Patient-Centric Approach to Personalized Electronic Medical Records via QR code in Japan

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Abstract

Background: Government policies in the U.S. and E.U. promote standardization and value creation in the use of FAIR (Findability, Accessibility, Interoperability and Reusability) data.

Objective: In this global trend, the interoperable interface called Sync for Science-J (S4S-J) for linking Electronic Medical Record (EMR) and Personal Health Record (PHR) was launched on the Basic Policy for Economic and Fiscal Management and Reform in Japan.

Methods: S4S-J controls data distribution consisting of EMR and Patient-Generated Health Data (PGHD) and converts this information into QR codes that can be scanned by mobile applications. This system facilitates data sharing based on personal information beliefs and unlocks siloed IoT systems with Privacy Preference Manager (PPM). In line with Japanese information handling practices, the development of a mobile-cloud network will lower barriers to entry and enable accelerated data sharing. To ensure cross-compatibility and compliance with future international data standardization, S4S-J conforms to the HL7-FHIR standard and uses the international standardized LOINC to redefine medical terms used in different terminology standards in different medical fields. It is developed as an applied standard in the medical information intended for industry, healthcare services and research through secondary use of data.

Results: A multicenter collaborative study was initiated to investigate the effectiveness of this system as a registry clinical trial and a multicenter randomized controlled trial, the EMBRACE study of the mobile health (mHealth) application M?Link for hyperglycemic disorders in pregnancy, which implements EMR-PHR interoperable interface S4S-J.

Conclusions: The patient-centric data flow of the S4S-J in Japan is expected to guarantee the right to data portability, which promotes the maximum benefit of use by patients themselves, which in turn contributes to the promotion of open science. Clinical Trial: 1) Efficacy of MLink based telemedicine on GDM in a randomized controlled trial (EMBRACE), jRCT1032230258, https://jrct.niph.go.jp/en-latest-detail/jRCT1032230258

2) Study on Registry of Pregnancy with Abnormal Glucose Metabolism, jRCT1030220452, https://jrct.niph.go.jp/en-latest-

detail/jRCT1030220452

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Personal Health Records, Patient-Accessible Electronic Health Records, Patient Portals

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The patient-centric data flow of the S4S-J in Japan is expected to guarantee the right to data portability, which promotes the maximum benefit of use by patients themselves, which in turn contributes to the promotion of open science.

Keywords

Sync for Science-J (S4S-J); Electric Medical Record (EMR); Personal Health Record (PHR); Privacy Preference Manager (PPM); Patient Generated Health Data (PGHD); HL7-FHIR; LOINC; mobile health (mHealth); open science

Introduction

The standardized medical information network in Europe and the U.S. not only provides high-quality medical care in individual practice, but also serves as a development research infrastructure enables effective epidemiological research. The Data Governance Act (DGA), a new EC legal system, will come into effect in September 2023, promoting standardization by the EC as well as the creation of value in the use of findability, accessibility, interoperability, and reusability (FAIR) data in anticipation of improved computational technology[1]. The legal system is being developed to promote data-driven innovation as well as to develop low-cost medical technology. In response to this global trend, the "Basic Policies for Economic and Fiscal Management and Reform 2022,"[2] approved by Japan Cabinet Office on June 7, 2022, set forth a policy of linking health and medical data obtained within and outside medical institutions. In line with this policy, this research group was commissioned by the Japan Agency for Research and Development (AMED) to develop a mHealth-app "M♡Link". It designed and implemented the "Sync for Science-J (S4S-J)" interface to realize electronic medical record (EMR)-patient health record (PHR) interoperability using QR code®. In this research project, we implemented this system to construct a mobile-cloud network designed for Japan's medical situation that enables information sharing centered on individuals, and enables data sharing based on the personal free decision with Privacy Preference Manager (PPM) for siloed IoT systems.

Recently, the widespread use of Internet technologies and mHealth tools for public health and medical purposes has changed human life.[3], [4] Short message service text messages sent from cell phones using reminder systems had a positive effect on medication adherence among patients with chronic diseases and those in need of medical services[5], [6]. mHealth apps have been widely applied in the medical management of cancer patients[7], diabetes[8],[9] , cardiovascular disease[10],[11], and other chronic conditions[12] . Obstetric and gynecologic practices are also increasingly equipped with telemedicine to improve patient access to healthcare services. Previous studies have demonstrated the effectiveness of telemedicine services in obstetrics and gynecology, including improved health behaviors[13], [14], weight management[15], mental health problems [16], and postpartum depression [17] in pregnant women. The effects of telemedicine as another applied medical infrastructure have also been reported to be associated with improved health outcomes for high-risk obstetric patients, including hypertensive disorders, diabetes, fetal abnormalities, and pregnancy in underserved areas. [18] The patient-centric approach through the S4S-J in Japan is expected to guarantee the right to data portability, which is a patient right, and at the same time promote the maximum benefit of the utilization by the patients themselves. We have started clinical studies of the mHealth application M♡Link for hyperglycemic disorders in pregnancy, which implements this EMR-PHR interoperable interface S4S-J.

Method

Stratified health data in Japan

In this study, we have developed an M♡Link employing S4S-J and verified the effectiveness of the system. S4S-J is an interface for linking the warehouse data consisting of EMR and Patient-Generated Health Data (PGHD) and converting it into a QR (quick response) code that can be scanned into a mobile-application. S4S-J complies with the Health Level 7 Fast Health care Interoperability Resources (HL7-FHIR) standard and unifies medical language with global standardized terminology using Logical Observation Identifiers Names and Codes (LOINC). Developed as an applied standard in the medical information business, S4S-J is intended for medical applications in cooperation with Mynaportal, Japan's Public Individual Number Card Service, and for development research and healthcare services Leveraging clinical information through secondary use of data. Japanese medical information is stratified as follows. (Fig.1）Tier 3 provides public information on taxation, public medical insurance, and public health checkup systems through the Individual Number Card Service; Tier 2 provides FAIR data based on EMR-integrated PGHD with an individual consent for the enhancement of research; and Tier 1 provides Semantic metadata empowers algorithm for precision medicine. Meanwhile, S4S-J controls data distribution mainly for Tier 1 through Tier 2, making it facilitates the provision of purpose-built medical services to users, and at the same time promoting the industrial secondary use of data for drug discovery research. S4S-J and structured metadata will be used to provide precise telemedicine to pregnant women with hyperglycemic disorders in pregnancy using the mHealth-app M♡Link, and a clinical registry study will be conducted to evaluate the usefulness of the system.

EMR-PHR medical information interoperable interface S4S-J

S4S-J is an interface that has three main functions tailored to the actual situation of medical information sharing in Japan. The system information structure and design of S4S-J are shown in the following figure. (Fig. 2) The simple QR code system was specifically designed to interoperate the EMR among major obstetric medical record systems with the S4S-J cloud data warehouse. It covers the requirements of healthcare providers and health services that make primary-use of medical information, and third parties for secondary-use in research and development: (a) medical information sharing within QR coded EMR (b) conversion to global standard terminology, and (c) Privacy Data provision based on the consent of using personal information by Privacy Preference Manager (PPM). S4S-J exports the EMR of various electronic medical record vendors in the form of QR codes by converting them into JSON bundles in compliance with the HL7-FHIR and SMART health cards standards. (Fig.3) For enhanced security of personal information and to prevent accidental exposure, S4S-J implements Smart Health Cards compliant with RFC7515 (JWS) in a format enhanced with encryption based on RFC7516 (JWE) to prevent QR codes from being read by anyone other than the person in the QR code. The QR code, which is the key for personal identification, is output at the same time, and can be scanned via mobile-app to read the EMR when the personal code is authenticated and the verification is confirmed. (Fig.5, 6) This eliminates unintended and dishonest access. JLAC, a clinical laboratory code established by the Japanese Society for Laboratory Medicine, and medical information and others are converted to the international standard terminology LOINC. The user can choose to share the data to healthcare providers, government health agencies, private services, and research and development organizations according to preferences of patient's information use and contract various services. In this process, we have designed an easy-to-use interface to obtain informed consent electronically, using videos to provide clear explanations and aid in understanding. Consent can be withheld completely or temporarily for privacy with the ability for dynamic consent to adjust to changes in patient intent over time. (Fig. 7, 8)

System design and information framework for mHealth solution by S4S-J

This mobile app was developed for deployment on iOS and Android. In addition to PGHD such as blood glucose levels, insulin dosage units, nutrient and caloric intake, and patient reported outcomes (PRO) displayed over time as a data library, the EMR includes ultrasound fetal predicted weight, Maternal weight, medical history, family history, and pregnancy medical information are mapped in HL7-FHIR format and converted to QR codes. (Fig.5) The information is all captured by the mobile device and incorporated into the cloud information. From this sequence of operations, medical information for online medical care can now be easily registered from the mobile application by simply scanning the QR codes. (Fig.6) If the user grants permission to the primary-user, the healthcare provider, to use Participants' personal information, the medical information is projected via the user's smartphone application to the web-app of the healthcare providers. This enables remote medical care by displaying medical information on the web-app with a higher density of information than face-to-face medical care. This cloud-based operational design allowed for rapid deployment of a new mHealth system without requiring adjustments to the existing maternity EMR vendor's web-app architecture. All usage data, including symptoms, nutrient intake, and medication-related behaviors are stored in a Cloud Data Warehouse. Users can not only self-administer insulin dosing, but also share actual medication usage, nutrient and caloric intake, and detailed fetal medical data with their physicians via this standard aggregator device. This allows for smooth access to online medical care and other medical services.

Result

Implementation of the pilot study

Since 2022, a multicenter collaborative registry study (jRCT: CRB1030220452) and since 2023, a multicenter randomized controlled trial, the EMBRACE study (jRCT: CRB1032230258), have been conducted by establishing a mobile-cloud network between three obstetrics and gynecology hospitals and a core university hospital. The participants are women with hyperglycemic disorders in pregnancy, and we have established a treatment style in which the pregnant women receive concurrent medical outpatient treatment via an online medical service while attending obstetrics and gynecology departments. Using this app, online medical care in the form of mHealth, real-time blood glucose levels, nutrient and calorie intake, and medical information from the EMR-derived OB/GYN, such as estimated fetal and maternal weight, are displayed for diagnosis and decision making by healthcare providers, as well as medical instructions for insulin dose adjustment and nutrient intake. Text-style messages were exposed via the app 1-2 times per week, sometimes as needed. In order to provide in-depth counseling, and re-tension around the use of the app to help prevent high app attrition rates as counseling to improve pregnant women's motivation for treatment and adherence to app use. The data disclosed and provided by patients as PGHD and number of steps taken, as well as QR code-generated EMR, and the hierarchical metadata could be generated.

The first feature is that the participants were pregnant women, a homogeneous target population, which tends to minimize variation in the literacy of Information and Communication Technology (ICT) and makes the study design less susceptible to individual differences in app use skills. Even in the differences between genders, it has been shown in previous studies examining, gender differences in ICT literacy that this is a significant difference in favor of women scoring higher on cognitive measures of computer use frequency, perceived ICT skills, and attitudes toward computers.[19] Compliance was also high, despite limited understanding of the Gestational diabetes mellitus (GDM) and dietary requirements and why changes were necessary. [20] Moreover, almost without exception, patients negatively recalled the process of measuring blood glucose multiple times a day and taking medications during pregnancy, but recognized and showed resilience in making this work for the baby's health. Women reported and healthcare providers could recognize that maternal health increases motivation for lifestyle changes during pregnancy that directly affect the baby.[21] As in previous reports, pregnant women actively participated in telemedicine using the app, and then received mHealth on a patient-centric data flow infrastructure.

Discussion

In Japan, standardization of data distribution was adopted in 2022 as a standard by the Ministry of Health, Labor and Welfare, and is integrated in the HL7-FHIR standard, aiming to spread standardized electronic medical information and exchange systems. As a pilot operation, three documents and six pieces of information are provided: Medical information are including as Name of injury or disease, Allergy information, Information on infectious diseases, Information on contraindications to drugs, Examination information (tests useful in emergency situations, tests related to lifestyle-related diseases) and Prescription information. For example, documentary information includes the following forms: medical information form, discharge summary with key images, and health examination results report. However, as for the interoperable common API in Japan defined as likely Sync for Science (S4S) in the U.S. has not been officially released by bureau or enterprise organizations, then each tier of stored data isn’t not enough to utilize it for research in academia and industry.

S4S-J is endorsed by the Japan Agency for Research and Development (AMED) and distributed by the Life Course Design Consortium, a multi-stakeholder consortium consisting of telecom, pharmaceutical companies, medical devices, academic organizations, and academia. This common interface that provides interoperability for EMR-PHR is compliant with HL7-FHIR and SMART Health Cards as standardization and enables the distribution of EMR and PGHD in a patient centered manner. Because of avoiding subordinated to proprietary systems or applications defined by exclusive standards, S4S-J is characterized by converting EMRs to QR Codes for patient centered mobile circulation, which taking into account the tendency of notions that medical information stakeholders intend in Japan. Healthcare providers in Japan are hesitant to actively connect medical information to the IoT, preferring isolated networks due to concerns about cybersecurity and information disclosure.[22] Mobile and wearable devices are increasingly being developed for healthcare purposes. mHealth data includes personal health data collected from sensors and mobile applications. mHealth data and metadata standardization improves the ease of data aggregation and location accuracy (semantic interoperability) and reduce the cost of using this data for biomedical discovery, health improvement, and disease management.[23] Standardization of data along the entire PGHD integration pipeline is critical to ensure that it is device-independent, modular, flexible, versatile, and therefore low-cost to integrate into clinical workflows.[24] For healthcare provider organizations, standardization will make it simpler to integrate data into workflows and write easily to EMRs for billing purposes. EMRs in the U.S. are currently required by law to support HL7 FHIR data and protocol standards.[25] As a schema to promote R&D, Sync for Science (S4S) has collaborated with Harvard Medical School, various EMR vendors, and the US federal government (National Institutes of Health and the Office of the National Coordinator for Health Information Technology (ONC)). S4S is a technology that allows individuals to donate electronic clinical and health data to biomedical research studies, which provides the ability for participants to share their electronic health record-based clinical health data with selected research programs via an open, read-only API. The S4S API is based on the Health Level 7 (HL7) Fast Healthcare Interoperability Resources (FHIR) and OAuth 2.0 standards. The S4S API is being developed to allow applications to use OAuth 2.0 to provide read-only access to all or a portion of electronic personal health information about a patient available through the Healthcare Provider Organization (HPO)-Patient Portal via the patient's authentication credentials.[26] PGHD aggregation services that provide standards-based PGHD integration have a critical role to play in the transition from today's siloed and friction-prone data ecosystem to a frictionless, interoperable system appropriate for patients. Healthcare leaders responsible for telemonitoring and other PGHD programs should explore and adopt a pipeline-based approach to standardize the integration of PGHD into clinical care.[24] Likewise, in Japan, data mapping with HL7 -FHIR enables the integration of EMR-integrated PGHD, and data portability using QR codes provides the option of building a data flow that is adapted to Japanese usability. Moreover, the value sets are standardized using LOINC terminology. Meanwhile, since digital distribution in S4S-J is a patient- centric data flow, the amount of data distribution is limited by patient refusal to provide data and the frequency of data provision. Decline in adherence leads to loss of data provision opportunities and poor data quality. This means that healthcare providers need to encourage users to provide accurate data and record high-quality data in a text-based manner, and to control the quality of data flow through frequent communication. Agreement and trust in data handling between patients and healthcare providers will enable the generation of well-structured, highly useful EMR-integrated PGHD and enable healthcare providers to provide precise health services based on a patient- centric data flow system. In that context, a key factor is for healthcare service providers to offer services that are attractive enough for patients to willingly provide their own data, and to promote services that are mutually beneficial to both patients and healthcare providers in order to strengthen patient-centric data provision.

In considering application differences arising from gender differences in this study, young women reported greater gains in perceptions of empowerment with computer learning combined with ICT than men in a study that an ICT literacy test was administered to Norwegian students. [27] According to the results of a multi-group confirmatory factor analysis, the test had sufficient measurement invariance across genders to allow the researchers to make meaningful comparisons. The comparison revealed that girls were more ICT literate than boys. The impact of gender differences in the use of ICT applications (annotated multimedia electronic readers (AMEs)) was also tested in pre- and post-classroom learning. The results show that women use learning tools more frequently than men. [28] These also suggest that the use of ICT applications for pregnant women may be a good indication and an effective treatment target.

As an intervention effect of the one-directional messages through a mobile phone, it significantly improved physical activity, healthy eating, and medication adherence in chronic heart disease patients. In addition, more people may also control cardiovascular disease risk factors by following the recommendations via messages. The intervention group was 62% more likely to control all five risk factors according to recommendations.[29] Likewise in perinatal care, Text-4-Baby, another telemedicine service for pregnant women and its text message service was also associated with improvements in women's health behaviors and attitudes toward parenting.[30], [31] Thus, health outcome in telemedicine could prove to be non-inferior to traditional face-to-face care in the perinatal period. For example, the prenatal and newborn guidelines, education, and learning system of one of the largest telemedicine obstetric care programs providing telephone consultation services to pregnant women in the United States was as effective as traditional face-to-face services.[32], [33] In safety issue of telemedicine, programs involving synchronous videoconferencing were not associated with increased risk of health complications or medical adherence compared to traditional outreach programs.[30], [34] In an online obstetrics and gynecology consultation service in Japan, telemedicine services using multiple communication tools, such as chat messages and voice calls, have also been shown to be clinically safe.[34] The interim analysis of the registry using M♡Link suggests that it may improve postprandial blood glucose and improve target in range (data not shown), however, there are limitations due to the small number of cases and the retrospective nature of the study, and also suggests that further research is needed to evaluate the effect of telemedicine using EMR-integrated PGHD on the incidence of perinatal complications such as preterm birth or cesarean section. In the implementation of data distribution adapted to usability in each country, it is important to introduce a system that ensures data security and reliability according to habitual backgrounds in digitalization. Over the future, patient-centric approach will enable mHealth to effectively provide advanced healthcare services with EMR-integrated PGHD and metadata, both for the patients themselves and for healthcare providers and researchers.

Conclusions

QR code-based EMR- PGHD interoperable interface, S4S-J, was launched in medical field in Japan. S4S-J constructs a mobile-cloud network designed for Japan's medical situation that enables data sharing based on the personal decision with Privacy Preference Manager for siloed IoT systems. In accordance with Japanese information handling practices, the development of a mobile-cloud network through S4S-J is expected to lower barriers to entry and accelerate information sharing. To ensure cross-compatibility and compliance with future international data standardization, S4S-J complies with the HL7-FHIR standard and unifies medical language using globally standardized terminology via LOINC. The patient- centric data flow of the S4S-J in Japan is expected to guarantee the right to data portability and promote maximum benefit for patients themselves, which in turn will develop as an applied standard in healthcare services and contribute to open science through secondary use of data in Japan.

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Authors' Contributions

YI and TO contributed to conceptualization and study ideas. YI, TO, MF, SN, AY, SN and MH contributed technical development of systems and creation of mobile-app. YI, TO, SY, RN, WM, YO, SM, YI, YM, RO, JA, and YT contributed to data collection. KT and YY contributed ethical study design and statistical analysis. YI is the principal investigator and wrote the first draft of the manuscript.

Conflicts of Interest

The study was supported by Life Course Design, a general incorporated association, which provided the database free of charge.

Abbreviations

API: Application Programming Interface
DGA: Data Governance Act
EC: European Committee
EMR: Electric Medical Record
FAIR: Findability, Accessibility, Interoperability, and Reusability
GDM: Gestational diabetes mellitus
HL7-FHIR: Health Level 7 Fast Healthcare Interoperability Resources
HPO: Healthcare Provider Organization
ICT: Information and Communication Technology
JLAC: Japan Laboratory Analysis Code
JSON: JavaScript Object Notation
LOINC: Logical Observation Identifiers Names and Codes
mHealth: Mobile health
OB/GYN: Obstetrician and gynecologist
PGHD: Patient-Generated Health Data
PHR: Personal Health Record
PPM: Privacy Preference Manager
PRO: Patient reported outcomes
QR codes: Quick Response codes
S4S: Sync for Science
S4S-J: Sync for Science-J
UI/UX: User interface / User experience

Figure legend

Fig.1 Stratified health data in Japan

The direction to the lower tier is information that has a strong impact on the public, and the direction to the upper tier is information with high individual benefit. Tier 3: Information on medical insurance, health administration, and taxation, based on Mynaportal, the government's individual number in Japan. Tier 2: Data which meet principles of findability, accessibility, interoperability, and reusability (FAIR) based on electric medical records (EMR) and integrated patient-generated health data (PGHD) with a consent for promoting research and development in academia and the private sector through compliance with global standards. Tier 1: Semantic metadata to empower algorithm for computing a medical solution on mHealth and Telemedicine, which in turn, implement precision medicine. In Japan, standardization of data distribution was adopted in March 2022 as a standard by the Ministry of Health, Labor and Welfare, and is integrated in the HL7-FHIR standard, aiming to spread standardized electronic medical record information and exchange systems.

Fig.2 The information circulation on S4S-J interface

Electric Medical Records (EMR) standardized in the HL7-FHIR, SMART health cards and oneM2M aligned LOINC terminology is converted to a QR codes. The QR coded EMR is captured by the patient's mobile app and processed with Patient-Generated Health Data (PGHD) into a JSON bundle according to the Smart health cards standard to output structured EMR-integrated PGHD, which is stored in a cloud data warehouse. Healthcare providers (HPs) download the metadata and EMR-integrated PGHD via the cloud data warehouse and access highly detailed and rich clinical data to provide precise telemedicine. In the aspect of research promotion, data distribution with the consent of personal information use is available through S4S-J, and it is easy to analyze aggregated EMR-integrated PGHD as a resource for research and development.

Fig.3 FHIR bundle consists of EMR-integrated PGHD

EMR-integrated PGHD converting into JSON bundles in compliance with the HL7-FHIR and SMART health cards standards. The medical information contained in the payload portion of the Smart Health Cards, such as "hospital", "patient", "infectious disease test", etc., are described as an array in the "entry" field of the "Bundle" resource in HL7-FHIR. The entire data is bundled as a "Bundle" resource, and the resource type is "document" in according to the "Medical Information Form HL7FHIR Description Specification (Version 1)" (https://jpfhir.jp/fhir/eReferral/igv1/). The "Composition" resource at the beginning of the "entry" in the "Bundle" serves as the table of contents contained in the Bundle. Behind it, medical information expressed as resources are lined up. Medical and laboratory data such as "Blood Pressure" and "Blood Sugar" are represented as "Observation" resources.

Fig.4 UI/UX of web-app on mHealth system "M♡Link"

Displays for personal information permission: User interface for data sharing indicating the number of patients' consent obtained and HPs authorized to share their data.

Fig.5 S4S-J on features to facilitate compatibility of information via QR codes

Encryption key to identify the individuals (left): The QR Code is aligned with the Smart Health Cards (SHC) standard, which adopts HL7 FHIR as medical data and provides a signature framework to ensure the integrity of that medical data. SHC facilitates to Web-based signature format as JSON web signature; RFC 7515 as the means of the digital signature method. QR coded EMR-integrated PGHD (right): LOINC-converted EMR-integrated PGHD is generated in JSON on HL7-FHIR in which the volume of the data should be minimized. The JSON is compressed with Deflate and Base64 URL encoded into the payload.

Fig.6 Upload of the EMR-integrated PGHD to the cloud data warehouse via QR codes
QR codes captured by M♡Link-app: EMR-integrated PGHD is captured in the app through QR code style, displayed in the UI/UX, and stored in cloud data warehouse.

Fig.7 Displays to acquisition of dynamic e-consent
Explanatory movie for patients embedded in the mobile-app: The movie explains how the data will be used, what user could access the broad medical service and how the sharing data will contribute for the next research and drug discovery through the dynamic e-consent.

Fig.8 Set up data-sharing based on an individual's decision through dynamic e-consent
UI/UX for sharing data among medical area on the basis of mobile-cloud network (left): Checkboxes provide selectivity of HPs with which to share data. Dynamic e-Consent for secondary use of data (right): UI/UX facilitates the secondary use of data by providing the attributes of the data to be provided PGHD, medical history, clinical biochemical values, ultrasound values, and clinical physical values) and the attributes of the recipient, such as HPO, Government health agencies, academia, industry, and foreign organizations.

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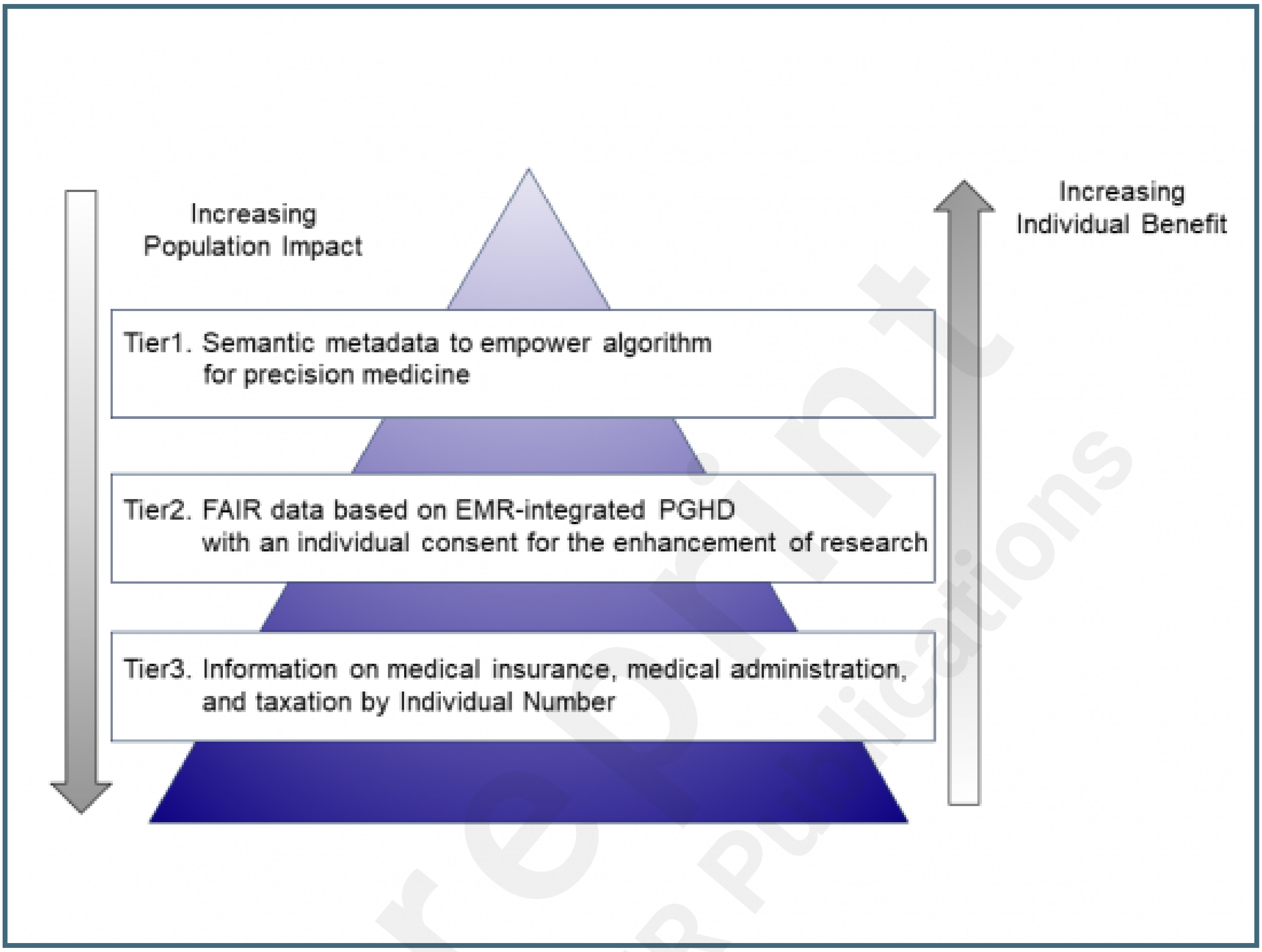
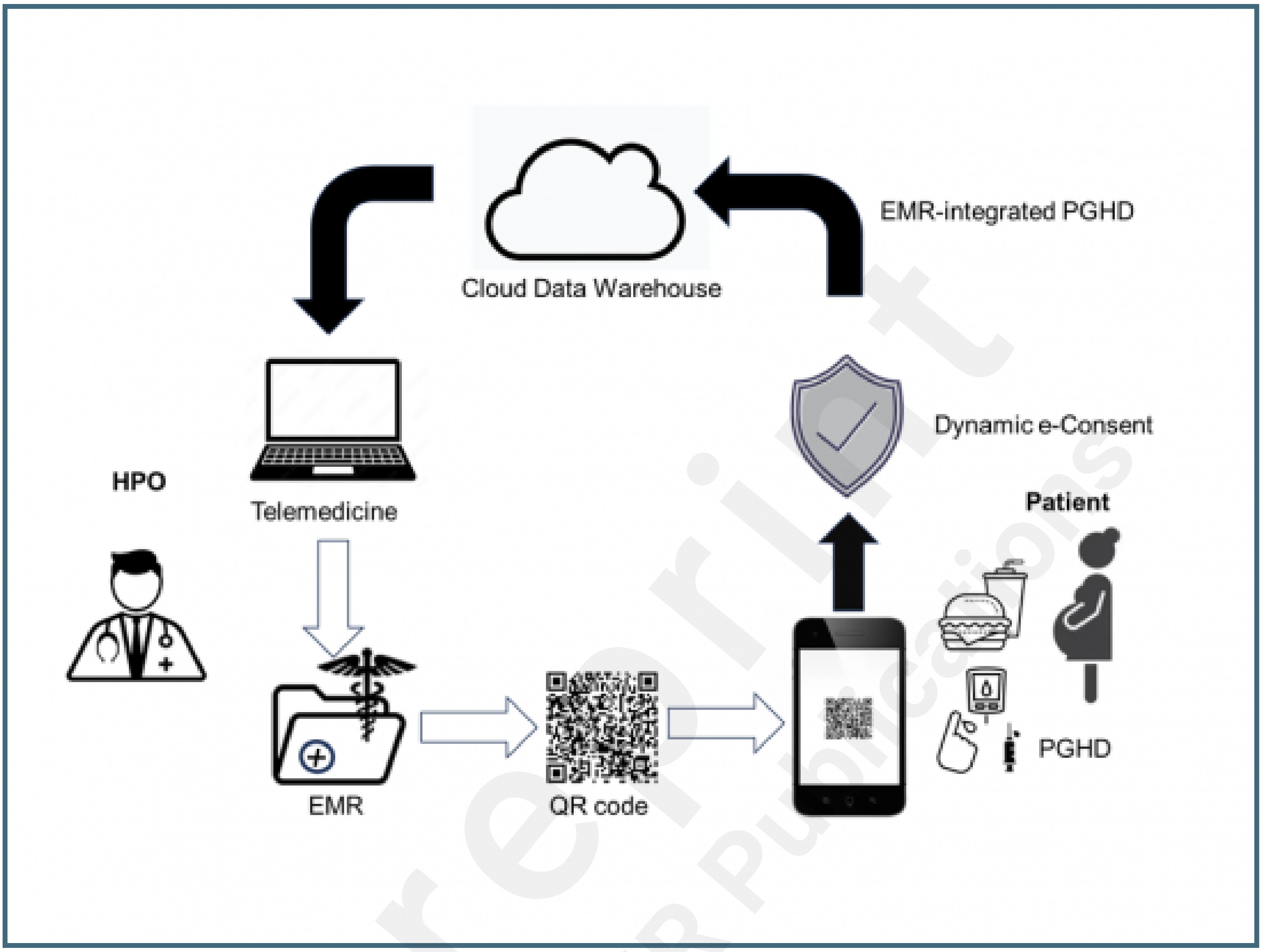
Supplementary Files

Figures

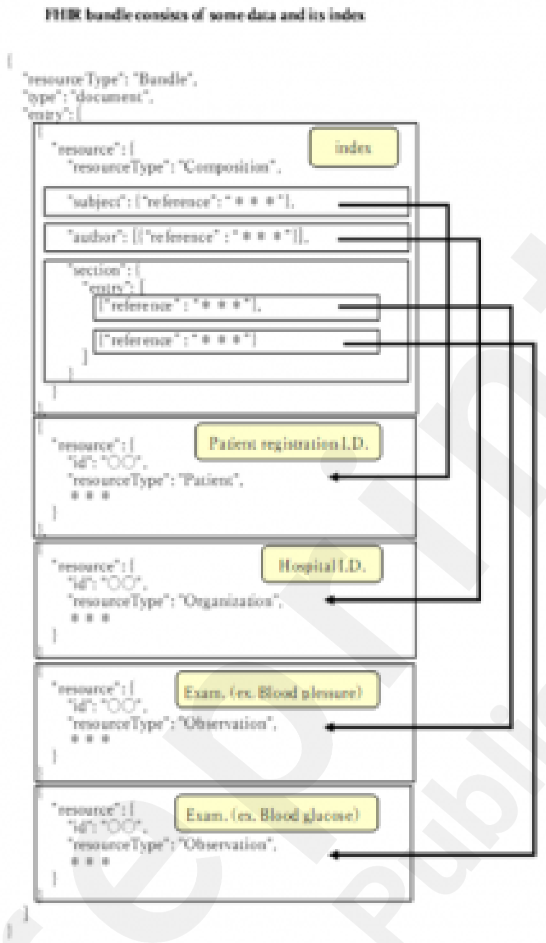
Stratified health data in Japan.



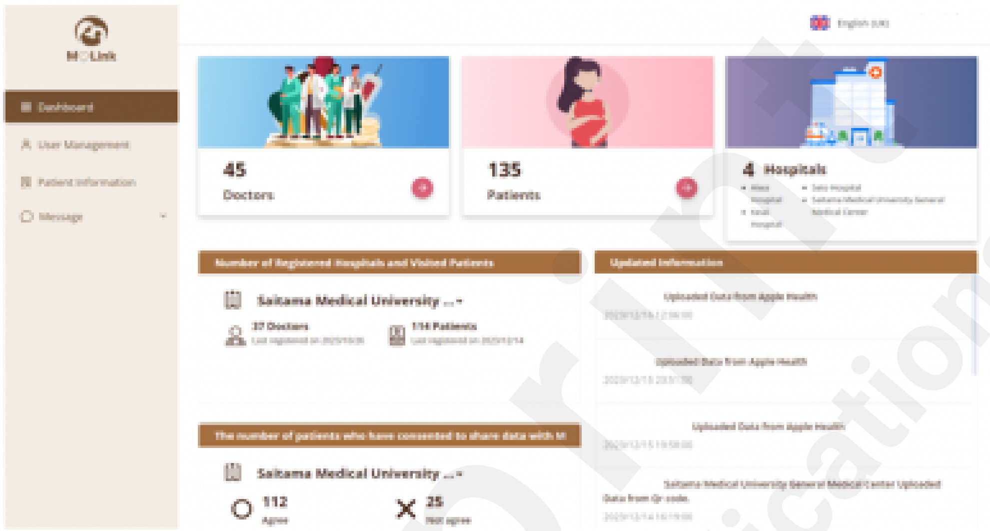
The information circulation on S4S-J interface.



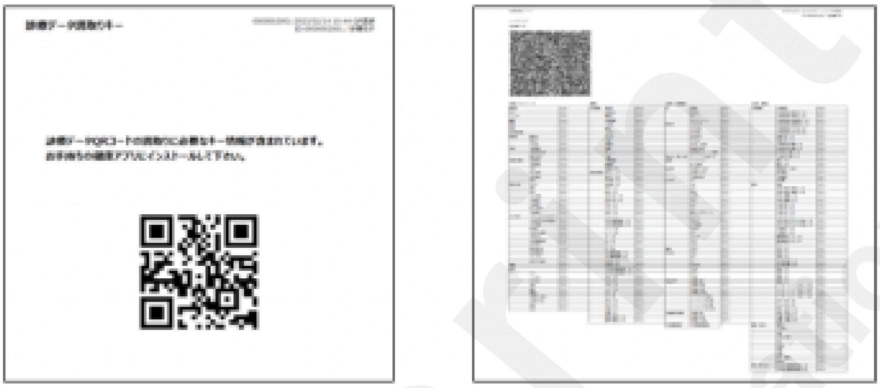
FHIR bundle consists of EMR-integrated PGHD.



UI/UX of web-app on mHealth system “M?Link”.

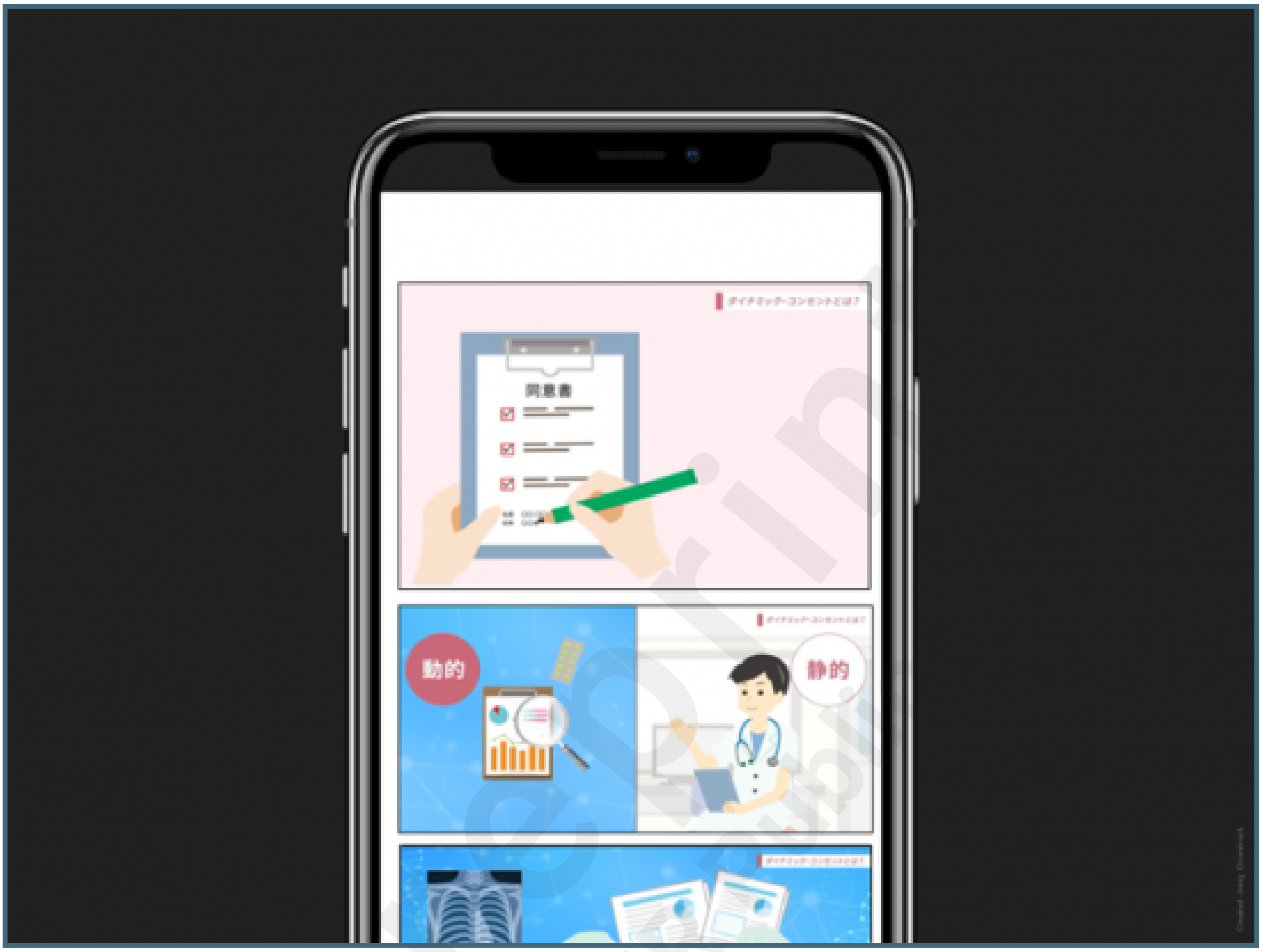


S4S-J on features to facilitate compatibility of information via QR codes.



Upload of the EMR-integrated PGHD to the cloud data warehouse via QR codes.

Displays to acquisition of dynamic e-consent.



Set up data-sharing based on an individual's decision through dynamic e-consent.