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THE BRAZILIAN INTERNATIONAL PATIENT SUMMARY INITIATIVE

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Author's Contribution:

BFL and IM conceived the overall structure of the paper with contributions to all its sections. JM was responsible for the Allergy and Adverse Reactions sections of Brazil IPS, as well as for adapting the FHIR Composition of IPS. She contributed to the Methods, Results and Discussion. AZ, MAM and RM were responsible for the Medication section of Brazil IPS. AZ and MAM also contributed to the Methods, Results and Discussion. KLACC contributed to the Results and Discussion section of the paper. BHM, ESS, GNN, PXS, JEBO, GGO and SDG contributed to the revision of the text as well as the results, discussion and conclusions. FM contributed to the discussion and made the editorial corrections and quality control of the text verifying its compliance with the author's recommendations. All authors reviewed the final version of the manuscript and approved the submission of this manuscript to this journal.

Abstract (250 words)

This paper describes the development of the Brazilian version of the International Patient Summary (IPS). The project is being developed by a joint technical team from Hospital Sirio-Libanês, São Paulo and the General Coordination of Innovation and Informatics in Health, Secretary of Information and Digital Health, Brazilian Ministry of Health. The five-phased approach used on the development of Brazil IPS starting with the identification of the local terminologies, their upload in a terminology server, and mapping to IPS ValueSets, the FHIR (Fast Healthcare Interoperability Resources) profiles customization and finally, the complete Brazil IPS Implementation Guide is described.

Introduction

The International Patient Summary (IPS) is the result of a coordinated and harmonized work between the main organizations producing standards in health informatics (OPPIS): the ISO European Committee on Health Informatics - CEN215, the ISO 215 Health Informatics, HL7 and SNOMED International [1,2]. IPS was published as an ISO standard in 2021 by the ISO 215 Committee as ISO 27269:2021 [3]. In June 2021, the G7 member countries signed the Oxford declaration, committing to adopt IPS as a standard for exchanging health information between countries [4]. The G7 initiative was extended to the G20 and the first IPS global deployment pilot focused on the COVID immunization block with the issuance of the international COVID-19 immunization certificate.

The IPS is an extract of an electronic health record that contains essential health information intended for use in unscheduled and cross-border care settings [1,2]. The IPS is made up of different main sections: Header – contains the patient's data, the health professional who generated the summary, the custodian organization of the information and the digital signature; Medication Summary – medications being used by the patient; Allergies and Intolerances – patient allergies and intolerances; List of Problems – clinical conditions of the patient; Immunizations – list of vaccines administered to the patient; Procedure History – list of relevant clinical/surgical procedures that the patient has undergone; Medical Devices – devices that the patient owns and Test Results – current patient test reports. Additional sections may also compose the IPS: vital signs, past history including obstetric and social history, functional status, care plan and advanced living directives [1,2]. The IPS is currently under development in several countries on different continents: New Zealand, Vietnam, Holland, Sweden, England, and Canada and in Latin America through Argentina and Brazil [5]. Some countries, such as Canada, are also using the IPS as a national patient summary for continuity of care [6].

The development of the Brazilian IPS attends three of the seven strategic axes of the Brazilian Digital Health Strategy (ESD20-28) [7]: 3-support for better healthcare delivery; 4- the user as protagonist; 7- connectivity environment. At the core of the ESD20-28 is the National Healthcare Data Network (RNDS) - a platform that connects health information from different health information systems from states and municipalities

throughout the country. The ESD20-28 vision statement says: "By 2028, RNDS will be established and recognized as the digital platform for innovation, information, and healthcare services for all Brazil, for the benefit of users, citizens, patients, communities, managers, healthcare professionals and healthcare organizations" [7]. Currently, August 2023, there are more than one billion vaccine registries and about 70 million results of COVID-19 and monkeypox exams on the RNDS repository. Data from the outpatient encounters from primary care are also now starting to be sent to RNDS. There are, up to now, 120,000 encounters available on RNDS.

The IPS can also be used nationally as the document to provide all the information necessary for the continuity of care. This is under consideration by the Brazilian Ministry of Health (BMoH) since the data currently being sent to RNDS reflects specific encounters but not a patient summary. The adoption of IPS nationally would guarantee that whenever necessary, the patient would be able to share his/her summary avoiding the search in different encounters to find information needed for the continuity of care.

The IPS-Brazil project is a collaboration between Sírio-Libanês Hospital and Brazilian Ministry of Health by the Support Program for Institutional Development of the Unified Health System (PROADI-SUS) [8].

Objective

To describe the status of the Brazilian International Patient Summary Project development and its contribution to the National Digital Health Strategy.

Methods

A five-phased approach is being adopted for the development of the Brazilian IPS as follows:

Phase One consists of the identification of all dictionaries adopted in the Brazilian RNDS for the sections of Immunization, Exams, Allergies-Adverse Reactions, Medications, Conditions as well as, all the CodeSystems and ValueSets indicated in the IPS Implementation Guide (IG) (http://hl7.org/fhir/uv/ips) and upload these dictionaries to a

terminology service compliant to the SVCM IHE Profile [9] and to the Common Terminology Service 2 standard [10] under the different organizations that are expected to maintain each of these dictionaries. IPS already establishes scope, use case, and design principles. Those govern the choices on structure, dictionaries, and vocabularies that should be used in Brazil for IPS.

Phase Two focused on constructing the ConceptMaps that express the mapping from the Brazilian dictionaries to the IPS preferred and required terminologies. The mapping process followed the ISO/TR 12300:2014 Health Informatics — Principles of mapping between terminological systems [11]. According to the standard, the purpose of the mapping process needs to be clearly stated with the definition of the source and target data dictionaries that are involved in the mapping. Moreover, it is necessary to indicate the cardinality and equivalence degree of the mapping between source and target. The cardinality must be expressed as: "one to one - a single source concept is linked with a single target concept or term; one to many - a single source concept is linked with multiple target concepts or terms; many to one - multiple source concepts are linked with a single target concept or term and many to many - multiple source concepts are linked with multiple target concepts or terms"[7]. The equivalence degree must be expressed as: "1 - Equivalence of meaning; lexical as well as conceptual; 2 - Equivalence of meaning, but with synonymy; 3 -Source concept is broader, and has a less specific meaning than the target concept/term; 4 - Source concept is narrower, and has a more specific meaning than the target concept/term; 5 - No map is possible. No concept was found in the target with some degree of equivalence (as measured by any other 4 ratings) [11]. The mapping was first depicted in a spreadsheet and later introduced as ConceptMaps with the equivalence degree in the term on a terminology server. All mappings were validated by the BMoH technical team.

Phase Three focused on the harmonization of IPS Brazil. Thus, all documents on RNDS were analyzed and harmonized with the IPS. All mandatory sections on IPS were supported. The IPS IG was strictly followed.

Phase Four consists of the assembling of IPS Brazil specification, depicting all profiles, terminologies, and mappings as well as project design decisions for each profile.

Phase Five should be to validate both the ability to display an IPS from an international patient, using examples available at http://hl7.org/fhir/uv/ips as well as to create a Brazilian IPS with data available at RNDS.

Results

Phase one - Terminology Definition.

International, National and Local terminologies that are part of the information model for Immunizations, Exams, Allergies/Adverse Reactions, Medications, as well as international terminologies adopted in the IPS including SNOMED CT IPS [12], LOINC [13], and the HL7 FHIR R4 CodeSystems and ValueSets were identified and uploaded to the terminology management system. The terminology platform chosen was OCL - OpenConceptLab (https://openconceptlab.org/), an open-source Terminology Management System that contains a SVCM IHE Profile and CTS2 compliant terminology service. Currently, there are 113 Dictionaries (CodeSystems) distributed in eight organizations. The BMoH has 58% of the CodeSystems while HL7 has 65% of the ValueSets.

Phase two - Terminology Mapping.

For immunizations, Exams, and Allergies/Adverse Reactions sections were mapped to IPS' terminologies, mainly SNOMED-CT IPS and LOINC. The Brazilian official comprises 103 immunizations including vaccines, antivenoms and some diluents were mapped to SNOMED IPS vaccine codes. Except for 12 diluents, 91 vaccine codes were mapped. Among those, 40 vaccine codes were mapped in semantic equivalence. 33 concepts were mapped with subsumption, meaning that the Brazilian concept was more restricted than the SNOMED IPS concept. For instance, COVID-19 PFIZER - COMINARTY PEDIÁTRICA is subsumed by SNOMED IPS concept - Vaccine product containing only severe acute respiratory syndrome coronavirus 2 messenger ribonucleic acid (medicinal product).

For allergies, the Brazilian Classification of Allergies and Adverse Reactions – CBARA was mapped to the IPS' Allergy/Intolerance set. CBARA is an adaptation from the

Portuguese classification of Allergies and Adverse Reactions CPARA [14]. The full list contains 152 concepts, including allergens, substances and adverse reactions. Most mappings between CBARA and IPS' Allergy/Intolerance set were mapped in semantic equivalence (semantically similar: 141 (92.8%). For 11(7.2%) of the remaining concepts, mapping to the IPS' Allergy Intolerance set was not possible due to these concepts belonging only to the SNOMED-CT Core.

For medications, the Brazilian National Ontology of Medications - OBM, an ontology inspired by dm+d was used to describe the medicines in use by the patients (https://www.gov.br/pt-br/servicos/consultar-o-portal-da-ontologia-brasileira-de-medicamentos-portal-obm). All medications described in OBM were mapped to ATC (Anatomic Therapeutic Classifications) which is one of the bindings recommended by IPS to classify medications [15].

Only COVID-19 and monkeypox exams are currently available on RNDS. The BMoH uses LOINC codes to describe these concepts. Thus, there was no need for mapping for observation results.

Phases Three and Four - Building and implementing the specification.

The IPS Brazil IG was built using FHIR ShortHand - FSH and FHIR IG Publisher. It is based on IPS, adding CodeSystems, ValueSets and ConceptMaps from National dictionaries to IPS terminologies. The specification is supposed to be the highest IG in the national hierarchy, meaning that it is open, minimal, agnostic and extensible. To accomplish that, every profile is based on their respective IPS profile, defining national identifiers, extensions, semantic binding and mapping. The IG was specified following HL7's national implementation guidelines. Thus, it contains minimal cardinality restriction for its elements, with optional extensions, open slices, and extensible bindings. A harmonization with existing RNDS identifiers and extensions was performed to represent information already available, such as the definition of some national identifiers for individuals, extensions for native Brazilian ethnicities, as well as to capture information on patients' birth sex and gender identity.

To implement the IPS Brazil, a patient summary curator had to be built. The curator is a FHIR Broker Adapter that consumes outpatient encounters' data from RNDS, and, based

on the patient's active problems; it composes the patient's summary. The data on RNDS conforms to national and local semantic definitions. Thus, the broker must transform syntax and semantics based on the definitions. The FHIR Broker Adapter also comprises a structure map that transforms data from RNDS documents to the IPS. The semantic mapping between local and IPS terminologies is also specified in the IG that governs the FHIR transformation and translation operations. The IPS Brazil IG is under construction and currently published as a draft here (https://ips-brasil.web.app).

Phase Five - Validating the IPS Brazil.

The IPS Brazil starts a patient request a summary using ConecteSUS (BMoH's patient health record superapp). A curator is responsible for selecting documents through outpatient encounters from Registro de Atendimento Clínico - RAC that contain active problems. These documents already contain data from Conditions, Medications, Allergies/Intolerances that will be extracted, composed and transformed into a summary. Subsequently, Immunization registries from *Registro de Imunobiológico Administrado* - RIA, and Observation results for COVID-19 and monkeypox exams from Registro de Exame Laboratorial - REL are added to the summary.

Once generated, the IPS Brazil summary can be visualized using the ConecteSUS super app. Also, the summary can be shared using a SMART Health Link compliant (https://docs.smarthealthit.org/smart-health-links/) QRCode. Thus, the patient can, configuring a pin or time-based access, share his/her summary via QR code with whoever he/she/they intend to.

Figure 1 - IPS Brazil's architecture.

Through a public-private partnership program in Brazil called PROADI-SUS, BmoH participated in the LACPass connecthaton in 2 of the event's 3 tracks (https://racsel.org/en/conectaton2023/). Track 1 dealt with International Patient Summary - the objective was for each country to generate a valid IPS according to the IPS IG and to interoperate among other countries according to Mobile access to Health Documents

(MHD) transactions, while Track 2 objective was to generate and interoperate a valid vaccine certificate according to the WHO DDCC standard. Seventeen countries from LAC participated in the event. Brazil received the highlight award for tracks 1 and 2 participation.

Discussion

According to the Handbook - Digital Health Platform - Building a Digital Information Infrastructure (Infostructure) for Health, from ITu and WHO (16) one key component of a digital health architecture is the Terminology Service, among others such as national registries to identify patients, healthcare professionals and healthcare providers as well as security and interoperability standards. Brazil has unique identifiers for all citizens with national database with more than 220 millions records. In addition to that there is a national registry of all healthcare providers private and public and all healthcare professionals. There is a General Data Protection Law in the country issued in 2018(LGPD ref), based on the European GDPR Law. On interoperability, RNDS is dictating the rule by mandating FHIR as the national standard to send data to RNDS repository. However, up to now, there was no terminology "infostructure" established. IPS project fills this void by offering an open source terminology service -OCL with the local dictionaries as well as SNOMED IPS and LOINC with the respective mapping between them incorporating it to the RNDS infrastructure.

During the COVID-19 pandemic BMoH had to rapidly develop the FHIR profiles to receive in RNDS repository all the COVID-19 and, more recently, monkeypox exams, from private and public labs throughout the country, as well as, all the vaccinations registries from COVID. In addition to that, at the same time the national vaccination registry was transferred to RNDS repository.

The FHIR profiles developed for RNDS are published on Simplifier on https://simplifier.net/RedeNacionaldeDadosemSaude. There are 40 FHIR profiles, 72 CodeSystems and 93 ValueSets defined, as well as 32 extensions. These profiles describe specific use cases of sending Lab reports or Immunization Registries. The Brazilian IPS IG corrects eventual flaws on the previous RNDS profiles creating an

extensible and open IG that attends the other use cases already defined by the BMoH, such as: hospital discharge summaries, electronic prescriptions, and obstetric discharge summaries, and private insurance claims.

IPS is a major contribution to patient care in Brazil, considering the challenges of territorial extension, rich cultural diversity, and over 230 million people - therefore users - of the Unified Health System (SUS). By adopting IPS it will be possible for healthcare data to overcome healthcare boundaries inside public health, and interconnect with private healthcare systems also available in the country. This is important, since it is not rare for citizens to rely on both public and private healthcare through different stages of life, depending on variables such as socioeconomic, demographic, and even disease-related factors, generating 'data blackouts' that can directly impact patients' care.

IPS also shifts the logic on patient data property while empowering citizens throughout the Healthcare System: It brings focus on the patient's right to own and discretionary share their medical records, reinforcing their role and responsibilities as participants in their own treatment.

Conclusion

This project makes a structuring contribution to the SUS, more specifically to the new Digital Health and Information Secretariat of the BMoH, created in January 2023. The infostructure of health terminology services for RNDS developed by this project will allow the MOH to manage in a single infrastructure and automatically distribute, via APIs, all the terminologies used in the country, with their respective versions and mappings between them.

Additionally, the GI of the IPS Brazil is a canonical guide of HL7 FHIR R4, open and extensible and may become the highest hierarchy GI in the RNDS, in such a way that other use cases in the country can fit a set of open and extensible profiles.

One of the critical success factors of the project are the weekly meetings with the MOH technical team allowing for fast resolutions of any project need such as revision of the mappings from the local dictionaries or access to data for the proof of concept.

The implementation of the IPS in Brazil puts the country in line with the other G20 countries and the GDHP – Global Digital Health Partnership initiative, which aims to accelerate the adoption of the Summary internationally.

The biggest contribution of this project is the construction of the digital health infostructure for the expansion of the RNDS.

Keywords: IPS; Patient Summary; Standards, interoperability, digital health

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Conflict of interest

The authors declare no conflict of interest.

Data availability

The data underlying this article will be shared on reasonable request to the corresponding author.

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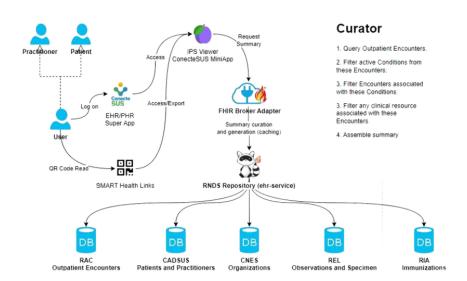


Figure 1 - IPS Brazil's architecture 81x45mm (300 x 300 DPI)