen-participating facilities and is typically about half that number, due to specialty-specific extraction gaps. Further extensions of data sources are continually required.

Conclusions

The authors proposed an integrated care EHR with a legal framework, thereby supporting the practical sustainability of the EHR. This paper identified significant issues in an EHR project in Japan under a new act that allows authorized companies to provide large-scale medical records for secondary use on a fee basis. Having advocated for an EHR for the last 11 years, the authors developed a national-level EHR. Hospital EMR data were extracted from more than 100 hospitals, using the MML standard. An authorized company offers the stored data for secondary use under the new act. The authors established a framework for sustaining the integrated care EHR through secondary use.

Acknowledgments

During the preparation of this work, the authors used Gemini (version 3.1 Pro; Alphabet Inc) to polish the language and improve the readability of the English text. After using this tool, the authors reviewed and edited the content as needed and take full responsibility for the final content of the publication.

Funding

This work was supported by the project titled "ICT Infrastructure Establishment for Clinical and Medical Research; Sustainable Massive Health and Clinical Data Repository for Secondary Use," funded by the Japan Agency for Medical Research and Development (AMED; grants 15lk1010001h0001, 16lk1010001h0002, and 17lk1010001h0003).

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Conflicts of Interest

The author HY is a former president of Life Data Initiative Inc (LDI), the authorized company mentioned in this study that handles the secondary use of medical data. HY and KA served as presidents, and NK served as vice president of the Japan Medical Network Association (JMNA), a now-dissolved nonprofit organization that originally operated the EHR system described in this paper. SK declares no relevant financial or nonfinancial conflicts of interest.

Multimedia Appendix 1

Governance and privacy protection in secondary use.
[PDF File (Adobe PDF File), 89 KB-Multimedia Appendix 1]

Multimedia Appendix 2

Data extraction and data limitations.
[PDF File (Adobe PDF File), 77 KB-Multimedia Appendix 2]

Multimedia Appendix 3

Statistics for the electronic health record dataset.
[PDF File (Adobe PDF File), 438 KB-Multimedia Appendix 3]

Multimedia Appendix 4

Sustainability in scalability and economy.
[PDF File (Adobe PDF File), 73 KB-Multimedia Appendix 4]

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Abbreviations

APPI: Act on the Protection of Personal Information
CDA: Clinical Document Architecture
DPC: diagnosis procedure combination
DRG: diagnosis-related group
EHR: electronic health record
EMR: electronic medical record
ETL: extract, transform, and load
FY: fiscal year
HL7: Health Level 7
JMNA: Japan Medical Network Association
MML: medical markup language

Edited by A Benis; submitted 02.Oct.2025; peer-reviewed by Y Chu, I Cerovecki; comments to author 17.Feb.2026; revised version received 07.Oct.2026; accepted 07.Oct.2026; published 11.Nov.2026

Please cite as:
Kume N, Kobayashi S, Araki K, Yoshihara H
The Sennen Karte Project for a Sustainable Nationwide Integrated Care Electronic Health Record in Japan: Design and Implementation Study
JMIR Med Inform 2026;14:e85158
URL: https://medinform.jmir.org/2026/1/e85158
doi: 10.2196/85158
PMID:

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