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**PROGRAMA DE PÓS-GRADUAÇÃO EM ENGENHARIA DE PRODUÇÃO**

# BRAZILIAN PATIENT SUMMARY
## An experience of exchange health data using FHIR

**NEUSA MARIA DE ANDRADE**

**SÃO PAULO**

**2020**

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Thesis presented to the Graduate Program in Production Engineering at Universidade Paulista - UNIP to obtain the title of Doctor in Production Engineering.

**Advisor**: Dr. Pedro Luiz de Oliveira Costa Neto

**Concentration Area**: Operation Systems Management
**Line of Research:** Networks enterprises and Production Planning
**Research project**: Continuous Improvement of Quality and Productivity

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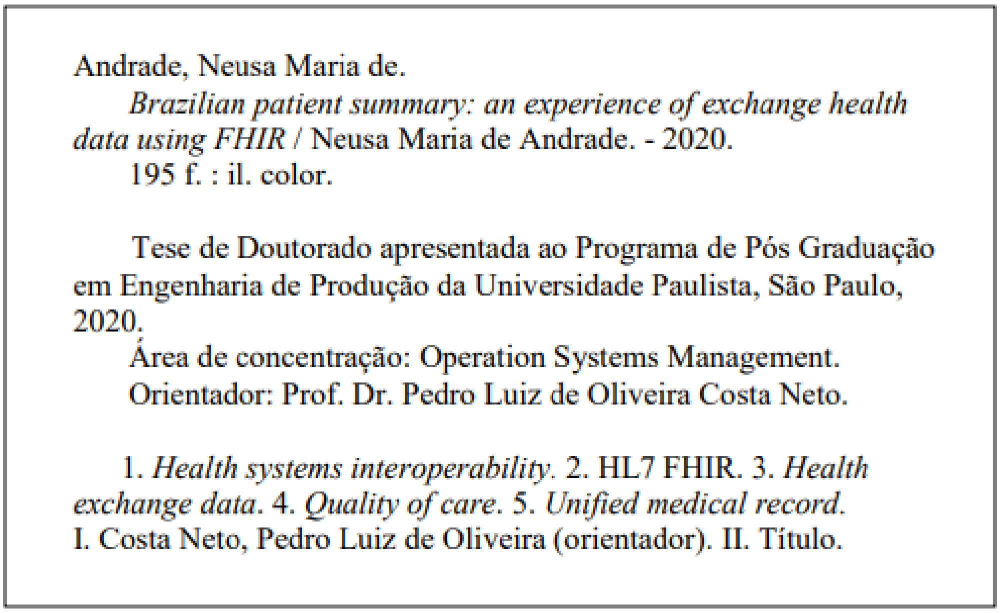
# CATALOGRAPHIC CARD



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# DEDICATORY

*To My father (in memoriam) and for all that cruised for the other side, especially health professionals that have died to save lives during the COVID-19 pandemic.*

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# EPÍGRAFE

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*“The big secret to fullness is very simple:* share."

*Socrates*

# RESUMO

Andrade, Neusa M. (2020). **- BRAZILIAN PATIENT SUMMARY. An experience of exchange health data using FHIR**. (Tese de Doutoramento). Universidade Paulista – UNIP, São Paulo, Brasil.

A sociedade passou a exigir melhores serviços e resultados de saúde, incluindo maior valor social, relação governo-cidadão e qualidade de acesso à saúde. Governos e organizações precisam contemplar privacidade, segurança, mobilidade e portabilidade utilizando as melhores tecnologias e inovação, com transparência, conforme recomendado pela melhores práticas.

Os Sistemas de Informação em Saúde (SIS) são um conjunto de instrumentos de base tecnológica projetados para prevenção, diagnóstico, tratamento, monitoramento. Também frequentemente fragmentados, coexistem com muitos softwares que não se comunicam e dependem da interoperabilidade, que pode ser vista como uma série de protocolos e padrões para estabelecer processos de comunicação para troca de dados que, quando negligenciados, afetam o gerenciamento e a tomada de decisões. A interoperabilidade molda e transforma a sociedade, criando conexões inteligentes por meio das organizações para produzir e trocar dados, melhorando o desempenho e oportunidades de inovação, com redução de custos.

O Resumo do paciente internacional (IPS) é uma experiência de sucesso na União Europeia, projetada para tornar os dados de pacientes de saúde transfronteiriços acessíveis aos profissionais de saúde. Fast Healthcare Interoperability Resources (FHIR) é um padrão estabelecido que pode lidar com grandes repositórios, anotações semânticas e um conjunto de terminologias usadas para criar e trocar dados de saúde. O projeto IPS projeto forneceu as diretrizes utilizadas neste trabalho realizada através de uma Pesquisa-ação utilizando as melhores práticas e respeitando o contexto brasileiro.

A experiência envolveu diferentes entidades (públicas e privadas) amparadas pelos padrões oferecidos pelo Instituto HL7 Brasil e pela Rede de Dados em Saúde (RNDS) como via de Interoperabilidade de utilizando FHIR. A pesquisa oferece um Guia de Implementação para coleta e intercâmbio de dados de saúde para preencher a lacuna de interoperabilidade com o objetivo de construir consenso, incluindo a cidadania no processo e melhorando os movimentos em direção ao conhecimento global dos dados de saúde.

**Palavras-chave**: 1. Health Systems Interoperability 2. HL7 FHIR 3. Health Exchange Data, 4. Quality of Care 5. Unified Medical Record.

# ABSTRACT

Andrade, Neusa M. (2020). **BRAZILIAN PATIENT SUMMARY. An experience of exchange health data using FHIR** (Doctoral Dissertation). Paulista University, São Paulo, Brazil.

Society demands better health services and results including greater social value, government-citizen relationship, and quality of access to health. Governments and organizations need to contemplate privacy, security, mobility, and portability using the best technologies and innovation, with transparency, as recommended by the best practices.

Health Information Systems (SIS) are more than formal and technological systems. They are a set of technology-based instruments designed for prevention, diagnosis, treatment, monitoring, and management. Health Systems are often fragmented coexisting with many software that does not communicate and depend on Interoperability that can be seen as a series of protocols and standards to establish communication processes for data exchange that when neglected affects management and better decision-making. Interoperability shapes and transforms society, creating smart connections through organizations to produce and exchange data, improving performance, and cost-cutting innovation opportunities.

International Patient Summary (IPS) is a successful cross-border experience in the European Union designed to make health patient data accessible to healthcare professionals. Fast Healthcare Interoperability Resources (FHIR) is an established standard that can handle large repositories, semantic annotations, and a set of global reference terminologies used to create and exchange health data in IPS that provided basic information used in this work. This Action Research aiming to exchanging health data using best practices as a model and respecting the Brazilian context.

The experience involved different entities (public and private) supported by the standards of the HL7 Brazil Institute and the Health Data Network (RNDS) as an Infovway Interoperability using FHIR. The research offers an Implementation Guide for collection and exchange of health data to fill the interoperability gap aiming to build consensus, including citizenship in the process and improving movements towards a global knowledge of health data.

**Keywords -chave**: 1. Health Systems Interoperability 2. HL7 FHIR 3. Health Exchange Data, 4. Quality of Care 5. Unified Medical Record.

# LIST OF ACRONYMS AND ABBREVIATIONS

**A**

ANSI – American National Standards Institute

AHRQ – Agency for HealthCare Research & Quality

API – Application Program Interface

APMS- Advances in Production Management Systems

**B**

BI – Buisness Intelligence

**C**

CCDA – Consolidated Clinical Document Architecture

CERIF-Common European Research Information Format

CRIS-Current Research Information Systems

CEHRT – Certified EHR Technology

CBIS – Congresso Brasileiro de Informática em Saúde.

CCD – Continuity of Care Document.

CCA – Continuity of Care Record

CDA – Clinical Document Architecture. CFM – Conselho Federal de Medicina.

CONECTSUS- data connection platform to the Brazilian health system

**D**

DATASUS -Departamento de Informática do Sistema Único de Saúde

DSN – Data Sharing Network

DOI -Digital Object Identifier

DSA- Data-Sharing Agreement

DSIP- Digital Science and Innovation Policy

DMIM – Domain Message Information Model.

DMAIC- Define, Measure, Analyse, Improve, Control

DICOM- Digital Imaging and Communications in Medicine

**E**

EC -European Commission

EDI – Electronic Data Interchange

ECE/UN -Economic Commission for Europe of the United Nations

EU -European Union

EHR – Electronic Health Record

EMPI – Enterprise Master Patient Index

EMR – Electronic Medical Record
EMRAM –Electronic Medical Record Adoption Model (HIMSS Analytics)

**F**

FHIR – Fast Healthcare Interoperability Resource

**G**

GaaP-Government as a Platform
GHC -Global Health Commission
GPT- General-Purpose Technology
GPU- Graphic Processing Unit
GRID- Global Research Identifier Database
GUI - Graphic Unit Intreface

**H**

HIS – Hospitalar Information System
HL7 – Health Level 7. Protocolo de Interoperabilidade entre Sistemas Hospitalares
HISPP – Healthcare Information Standards Planning Panel
HMD – Hierarchical Message Description
H2020- Horizon 2020
HIMSS – Healthcare Information and Management Systems Society
HIPAA – Health Insurance Portability and Accountability Act
HIS – Hospital Information System
HISTP – Health Information Technology Standards Panel
HITECH – Health Information Technology for Economic and Clinical Health Act
HITRUST – Health Information Trust Alliance
HPC-High-performance computing

**I**

IBGE -Instituto Brasileiro de Geografia e Estatística
IDE – Integrated Development Environment.
IHE – Integrating HealthCare Enterprises
ISO – International Organization for Standardization
ICT-Information and communication technology
ID-Identification
ISNI -International Standard Name Identifier
IoT-Internet of things
IPS- International Patient Summary

**J**

JSON – JavaScript Object Notation. JVM – Java Virtual Machine.

**K**

KBE- Knowledge-based engineering

**L**

LIS – Laboratory Information System.

LOINC – Logical Observation Identifiers Names and Codes.

**M**

MRN – Medical Record Number

NHIN – National Health Information Network

**N**

NHS - National Health Service

NP-Next Production Revolution

NPP – Notice of Patience Privacy

**O**

OAI-PMH - Open Archives Initiative Protocol for Metadata Harvesting

OAIS - Open Archival Information System

OECD - Organization for Economic Co-operation and Development

ONC- The Office of the National Coordinator for Health Information Technology

ONA - National Accreditation Organization

**P**

PDQ - Patient Demographics Query

PIX - Patient Identifier Cross-referencing

PHI - Protected Health Information

PIP - Practice Improvement Plan

PEP - Prontuário Eletrônico do Paciente/ Electronic Patient Record

POM - Project Object Manager.

PQRS - Patient Quality Reporting System

PDCA - plan–do–study–act.

**R**

RIM - Reference Information Model.

RMIM - Refined Message Information Model.

RNDS - National Health Data Network (BRAZIL)

RES - Registro eletrônico de saúde (RES) / Electronic Health Record (EHR)

REST- Representational State Transfer

**S**
SBIS – Sociedade Brasileira de Informática em Saúde.
SQL – Structured Query Language.
SNOMED-CT – Systematized Nomenclature of Medicine - Clinical Terms.
SDGs- Sustainable Development Goals
SHIEC – Strategic Health Information Exchange Collaborative
SOA – Service-Oriented Architecture.
STI -Science, Technology and Innovation
S&T- Science and Technology
SUS - Unified Health System

**T**
TOP- Transparency and Openness Promotion

**U**
UK- United Kingdom
UN- United Nations
UPPIs- Unique, persistent and pervasive identifier
USA -United States of America

**V**
V2 – Health Level Seven Version 2
V3 – Health Level Seven Version 3
VIPR – Virtual Integrated Patient Record

**X**
XML – EXtended Markup Language.
XDR – Cross-Enterprise Document Reliability Interchange

**W**
WBCSD- World Business Council for Development
WHO -World Health Organization

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# SUMÁRIO

# 1. INTRODUCTION

## 1.1. Context and Remarks

All human activities, segments, and industries, especially in the health domain have been reshaping due to technologies increasing, and since 2019, COVID-19 accelerated and changed many processes. Health engineering is a subfield and a cross-disciplinary approach that can use the generated knowledge processes by Engineering Production deploying technologies aiming to provide a healthcare transformation to attend to new demands of society (ALSHURAFA et al, 2017; PAVEL et al, 2013; CORREIA et al, 2020; FAGHERAZZI et al, 2020).

Healthcare systems are often fragmented coexisting with many software that does not talk to each other, therefore can not fulfilling interoperability standards, quality, security, scalability, and reliability to exchange information generating an enormous legacy of IT (JARDIM, 2013). As demand by society, to exchange health data is at the same time a request and a challenge to be accomplished by technological systems (BANOUAR; RAGHAY, 2016; AL-JANABI et al, 2018; BROOKS et al, 2013).

However, to analyze the performance of any health system, it is also necessary to consider the entire context of demographic and cultural aspects, its health determinants, and the evolution of the studied population, considering coverage, financing, integration between actors and services, and the model of organization (AHA, 2019; KRUK et al, 2018; AL-JANABI et al, 2018).

The aging population, for example, leads countries to restructure their assistance and payment models, but regardless of the political and economic situation, all systems face common challenges, as the ability to predict and interact with citizens to offer accurate information to managers. Based on the profiles of the population, best practices recommend that managers trying to meet the implementation of regulatory mechanisms and allocation of resources allowing accountability to society (THE LANCET, 2018).

The need for a transformative change in Healthcare is central and a major determinant of life quality that can provide better outcomes engaging stakeholders and saving lives (AHA, 2019). According to the American Hospital Association (AHA) and Global Health Commission (GHC), health data are scattered and fragmented and interoperability is considered a particularly important and complex task. Aiming to deal with the flow of information usually supported through tools of Health Informatics healthcare organizations need to find a way to deal and exchange large amounts of data (PAVEL et al, 2013; THE LANCET, 2018).

Computational systems in healthcare activity arose from the need for providing useful information for decision making to health professionals, but it is important to note that many Health Information Systems (HIS) resulted from years of development based on various technological platforms, and also different programming languages (ALSHURAFA et al, 2017; SABBATINI, 2014; MESQUITA SALES; BENTES PINTO, 2019).

It exists a real interconnection between Information Technology and the practice of Medicine, both depend on competence and knowledge to obtain accurate access to information to produce measurable effects. Many researchers are working to understand aiming to prevent diseases using systems thah talk and exchange information getting best results, reducing costs, time and efforts (GREER et al, 2013; ALSHURAFA et al, 2017).

The clinical interoperability specifications are referenced by events and terminologies subsets or mappings specified. (LEE, D et al, 2010). It is necessary for the engagement of stakeholders to validate the requirements to fulfill interoperability specifications that intended to be extensively reused. The Commission on Health System Quality (HQSS) and World Health Organization (WHO) offering some frameworks and guidelines to produce well-functioning health systems better performance to ensure the use of reliable and timely information regarding also to protecting privacy and security of patient data (THE LANCET, 2018; WHO, 2007; BLOBEL et al, 2006).

Lee, Y et al (2011) say that Care Providers and health care generally have different systems for different aspects of services, which are often unable to communicate with each other, even though they are on the same network. HL7 acts on the seventh level of the protocol of the Open Systems Interconnection (OSI) model of the International Standards Organization. An HL7 interface acts as a link between different applications such as patient registration systems through a standard message protocol. Health Level 7 (HL7) standard solves this problem by providing a framework for exchanging, integrating, sharing, and retrieving information from electronic health records. (HL7, 2019-b; HL7, 2019-c).

The HL7 standard contains messages for all areas of health care attention automation contemplating several different roles and processes information sources need to interoperate through Registration, Document Control, Orders, Scheduling, Logistics, Results and Observations, Personnel administration, Querys, Finances, Network Synchronization and many others (SPYROU et al, 2003; WHO, 2007; HL7, 2020-b).

Interfaces can provide encrypted and secure data transfer between systems. Unlike other standards, HL7 specifies almost without restrictions the protocols to be used in the lower layers of the interface (HL7, 2020-b). The definitions of the HL7 focus on the logical arrangement of the data and the information in various parts of the message. Fast Healthcare Interoperability Resources (FHIR) was created by the Health Level Seven International aiming to describes syntactic and semantic formats and elements that must through an application programming interface for exchanging Electronic Health Records data (HL7, 2019-a).

Interoperability could be seen as a series of protocols, standards, and norms rule how communication will be established to acquire comprehension depending on each part involved in the process (ROBKIN et al, 2015). As best results worldwide about interoperability and exchange data, the definition of the Patient Summary brought answers to the research questions regarding used health informatics standards and related artifacts (e-HEALTH NETWORK, 2016; EUROPEAN COMMISSION, 2020).

European countries have been challenged to exchanged health records of patients and data protection rules providing consent before these services are accessed (EUROPEAN COMMISSION, 2020). The EU Member States are already part of the e- Health Digital Service Infrastructure expecting to exchange Patient Summaries. Seven Member States (Finland, Estonia, Czechia, Luxembourg, Portugal, Croatia, and Malta) are already progressively launching ePrescriptions exchanges (EUROPEAN COMMISSION, 2015; GREG, 2020).

International Patient Summary (IPS) is an experience created to make accessible for health professionals cross-border health patient data when they are visiting another country. This cross-border experience provides background information on important health-related aspects issues already experienced by Czechia, Luxembourg, and Croatia in eHealth cooperation (HL7, 2020-a; GREG, 2020; BOSSENKO; NORTAL, 2020).

Sharing Patient Summaries and ePrescriptions is important for patient safety, and in an emergency situation, this can save lives helping doctors to better understand patient's medical history reducing risks of incorrect medication and can contribute to better care. A Patient Summary to be valid need a minimum set of information to be provided in a structured and coded format (HL7, 2020-a). The issue raised by some countries is that they cannot provide the minimum set of information, but the exchange of patients health records have already exchanged in the EU thanks to this cross-border experience, as example physicians in Luxembourg are able to receive digital Patient Summaries of travelers coming from Czechia or yet to send Pharmacy prescriptions to Estonia (SALUSE et al, 2010; BOSSENKO; NORTAL, 2020).

The project brought tangible benefits for Europe. In countries like Estonia, as an example, citizens can access their data through centralized eHealth national services. The results from the sharing of information introduce other levels of interaction, as the need for semantic interoperability and exchange of EHR. The experiences increase the use of standards and methodologies to deal with requirements, as provided by standards like HL7 (SALUSE et al, 2010; BOSSENKO; NORTAL, 2020; GDHP, 2020).

The use of standards building consensus in a community and also an important citizenship process, the project raises specialized health communities able to produce raw material to improve global knowledge, a crucial issue for the management of quality in health which is also a new demand of society (THE LANCET, 2018).

Studies from the European Commission (EC) say that some countries are yet struggling with challenges to exchange their health data, but this is more visible in developing countries that suffer from a lack of infrastructure and financial resources, presenting a systematic deficit in the quality of care, deficient management of costs and transparency (GONZÁLEZ et al, 2011; GONZÁLEZ et al, 2016; WOOD et al, 2016; GREER et al, 2013).

Brazil has wide inequalities as many other developing countries but is unique in a continental dimension that offers a Unified Health System (SUS). According to Dawson Report (1920), it was born inspired by England NHS (KRUK et al, 2018; BARNES et al, 2009). The system was structured to benefit all Brazilian population in a model of universality and equity, guaranteeing assistance to the individual in accordance with local needs, their services are structured in the concept of network organization. Since 1988, the

Unified Health System (SUS) is constitutionally guaranteed and maintained by collected taxes, but the model faces management problems that guarantee its sustainability and equity. People who can afford preferring to use a supplementary and private health system (SILVA, 2018; VÁZQUEZ, et al, 2017).

All kinds of facilities of health, public or private must interact with the regulation of government systems and exchange data with Federal instances. Brazilian Ministery of Health offers several kinds of systems aiming to get data in all Health Ecosystem, but due to a tripartite model of shared responsibilities, the municipalities are encharged to provide all infrastructure and resources in towns (BARNES et al, 2009; COLETIVA SAÚDE, 2011; GONZÁLEZ et al, 2016).

The present work presents an experience for health data exchange using model best practices and experiences following Brazilian policies. The experience is based on International Patient Summary (IPS) to exchange data creating a Brazilian model of the unified medical record to allow interoperability, also engaging different entities (private and public) supported by rules of the HL7 Brasil Institute and National Health Data Network (RNDS) as Interoperability Bus using FHIR as standard (HL7, 2020-a; HL7, 2020-b; VENÂNCIO DE BARROS, 2019).

The research was developed through a partnership with the City of Bananal allowing to researchers present a local solution that further can be implemented in other cities resulting in an implementation guide to offer a model of standardization for collect and exchange health data. The work improved knowledge and experiences between all stakeholders. An implementation guide is a result that offers a step-by-step transcription of what was successfully done in Bananal city. By engaging IT resources, Health agents, and citizen collaboration the city converted its paper health register reaching more than 90% in digital data in less than a year.

As a result of Action Research (THIOLLENT, 1994) this work brings two main contributions. The first is that the experience showed that applying best practices allow maximizing resources to able health professionals to obtain an overview of patients' health data. The second is a proposal to apply these practices in a step-by-step guide that aims help managers to evaluate health resources regarding 1) Assets, 2) Capabilities, 3) Policies, and also 4) Engagement and acknowledgment through Communities of Practices (CoP) aiming to reach bus interoperability and exchange data (WALKER et al, 2005).

## 1.2 New Society Demands

The society is claiming better services of providing health care contemplating at same time reduction of costs, through governments and organizations able to build policies that also contemplating privacy, safety, mobility, and portability using the best technologies and innovation, with total transparency, as recommended for best practices frameworks and ontologies (PANG et al, 2018; FAGHERAZZI et al, 2020).

As new goals of society, there is a demand to produce better health outcomes, including greater social value through citizens interested in collaborating on their own health, and even improving government-citizen relationship, quality of access, transparency, and supporting decision making (THE LANCET, 2018).

Philips Research Americas conducted a survey through healthcare professionals, and a lack of interoperability and access to data sharing systems showed to be the main concern and a top barrier to sharing (PHILIPS, 2019). Some trends in the healthcare sector rely on interoperability data for seeking solutions in the axes preventive medicine, which studies such as minimizing disease or illness of the patient can identify diseases based on population mapping and genetic research, participatory medicine, and health democratization, which creates a humanized relationship between health professionals, patients, and society (X. LIANG et al, 2017; JCI, 2019; HRISTIDIS et al, 2006).

The OECD survey on access-to-data policies among policymakers from 27 countries showed within 171 policy initiatives which are the most pertinent and relevant 1) Openness, 2) Quality, 3) Security, 4) Interoperability, 5) Transparency, 6) Sustainability,
7) Legal conformity. The survey was applied in a diverse set of stakeholders representing academia, scholarly publishers, industry, and funding agencies, and is now becoming a mainstream reference for policymakers (OECD, 2019).

## 1.3 Motivation

Topics as Interoperability, Technology, and Transparency are appearing in several surveys as conducted by OECD, McKinseyGlobal Institute (Digital identification: A key to inclusive growth), United Health Foundation (UnitedHealthcare Consumer Sentiment), Delloite (Interoperability). These trends are impacting lives and changing society (OECD, 2019; MGI, 2019; UNITEDHEALTHCARE, 2019, DELOITTE, 2019).

These subjects are very important to measure the quality and performance of the health sector that is dependent on diagnoses to define what must be adjusted and refined, as an example, the lack of interoperable Electronic Health Records (EHRs) leads to care being repeated creating many opportunities to errors and fraud (PAVEL et al, 2013).

The goal of interoperability depends essencialy on 1) Right Information, 2) Right Interpretation, 3) Right Time, 4) Right Workflow, 5) Right Value. This research has the premise that interoperability needs an accurate acquire of register of patient data to offer an instrument for decision-making (HIMMELSTEIN, 2010).

## 1.4 Objectives

Contextualized in Brazil, and respecting its policies, the following objectives are based on global best practices and recommended standards. The research aims to offer an implementation guide for the application of good practices for the collection and exchange of health data without which it is not possible to fill the interoperability gap.

This work is being guided by the following key research question: *Based on best practices, how to acquire and implement a health data exchange model to build interoperability in the Brazilian context*?

### 1.4.1 General Objective

Based on best practices and standards, design and provide an Implementation Guide to collect and exchange health data among and within entities contextualized of the Brazilian Unified Health System (SUS).

### 1.4.2 Specific Objectives

To achieve the General Objective, it is necessary:

1. Obtain an overview of practices in the Healthcare System worldwide;
2. Obtain an overview of concepts of global standards used for the exchange of health data;
3. Present an overview of the best practices and standards used to promote interoperability to build Global Medical Records;

4. Present the tools and methodological to be used applied to the Brazilian context;
5. Present a proposal for an Implementation Guide.

## 1.5 Field of Research

The multidisciplinary teamwork model was recognized as a prerequisite for implementing new solutions and creating innovation (HILLS et al, 2007). Production Engineering and Health Informatics have great synergy, interdisciplinary, and convergence working together on the automation process that can transform and remodel the health value chain. Research in both areas shows that these developments can help patients and clinical professionals overcome challenges in order to improve processes for safety, efficiency, accuracy, and create interoperability systems (PANG et al, 2018; GOBBO et al, 2017; VERSCHOORE, 2020).

## 1.6 Research Thesis Statement and Metodology

*Is it possible to reach interoperability, track, and exchange health data through entities by using a single key of patient data according to premises of best worldwide practices*? This research shows the Interoperability requirements to exchange health data through best practices and standards.

## 1.7 Organization and Structure

This work is structured into 6 chapters as follows.

Chapter 1 (INTRODUCTION) shows an overview, context, and remarks of new society demands, especially about standards with an approach focused on interoperability.

Chapter 2 (LITERATURE REVIEW) shows the foundations of main concepts that allow gathering the elements to validate the objectives. The concepts aimed to deepen in knowledge at themes like Compliance and Regulations, Quality Standardization, Health Quality Standards, Interoperability's concepts, Medical Records Standards and Health Exchange Data, Practices, and Standards.

Chapter 3 (METHODOLOGY) describes the Action Research, the applied Pilot in the city Bananal, and tools used to reach the objectives. This methodology helped to show advantages and disadvantages, limitations, best practices, and models that promote the interoperability of health data.

Chapter 4 (EMPIRICAL RESULTS AND DISCUSSION) presents a summary of the four articles already published that make up the research. A fifth submitted paper summarizes the results obtained in the pilot project experience in the city of Bananal. The chapter is complemented by a step-by-step Implementation Guide that could be applied in other municipalities.

Chapter 5 (CONCLUSIONS) shows how objectives were reached in this research and recommendations, limitations, and further studies with suggestions and recommendations.

Chapter 6 (REFERENCES) presents references quoted in the text. Appendixes present the complete papers.

# 2. LITERATURE REVIEW

This chapter describes the main concepts used to compound the research. The criteria of concepts searching consisted of uses several combined uses for healthcare terms and approaches due to being necessary to articulate quantitative and qualitative methods enhancing confidence in finding (LAZARUS et al, 2016; WESTBROOK, 1995).

Martín-Martín et al (2018) proposed a systematic review of the literature used in this work. The terms were research in Google Scholar, Web of Science, Pubmed, Scielo, and Scopus, resulting in 562 papers that were refined resulting in 230 references listed in the sixth chapter. The searched concepts in the combined manner were: 1) Health Systems Interoperability, 2) Health Exchange Data, 3) Quality of HealthCare, 4) Health Governance, Compliance, and Regulations. The results of the search lead to news concepts like 5) Unified Medical Record, and 6) HL7 FHIR that brought a bundle of terminologies, ontologies that permeate the health ecosystem showing also trends and gaps to be explored (MARTÍN-MARTÍN et al, 2018).

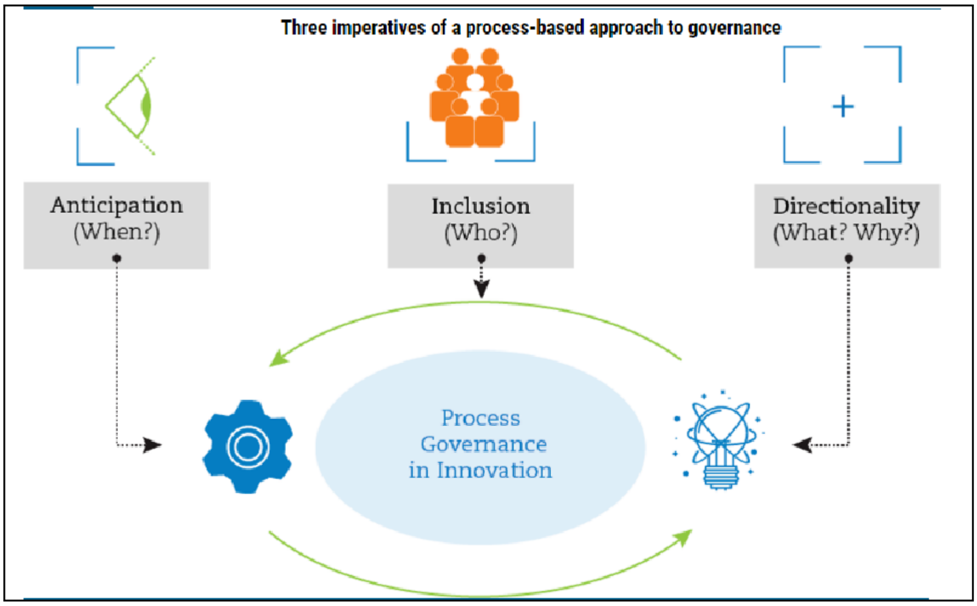
All used references are listed and the concepts and terms used to compound this document was acquired from journal publications, conference papers, books or book chapters, thesis or dissertations, and also magazine articles. They were downloaded in PDF file format and gathered in a bibliographic reference software (YAMAKAWA et al, 2014) and so consolidated using R (Programming language and free software environment which functions are developed by a community aiming to import, tidy, transform, visualize, and to model data). Acronyms of Health Information and Technology terms were based on the HIMSS Dictionary (2019). The next topics presenting the main dimensions of concepts presented in this research.

## 2.1 Compliance and Regulations

Healthcare Sector is of the most globally regulated and in the search terms, results showed that Governance and Compliance are trends once they help clinical facilities and health organizations to face government regulations. The Sector faces an extensive list of compliance requirements and regulations such as the Data Protection Act 2018 (DPA 2018) in The United States, and the General Data Protection Regulation (GDPR, 2016) in Europe. Both brought changes regarding privacy and protection of patient care demanding the use of standards ensuring quality, prevention of fraud, and an adjustment of the mindset of all healthcare staff putting patients at the center of the process (GREER et al, 2013 OECD, 2019).

Figure 1 showed results of an OECD survey regarding access-to-data policies was conducted among policymakers from 27 countries identifying a total of 171 policy initiatives remarking 13 principles considered the most pertinent. These principles are ruled by three imperatives process of governance that could be applied at the healthcare sector: 1) Anticipation (When?), 2) Inclusion (Who?), and 3) Directionality (What/Why?) (OECD, 2019).

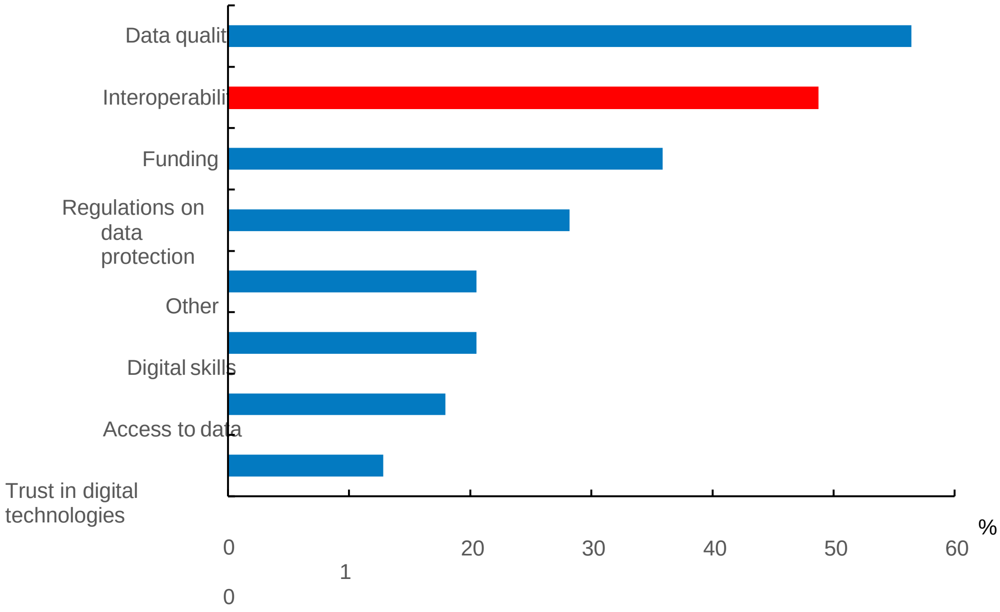
**Figure 1 – Three imperatives of governance process**



Source: OECD, 2019.

The survey was conducted in 39 OECD member countries and had the objective to identify the most important challenges that they are facing, and which are possible barriers that could block their main growth initiatives. Figure 2 shows answers, and the first concern was about data protection regulations, and the second was about interoperability, which we remarked in red, once is the object of this study. The final report concluded that these dimensions could influence regards to the acquisition of digital skills and shaping a New Society (OECD, 2019).

**Figure 2 – Data dimensions that are shaping society**



Source: OECD, 2019 - Avaliable in https://doi.org/10.1787/888933858335

According to OECD, these principles resulting in main dimensions that allow to include citizens into processes and enabling design and standardize transparent policies to promote social values as goals and integrate with technology. The dimensions presented are openness, quality, security, interoperability, transparency, sustainability, legal, and conformity (OECD, 2019).

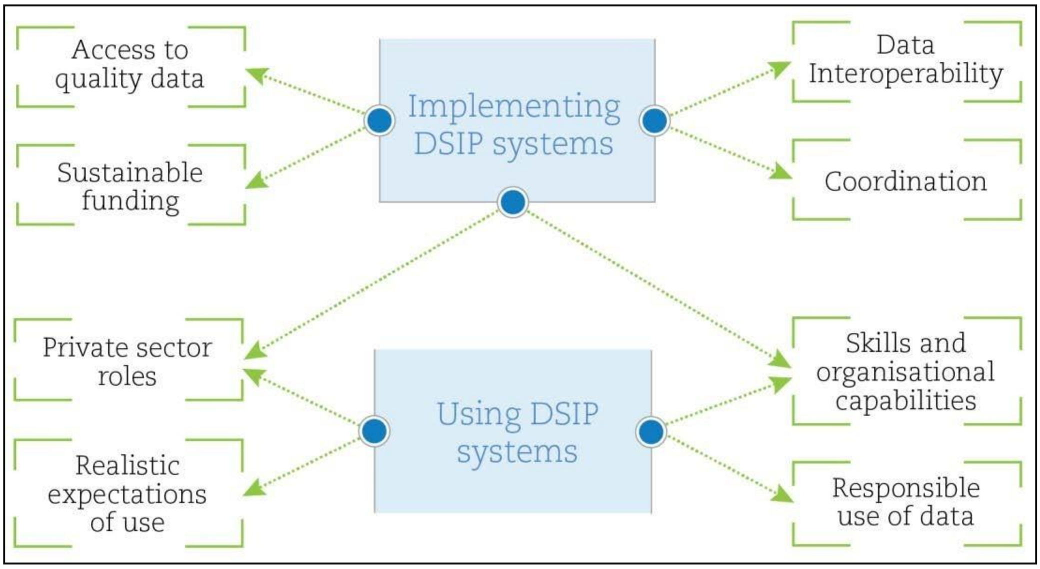
In 2019, an Interoperability Survey was conducted by the Deloitte Center for Health Solutions. The results showed that 43% of health systems and 63% of health plan leaders say that they intend to use compliance requirements and a broader interoperability strategy since data integration systems allow combining data from multiple sources. (DELOITTE, 2019).

Interoperability could also shape and transforming society by the use of digital technologies creating smart and connections through organizations to produce and exchange data enhancing performance and opportunities for innovation that reduces costs. The access to data as a tool in times of digital innovation creates knowledge that facilitates and producing a gain in efficiency and transparency, as well as economic and non- economic constraints (OECD, 2019).

The survey conducted by OECD was made with stakeholders of Academia, Publishers, Industry, and Funding Agencies showed which Rationales have been a demand by Society and must be implemented. Figure 3 presents how they were grouped as 1)

Accessibility (Access to quality data); 2) Data Interoperability (Reusability of data) and 3) Skills and organizational (Capabilities). These groups are becoming a reference to draw policies. Data Interoperability allows updates across systems and automatically comparing information from multiple sources as one of the next subjects that reinforcing the research demand of this subject (OECD, 2019).

**Figure 3 – Rationales drawing policies**



Source: OECD, 2019.

> Although every nation has a different healthcare system, all nations use health data standards. Countries and territories are at different stages of adoption and implementation of these standards. Thus, harmonization is crucial in promoting the interoperability of electronic health records (EHRs) and empowering patients with their data across the globe there is evidence of progress among some health systems in advancing internal interoperability. However, external interoperability remains elusive, as the number of challenges and barriers have limited progress toward seamless interoperability across global jurisdictions. External interoperability that transcends global borders and offers access to people and populations remains vastly underdeveloped in the health sector (GDHP, 2020).

### 2.1.1 Patient-centered demands as a trend

A patient-centeredness is another current trend and Patient-centered care (PCC) is a quality that the health systems are trying to offer. Almost worldwide's Patients are requesting to carry their own data with privacy safety using mobility data and requiring tracing technologies like Blockchain. Researchers are showing that it could improve citizen care and monitoring government transparency (FLOTT et al, 2016; BROOKS et al, 2013).

Policies are also shaping the instruments for Data access brought by a massive technology diffusion. Knowledge transfer can contemplate the co-creation of information between governments and citizens, but society is, even more, requesting access through digital technologies and paperless. Good Digital ID is The EU Data Protection Regulation project already adopted for some countries that created a Unique Digital ID enabling civic and social empowerment implementing digital authentication as a social value. Table 1 show Good ID attributes that also affect the collection of Healthcare Data listed through five principles: 1) Quickness; 2) Effectiveness; 3) Consumer-friendly; 4) Low Cost; 5) Global Applications (GOOD-ID, 2019).

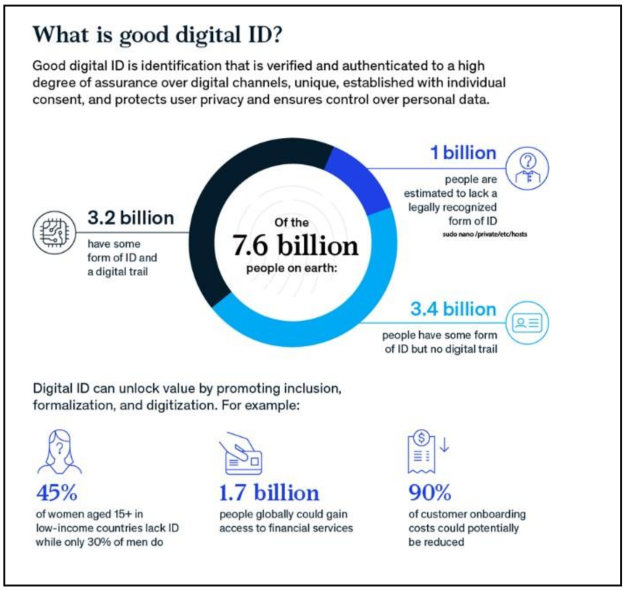
**Table 1 – Chart of good digital ID attributes**

| ATTRIBUTE | BENEFIT TO SOCIETY | DESCRIPTION |
|---|---|---|
| Verified and authenticated to a high degree of assurance | High-assurance meets both government and private-sector institutions standards for initial registration and subsequent acceptance for a multitude of civic and economic uses. | This attribute does not rely on any particular underlying technology. |
| Unique | Unique high-assurance authentication and verification. | Include biometrics, passwords, QR codes, and smart devices with identity information embedded in. |
| Established with individual consent | Consent means that individuals knowingly register for and use. | Contemplate what personal data will be captured and how they will be used. |
| Protects user privacy and ensures control over personal data | Built-in safeguards to ensure privacy and security while also giving users access to their personal data. | Decision rights over who has access to data with transparency. |

Source: Adapted from https://www.good-id.org/en/ (GOOD-ID, 2019)

Developed countries like the United Kingdom and the United States are already implementing digital ID aiming to measure and understand the risks and values of how individuals and institutions could benefit from it. Countries like Brazil, China, Ethiopia, India, Nigeria are being encouraged to using Digital ID. Figure 4 presents a summary of the concepts and numbers reached by the project. Figure 5 shows six key types of interactions between individuals and institutions (GOOD-ID, 2019).

**Figure 4 – What is good digital ID?**



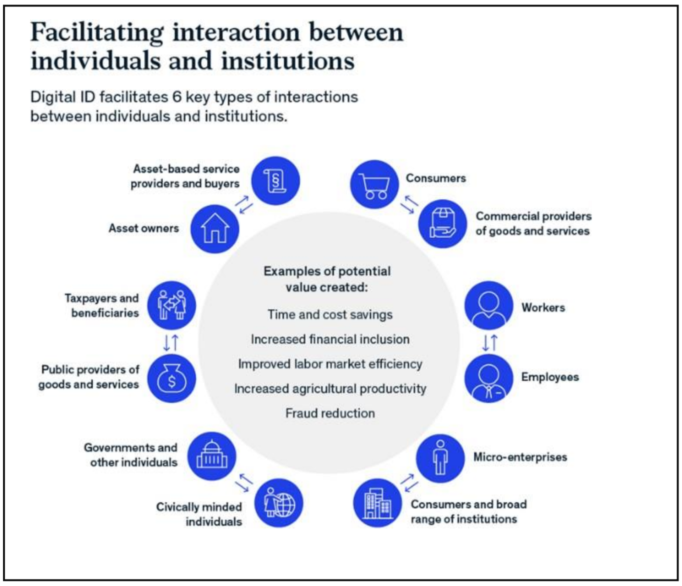
What is good digital ID?

Good digital ID is identification that is verified and authenticated to a high degree of assurance over digital channels, unique, established with individual consent, and protects user privacy and ensures control over personal data.

Digital ID can unlock value by promoting inclusion, formalization, and digitization. For example:

Source: (GOOD-ID, 2019)

**Figure 5 – Facilitating interaction between individuals and institutions**



Facilitating interaction between individuals and institutions

Digital ID facilitates 6 key types of interactions between individuals and institutions.

Source: (GOOD-ID, 2019)

## 2.2 Quality Standardization

Efficiency is an economic concept that relates efficacy and effectiveness achieved with an optimal mix of resources. Efficacy can be defined as the performance under ideal and controlled circumstances also describing the technical relationship between the technology and its effects or performance under real conditions. performance is a numerical measurement for organization, division or process that can be assessed through measurements, statistical sampling of the output of processes, etc (COSTA NETO; CANUTO, 2010).

These concepts are central to Quality and a worldwide request. In 1947, the International Organization for Standardization, known by the acronym ISO began to unify standards referring to various technical subjects, eliminating and reconciling their differences concerning quality and performance (COSTA NETO; CANUTO, 2010).

Quality of life is a goal to be pursued that benefits society and their evolutionary process that is not achieved by the isolated efforts but by the participation of all organizations. Quality in Health care involves many stakeholders and groups like customers (clients), decision-makers and providers, employees and health professionals that need to interact with each other (THE LANCET, 2018; AL-JANABI et al, 2018).

Thus, it is necessary to understand the difference between quality and performance and the relationship between them. Although quality is linked to certain specific characteristics, performance says more about efficiency than in the health sector, it could be divided into two categories: 1) Quality of care is doing the right things (what), for people certain (who), at the right time (when) and doing the right things the first time and
2) Quality assurance in relation to measurement (evaluation) or quality improvement that can be considered five approaches: 1) The Transcendent, 2) O Product-based, 3) O User-based, 4) The manufacturing-based approach, 5) The value-based approach (COSTA NETO; CANUTO, 2010; DONABEDIAN, 2003).

Total Quality Control and Total Quality Management (TQM) in a hospital and Healthcare Organizations mean to do it right every time requires that everyone in the organization is aware of the need. TQM emphasizes "Quality" as a part of the management process (FONSECA, 2015; COSTA NETO; CANUTO, 2010).

This involves that the team is qualified and have the necessary knowledge and skills to attend knowing 1) Defined and specific quality policies; 2) Strong customer orientation; 3) Necessary activities to achieve quality policies and objectives; 4) Organization and wide integration of the activities; 5) Clear personnel assignments and quality; 6) Specific vendor-control activities and equipment identification; 7) Flow, processing, control and defined and effective quality of information necessary (COSTA NETO; CANUTO, 2010; L.X.Li et al, 1997).

Donabedian (2003) is one of the precursors in Quality in Health who presented quality as the maximum well-being of the patient. In 2001, the concept of the Institute of Medicine (IOM) about patient safety as a dimension of quality of care was internationally accepted. In 2003, Donabedian started to incorporate scientific and technological knowledge into patient care. In their work, the author made references to the importance of interpersonal relationships and the talent of health professionals, and the trust of the patient, emphasizing respect and communication skills (DONABEDIAN, 2003, L.X.Li et al, 1997).

The Healthcare sector is dependent on quality essential dimensions (Evaluation, Maintain, Improve, or Ensure) establishing levels of requirements and legal recognition that could be verified. According to ISO 9000, quality is designed and defined to which a set of inherent characteristics fulfills requirements. According to WHO (2019), quality of care is the level of attainment of health systems' intrinsic goals for health improvement and responsiveness to legitimate expectations of the population (ABNT, 2008; WHO, 2019).

Dependent on the interaction between several players the model of Triple Aim was designed by Donald Berwick proposing three strategies 1) Quality of care for the population, 2) Better treatment, 3) Lowest cost. The joint of Donabedian and Berwick's concepts resulted in studies to develop of Quadruple Aim that focus on all health professionals, who must have a feeling of success and accomplishment in the work (DONABEDIAN, 2003; FONSECA, 2015).

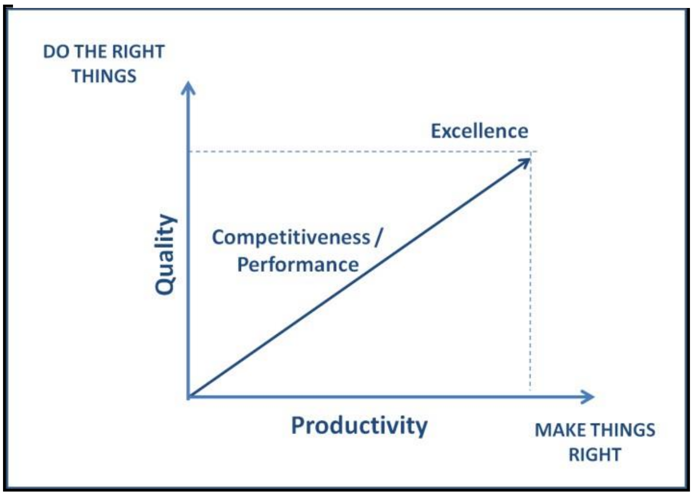
### 2.2.1 Evaluation of Health Quality and Performance

Strategies to manage quality and improve performance have been discussed by several authors. A lot of concepts that define quality and performance (productivity) have been properly studied in the literature and applied to business practices, but in the health sector, these concepts are essential for competitiveness and also could be a determining survival factor (COSTA NETO; CANUTO, 2010).

Figure 6 presents a ratio of quality and productivity to acquire excellence that could be applied for any business to improve performance. Performance measurement is intended to generate information to be used aiming to improve a quality program.

Performance measurement needs to collect and report data that will be used to summarize and assess the way a program is being implemented. A process often described as continuous improvement and used to Evaluation Methods for Quality Measurement or Performance Measurement Methods usually conceived as an organized set of indicators. "*Indicators are things we measure to evaluate progress toward goals"* (COSTA NETO; CANUTO, 2010; GÜLÇIN et al, 2011; FONSECA, 2015).

**Figure 6 - Quality performance Vs Productivity**



Source: Adapted from Costa Neto and Canuto, 2010.

## 2.3 Health Quality Standards

Quality is considered a grade of excellence that reveals the performance or the efficiency acquired as a milestone on the continuous journey of improvement. The accreditation systems of the Health Sector also consider quality as a maturity model or a way of identifying the strengths and weaknesses presented during a period of time (JCI, 2019; TING et al, 2013).

According to theoretical models, Health Quality Systems can combine several resources to allow the optimization of results also considering the need for alignment of information and high performance with the engagement of professionals and patients affecting the entire decision-making process (GREER et al, 2013; TING et al, 2013).

The ISO 13606-2 defines a quality standard through the information architecture for communication of the RES, so that it allows interoperability between systems and components through electronic messages preserving the meaning and reflecting the confidentiality of the data. (MESQUITA SALES; BENTES PINTO, 2019). Accreditation Standards provide a set of expectations of common quality to point the way forward also establishing a permanent organizational culture. Quality is essential for sustaining improvement is not only for the exhibition of certificates but especially for the safety of patients' health. (CARVALHO et al, 2019; FLOTT et al, 2016).

The Hospital Accreditation approach is a concept that yields beneficial results to patients, customers, hospital personnel and health professionals, Universities, and Society, as shown in table 2.

**Table 2 – Chart of benefits of quality accreditation**

| FOR PATIENTS | FOR THE STAFFS | FOR THE HOSPITAL | FOR THE COMMUNITY |
|---|---|---|---|
| Continuity of care & Safe transport<br>Pain management & Focus on patient safety<br>Patient satisfaction is evaluated<br>Rights are respected and protected<br>Access to quality-focused organization<br>Credentialed and privileged medical staff<br>High quality of care<br>Understandable education and communication. | Improves professional staff development.<br>Provides education on consensus standards.<br>Provides leadership for quality improvement within medicine and nursing.<br>Increases satisfaction with continuous learning, good working environment, leadership, and ownership. | Improves care<br>Stimulates continuous improvement.<br>Demonstrates commitment to quality care.<br>Raises community confidence.<br>Opportunity to benchmark | Quality revolution<br>Disaster preparedness<br>Epidemics<br>Access to a comparative database |

Source: Adapted from ISQUA. 2019, JCI, 2019.

### 2.3.1. ISQua

Quality and productivity are crucial elements for the health sector, and can also a requirement for continuous improvement processes that depend on standards organized around the important common functions important for all healthcare organizations as the International Society for Quality of Health Care and Standards (ISQua). Most widely used standards around the world have been validated by scientific studies and testing by accreditation as offered by (ISQua, 2019).

In health care several countries use some Standard ad ISO 9000 approach may in their designing quality control systems for certain “production” and services, such as laboratory, radiology, and food services (ISQua, 2019).

The Joint Commission International (JCI) operates in more than 100 countries to promote rigorous standards solutions to achieve the best performance and quality in healthcare in partnerships with hospitals, clinics, academic medical centers through an international community offering education, publications, international advisory, and accreditation, and certification services (JCI, 2019, CARVALHO et al, 2019).

In Brazil, hospitals are using standard rules like the Brazilian Accreditation Consortium (CBA) and other international standards as the Joint Commission International (JCI) and Association of Health Systems and Services Accreditation (JCI, 2019).

The Accreditation Standards are concerned with the organizational analysis, self-assessment, strategic formulation of organizational development planning, human resource development, teamwork, and service systems with a focus on patient-focused care as part of requirements (CARVALHO et al, 2019). They are based on objective criteria and metrics that seek to direct companies and organizations in general in the pursuit of excellence in their management processe (COSTA NETO; CANUTO, 2010).

### 2.3.2 JCI

In 1917, the American College of Surgeons established a set of minimum standards for hospitals. In 1951, the American College of Surgeons joined with several other professional associations to form the Joint Commission on Accreditation of Hospitals (JCI). The Joint Commission on Accreditation of Healthcare Organizations to more accurately reflect its scope of health services evaluation Hospital Accreditation is a process to create a collective organizational commitment to quality improvement (JCI, 2019).

The Joint Commission on Accreditation of Healthcare Organizations initiated the development of an international accreditation program in 1998 and was fully implemented in late 1999. The standards organized according to either patient care functions or management functions and benefits (JCI, 2019).

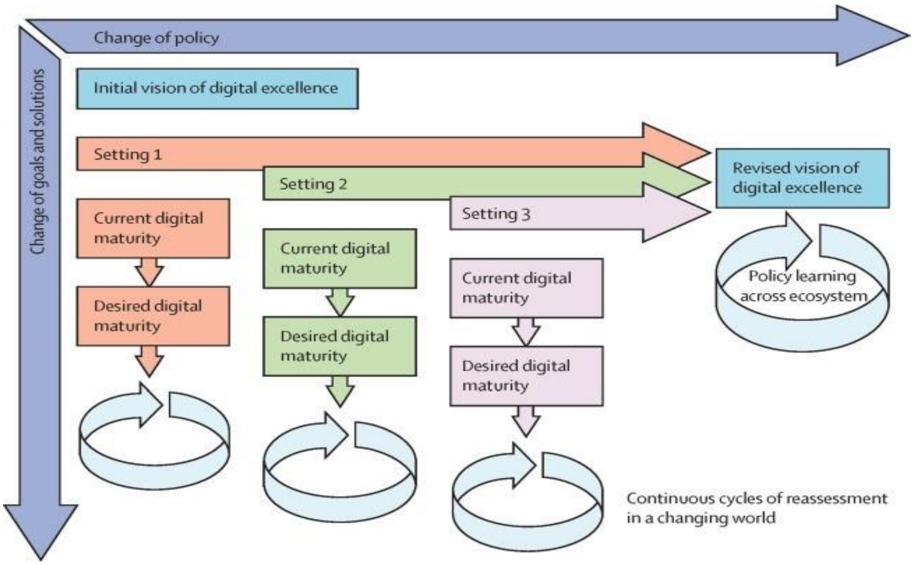
### 2.3.3 ONA

The Ministry of Health and its regulatory national agency (ANVISA) regulates the quality of care in all health service organizations in Brazil. National Accreditation Organization (ONA) is a non-governmental organization, a non-economic private entity that offers a set of standards used in the country. The ONA coordinates the Brazilian Accreditation System defining evaluation systems, quality standards, and empowering multipliers and facilitators (ONA, 2019).

### 2.3.4 HIMSS

Healthcare Information and Management Systems (HIMSS) is a worldwide non-profit organization that provides Standards and Information Systems aiming to optimize and make effective management and evaluating the quality of health institutions regarding the use of technologies and digitization. HIMSS developed models and levels of maturity that aims to identify and track which stage the organization fit. Figure 7 shows the Continuity of Care Maturity Model (CCMM) offered by HIMSS to measure the digital performance of healthcare organizations (HIMSS, 2019; THE LANCET, 2018).

**Figure 7 – Continuity of care maturity model (CCMM)**



Source: THE LANCET, 2018

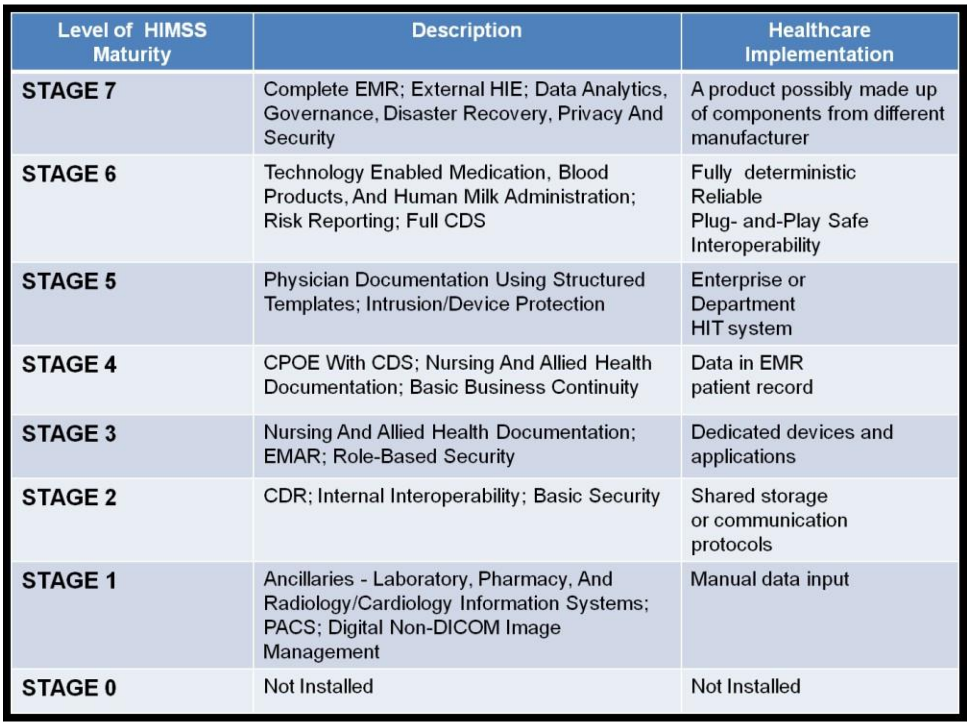
Headquartered in Chicago, with offices in the United States, Europe, and Asia, HIMSS serves the global healthcare IT community. She is a global nonprofit organization focused on providing evaluation metrics for uses of Health Information Technology (IT) that employs efforts to optimize health management and care outcomes even if current systems using a centralized architecture (HIMSS, 2019).

HIMSS encourages partnerships in areas of medicine, management, and engineering. New areas as of implementation of 4P (Preventive, Predictive, Participatory, Patient) are trending once patients are requiring control over their personal health data (HIMSS, 2019; BROOKS et al, 2013).

Figure 8 describes the stages of the Continuity of Care Maturity Model (CCMM) focusing on technological functionalities rather than human and organizational capabilities (HIMSS EMRAM also focuses on improving the efficiency and effectiveness of data exchange within hospitals rather than with other healthcare organizations. (HIMSS, 2019).

Source: HIMSS, 2019.

**Figure 8 – Chart of continuity of care model stages**



| Level of HIMSS Maturity | Description | Healthcare Implementation |
|---|---|---|
| **STAGE 7** | Complete EMR; External HIE; Data Analytics, Governance, Disaster Recovery, Privacy And Security | A product possibly made up of components from different manufacturer |
| **STAGE 6** | Technology Enabled Medication, Blood Products, And Human Milk Administration; Risk Reporting; Full CDS | Fully deterministic<br>Reliable<br>Plug- and-Play Safe Interoperability |
| **STAGE 5** | Physician Documentation Using Structured Templates; Intrusion/Device Protection | Enterprise or Department HIT system |
| **STAGE 4** | CPOE With CDS; Nursing And Allied Health Documentation; Basic Business Continuity | Data in EMR patient record |
| **STAGE 3** | Nursing And Allied Health Documentation; EMAR; Role-Based Security | Dedicated devices and applications |
| **STAGE 2** | CDR; Internal Interoperability; Basic Security | Shared storage or communication protocols |
| **STAGE 1** | Ancillaries - Laboratory, Pharmacy, And Radiology/Cardiology Information Systems; PACS; Digital Non-DICOM Image Management | Manual data input |
| **STAGE 0** | Not Installed | Not Installed |

HIMSS Analytics Infrastructure Adoption Model (INFRAM) is used in many countries. England adapted an EMRAM (Electronic Medical Record Adoption Model), adding dimensions of interoperability, technological readiness, and infrastructure components (BUTTERFIELD, 2011).

## 2.4 Interoperability’s concepts

Interoperability according to IEEE Standard Computer Dictionary (IEEE Standard Computer Dictionary, 1991) is:

> Interoperability is the ability of two or more systems or components to exchange information which methods must allow:
> 1. Unambiguously identify and authenticate users across all participating systems;
> 2. Define and enforce data access authorization policies for each system;
> 3. Ensure the authenticity and integrity of data and the security of transmission and storage;
> 4. Use information exchange standards;
> 5. Use semantic and terminology standards;
> 6. The interoperability between health information systems is only possible through the definition of standard messages, to not question the effective functioning of these systems. An integrated and interoperable system leads to a considerable reduction in the reporting and compliance burden, freeing up more time and money.

The HIMSS dictionary explain Interoperability as:

> Interoperability of health information systems as the ability “to work together within and across organizational boundaries in order to advance the effective delivery of healthcare for individuals and communities” with three types of interoperability: **Foundational interoperability**: Ability to exchange data, **Structural (or syntactical) interoperability**: Structure or format of the exchanged data and **Semantic interoperability**: Ability of two or more systems to exchange information, interpret this information correctly, and use this information (HIMSS Dictionary, 2019).

The Health Level 7 Institute (HL7) explain Interoperability as:

> The ability of different information systems, devices and applications to access, exchange, integrate and cooperatively use data in a coordinated manner, within and across organizational, regional and national boundaries, to provide timely and seamless portability of information and optimize the health of individuals and populations globally. Health data exchange architectures, application interfaces and standards enable data (HL7,2019).

Benabe et al (2015) state that interoperability occurs between multiple and varied sources. Health services are emphasized on this point because they require agreement between many stakeholders, starting with citizens' consent and agreement on how, when, and for what purpose their data can be accessed (BENABE et al, 2015).

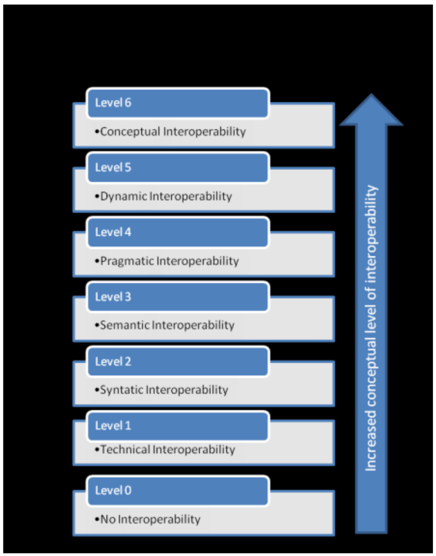
The exchange of health data concerns various types of transactions and their purposes (acceptable uses) that depend on the transport patterns, vocabulary, and data format. Access management, the consequences of security levels, responsibilities, and duties charged for violating the rules. These rules are established by governments, payers, providers, health professionals who are called to work in partnership (GDHP, 2020).

The engagement and collaboration of all stakeholders in strengthening the use of current and future digital technologies must be supported and incentivized by governance policies guidelines and best practices (GARCIA-SUBIRATS et al, 2014). The use of industry standards avoids proprietary solutions and also allows for better implementation of solutions based on global standards and protocols, terminologies, and also standards that are not yet available for actual global use (such as medicinal product identification) (GDHP, 2020; BROOKS et al, 2013; ROCHA, 2011; CRESSWELL et al, 2019).

Iroju et al (2013) say that healthcare needs to exchange information as clinical notes, observations, laboratory tests, diagnostic imaging reports, treatments, therapies, drugs administered, allergies x-rays, and bills (IROJU et al, 2013). However, this information may be heterogeneous in terminologies, schema, syntax, semantics, data types, data formats, and constraints.

Banouar and Raghay (2016) described interoperability maturity levels presented in figure 09. When is stuck at level 0 no exists interoperability. The first level is Technical Interoperability, the second a Syntactic, the third is a Semantic, the fourth as Pragmatic, the fifth is Dynamic, and the sixth level is Conceptual. (AMATO et al, 2011; GDHP, 2020).

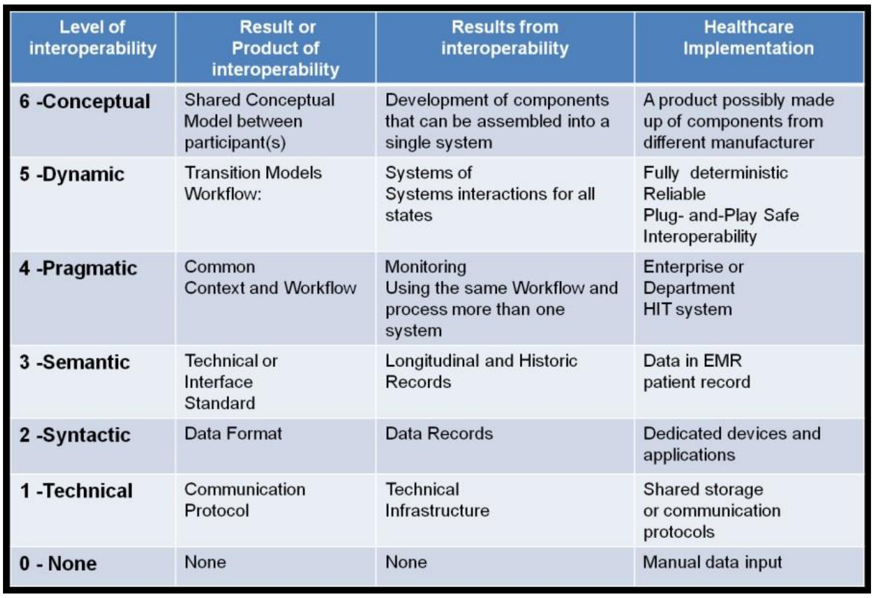
**Figure 9 – Levels of Conceptual Interoperability Model for Healthcare**



Source: Adapted from Banouar and Raghay, 2016.

Robkin et al (2015) describe these kinds of Interoperability, and it is important to remark on the concepts that are specially related to this work. Figure 10 shows the Levels of Interoperability for Healthcare. Understanding these concepts contributes to the design of a set of common clinical records to be exchanged. These definitions are all used to build a Universal Model of Medical Records (ROBKIN et al, 2015; BANOUAR; RAGHAY, 2016).

**Figure 10 – Chart of implementation of interoperability in healthcare**



| Level of interoperability | Result or Product of interoperability | Results from interoperability | Healthcare Implementation |
|---|---|---|---|
| **6 -Conceptual** | Shared Conceptual Model between participant(s) | Development of components that can be assembled into a single system | A product possibly made up of components from different manufacturer |
| **5 -Dynamic** | Transition Models Workflow: | Systems of Systems interactions for all states | Fully deterministic<br>Reliable<br>Plug- and-Play Safe Interoperability |
| **4 -Pragmatic** | Common Context and Workflow | Monitoring<br>Using the same Workflow and process more than one system | Enterprise or Department HIT system |
| **3 -Semantic** | Technical or Interface Standard | Longitudinal and Historic Records | Data in EMR patient record |
| **2 -Syntactic** | Data Format | Data Records | Dedicated devices and applications |
| **1 -Technical** | Communication Protocol | Technical Infrastructure | Shared storage or communication protocols |
| **0 - None** | None | None | Manual data input |

Source: Adapted from Robkin et al (2015)

Interoperability has been considered a critical infrastructure capacity of health systems to enable data to be seamlessly mobilized across multiple sources (ACHARYA et al, 2013; IROJU et al, 2013). According to Amato et al (2013), interoperability requires at least a syntactic and semantic level of comprehension between parts that aiming to exchange information and work together. All participants of systems to be agreed upon rules and policies through an agreement on which resources will be implemented (CARDOSO et al, 2014; AMATO et al, 2013).

There are different levels of interoperability where level 0 is regarded as no Interoperability, usually characterized by stand-alone systems. Level 1, or Technical Interoperability involves the use of a communication protocol for the exchange of data between systems. Level 2, or Syntactic interoperability occurs when two or more systems exchanging data. Level 3, or Semantic Interoperability occurs when two or more systems automatically interpret the information are exchanged meaningfully and accurately with the precise meaning. Level 4 is the Pragmatic when systems aware of the methods and procedures that each other are employing. Level 5 refers to Dynamic Interoperability when two or more systems can comprehend changes of state. Level 6 is Conceptual Interoperability is reached only if the assumptions and constraints of the meaningful abstraction of reality are aligned (LEE, Y et al, 2011, 2011; IROJU et al, 2013).

**Structural interoperability** is regarded as the data field and the level for interpretation that defines the format, syntax, and organization of data to be exchanged between health systems to achieve interoperability. However, without the ability to access, use, and see that data any interoperability is absent. This level describes the flow of data and information that is automated and integrated through several sources of data allowing data integrity, and information exchange across multiple platforms and when implemented reduces the silos of data and information, enables the capture of personal health data (BANOUAR; RAGHAY, 2016; SACHDEVA; SUBHASH, 2012; IROJU et al, 2013).

**Foundational Interoperability** level is reagarding about the possible to acquire inter-connectivity requirements needed for one system to another or application aiming to securely communicate and receive data. This level is defined as the individual level settings and include capture of data and information, capacity for data storage and management (BANOUAR; RAGHAY, 2016; SACHDEVA; SUBHASH, 2012).

**Organizational Interoperability** level is regarded about communication and use of data both within and between organizations including components as workflows, shared consent, trust and integrated end-user processes. Frameworks cointains governance, policy, social, legal and organizational considerations to facilitate the secure are and legacy technologies to support interoperability (BANOUAR; RAGHAY, 2016; IROJU et al, 2013).

**Syntactic Interoperability** (Level 2) is where devices can share and understand the format of the data exchanged but may not share an understanding of the meaning of the data. This level is also a result of fragmented design system in EHRs and other health IT (HIT) systems or technologies that remains a key barrier but Interoperability in digital health systems reaches beyond EHR data, enabling access and usability of personal health data (ROBKIN et al, 2015; BERGES et al, 2011).

**Semantic Interoperability** is the level 3 showed at figure 9 use data as elements with standardized definitions, available value sets and coding vocabularies, providing shared understanding and meaning to the users. This level drives the key aspect of the information exchange where interoperable devices can share and understanding the meaning of the data exchanged. Semantic interoperability is also complex and aspires to not only achieve interoperability within global health systems but aspires to achieve interoperability across global borders (BLOBEL et al, 2006a; IROJU et al, 2013).

**Pragmatic Interoperability** (Level 4) is regarded about a data exchanged for a right purpose and where devices share an understanding the context of the data associating information (IROJU et al, 2013).

**Dynamic Interoperability** (Level 5) says that occur in the assumptions and constraints that they are making over time, and they can take advantage of those change (BENNACEUR et al, 2010; IROJU et al, 2013).

**Conceptual Interoperability** (Level 6) is considered the highest level of understanding after well-defined real-world clinical scenarios that can be generalized and provide critical input into the applicable medical device and process standards development processes (IROJU et al, 2013).

### 2.4.1 Interoperability of Systems

Wileden and Kaplan (1997) state that software interoperability is defined as the ability for multiple software components written in different programming languages, and it is important considerate to evaluate interoperability mechanisms and the kinds of situations to which they are applied (WILEDEN; KAPLAN, 1997).

There are rationales that contribute to a more efficient and effective science through research efforts at interoperability as avoiding duplication and sharing data. Implementing a strategic interoperability plan can improve health systems to gain insights and opportunities to provide more effective care, reducing inefficiencies, adjusting demands, and also enable the organization to compete effectively in the future (BANOUAR; RAGHAY, 2016).

Data interoperability may be dependent on the reusability of data as a major source of efficiency and collected data quality, as a multi-dimensional concept, encompassing relevance, accuracy, credibility, timeliness, accessibility, interpretability, coherence, and cost efficiency (OECD, 2011).

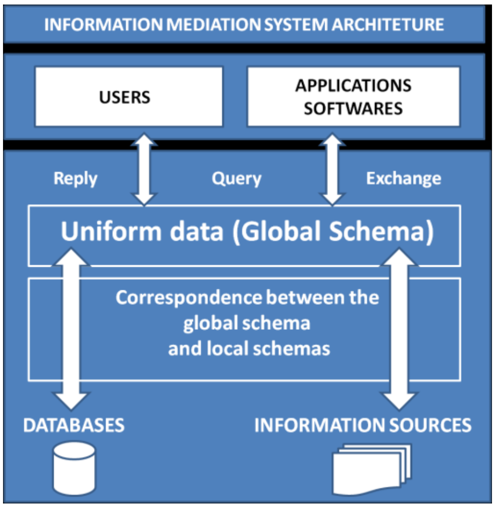
Jardim (2013) says that Health Information Systems must fulfill interoperability standards, quality, security, scalability, reliability, and timeliness in data storage. Processing terms main existing problems in this area is the fact that informatics applications do not share information, or share it at an extremely low level, but mainly achieved through proprietary integration solutions (SCHEID et al, 2013). A Ten Year Vision to Achieve Interoperable Health IT Infrastructure outlining policies and technical approach to implementing interoperability successfully (AHA, 2019, LANCET, 2018, SPYROU et al, 2003).

### 2.4.2 Design Systems for Interoperability

The American Hospital Association (AHA) suggests an interoperability ontology through Electronic Health Records to build an efficient solution with a cost-effective platform for improving health care and sharing best practices with stakeholders (AHA, 2019; BENABEN et al, 2015).

Figure 11 shows a mediated Interoperability Architecture Schema as a set of relations designed for a specific data integration application and contains aspects of the domain under consideration and its end users (BANOUAR; RAGHAY, 2016).

**Figure 11 – Interoperability Architecture Schema**



Source: Adapted from Banouar and Raghay, 2016.

The Lancet Global Health Commission presents a framework to reach transparency by implementing high-quality health systems that could save millions of lives worldwide. This framework was chosen for this research as a guideline to create reliable Health Systems including delivering data on the palm of patients on their mobile phones (THE LANCET, 2018; SPYROU et al, 2003; WHO, 2007).

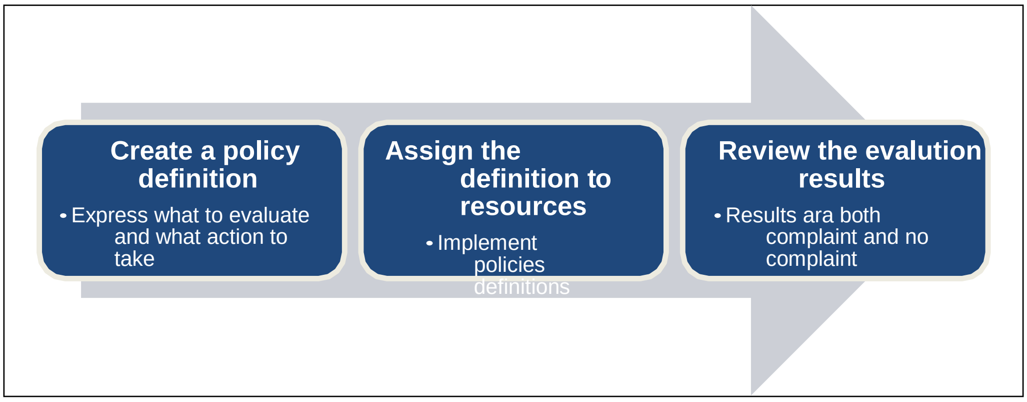
For some interoperability, needs are required Clinical Interoperability specifications, but if they do not exist, the health care delivery requirements along with the architectural context are provided (ANDRADE et al, 2013). The definition of standard Clinical Document Architecture (CDA) ensures the structure consistency to allow their interpretation by computer systems (HL7, 2019-b).

## 2.5 Medical Records Standards and Health Exchange Data

Ellouze et al (2016) say that the Medical domain is a complex area that requires handling and processing a large amount of data. Health Information Systems (HIS) have been adopted to enable the structuring of clinical data and to support care actors in their medical activities (MONSEN et al, 2019).

Standards are defined, updated, and maintained by Standards Development Organizations (SDOs) through a collaborative descriptive process. González et al (2011) state three steps to structure a standard as shown in figure 12. 1) Create a policy definition, 2) Assign the definition to resources, 3) Review the evaluation results to create standards to evaluate Maturity Models. They must be created based on best practices and should serve different purposes, identify gaps, compare stages, and evaluate levels (GONZÁLEZ et al, 2011, MONSEN et al, 2019).

**Figure 12 – Structuring a standard**



SOURCE: Author adapted from González et al (2011)

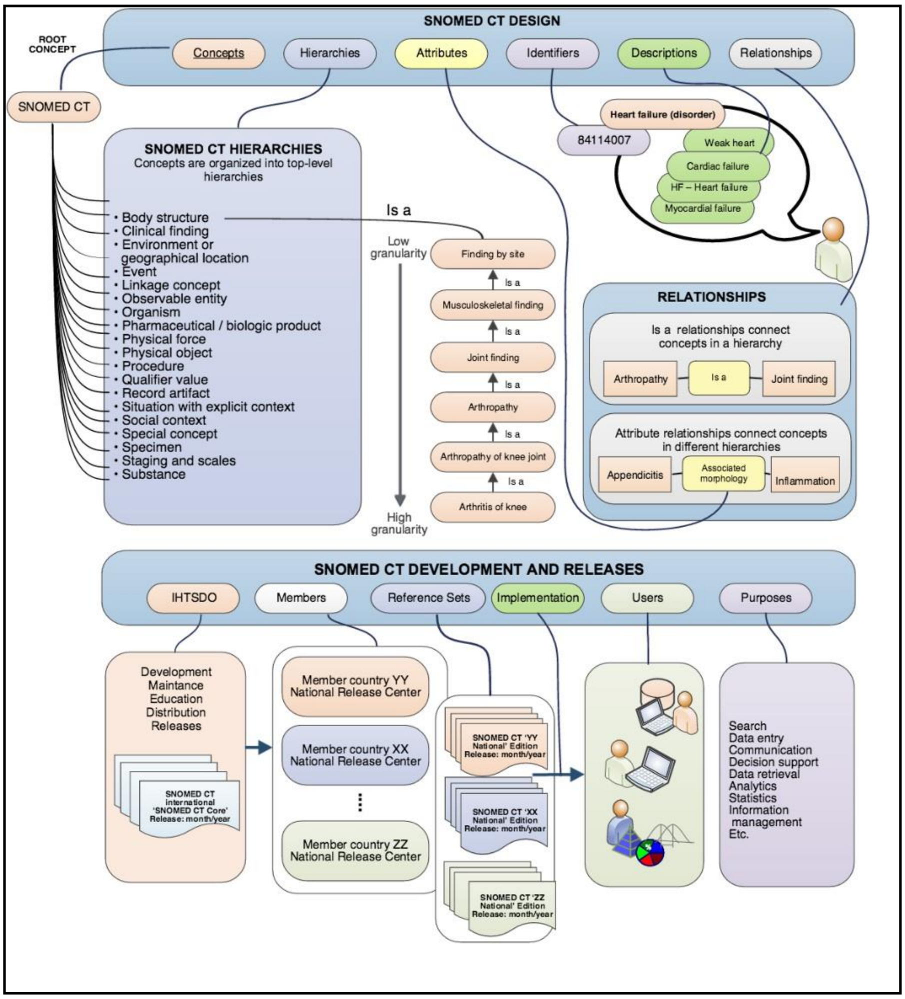
A typical clinical IT infrastructure could also use interoperability requirements. Clinical Information System (CIS), Patient Data Management System (PDMS), or Picture Archiving and Communication System (PACS) are standards of Health Information Systems that are rather complementaries. Health Level Seven (HL7) and Digital Imaging and Communications in Medicine (DICOM). The HL7 Fast Healthcare Interoperability Resources (FHIR), and the EEE Standard 11073-10101 using nomenclatures on their Domain Information Model (DIM) establishing communication patterns for Application Profile, Communication Transport Profiles, Architecture & Binding, Point-of-Care Device, and Personal Health Device, etc (LEE, Y et al, 2011, 2011; MONSEN et al, 2019; SABBATINI, 2014).

### 2.5.1 Healthcare Standards, Terminologies and Protocols

Health Care organizations are strongly dependent on terminologies, protocols, and standards to exchange information, in ideal approach would be developed in a universal set of clinical models (including terminologies, ontologies, subsets, archetypes, templates, guidelines, and etc), but it doesn´t happen then healthcare professionals (e.g. doctors, physicians, nurses, and health informatics experts, etc) usually join their interests join Communities and Related Entities aiming to discuss, solve problems or interact (CARDOSO et al, 2014; COMMITTEE, 2020-a; RAPPAPORT et al, 2008; SABBATINI, 2014).

SNOMED CT is a consecrated standard by the community of Integrating the Healthcare Enterprise (IHE) guarantees security, data transport, and format through codes and meanings of terms that incorporate multidimensional complex concepts regarding processes, workflow, interoperability, decision support, performance evaluation, and quality improvement. Figure 13 shows the features embraced in their structure (MONSEN et al, 2010; LEE, D et al, 2010).

**Figure 13 – Snomed C T Design Structure**



Source: https://confluence.ihtsdotools.org/display/DOCSTART/4.+SNOMED+CT+Basics

Table 3 shows a shortlist of SDOs, Related Entities, and Official Observers that usually join efforts to exchange health data, implementation guides, ontologies, terminologies, specifications, or protocols (HEALTH IT GOV, 2020).

**Table 3 – Summary of Terminologies used for exchange health data**

| STANDARD | DEFINITION |
|---|---|
| C-CDA | Consolidated-Clinical Document Architecture is a framework for creating clinical documents that contain both human-readable text and machine-readable XML. |
| CDS | Service a decision support that accepts requests containing patient information,and provides responses. |
| CPT | Current Procedures Terminology Code set. American Medical |
| DICOM | Digital Imaging and Communication in Medicine |
| DIRECT | A standard for sending Health Information securely over the internet. |
| FHIR | FHIR is a specification for exchanging clinical and administrative health care data. The standard is based on REST and OAuth. |
| ICD | International Classification of Diseases codes |
| HEART | Health RelationshipTrust is a set of profiles that enables patients to control how, when and with whom their clinical data is shared. |
| HL7 | The v2 is used standard including specifications for patient administration, orders, results, scheduling, claims management, document management, etc to implement profiles as ATNA (audit trail and node authentication)/XCA (cross-community access: query and retrieve patient records held by other communities)/XCPD(cross-community patient discovery: locates patient records in other communities and resolves different patient identifiers)//XDR (cross-community interchange: point-to-point sharing of electronic documents)/XDS(cross community document sharing: discovery and sharing of e- documents)/PDQ (patient demographics query: consult a central patient information server to look up patient identity based on demographics)/PIX (queries for patient identity cross references among different sites) and HL7 RIM- HealthLevel Seven Reference Information Model |
| HQMF | Health Quality Measure Format is a standard-based in representation of quality measures as electronic documents |
| LOINC | Logical Observation Identifiers Names & Codes |
| NUCC | American Medical Association. Health Care Provider Taxonomy code set |
| OpenID | A simple identity layer designed to work with Oauth 2.0. |
| OAuth 2.0 | A simple authorization framework that enables a third-party application to obtain access to an HTTP service. |
| PDMP | Prescription Drug Monitoring Program |
| QRDA | Quality Reporting Document Architecture is a standard for communicating health care quality measures |
| SNOMED CT | Scientifically validated multilingual clinical content healthcare terminology |

Source: compilation of https://www.healthit.gov/topic/standards-technology/health-it-standards and https://www.ajmc.com/view/exchanging-healthcare-data-a-look-at-3-standards-competing-to-provide-interoperability

According to HEALTH IT GOV (2020), in general, these organizations are presented in three categories as examples. **1) Standards Development Organizations (SDOs):** ADA (American Dental Association), ASTM CDISC (Clinical Data Interchange

Standards Consortium), HL7 (Health Level Seven), IAIABC (International Association of Industrial Accident Boards and Commissions), ISO/TC215, NCPDP (National Council for Prescription Drug Programs), Regenstrief (LOINC) **2) Standards Development Organizations-related entities** as GS1 US, IHE, The Open Group Healthcare Forum WEDI (Workgroup for Electronic Data Interchange), RTI International and **3) Official Observers**: Accenture, ANSI (American National Standards Institute), ONC (Office of the National Coordinator), Social Security Administration (SSA).

Specifically for nursing care also there are also important terminologies (NANDA, NIC, NOC, Omaha System, CCC, PNDS) some are integrated into SNOMED CT as ICNP (International Classification of Nursing Practice). Nursing Management Minimum Data Set (NMMDS) has not yet been fully mapped to SNOMED. Regarding the AAMI Foundation, they are not self considering as an SDO but dedicated to advancing the professional development of health technology professionals and the safety of technology health professionals (HUARD; MONSEN, 2017; BASKARADA; KORONIOS, 2013).

Beyond the quoted organizations, DirectTrust is a non-profit association that gathers over 100 health IT and health care provider organizations memberships aiming to support health information exchange developing Scope of Standards and specifications enabling and promote healthcare interoperability using Direct exchange and trusted frameworks regarding security, interoperability, etc (BASKARADA; KORONIOS, 2013).

## 2.6 Health Level 7 (HL7)

Standards are a priority of the American Health Information Community (AHIC). Health Level 7 International is an American National Standards Institute (ANSI) accredited Standards Developing Organizations (SDOs). The HL7 International is a not- for-profit SDO headquartered in Michigan, USA. The HL7 standard was originally developed in 1987 aiming to build consensus and it has been adopted in more than 55 countries, including Brazil (HL7, 2019-c).

HL7 International's Vision states:

> "*A world in which everyone can securely access and use the right health data when and where they need it"* and their mission is *"to empower global health data interoperability."*

HL7 International adheres to a strict and well-defined set of operating procedures that ensures consensus, transparency, and balance of interest that collaborates or working together with other SDOs like The Joint Initiative Council for Global Health Informatics Standardization (JIC) or SO TC-215, etc. HL7 standards are widely used in healthcare IT to exchange keys and both sets of clinical and administrative data (HL7, 2020).

However, HL7 International produces more than only messaging Standards for particular healthcare domains such as pharmacy, medical devices, imaging, or insurance transactions. Their implementation guides used pre-defined logics and formats for the exchange of health data between different and diverse computerized systems. The HL7 Clinical Document Architecture (CDA) is a document that specifies the structure and semantics of "clinical documents" for the purpose of exchange used in dozens of countries (HL7, 2020).

### 2.6.1 FHIR (Health Level 7 Standard)

HL7 is a (Health Level 7) standard for health interoperability and a Reference Information Model (RIM) representing the domain of medical information among different standards (BANOUAR; RAGHAY, 2016). The version 2.x of HL7 protocol for electronic data exchange is one of industry-standard used to convey clinical and administrative information between heterogeneous health applications, which is based in the context of the application-application messaging exchange (COMMITTEE, 2020b).

The version protocol HL7 v2.x uses the principles of the Unified Modeling Language (UML). The HL7 version 3 (HL7 v3) adopts an object-oriented approach, which is based on Reference Information Model (RIM). The XML schemas derived from the conceptual model, which is suitable for data transportation between heterogeneous systems, allowing structured information encoding, separating content from formatting. The process of developing the standard HL7 v.3 defines the rules used in the implementation and drift specific domain information models (BANOUAR; RAGHAY, 2016; YAMAGUTI, 2018).

The second version of HL7 V.2 was a successful model which flaws was corrected in version 3, but this transformed it in a slow and complex pattern. Fast Health Interoperability Resources (FHIR) in practice is the fourth version with several new features creating a robust and effective data standard committed with democratization of technologies that contribute to standardize semantics of medical writing (KASPARICK et al, 2019).

The standard HL7 RIM provides a significant level of functionality of messaging between applications using worldwide and popular standards for exchange information as:

**PIX** - Patient Identifier Cross-referencing HL7 V3 (PIXV3) enables multiple distributed applications to correlate information about a single patient, from sources that know this patient by different identifiers.

**PDQ** - Patient Demographics Query HL7 V3 (PDQV3) is a set of predefined demographic data that enables multiple distributed applications to query the demographic data of people stored on a central server.

Fast Healthcare Interoperability Resources (FHIR) standard became popular due to its simplicity through use already established standards through Internet. Acording Andrade et al (2013) REST and OAuth provide a data structure syntax for clinical IT infrastructure that also includes clinical syntax. FHIR can deal with large repositories, semantic annotations, and a set of global reference terminologies aldo including locally terminologies and protocols (YAMAGUTI, 2018; D, L. J. et al, 2016).

The FHIR API treats complexities presenting a simple service that can be easily consumed in applications using Representational State Transfer (REST) which is a language-independent architectural and software architecture to develop features using the internet's Hypertext Transfer Protocol (HTTP) that allow creating web services build upon existing systems (DOGAC et al, 2007; YAMAGUTI, 2018; D, L. J. et al, 2016).

REST-based applications can be written using any language allowing them to create APIs with the ability to improve the speed and efficiency of their operations. OAuth 2.0 is a simple authorization framework that enables third-party applications to obtain access to an HTTP service (DOGAC et al, 2007; PANG et al, 2018).

The use of these languages enables support document, messaging & services paradigms attending 1) Faster implementations, 2) Conformance & Conformability testing, 3) Semantic Interoperability, 4) Better Quality, Methodology & Tools, 5) Confidentiality/Security and Harmonization (DOGAC et al, 2007; YAMAGUTI, 2018). HL7 International supports a lot of projects to use the Fast Healthcare Interoperability Resource (FHIR) through several initiatives (HL7, 2020-b).

A sucessfull example is *The Argonaut Project* that aims to exchange clinical and administrative health care data through a system that can smooth the flow of health information softwares and their architectural for attesting, validating and exchanging data. (HL7, 2020-c).

### 2.6.2 HL7 Workgroups

Members of HL7 International is widely organized by workgroups. HL7'workgroups members could be from academia, providers, vendors, payers, consultants, government groups, and driver stakeholders interested in the development and advancement of clinical and administrative standards for healthcare (HL7, 2020-a; BLOBEL et al, 2006; KHATCHERIAN et al, 2019; D, L. J. et al, 2016).

The working groups are guardians of the HL7 standards. Their members participate voluntarily in governance processes, protocols, and specifications. They are, in fact, commissioners designed to educate, inform, support, produce HL7 Educational Materials with the aim of promoting and disseminating HL7 standards and rules. The Pareto rule (80-20) that represents 80% of the assertive is employed for systems development and used by Working Groups to solve disputes and controversy generated by diverse ecosystem stakeholders participating in the groups (COMMITTEE, 2020-b; BLOBEL et al, 2006; HL7, 2019-b, e-HEALTH NETWORK, 2016).

### 2.6.3 International Patient Summary using HL7 FHIR

Several healthcare stakeholders committed to advances of legislation and regulations were joined to solve the exchange of health data from cross-border patients. In April 2017, HL7 International and CEN/TC 251 signed a formal agreement aiming to collaborate under principles for building a global solution that was previously studied by both organizations (EUROPEAN COMMISSION, 2015).

The European initiative was operationalized by the *Smart Open Services for European Patients* (epSOS) and expand for the exchange of patient summaries and e- prescriptions embracing the idea of a globally accessible specification involving also health informatics communities. (e-HEALTH NETWORK, 2016; epSOS, 2018 EUROPEAN COMMISSION, 2020).

> *"epSOS, meaning "Smart Open Services for European Patients", was a European large-scale pilot testing the cross-border sharing of certain health data: a summary of a patient's most important health data in case of unplanned care (the patient summary) and the electronic prescription" (epSOS , 2018).*

As the healthcare industry evolves and needs to reach new levels of complexity the effectiveness of data exchange becomes even more critical and interoperability non-negotiable. Since the world of healthcare operates around exchanging clinical data the consortium guided the industry to use code systems to be universally exchangeable and understood through a model of International Patient Summary (IPS). The template follows best practices and relies on case uses of data with multilingual support and international reference terminologies licensed at no cost for global use (HL7, 2020-a, e-HEALTH NETWORK, 2016).

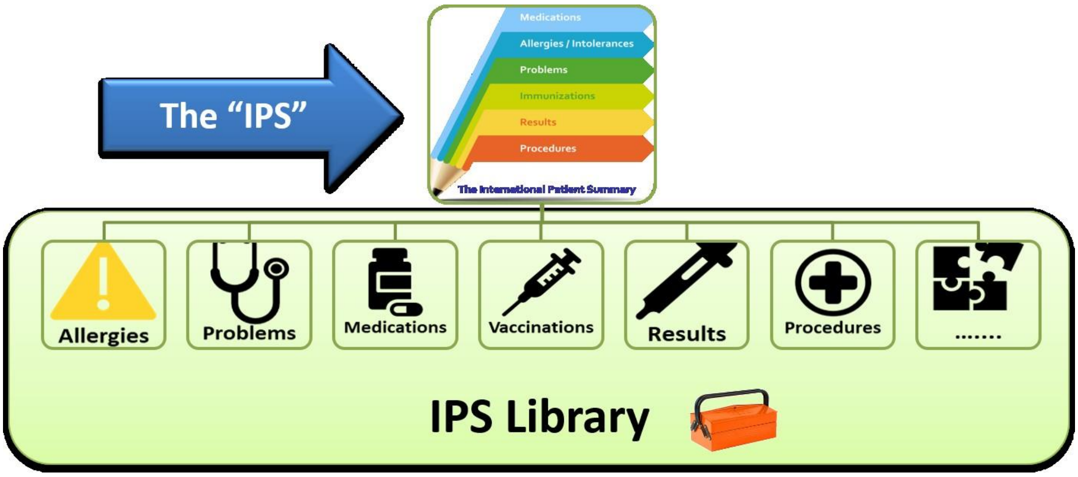
Within the scope of the IPS the "*implementable*" principle as shown in figure 14, attempts to be sufficiently generic in the design of the templates providing generic solutions for global application, but the evolution of IPS was projected for supporting new scenarios, specific specialties, and also conditions (HL7, 2020-a).

**Figure 14 – IPS Principles**

Source: HL7, 2020-a

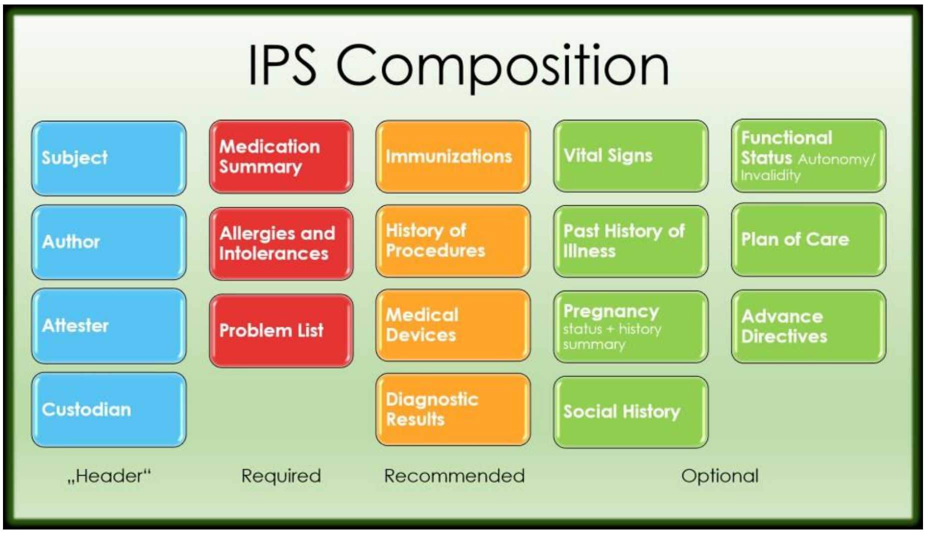
The International Patient Summary (IPS) is a document that will result from clinical encounters in electronic health records oriented by a common data set library as shown in figure 15. Several European countries adopted the EU eHealth Digital Service Infrastructure (eHDSI) project for the operational deployment of the EU cross-borders patient summary and ePrescription services. The well-defined core data sets of IPS composition are shown in figure 16 aiming to facilitate the re-use of data (HL7, 2020-a).

**Figure 15 – IPS Library**



Source: HL7 (2020-a)

**Figure 16 – IPS Composition**



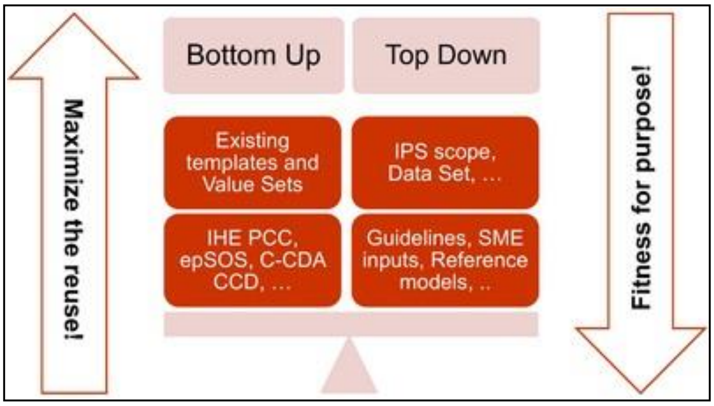
Source: HL7 (2020-a)

The International Patient Summary (IPS) congregates SNOMED CT as a primary terminology embracing the essential healthcare as a core usable value sets information using FHIR to enabling applications to connect to back-ends using REST aiming to application programmers' experience better and FHIR as a modern approach to connecting several components (HL7, 2020-a).

However, the use of reliables standards also depends on several globally usable reference terminologies as examples, the Unified Code for Units of Measure (UCUM) and the European Directorate for the Quality of Medicines & HealthCare (EDQM) currently provided in 34 languages. ART-DECOR is another standard used as an exchange format model, as the specification platform aligned with the FHIr standard (HL7, 2020-a; HL7, 2020-b).

Figure 17 shows the concept of maximizing for the reuse of data through a template aiming to facilitate the implementation-defined at the IPS scope to be considered by several countries to exchange patient health data (e-HEALTH NETWORK, 2016, HL7, 2020-a).

**Figure 17 – IPS Concepts of reuse of data**



Source: HL7 (2020-a)

The HL7 “implementation guides" has been designed to help in specific purposes. Their elements it's usually designated as “Required,” “Required But May Be Empty, “Conditional” or “Conditional But May Be Empty". The HL7 standard also could state data as “Optional” or “Backward Compatibility" and All data are standardized rules. Table 4 shows these elements when acquiring data in the IPS sections as 1) Patient Administrative, 2) Clinical Data, 3) Medical problems. They will build a summary of content captured aiming to be exchanged through cross-border countries helping medical care when requested (HL7, 2020-a, HL7, 2020-b).

**Table 4 – Summary of cross data exchanged with HL7 FHIR Resource**

| PATIENT ADMINISTRATIVE DATA | | | | |
|---|---|---|---|---|
| **variable (nesting level 1)** | **variables (nesting level 2)** | **variables (nesting level 3)** | **definition and comments** | **basic (basic)/ extended / (ext) dataset** |
| **Identification** | National healthcare patient ID | National healthcare patient ID | Country ID, unique to the patient in that country. Example: ID for United Kingdom patient | Basic |
| **Personal information** | Full name | Given name | The first name of the patient (example: John). This field can contain more than one element. | Basic |
| | | Family name/surname | This field can contain more than one element. Example: Español Smith Note: some countries require surnames to be the birth name [to avoid potential problems with married women's surnames). | Basic |
| | Date of birth | Date of birth | This field may contain only the year if the day and month are not available, e.g. 01/01/2009 | Basic |
| | Gender | Gender code | This field must contain a recognized valid value. | Basic |
| **Contact information** | | Street | Example: rue des Camélias | Ext |
| | | House number | Example: 221 | Ext |
| | | City | Example: Dijon | Ext |
| | | Post code | Example: 21000 | Ext |
| | | State or province | Example: Côte d'Or | Ext |
| | | Country | Example: FR | Ext |
| | Telephone no. | Telephone no. | Example: +33 20 7025 6161 | Ext |
| | e-mail | e-mail | Example: jens@hotmail.com | Ext |
| | Preferred HP/HPO to contact3 | Name of the HP/HPO | Name of the HP/ HPO that has been treating the patient. If this is an HP, the structure of the name will be the same as described in 'Full name' (given name, family name/surname). | Basic |
| | | Telephone no. | Example: +33 20 45 89 64 21 | Basic |
| | | e-mail | e-mail of the HP/legal organization | Basic |
| | | Role of that person | Legal guardian or contact person | Ext |

| | | | | |
|---|---|---|---|---|
| | Contact person/ legal guardian (if available) | Given name | The first name of the contact person/guardian (example: Peter). This field can contain more than one element. | Ext |
| | | Family name/surname | This field can contain more than one element. Example: Español Smith | Ext |
| | | Telephone no. | Example: +33 20 45 89 64 21 | Ext |
| | | e-mail | e-mail of the contact person/legal guardian | Ext |
| Insurance information | Insurance number | Insurance number | Example: QQ 12 34 56 A | Ext |
| Country | Country | Country | Name of country A | Basic |
| Patient Summary | Date created | Date created | Date on which PS was generated | Basic |
| | Date of last update | Date of last update | Date on which PS was updated (date of most recent version) | Basic |
| Nature of the PS | Nature of the OS | Nature of the PS | Defines the context in which it was generated. Distinguishes between three methodological approaches for genera-ting the PS: direct human intervention by an HP, automatically generated approach and mixed approach | Basic |
| Author organization | Author organization | Author organization | At least one author organization (HCP) shall be listed. If there is no HCP, at least one HP shall be listed. | Basic |
| **PATIENT CLINICAL DATA** | | | | |
| **Alerts** | Allergy | Allergy description | Description of the clinical manifestation of the allergic reaction. Example: anaphylactic shock, angioedema (the clinical manifestation also gives information about the severity of the observed reaction | Basic |
| | | Allergy description ID code | Normalized identifier | Basic |
| | | Onset date | Date of the observation of the reaction | Ext |
| | | Agent | Describes the agent (drug, food, chemical agent, etc.) that is responsible for the adverse reaction | Basic |

| | | | | |
|---|---|---|---|---|
| | | Agent ID code | Normalized identifier | Basic |
| | Medical alert information (other alerts not included in allergies) | Healthcare alert description | Medical alert information: any other clinical information that is essential to know so that the life or health of the patient does not come under threat.<br>Example 1: Intolerance to aspirin due to gastrointestinal bleeding.<br>Example 2: intolerance to captopril because of cough (the patient is not allergic but cannot tolerate it because of persistent cough). | Basic |
| | | Healthcare alert ID code | Normalized identifier | Basic |
| **Medical history** | Vaccinations | Vaccinations | Contains each disease against which the patient has been immunized | Ext |
| | | Brand name | | Ext |
| | | Vaccination ID code | Normalized identifier | Ext |
| | | Vaccination date | Date when the immunization was given | Ext |
| | List of resolved, closed or inactive problems | Problem description | Problems or diagnoses not included in the definition of "current problems or diagnosis". Example: hepatic cyst (the patient has been treated with an hepatic cystectomy that solved the problem, which is therefore a closed problem) | Ext |
| | | Problem ID code | Normalized identifier | Ext |
| | | Onset time | Date of onset of problem | Ext |
| | | End date | Problem resolution date | Ext |
| | | Resolution circumstances | Describes the reason for which the status of the problem changed from current to inactive (e.g. surgical procedure, medical treatment, etc.). This field includes "free text" if the resolution circumstances are not already included in other fields such as surgical procedure, medical device, etc., e.g. hepatic cystectomy (this will be the resolution circumstances for the problem "hepatic cyst" and | Ext |

| | | | | |
|---|---|---|---|---|
| | | | will be included in surgical procedures). | |
| | Surgical procedures prior to the past six months | Procedure description | Describes the type of procedure | Basic |
| | | Procedure ID (code) | Normalized identifier | Basic |
| | | Procedure date | Date when procedure was performed | Basic |
| **MEDICAL PROBLEMS** | | | | |
| **Medical problems** | List of current problems/diagnoses | Problem/ diagnosis description | Problems/diagnoses that fit these conditions: conditions that may have a chronic or relapsing course (e.g. exacerbations of asthma, irritable bowel syndrome), conditions for which the patient receives repeat medications (e.g. diabetes mellitus, hypertension) and conditions that are persistent and serious contraindications for classes of medication (e.g. dyspepsia, migraine and asthma) | Basic |
| | | Problem ID (code) | Normalized identifier | Basic |
| | | Onset time | Date of onset of problem | Basic |
| | Medical devices and implants | Device and implant description | Describes the patient's implanted and external medical devices and equipment upon which their health status depends. Includes devices such as cardiac pacemakers, implantable fibrillators, prostheses, ferromagnetic bone implants, etc. of which the HP needs to be aware | Basic |
| | | Device ID code | Normalized identifier | Basic |
| | | Implant date | Date when procedure was performed | Basic |
| | Major surgical procedures in the past six months | Procedure description | Describes the type of procedure | Basic |
| | | Procedure ID (code) | Normalized identifier | Basic |
| | | Procedure date | Date when procedure was performed | Basic |
| | Treatment recommendations | Description of recommendations | Therapeutic recommendations that do not include drugs (diet, physical exercise constraints, etc.) | Basic |

| | | | | |
|---|---|---|---|---|
| | | Recommendation ID (code) | Normalized identifier | Basic |
| | Autonomy/invalidity | Description | Need for the patient to be continuously assessed by third parties; invalidity status may influence decisions about how to administer treatments | Basic |
| | | Invalidity ID code | Normalized invalidity identifier (if any, otherwise free text) | Basic |
| **Medication summary** | List of current medicines (All prescribed medicines whose period of time indicated for the treatment has not yet expired whether it has been dispensed or not) | Active ingredient | Substance that alone or in combination with one or more other ingredients produces the intended activity of a medicinal product. Example: “paracetamol” | Basic |
| | | Exemption: brand name | Brand name if a biological medicinal product or when justified by the health professional (ref. Commission Directive 2012/52/EU) | |
| | | Active ingredient ID code | Code that identifies the active ingredient | Basic |
| | | Strength | Content of the active ingredient expressed quantifiably per dosage unit, per unit of volume or per unit of weight, according to the pharmaceutical dose form. Example: 500 mg per tablet | Basic |
| | | Pharmaceutical dose form | Form in which a pharmaceutical product is presented in the medicinal product packaging (e.g. tablet, syrup) | Basic |
| | | Number of units per intake | Number of units per intake that the patient is taking. Example: 1 tablet | Basic |
| | | Frequency of intakes | Frequency of intakes per hour/day/week/month. Example: every 24 hours | Basic |
| | | Duration of treatment | Example: 14 days | Basic |
| **Date of onset of treatment** | | | Date when patient needs to start taking the medicine prescribed | Basic |

| | | | | |
|---|---|---|---|---|
| **Social history** | Social history observations | Social history observations related to smoking, alcohol, and diet | Health-related “lifestyle factors" or "lifestyle observations" Example: cigarette smoker, alcohol consumption. | Ext |
| | | Reference date range | Example: from 1974 to 2004. | Ext |
| **Pregnancy history** | Expected date of delivery | Expected date of delivery | Date on which the woman is due to give birth. Year, month and day are required (e.g. 01/01/2014). | Ext |
| **Physical findings** | Vital signs observations | Blood pressure | One blood pressure value, which includes systolic blood pressure and diastolic blood pressure. | Ext |
| | | | Date when blood pressure was measured. | Ext |
| **Diagnostic tests** | Blood group | Result of blood group | Result of blood group test performed on the patient. | Ext |
| | | Date | Date on which the blood group test was performed. This field may contain only the year if the day and month are not available. | Ext |

Source: TRILLIUM II PROJECT, 2019.

### 2.6.4 Trillium II Project

TRILLIUM II is an EU/US Cooperation Project aiming to promote Global Interoperability in Digital Health and advance the IPS dataset and Table 5 shows using guidelines. Trillium Bridge provided interoperability standards under the ONC Standards and Interoperability Framework (ONC S&I). The EU/US eHealth Cooperation is an initiative to improve quality and reduce costs through this International project. The document also describes the journey of patients and two use cases that generated a minimum consensus for the build of a Patient Summary (TRILLIUM II PROJECT, 2019).

The report eHealth Network Guideline on the electronic exchange of health data under Cross-Border (Release 2) presented organizational and policy considerations (legal and regulatory), semantic issues and terminologies (standards), and technical requirements (security, testing and audit).

Inspired by the CEN/HL7, the implementation guide follows the standards of HL7 IPS standards. FHIR is used to exchange clinical data, vocabulary, and value sets and adopted by consensus by the eHealth Network as standard (SALMI et al, 2020).

**Table 5 – Description of patient summary sharing on a cross-border**

| | |
|---|---|
| **Purpose Sharing** | Information about the medical background and history of a patient from Country A (the patient's country of affiliation) with a healthcare professional in another Member State Country B (the country of treatment). |
| **Relevance** | Many people request medical help when travelling, working or living abroad. Medical information from the country of origin should be available to all citizens in Europe (in their native language). The current solutions (if any) for obtaining medical information from another country are often cumbersome, unsafe, incomplete and non-standard. The treatment of patients without proper medical background information is hazardous and should be avoided. Benefits can be gained from increased quality of care (e.g. patient safety) (both medical and economical) and from a decrease in the effort of gathering/exchanging health information. |
| **Domain Patient** | Situation Cross-border |
| **Context** | The definition of a Patient Summary was laid down by the epSOS project as a starting point for the development and pilot testing of a Patient Summary for citizens who are travelling abroad and need medical help (unplanned). Challenges are related to the level of data required and the quality of information relevant to support patient treatment effectively across different participating European countries. Different countries operate different health care systems, support their own culture for healthcare provision, and may use a different (or several different) language(s). A Patient Summary provides background information on important aspects such as allergies, current medication, previous illnesses and surgeries, etc. These are necessary for the proper treatment of a patient abroad, especially when there is a language barrier between the healthcare professional (HP) and the patient. Two Use Cases are possible regarding the Patient Summary (PS). The first is the one in which an occasional visitor needs his/her PS in country B. The second is which the person is a regular visitor in country B. The distinguishing characteristic is that the HP may have some information available from previous encounters in this type of occasional situation. Both a PS from country A and one from country B need to be consulted. In this Use Case, of the occasional visitor is described. Information Patient Summary (in patient's language and country B language). |
| **Patient consent** | Participants Patient. Health professional in patient's country of origin/affiliation (country A) and Health professional in country of treatment (country B). |
| **Functional process steps (With the reservation that preconditions are met)** | The patient consults a health professional in country B. The patient is identified (identity confirmed by country A. The health professional is identified, authenticated and authorized. The patient may have given consent before travelling to country B or in country B to the health professional (except for emergency cases) In the latter case, the health professional will then register this confirmation. The Patient summary is electronically transferred from the patient's country of origin to the health professional in the country that s/he is visiting (the "visiting country") in a secure way. The health professional retrieves the Patient Summary and uses it for the consultation. The PS is received in both the language of the patient (PDF of original PS) in translated version for the health professional. |

Source: Adapted from TRILLIUM II PROJECT, 2019.

Table 6 shows the directives used to build the Patient Summary dataset (EUROPEAN COMMISSION, 2016).

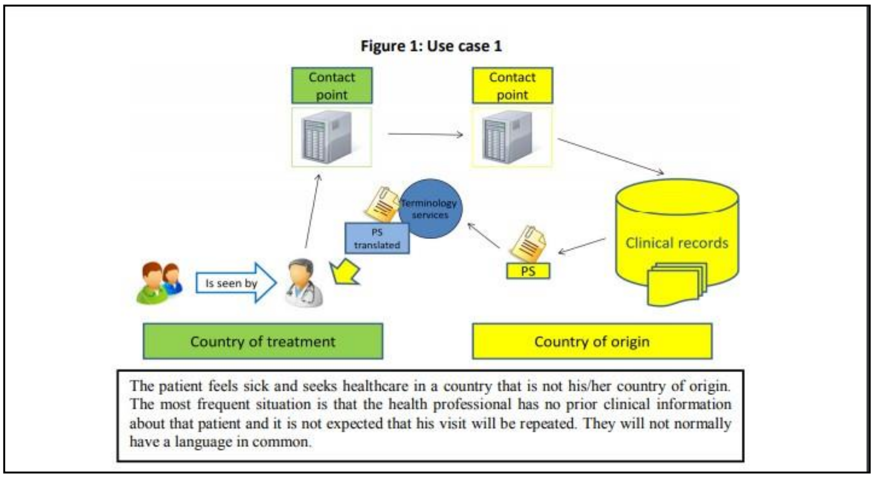
**Table 6 – Summary of benefits of international patient summary**

| Health Systems | Citizens/Patients | Emergency doctors (clinical) | Standards developers and SDOs | Vendors and developers |
|---|---|---|---|---|
| Increased safety, quality care and universal access. | Increased safety in administration of treatment in emergencies. | Facilitate the identification of patients and consult their essential healthcare data. | Support in validating and receiving endorsements on the accuracy of cross-border clinical. | Increased understanding of use cases will contribute to reduce dependency upon locked-in solutions and to open-up the market to innovative products from SMEs. |
| Faster integration of health informa-tion across care providers, therefore enabling care decisions based on more complete information. | Increased trust in provided health care. | Improve the decision-making process in diagnosis, based on the patient's relevant clinical data. | Bridge the gap between standardization and adoption - collaboration between development teams are likely to achieve a result that standards are more widely adopted. | Use of Harmonized standards will likely decrease unnecessary regulatory divergences, which constitute barriers in key economic sectors such as health and health IT. |
| Increase interoperability between procured components of national, regional and local eHealth architectures and applications, is likely to improve quality and reduce costs. | Increased access and quality of care and information on patients' clinical history. | Increased likelihood of obtaining patient consent for healthcare services. | Increased funding resulting from engagement with open innovation and from the evolution of governance of the international patient summary. | Development of solutions based on Open Source codes and Standards (e.g. CDA). Making market more competitive on the global scale. |
| Better alignment of the eHealth standardization process and Health policy development in Europe, the US and globally. | Security increase deriving from the use of a paperless electronic patient data system. | Better patient care through cross-border healthcare data exchange. | information structures and associated terminology value sets. | Advance of EU-US innovation capacity on industry development and market growth (eHealth and pharma). |
| Availability of just-in-time standards and specifications for agreed policy decisions or initiatives. | Efficient use of resources providing healthcare to foreign patients. | Available in own language (with an original copy). | interoperability assets in the form of libraries for FHIR, building blocks that dynamic developers can rapidly adopt. | e) Impact on the mobile Health industry, an industry that, in general, is driven by low budgets and cannot afford adoption of complex standards. |

Source: Adapted from TRILLIUM II PROJECT, 2019.

Figure 18 shows a graphical of the first use case that establishes a journey to attend trans boundaries patients. Figure 19 shows the second example of a use case. These cases were used to build some experimental artifacts through an HL7 implementation guide. The project has pilots in Six countries: Australia, Canada, Chile, Japan, Sweden, and the USA (TRILLIUM II PROJECT, 2019).

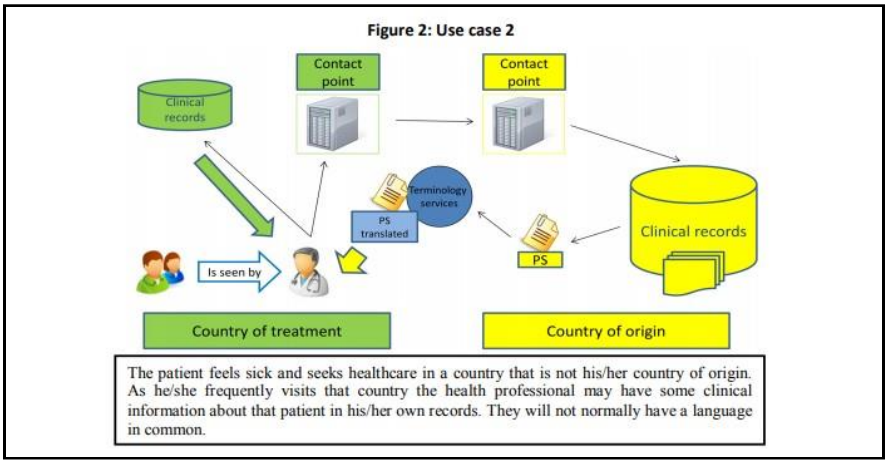
**Figure 18 – IPS – Patient journey cross-border first use case**



The patient feels sick and seeks healthcare in a country that is not his/her country of origin. The most frequent situation is that the health professional has no prior clinical information about that patient and it is not expected that his visit will be repeated. They will not normally have a language in common.

Source: Adapted from TRILLIUM II PROJECT, 2019.

**Figure 19 – IPS Patient journey cross-border second use case**



The patient feels sick and seeks healthcare in a country that is not his/her country of origin. As he/she frequently visits that country the health professional may have some clinical information about that patient in his/her own records. They will not normally have a language in common.

Source: Adapted from TRILLIUM II PROJECT, 2019.

## 2.7 OpenEHR and FHIR

Interoperability is necessary for the health care system to operate supported and integrated by heterogeneous electronic health records. The OpenEHR proposal, which is an international standard that is defined dynamically from a Reference Information Model

(RIM), whose objective is to provide a semantically interoperable architecture for RES organized in the form of archetypes (standardized, but flexible models) for capture and representation of patient clinical data. The standard uses terminology, vocabularies and external classification systems and provides content-based Decision Support Systems.The openEHR specifications are maintained by the openEHR Foundation and are the result of 15 years of research by a team of Europeans and Australians (ELLOUZE et al, 2016; MESQUITA SALES; BENTES PINTO, 2019).

OpenEHR Reference Model is a standard important to quote. Consecrated in the Informatic Health Community that provides an extensive theoretical basis for the EHR represented in an Archetype Definition Language (ADL) or Archetype Object Model (AOM, an ISO standard) in layers of separate clinical domains (ELLOUZE et al, 2016).

The OpenEHR International offers an online tool, the Clinical Knowledge Manager (CKM) which content of archetypes is gradually developed as a comprehensive library of high quality, multilingual, purpose-agnostic, progressively created, peer-reviewed, and published (LESLIE, 2020, ELLOUZE et al, 2016).

These archetypes specifications describing a single clinical concept intending to reach a maximal data set, universal use cases, and agnostic approach purpose. The data set specifications, known as openEHR templates, are developed by aggregating and constraining the archetypes to represent the data set required for a specific clinical purpose. The archetypes are hosted in 29 languages and translations including Brazilian Portuguese (LESLIE, 2020).

> The two-layered openEHR modeling methodology supports rigorous governance of multilingual archetypes as the reusable building blocks of clinical content, while templates enable the expression of diverse clinical requirements by aggregating, configuring and constraining the archetypes as required for a given clinical use case, domain, profession, or geographical location " (LESLIE, 2020).

FHIR is based on a set of basic modular components called Resources, which describe the clinical or administrative contents of the health records that can be exchanged. OpenEHR uses the archetypes as datasets to represent all the clinical content, while FHIR resources only contain the most used clinical information, that can be extended with additional items for a specific use case. In order to create FHIR archetypes is necessary to define a Reference Model that could offer some key advantages, as an example to be able to check if a resource is valid in the reference model in an easy way (ELLOUZE et al, 2016; LESLIE, 2020).

In a digital society, interoperability is not only desirable but essential and today is possible to choose the better tool to implement solutions. FHIR and openEHR are open standards and both have core interoperability (STONE, 2014). The key point for choosing any development is to select the approach, standard, or technology that best meets the needs to be attended to the scope. OpenEHR uses over 300 complex archetypes designed to provide a maximal set of data elements optimized providing a data platform with a stronger focus on the persistence of data. FHIR is also an easy and consensual standard for data exchange in digital health (ELLOUZE et al, 2016; LESLIE, 2020).

The main difference between OpenEHR and FHIR is that the first has been designed to model clinical information, and the second has been designed to exchange information. OpenEHR is a standard that represents the maximum dataset and FHIR, oriented by HL7 principles, was conceived as a standard to attend the 80/20 rule (ELLOUZE et al, 2016; LESLIE, 2020).

## 2.8 The USA: An Overview of Health Data Laws and Rules

As a country ruled by laws, the USA inspiring other countries in the western world to use their patterns, policies, and norms, but it is the only industrialized nation without universal health coverage for their citizens, however, their laws largely to protecting privacy, especially regarding health data are very consistent engaging worldwide society (SALMI et al, 2020; BERRY, 2018; BLUMENTHAL, 2012).

In December 2016, focused to advance nationwide interoperability the United States enacted the 21st Century Cures Act: The 21st Century Cures Act and Trusted Exchange Framework (TEFCA). One of the requirements mandated by law was the creation of a TEF (Trusted Exchange Framework) released by ONC in an initial draft in January 2018 (BERRY, 2018; IYIEWUARE et al, 2018). The second draft was published in April 2019, determining how components fit legal and technical requirements (GONZÁLEZ et al, 2016).

According to the American Hospital Association (AHA), the United States is ruled by the Healthcare Information Portability and Accountability Act (HIPAA) was approved in 1996 and implemented in 2003. The law dictates healthcare compliance norms across the industry and the Health Insurance Portability and Accountability Act (HIPAA) establishes requirements for HIPAA and Health Information Technology (AHA, 2016).

The Office of the National Coordinator for Health Information Technology (ONC) is responsible to support the adoption of information technology and the promotion of health information exchange including timelines, projects, contents, playbooks, and call to action grouped in five areas 1) Population health; 2) Care coordination and interoperable health IT systems; 3) Value-based care; 4) Healthcare data analytics; 5) Patient-centered care (SCHEID et al, 2013; HUSSAIN et al, 2016; SITTIG et al, 2018).

The Health Information Technology for Economic and Clinical Health Act (HITECH) promotes standardized Electronic Health Records (EHR). The act was implemented in 2009 to address the privacy and security concerns of patient data through EHR and how they are shared. HIPAA mandates industry-wide standards and processes for the protection and confidential handling of patient health information. The full name is "*The Patient Protection and Affordable Care Act*", which creates rules and standards to protected patient information (ROBKIN et al, 2015; AHA, 2019; HIPAA, 2020).

The Department of Health and Human Services and Office for Civil Rights provider audits penalties for breaches of information and non-compliant up to $1.5 million (ROBKIN et al, 2015; AHA, 2019). The U.S. Department of Health and Human Services (HHS) Office of the Inspector General (OIG) is the governmental wing responsible for protecting patient privacy, ensuring quality, and fraud combating ensuring the healthcare organizations to be compliant with federal healthcare laws and programs (ROBKIN et al, 2015; AHA, 2019).

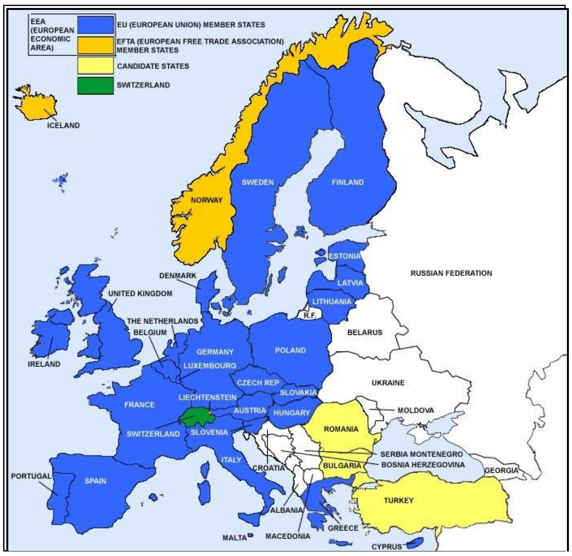
The HIPAA Privacy Rule focuses on the right of individuals to control the use of their personal information and covers confidentiality limiting its use and disclosure applying to entities as doctors' offices, hospitals, health insurers, and other healthcare companies abling access to patients' to Protect their Health Information (PHI). The law regulates the use and dissemination of PHI in four areas 1) Privacy, which covers patient confidentiality; 2) Security, which deals with the protection of information, including physical, technological, and administrative safeguards; 3) Identifiers, which are the types of information that cannot be released if collected for research purposes; 4) Codes for electronic transmission of data in healthcare-related transactions, including eligibility and insurance claims and payments (BERRY, 2018; IYIEWUARE et al, 2018; HIPAA, 2020; GONZÁLEZ et al, 2016).

The scope of HIPAA was extended with the enactment of the Health Information Technology for Economic and Clinical Health (HITECH) Act. Together, HIPAA and HITECH Act rules include The HIPAA Security Rule settles the standards for administrative, technical, and physical safeguards to protect electronic PHI from unauthorized access, use, and disclosure. Business Associate Agreements (BAAs) were also included in such organizational requirements (BERRY, 2018; IYIEWUARE et al, 2018; SITTIG et al, 2018; HIPAA, 2020).

## 2.9 Estonia: A successful health exchange model

Since 2004, Estonia is a country member of the EU and since 2011 is in the Euro-zone. Figure 20 shows its map location in Europe. In their 45.000 km area,  lives1.3 million people with an expectancy of life of about 71. Approximately 17% of the population are aged between 0 to 14 years and 16% are 65 and older (ESTONIA, 2019; BOSSENKO; NORTAL, 2020).

**Figure 20 – Estonia map location**



Source: https://www.mapsofworld.com

In Estonia, there is almost no paper exchanged between government agencies and people. The country has a successful experience using 99% of digital data that saves annually approximately 2% of GDP. They have 100% of schools and government organizations with a broadband connection and 99% of bank transfers are performed electronically (ESTONIA, 2019; EISA, 2019).

Estonia is also the first country that has implemented a nationwide electronic health record system and gives full access to citizens, healthcare providers, and e-health developers. The European Commission (EC) suggests that depending on the context of the national health model, it is possible to develop a successful protocol for sharing data in appropriate infrastructure offering access to the population and this is the case of Estonia (ESTONIA, 2019; GONZÁLEZ et al, 2011; EISA, 2019; BOSSENKO; NORTAL, 2020).

The Estonian National Health Information System (ENHIS) has been improved since the country gained independence in 1991. This enabled actions to promote health information exchange through an EHR as a central project and broader initiative aiming to improve and extend health services for patients and citizens with policies that regulated eHealth as 1) Health Care Services Organisation Act; 2) Statute of Health Information System; 3) The Statute number 53; 4) Data protection law (GDPR); 5) Public Information Act (EISA, 2019; SALUSE et al, 2010).

The Estonian Electronic Health Record (EHR) began in 2000 extending health services for patients and citizens. Within this initiative, there are other several projects like OnDigital Registration, Digital Imaging, and Digital Prescription. Since 2011, infrastructure services have been offered by a private service provider. Between 2000 and 2010 the main focus was Health information exchange and the planning of health data exchange. The ePrescription project includes Electronic Health Record/ Digital Images/ Digital Prescription/ Digital Registration (EISA, 2019; BOSSENKO; NORTAL, 2020).

The country adopted an action plan using a step-by-step approach by dividing them into smaller components to manage risks. This plan compiled standards, modified the legislation, integrating the platforms, and planning the procurement of development technologies in an associated model that engaged providers. Through HL7 V3 the standards were developed to able medical data collection. Since 2009, the central Health Information Exchange (HIE) is a central data where each visit to the doctor, diagnosis, procedures, cost, offer a secure patient access to their history and medical data using a unique digital ID to register in the platform. The system covers access to 99% of citizens (ESTONIA, 2019; EISA, 2019; BOSSENKO; NORTAL, 2020).

The digital registration module includes a unified patient registration system and information about patients' waiting times. Patients use the patient portal to register and access registration and waiting list information. The portal links to the registers of healthcare providers and doctors and specialists to provide this information to patients. The EHR serves healthcare professionals and citizens simultaneously. The Patient Portal is the mean of access and allows citizens to view their medical data and related information (ESTONIA, 2019; GONZÁLEZ et al, 2011; EISA, 2019).

Estonian Health Information system is designed through ID card for authentication and digital signature and 6 main security principles: 1) Secure authentication of all users with ID-card, or Mobile-ID; 2) Digital signing or stamping of all medical documents; 3) Maximum accountability (transparency) to all actions that will leave an unchangeable (and unremovable) secure trail protected by blockchain coding of personal data, separating of personal data from medical data; 4) Encrypted database that allows removing the confidentiality risk from the technical administrators; 5)Monitoring of all actions together with the corresponding counter-measures (both organizational and technical); 6) Responsibilities to health care facilities (ESTONIA, 2019; BOSSENKO; NORTAL, 2020; SALUSE et al, 2010).

All healthcare providers must send data to Health Information System and Patient has the right to close his/her own data collected in the central database (opt-out), can access their own data (Patient’s Portal), can declare their intentions and preferences, patient can monitoring and access only to licensed medical professionals and other persons have access to personal data in the HIS if such right arises from the law (ESTONIA, 2019 BOSSENKO; NORTAL, 2020; SALUSE et al, 2010).

The central database of EHR includes the Patient’s primary information (for example contacts, allergies, drugs, etc) to health professionals. A link to a directory points to other sources which include some medical data about the patient. Patients have full access to their medical records offers an opportunity to improve their choices. In the iPatient application (http://recordaccess.icmcc.org/tag/portal/) professionals can: 1) Quick and safe access to the EHR for medical history, 2) Access to images, results of exams and analyses; 3) Access to all medical data, including medical image reports; 4) Up-to-date information from any location; 5) Patient choice and involvement in their care; 5) Sharing the information in the EHR with other clinical specialists (EISA, 2019; BOSSENKO; NORTAL, 2020; SALUSE et al, 2010).

Legal regulations specify the security requirements for the EHR and its access. All healthcare providers must send agreed data to the EHR. The electronic documents use the standard Health Level Seven International (HL7) documents are kept in Extensible Markup Language (XML) format HL7 Clinical Document Architecture (CDA). The HIE platform utilizes already existing state infrastructures such as electronic ID cards and X- Road security and communications. All structured data fields have Object Identifiers (OID) CDA to format documents that are stored in a central database and archived electronically (EISA, 2019; BOSSENKO; NORTAL, 2020; SALUSE et al, 2010).

## 2.10 The UAE and Abu Dhabi first implementation of FHIR in the Gulf

United Arab Emirates (UAE) is composed of seven emirates and 9.77 Million inhabitants in 2019, according to data provided by the World Bank. Abu Dhabi is the capital city and leader in healthcare in the Middle East embracing people from all emirates integrating health information that improve patient care quality and better manage costs fulfilling an ambition to compete internationally, Abu Dhabi’s healthcare system is expanding their centralization to exchange and analyze massive amounts of data. The HIE will facilitate this and enable critical care insights to be extracted from population health data (UAE, 2019; KOORNNEEF et al, 2012; MOGHADDASI, 2018).

Abu Dhabi is responsible for about 70% of the country's GDP due to the oil revenue that creates the highest per capita income in the world. Software companies like American Cerner & Epic software are applied in hospitals and healthcare systems where drug use is prohibited and regulated by the Abu Dhabi Department of Health (DoH), this context helped to create the first project with blockchain support for the health of the Emirate of Abu Dhabi on a secure health information platform to exchange data between providers and improve the quality of care and patient outcomes (UAE, 2019; SPICER; WALSH, 2012; KOORNNEEF et al, 2012).

In the UAE, the Ministry of Health and Prevention (MOHAP) implemented a wide health IT system that supported seventeen UAE health facilities and eight-six primary care clinics designed to establish an electronic health record (EHR) between UAE health facilities and MOHAP patients to the use of integrated health care IT system. Each patient is assigned with a unique record number to access facilities and consult with physicians facilitating patients transfer and exchange of medical record data between public hospitals and private clinics (UAE, 2019).

In Abu Dhabi's healthcare, the first Health Information Exchange (HIE) in the Middle East created a service named "Malaffi" that was designed to exchange healthcare data. The service is operated by Abu Dhabi Health Data Services, as a company Public- Private Partnership (PPP) between the DoH and Injazat Data Systems is a subsidiary of the Abu Dhabi Government-owned Mubadala Investment Company (UAE, 2019; KOORNNEEF et al, 2012).

Unified National Medical Record Initiative is running in the United Arab Emirates (UAE) is set to become the first in Western Asia with a unified national database of patients' medical records for public and private hospitals. (MOGHADDASI et al. 2018). The project forecast is to be concluded by 2022 and intends to share the medical record, minimize prescription errors and repeat tests, also cutting down costs (UAE, 2019; SPICER; WALSH, 2012; HASSOUNAH et al, 2020).

These projects intend to enable doctors to make accurate decisions and to increase the quality of service, while also maintaining confidentiality (MOGHADDASI et al. 2018). For patients, the system will ensure empower them with knowledge about their own healthcare history. The Department of Health is leading the movement between healthcare providers and patients, as well as connecting public hospitals and clinics with a mobile APP (UAE, 2019; HASSOUNAH et al, 2020).

These services also offer a comprehensive EHR as a value to patients with complex chronic conditions, such as diabetes, heart disease, and other care needs. A partnership with Canadians is playing a critical role in the implementation of this kind of EHR model that created a longitudinal patient record with high quality, integrated information about patients across all aspects including demographics, clinical history, documentation, medication list, radiology history, diagnostic investigations, procedures, etc. Making this type of clinical information accessible irrespective of location ensures care revolves around the patient and is based on a comprehensive understanding of their unique clinical situation (MOGHADDASI et al. 2018; KOORNNEEF et al, 2012).

The project will connect the 2,000 public and private healthcare providers. It will enable physicians with tools to make rapid, well-informed decisions about their patients, enhance safety, reduce duplication of diagnostic procedures and improve quality of care and outcomes (UAE, 2019; KOORNNEEF et al, 2012).

## 2.11 Canada Health Infoway

Canada Health Infoway is an independent and non-profit organization that works with digital health solutions to improve Canadian health care system, the access and sharing of information. A study done for Canada Health Infoway says that in the last six years the use of electronic medical health records has saved over $1.3 billion making efficient and increasing productivity and interoperability (CANADA HEALTH INFOWAY, 2018).

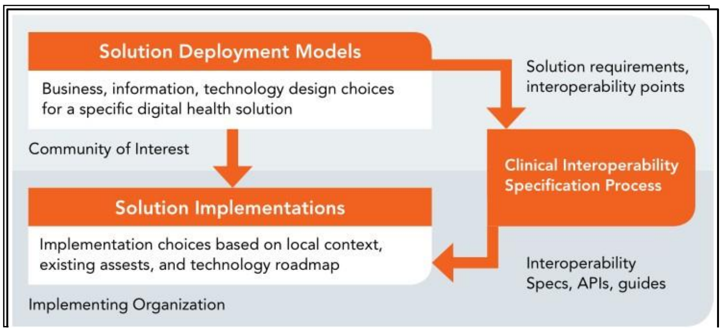
Canadian Health Infoway plays an important role in interoperability solutions and use of terminologies tools in the Canadian health ecosystem, including Digital Health Alliance and InfoCentral aiming to improve the patient experience by providing access to personal health information for all Canadians and safer access to medicines, like PrescribeIT, as an example (CANADA HEALTH INFOWAY, 2018).

This national prescribe service also regulating how patient data will be electronically transmitted directly from an EMR to a pharmacy. The purpose is to safeguard patient health data for commercial use as a choice of the patient (CANADA HEALTH INFOWAY, 2018).

Canada Health Infoway offers documents with suggestions on how to deal with digital health solutions and how they must be implemented by organizations in their set of legacy systems, policies, and resources. The InfoCentral is a hub for communities of digital health interests dialogue that hosts over 50 active virtual communities in Canada (CANADA HEALTH INFOWAY, 2018).

In Canada, patients have access to their entire records and 85% of family practice physicians and 79% of specialist physicians report using some kind of Electronic Medical Record. Figure 21 shows a scheme of Solutions Deployment Model which inputs generated an implementation guide including tools as 1) Business and technology roadmaps, 2) Current state and future state gap analysis, 3) Interoperability specifications and embedded standards (CANADA HEALTH INFOWAY, 2018; APPERTA FOUNDATION, 2020).

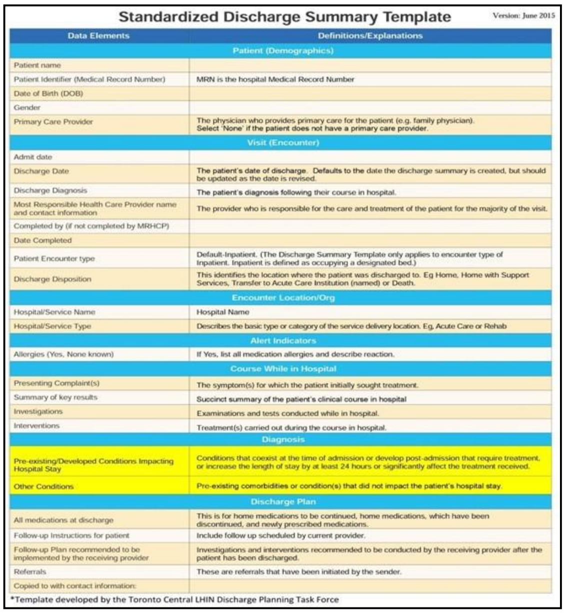
**Figure 21 – Solution deployment models**



Source: Canada Health Infoway Digital Health Blueprint, p.25.

Health Quality Ontario is dedicated to finding creative health care solutions that in a joint program of the Council of Academic Hospitals of Ontario and innovation group from University Health Network's OpenLab and support from ARTIC (Adopting Research to Improve Care) created a Patient-Oriented Discharge Summary (PODS) as show in Figure 22. The tool was co-developed by patients, caregivers, and health care providers at the University Health Networks. The solution is a discharge summary that uses plain language and easy to comprehend available in 15 languages that able also to patients' notes used by 27 hospitals across Ontario (APPERTA FOUNDATION, 2020).

**Figure 22 – Patient-oriented discharge summary (POD)**



Standardized Discharge Summary Template

Version: June 2015

| Data Elements | Definitions/Explanations |
|---|---|
| **Patient (Demographics)** | |
| Patient name | |
| Patient Identifier (Medical Record Number) | MRN is the hospital Medical Record Number |
| Date of Birth (DOB) | |
| Gender | |
| Primary Care Provider | The physician who provides primary care for the patient (e.g. family physician).<br>Select 'None' if the patient does not have a primary care provider. |
| **Visit (Encounter)** | |
| Admit date | |
| Discharge Date | The patient's date of discharge. Defaults to the date the discharge summary is created, but should be updated as the date is revised. |
| Discharge Diagnosis | The patient's diagnosis following their course in hospital. |
| Most Responsible Health Care Provider name and contact information | The provider who is responsible for the care and treatment of the patient for the majority of the visit. |
| Completed by (if not completed by MRHCP) | |
| Date Completed | |
| Patient Encounter type | Default-Inpatient. (The Discharge Summary Template only applies to encounter type of Inpatient. Inpatient is defined as occupying a designated bed.) |
| Discharge Disposition | This identifies the location where the patient was discharged to. Eg Home, Home with Support Services, Transfer to Acute Care Institution (named) or Death. |
| **Encounter Location/Org** | |
| Hospital/Service Name | Hospital Name |
| Hospital/Service Type | Describes the basic type or category of the service delivery location. Eg, Acute Care or Rehab |
| **Alert Indicators** | |
| Allergies (Yes, None known) | If Yes, list all medication allergies and describe reaction. |
| **Course While in Hospital** | |
| Presenting Complaint(s) | The symptom(s) for which the patient initially sought treatment. |
| Summary of key results | Succinct summary of the patient's clinical course in hospital |
| Investigations | Examinations and tests conducted while in hospital. |
| Interventions | Treatment(s) carried out during the course in hospital. |
| **Diagnosis** | |
| Pre-existing/Developed Conditions Impacting Hospital Stay | Conditions that coexist at the time of admission or develop post-admission that require treatment, or increase the length of stay by at least 24 hours or significantly affect the treatment received. |
| Other Conditions | Pre-existing comorbidities or condition(s) that did not impact the patient's hospital stay. |
| **Discharge Plan** | |
| All medications at discharge | This is for home medications to be continued, home medications, which have been discontinued, and newly prescribed medications. |
| Follow-up Instructions for patient | Include follow up scheduled by current provider. |
| Follow-up Plan recommended to be implemented by the receiving provider | Investigations and interventions recommended to be conducted by the receiving provider after the patient has been discharged. |
| Referrals | These are referrals that have been initiated by the sender. |
| Copied to with contact information: | |

*Template developed by the Toronto Central LHIN Discharge Planning Task Force

Source: APPERTA FOUNDATION, 2020.

## 2.12 China

Managed by a National Health Commission and a National Basic Public Health Service Program, public health in China plays a vital role in the development of the health sector. China's movements could affect all chain worldwide industry. China reached the stage to a more equitable and people-centered system (NBPHS) based on prevention-first managed by a flexible structure of the system, multi-agency collaboration, and mass mobilization and social participation in the early stage after the SARS (Severe Acute Respiratory Syndromes) crisis (WANG et al. 2019; LIAO et al, 2020).

China's system is a fertile ground for the e-health market. Their problems (huge populations and rural areas) presenting a huge adoption of mobile platforms and a significant mark-up in the distribution channel (WANG et al, 2019).

WHO recognized the model financed by both national and local governments, as an example for health systems in developing countries, especially to develop continuous efforts such as vaccination and disease surveillance, that are still required to control the spread of infectious (WANG et al, 2019).

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WANG et al (2019) say that an eHealth service to standardizing the IT system building a public EMR system and regional medical information platform received a large amount of access to capital in 2019. China's government offered an initial budget of USD 9.8 billion to support and develop the system to share medical information where patients can share information with doctors through connecting devices and the physicians can follow as consistency and continuity of medical records with the historical medical record for each patient (WHITELAW, 2020).

China is working to contribute to international cooperation with several countries like Singapore, South Korea, and India to combat COVID-19 creating digital tools to monitor and tracing contacts. 200 cities in China including Hangzhou, Wenzhou Zhejiang, Sichuan, Hainan, Chongqing, Shanghai, Yunnan, Shanxi are using a health code on Alipay as a digital epidemic prevention measure. The tool offers consultations to doctors and buys medicines with a back-end system operated by the local government automatically that checks and generates a personal QR code Kanban model to implement dynamic management (MGI, 2020; WANG et al. 2019; LIAO et al, 2020).

## 2.13 Remarks of other Health Experiences

Diverse countries adopt different solutions to attend to their health governance according to their contexts. There are some remarkable experience interoperability solutions been implemented worldwide, especially when using some standards related to HL7. The following experiences listed are summarized and are more detailed in annual health reports offered by Deloitte or OECD (BANDI et al, 2015; BROOKS et al, 2013).

**Argentina**

The Ministry of Health and Social Development of Argentina sanctioned in 2018 a resolution a National Interoperability Network including the public and private subsectors guaranteeing at the same time the rights of the patient regarding access to their health information. The IPS model has been used as a standard to exchange minimal data and the interoperability of the information systems used, allowing the exchange of data from different sources (ARGENTINA, 2020).

In the model chosen by Argentina, the "existence of the document" is persisted and allowed by all nodes, any node that is consulted knows where the document is and the chain itself is in charge of requesting the document for the node that owns it, and the latter responds by taking the document from the database and returning the document to the requesting node, similar to Brazilian RNDS. They are also guided by published governance rules and Standards Development Organizations (SDO) as SNOMED CT and LOINC hosted by the HL7 version 3 (VÁZQUEZ, et al, 2017).

**Australia**

Since 2019, the Australian government assigned citizens a secure, online health record. My Health Record offer a summary information from encounters in a strong health system nationwide. The health data networks are used for a shared national multipurpose and could be considered an excellent model (AUSTRALIA, 2020; KIM, 2015; CURTIS et al, 2014).

**Chile**

Chile has a health system with public and private health insurance where 73% of community hospitals, 68% of primary care networks, and 50% of emergency care units use electronic health records (VÁZQUEZ, et al, 2017).

Supported by HL7 Chile the second annual Health Interoperability Meeting occurred in November 2020 and presented a series of experiences as Connected Health, a pilot project that enables doctors of the Guillermo Grant Benavente Hospital to manage the clinical information of the users of Health Services to share information and form a community in line with the Connected Health Digital Strategy carried out by the Ministry of Health (Minsal) which seeks to implement a solution at the country level (CHILE, 2020).

**England**

United Kingdom is a worldwide healthcare model reference and also regarding implementation and interoperability using the HL7 framework and Fast Healthcare Interoperability Resources (FHIR). CareConnect APIs is an example of health records that contain metadata, statements (e.g diagnosis, medications, procedures, allergies), and coded entries (e.g medication, diagnosis, procedure) that use FHIR in its resources for transfer of care (e.g discharge summaries). United Kingdom National Health Service (NHS) selected the FHIR standard for exchanging information but also use OpenEHR as a required pattern to implement CareConnect FHIR APIs profiles. (BARNES et al, 2009; BLUMENTHAL, 2012).

**Lithuania and Estonia**

Estonia and Lithuania are considered small countries regarding their population (up to 3 million inhabitants) but they share also common characteristics about successful best practices in Digital health. Lithuania was the first country to implement the FHIR standard at the national level and provide hospitals and patients with access to medical records, documents, prescriptions, and digital images (BOSSENKO; NORTAL, 2020).

**Japan**

In Japan, health systems, hospitals, and small practices work with various electronic health record systems. Citizens have the legal right to request medical records, but most are unaware of this. The majority of citizens do not have digital access to their health records, although apps are available that display lists of prescriptions available at pharmacies and the country is working on an approach to improve healthcare quality of electronic health records through the implementation of models aiming at digital maturity for their health systems (STOJANOVIC et al, 2017; CRESSWELL et al, 2019; ROCHA, 2011).

#### Sweden

Swedish citizens have the right to receive copies of their medical records. The Swedish government established a national health information infrastructure connecting a national patient portal with all different electronic health record systems used in the country. The patient portal gives everyone access to their electronic health record, which is accessible using an ID based on a national personal identification number. Individual counties decide what information patients can access from their electronic health record systems (SCANDURRA et al, 2017; BUTTERFIELD, 2011).

#### Uruguay

In Uruguay, the government promotes initiatives with the goal of improving the quality of public services offered to citizens. The Uruguayan Interoperability Platform provides an intermediate layer with reusable integration capabilities in order to enable the interaction as a platform-centric approach for data protection compliance and has the goal of facilitating and promoting the development of e-government services (ALLE et al, 2019; OECD, 2019).

### 2.14 Consolidation of Best Practices

Independent of the economic model, size of the population, or choice of the standard to exchange data, regarding digital health implementation in these countries its is possible to present a list of common practices (GDHP, 2020; IQVIA, 2017; IROJU et al, 2013; CYLUS; PAPANICOLAS, 2015).

1. Usage of worldwide standards
2. Interoperability Network with the creation of a National Bus
3. Network that enables the integration of the information systems
4. Presence of a unique national ID and security for an authentication system
5. Presence of governmental IT infrastructure

6. Presence of legislative base and rules
7. Digital Health Alliance
8. Deadlines requirement to implement the systems
9. Prepared teams to avoid controversy when implementing the system
10. Patient as Centrical of the Process
11. Ensurance of Continuity of Care
12. Presence of Hubs for Communities of Practices

### Global Digital Health Partnership (GDHP)

The Global Digital Health Partnership (GDHP) is a range from 6 continents represent over 2.8 billion people; and the only existing government-to-government global health IT partnership (GDHP, 2020).

GDHP was established in 2018 to advance global digital health where country governments were not working together. 30 countries and territories and the World Health Organization forming 31 members aiming to collaborate to an effective implementation of digital health, exchanging global best practices, and advance mutually beneficial projects providing opportunities for networking (GDHP, 2020).

> The GDHP's vision is to "support governments and health system reformers to improve the health and well-being of their citizens through the best use of evidence-based digital technologies." (GDHP, 2020).

GDHP countries are progressively generating initiatives based on International Patient Summary (IPS). They were invited to be engaged in a Global Community of Practice as a mechanism to support the activities of the Trillium II project aiming to globally promoting the widespread adoption of interoperable health records, generating products in accordance with the terms of innovation 2.0 and the quadruple helix model that engaging stakeholders and European Health Ecosystem (TRILLIUM II, 2019).

GDHP was create due to support implementation of digital health, exchanging global best practices, and mutually projects aiming to reach Interoperability Health Data Standards. Table 7 present a snapshot of 30 countries and their standards summed to World Health Organization forming 31 members (GDHP, 2020).

**Table 7 – Summary of interoperability health data standards**

| COUNTRY | Standard | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | HL7® V2 | HL7® V3 | HL7 CDA® | HL7 FHIR® | IHE | OPENEHR | ISO | ICD (9 / 10 / 11) | SNOMED CT | LOINC | DICOM | IPSPILOT |
| Argentina | | | | √ | √ | | | √ | √ | | | √ |
| Australia | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | |
| Austria | √ | √ | √ | | √ | | | √ | √ | √ | √ | |
| Brazil | √ | √ | | √ | √ | √ | | √ | | | | |
| Canada | √ | √ | √ | √ | √ | | √ | √ | √ | √ | √ | |
| Estonia | | √ | √ | | √ | | | √ | √ | √ | √ | √ |
| Hong Kong SAR | √ | | √ | | | | | √ | √ | √ | √ | |
| India | √ | | √ | √ | | √ | √ | √ | √ | √ | √ | |
| Italy | √ | √ | | | | | √ | √ | √ | √ | √ | √ |
| Japan | √ | | √ | | √ | | √ | √ | | | √ | √ |
| Kingdom of Saudi Arabia | √ | √ | √ | √ | √ | | √ | | √ | √ | √ | |
| The Netherlands | √ | √ | √ | √ | √ | | | √ | √ | √ | √ | |
| New Zealand | √ | | √ | √ | | | | √ | √ | √ | √ | |
| Poland | √ | √ | √ | √ | √ | | | √ | √ | | √ | |
| Portugal | √ | √ | √ | √ | √ | | √ | √ | √ | √ | | |
| Republic of Korea | √ | | √ | √ | √ | | √ | √ | | √ | √ | |
| Singapore | | √ | | √ | | | | √ | √ | √ | √ | |
| Sweden | √ | √ | √ | √ | √ | √ | √ | √ | √ | | √ | √ |
| Switzerland | √ | √ | √ | √ | √ | | | √ | √ | √ | √ | √ |
| United Kingdom | √ | √ | | √ | √ | | | √ | √ | | √ | |
| United States | √ | √ | √ | √ | √ | | √ | √ | √ | √ | √ | √ |
| Uruguay | √ | √ | √ | √ | √ | | | √ | √ | √ | | √ |
| **Total Countries/ Territories Using** | **19** | **16** | **17** | **17** | **17** | **4** | **10** | **21** | **19** | **16** | **18** | **8** |

Source: Adapted from https://www.healthit.gov/topic/global-digital-health-partnership from CONNECTED HEALTH: EMPOWERING HEALTH THROUGH INTEROPERABILITY- GDHP 9White Paper on Interoperability, 2020) + TRILLIUM PROJECT IPS STATUS.

## 2.15 Context of the Brazilian Health model

Brazil has a continental area and is the 5th in the world and the largest in Latin America. Their population totalizing 210.2 million inhabitants which a general life expectance around 77 years (BRASIL, 2018-B).

The country has a strong healthcare sector, contemplating 6.700 hospitals, around 500.000 beds, and 45.000 primary care units. In 1990, created the largest universal public healthcare system known as the Unified Health System (SUS) which almost 75% of the Brazilian population depends on. Brazil also has a total of 5,500 municipalities, most of which are little towns whose population using a Unified Health System (SUS) fully funded by citizens' taxes (BRASIL, 2018-b).

The Brazilian Health model was inspired by the National Health Service of the United Kingdom (NHS), which understands health as a good and form of citizenship, this model is also adopted in countries like Portugal (1974), Italy (1978), and Spain (1986) these countries whose offering healthcare coverage to their citizens (GARCIA- SUBIRATS et al, 2014).

A Brazilian Unified Health System (SUS) was created when a Federal Constitution was enacted in 1988. The project linked to the idea that everyone has the right to health as a citizen, belonging to the government the obligation of coverage. Brazil is a country with vastly different economic, social, and health realities then it was necessary to create a decentralized system due to this diversity so generating a complex healthcare network that also required connection or integration between services without a single owner. In Brazil, public health establishments belong to municipalities, states, the Federal District, and the Union, with private services contracted being privately owned (THE LANCET, 2011, FLEURY, 2011).

However, in 1990 the country experienced one of the first serious economic crises that creates a very adverse environment for the Unified Health System (SUS) and many states and municipalities were not able to fully exercise their duties. This context brought space to a segment of the market called supplementary health, involving care modalities such as group medicine, cooperatives medical care, self-management plans, and health insurance (FLEURY, 2011).

Unified Health System (SUS) is one of the largest public health systems in the world and their programs working in conjunction with surveillance, integrating its practices and develops one of the most comprehensive primary health care proposals on the planet. In Brazil, this also configured as an answer to the population's problems and needs, figuring out around 2.8 billion procedures per year, 11.3 million hospital admissions, 619 million consultations; 2.5 million births, etc. Brazilian Unified Health System (SUS) has several unintegrated Hospital Information systems dealing with the largest set of procedures performed in hospitals in the world paid for by the same financier (FLEURY, 2011).

The Brazilian health system is split into three subsectors: 1) The public subsector (SUS) in which services are financed and provided by the state at the federal, state, and municipal levels, including military health services; 2) The private (for-profit and non-profit) subsector, in which services are financed in various ways with public or private funds; 3) The private health insurance subsector, with different forms of health plans, varying insurance premiums, and tax subsidies. The public and private components of the system are distinct but interconnected, and people can use services in all three subsectors, depending on the ease of access or their ability to pay (PASCHOALOTTO et al, 2018).

Social participation and co-management by the government and society are regarded as important in any sustainable health program. Brazil has great diversity and the unequal distribution of resources among its residents and social security is characterized by the State’s duty in a decentralized integrated network funding at each level of government (municipal, state, and federal). These mechanisms of social control and budget approval assess executive proposals and their performance since fulfilling the rules for the universality of coverage, recognition of social rights, and a public-oriented approach, instead of a market approach (THE LANCET, 2011).

> An important feature of social security in Brazil lies in the component of strong state reform, in redrawing the relations between federal entities and instituting participants, and social control with mechanisms for negotiation and consensus building, which involve municipal, state, and federal government (THE LANCET, 2011).

The Ministry of Health is responsible for Federated health management, but managers (state and municipal) must plan implement, coordinate, and plan actions respecting all levels of regulations. The municipality formulates its own health policies and is also one of the partners for the application of national and state health policies. SUS works in the form of a regionalized network enabling the distribution of health establishments (health centers, outpatient clinics, laboratories, hospitals, etc.) based on three fronts: 1) Decentralization, with a single direction in each sphere of government; 2) Comprehensive care, with priority for preventive activities, without prejudice to assistance services; 3) Community participation (FLEURY, 2011).

The Unified Health System (SUS) is responsible for health surveillance, the supply of medicines, regulation of blood centers, organ transplantation, and also funds epidemiological research and data, disease control and prevention, in addition to the National Health Surveillance Agency (ANVISA), which is the Brazilian body created to inspect the quality of food in restaurants and supermarkets. All maintenance of this structure is financed by taxes collected from the citizen, however, considering the relationship with GDP, other countries with equivalent health systems investing values much higher than those of Brazil to maintain their quality standards (GARCIA- SUBIRATS, 2014; BRASIL, 2018-b).

Since 2011, aiming to better attend so diverse Brazilian scenarios the Health IT division manages a digital health strategy that suggests the use of technologies to offer access to information to the citizens. Brazil is regulated by a National Health Informatics and Information Policy requiring to adopt international interoperability standards, including HL7 (BRASIL, 2019-a). The National Policy on Health Informatics and Information encourages the use of TICs aiming to democratize access and efficiency and effectiveness delivery of public services (PASCHOALOTTO et al, 2018).

The Unified Health System (SUS) offered in Brazil was designed to fulfill all kinds of health care that depend on Information Policies. The government supplies a lot of software to manage data seeking to encourage a transparent relationship between government-citizen improving access and quality, security, and also support for health professionals to obtain efficiency gains in resource management, people, and inputs, as well as monitoring and evaluation of actions (BRASIL, 2019-a).

In 2017, Brazil formalized a National e-Health Strategic Plan that was consolidated in 2018 contemplating also a National Health Data Network (RNDS). Despite the economic and political problems faced by the country, in 2020 when the world faced pandemic COVID-19, an expert team had already conceived (last years), a digital health strategy policy that was applied through a national network infrastructure put to work in its available Primary Care (FLEURY, S. 2017).

In Brazil, Information Heath Systems in general, were developed without any form of standardization of information, according to criteria developed by national or international institutions (MESQUITA SALES; BENTES PINTO, 2019) and and it is important to pay attention for the contribution of a specialist in Medical Informatics Systems, Professor Sabbatini.

> Unambiguous and universal identifications of patients, such as the SUS Card, would be an absolutely essential initial step for this to happen. Another requirement would be the use of standards for the representation, storage and transmission of this information between different systems, such as Health Level 7 (HL7), SNOMED, CID, TISS, TUSS, national models of electronic medical records, and many others (SABBATINI, 2014).

The strategy to face COVID-19 was coordinated by the Ministry of Health, this generated an opportunity to allow users to nationally identify by building a consolidated Health Database. The first attempt at gathering health data of those who visit government agencies was by assigning a number that manages a National Health Card. This number is valid throughout the national territory and identifies citizens who use public health services, but it is not a unique ID generating and this National Health Card system fails due to its governance. The system can generate more than one number associated with the same citizen, duplicating records in the database. This occurs if the patient declares that there is no previous National Health Card requesting a new card in any public health office available (BRASIL, 2003).

Following worldwide tendencies as GDPR or Cure Act, in August 2017, Brazil released a law that established the guidelines on the processing of personal data, with the objective of protecting the citizen's freedom and privacy rights, including the possession of their health data, which require specific treatment and support and maintenance of quality on a permanent basis (BRASIL, 2018-c).

## 2.16 Brazilian National Health Network (RNDS): A Bus of Interoperability

The idea of a National Health Network (RNDS) started at the Department of Informatics (DATASUS) in the Ministry of Health to deal with exchange health information, so then they chose the main worldwide recognized standards due to offer interoperability like the Health Level 7 (HL7), for coding laboratory tests the Logical Observation Identifiers Names and Codes (LOINC), for clinical standard the HL7 CDA. (VENÂNCIO DE BARROS, 2019).

The National Health Data Network (RNDS) federated interoperability layer can support several Digital Health applications integrated with Electronic Patient Records, Hospital and Laboratory Management Systems, portals, and mobile applications aiming to exchange information through a service bus. In its first phase, RNDS allows the sharing of COVID-19 laboratory test results carried out anywhere in the country, through services developed in accordance with the FHIR standard and using the LOINC terminology. BRASIL, 2019-a, BRASIL, 2020).

The National Health Data Network (RNDS) is an “Enterprise Service Bus" in a service-oriented architecture (SOA) that contains a document repository responsible for storing citizens' health information, maintaining data privacy, integrity and auditability and promoting accessibility and interoperability of information in a safe and controlled manner, as a federated interoperability layer that aimed at citizens, health professionals, and managers through several Digital Health applications (e.g. Electronic Patient Records, Hospital and Laboratory Management Systems, portals, and mobile applications) to exchange information through a service bus (VENÂNCIO DE BARROS, 2019).

When the COVID-19 pandemic landed in Brazil, this becomes an opportunity for the distribution and sharing of data and information to citizens and health professionals at various levels. Supported by public and private laboratories allowed the integration between 27 federative entities, the project Connect SUS effectively did the first delivery of the National Health Data Network (RNDS) using interoperability standards receiving and sharing results of laboratory tests of COVID-19 (BRASIL, 2020; FAGHERAZZI et al, 2020).

In a set of tools (portal, mobile application, etc), the project offers diverse interactive services according to each kind of public (citizen, professionals, and health managers) providing personal and clinical information that also allows City Halls to collect and manage the citizen's health records. Through Connect SUS was possible to make the laboratory exam data interoperable anywhere in the country and following the RNDS guidelines, meeting 100% of the systematization requirements through the HL7 Fast Healthcare Interoperability (FHIR) standard associated with the Logical Observation Identifiers Names and Codes (LOINC) as terminology (BRASIL, 2020).

As a successful project, CONECTE SUS has paved for the Digital Health Strategy in Brazil sharing as a system effectively tested designed to serve citizens, health professionals, organizations, and managers through access to test results related to COVID-19 for patients and health professionals (BRASIL, 2020).

The National Health Data Network (RNDS) is being gradually implemented in each State in Brazil through the provision of virtual "containers" available in the cloud system. The acquisition, installation, and maintenance of these containers will be under the responsibility of DATASUS. Regarding Technological services, the Brazilian National Health Data Network (RNDS) forecasts Electronic Health Services, FHIR Services, Health Terminology Repository, Blockchain, Consent, CMD Management Processing, Notification Services, Artificial intelligence, and Telehealth. Table 8 shows the available information services (BRASIL, 2020).

**Table 8 – RNDS information services**

| | | | |
|---|---|---|---|
| Service Summary | Liberation Summary | Immunization | Dispensed Drugs |
| Performed Exams | Data Analytics | Establishment Registration | Authorship Trail |
| Regulation | Medical Images | Drug Prescription | Birth and Death Notification |
| Compulsory Notification | General prescription | COVID-19 notification | |

Source: https://conectesus.saude.gov.br/home

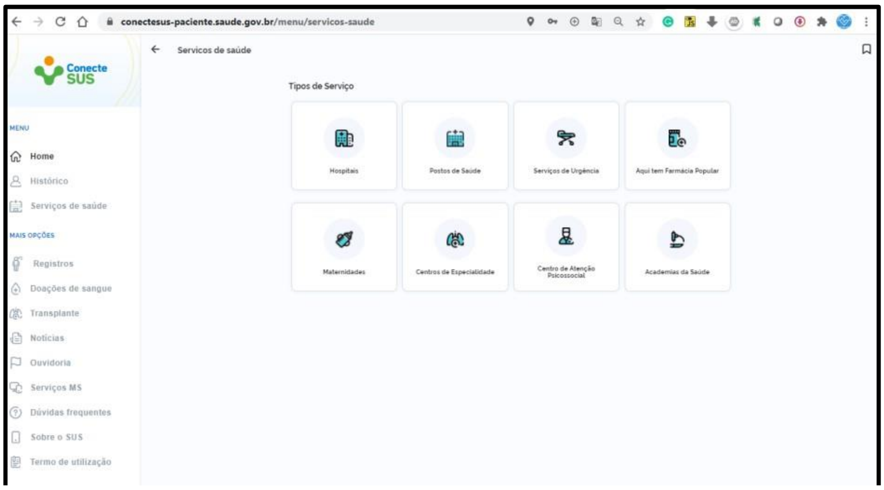
Considered as a public health Infoway, the project supported for health information, focusing on Primary Care producing qualified information improving efficiency in public resource management, and reach goals like 1) Map of needs, 2) Plan of actions, 3) Information Control, 3) Monitoring and 4) Combat fraud (BRASIL, 2019-a).

The medical history will be registered at the National Health Network (RNDS) linked at key CPF. FHIR rules will be used to control transactions that generate patient information that will be available to health professionals' access with the consent of them (VENÂNCIO DE, BARROS, 2019).

Associating the number of the National Card through unique Brazilian register ID (CPF), the platform will able citizens to consume health services provided by the government. But even if both numbers will be available on the platform as shown in figure 23 and figure 24 that show a screenshot of available services in the portal that able citizens to directly interact with the government (BRASIL, 2020).

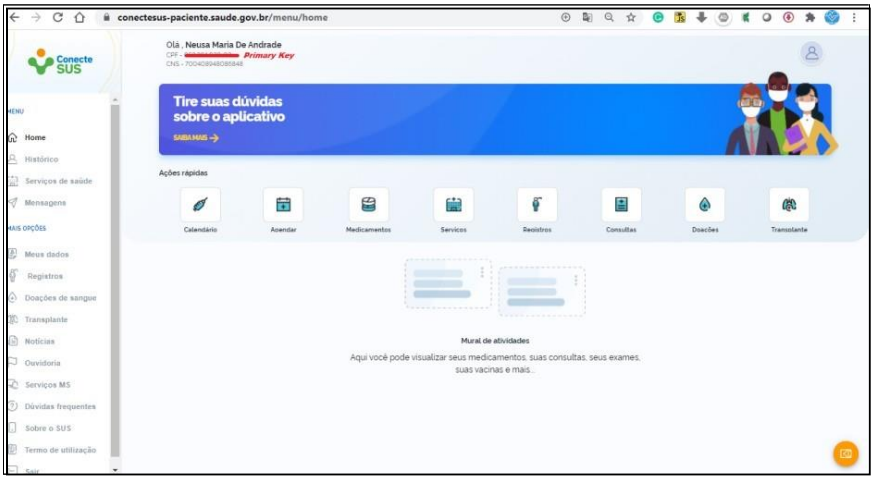
Figure 23 shows the first screen of acess of ConectSus portal patient view and Figure 24 shows ConectSUS Acess to Patient with Unique Key Data. Through a portal (https://conectesus.saude.gov.br/home) all history included in the platform will generate a traceable trajectory.

**Figure 23 – Conectsus portal patient view**



Source: data avaliable at: https://conectesus.saude.gov.br/home

**Figure 24 – Conectsus access to patient (Unique Key Data)**



Olá , Neusa Maria De Andrade
CPF - [redacted] *Primary Key*
CNS - 700408948086848

Aqui você pode visualizar seus medicamentos, suas consultas, seus exames, suas vacinas e mais...

Source: data avaliable at: https://conectesus.saude.gov.br/home

### 2.16.1 Blockchain Role in RNDS

Following the best practices from countries like England, the United States, and Big Technology Companies like Amazon, Google, and Microsoft, the Blockchain was chosen to be implemented in Brazilian RNDS due to being the strongest solution in security issues, performance, access, and scalability issues. The technology used is the Hyperledger Fabric, a licensed implementation (BRASIL, 2020; BROGAN et al, 2018).

As a technical component of the National Health Data Network (RNDS) to fulfill the requirements of consent and federation, the Blockchain is the best choice as a tool since each block of information cannot be changed and all distribution needs to be registered in a chain that could be traceable (EL-GAZZAR, STENDAL, 2020). The network uses a kind of cloud-based virtual containers for each state, thus allowing all healthcare facilities to exchange information via the blockchain, on a secure network in which data lake goes to the Blockchain (AZARIA, 2016; GORDON et al, 2018; CASINO et al, 2019).

The choice of Blockchain, therefore, would only be the starting point for a greater objective to integrate information related to Health that is already working with the FHIR (Fast Healthcare Interoperability Resources). The blockchain records separate the person's identification from the clinical data. The identification and registration data of a document is given in the context of persistence and consensus in all nodes in the chain that is unique for each document record and unbreakable for the set of documents (AZARIA, 2016; GORDON et al, 2018; BANERJEE et al, 2018).

Focused on traceability include a digital vaccination card with a vaccination certificate in PDF format and validation QRCode, offering the security of the issued document adopted a unique ID (CPF) which will allow the monitoring of adverse behavior (GORDON et al, 2018).

The choice of Blockchain in the National Health Data Network (RNDS) was due to deal with security challenges, privacy in order to support exchanges in a concept of a data lake that will be used to exchange health data in the future (GORDON et al, 2018). Standardized terminology and taxonomy ensure every provider and every individual can view and comprehend the exchanged data, and software can accurately understand and interpret the data’s meaning, using analytics, in a standardized way (AZARIA, 2016; CASINO et al, 2019).

# 3. METHODOLOGY

This chapter aims to describe the research methodology used in the development of the thesis. It presents how the research was designed, the methods, and tools used to collect data, research questions, hypotheses, and objectives. Research can contribute to the construction of a new theory clarifying why a decision or set of decisions was made, how it was implemented, and what results it achieved (ARGYRIS et al, 1985).

Every scientific method of research must be based on the validity of the reliability of the information whose characteristics measure its quality or scientific rigor (HILLS et al, 2007). Ethical considerations were used according to Brazilian norms. A literature review allows us to consolidate concepts and relationships between them and to support the methodological development of the following chapters (LAZARUS et al, 2016).

This work used a list of terminologies of Health Informatics depending on the principles of the semantic and complex models to acquire and generate knowledge using tools focused on decision support and instances that use the main benefits of ontologies aiming to produce guidelines to create an intentional modification of a given reality (THIOLLENT, 1994). The methodological procedure chosen for this research used a conceptual bibliography through Action Research (KUHN, 2010; PUTNAM, 1999; WESTBROOK, 1995).

## 3.1 Action Research

This work has started with a diagnosis leading to an action plan. Action Research is a tool whose cycles aiming to affect and change the social reality using observations, explanations, and understandings. Table 1 shows the summarized steps used to fulfill the objectives of this research providing a structure for futures replications (PUTNAM, 1999; WESTBROOK, 1995; ARGYRIS, 1985).

The term "Research" refers to the production of knowledge, and the term "Action" refers to an intentional modification of a given reality. Table 9 shows the summary of steps to drive this project. A plan of action is crucial to get collaboration and involve stakeholders in a diagnostic and produce active-learning (THIOLLENT, 1994; ARGYRIS et al, 1985).

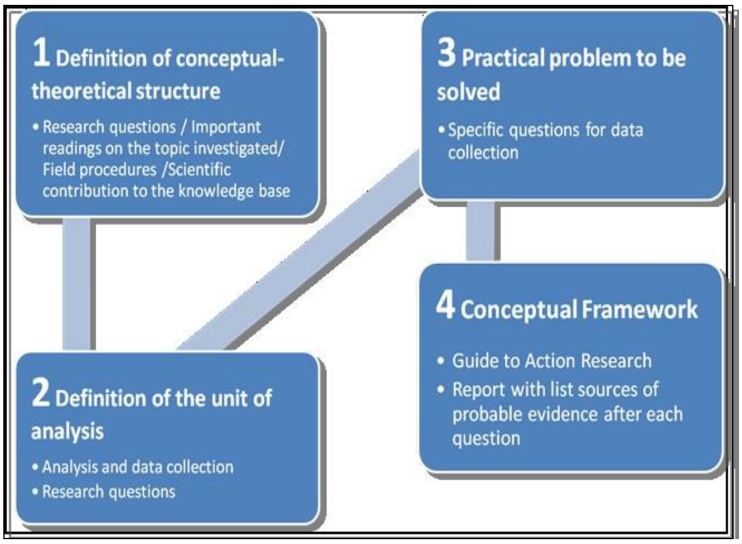
**Table 9 – Summary of steps of this action research**

| STEP | MAIN OBJECTIVE | EXPECTED OUTCOME |
|---|---|---|
| Identify the problem and theories | Research literature and cases and concepts | Set goal and target audience |
| Develop a plan | Envision Success | Invites to participate, |
| Collect of Data | Describe actual situation | Register Data |
| Analyze Data | Develop a plan for improvement | Compare Theories and Practices |
| Adjust the Theory and Plan | Implement the plan | Actions Plan Improvements |
| Reports and Results | Framework Guidelines | Provide structure for replication |

Source: Adapted from (PUTNAM, 1999; WESTBROOK, 1995; ARGYRIS, 1985).

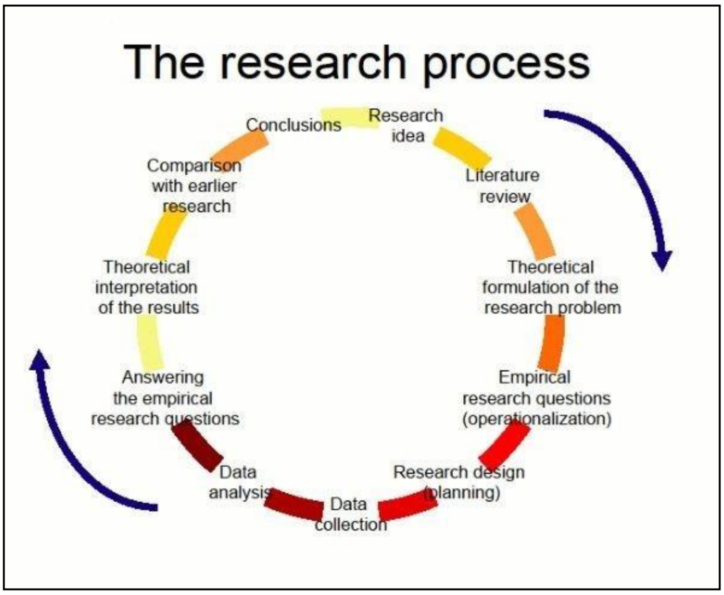
As illustrated in the figure 26, Putnam (1999) suggests to pursuit five steps to acquire knowledge (Observation, Reflection, Action, Evaluation and Modification) aiming to accomplish the goals proposed in Action Research (PUTNAM, 1999; WESTBROOK, 1995). Action Research is a Research Strategy adopted in production engineering built through cycles that generate new improvements and learning. This method is used to solve problems by producing guidelines for best practices, generating knowledge that leads to the intentional modification of a given reality as shown in figure 25 and 26. (PUTNAM, 1999; WESTBROOK, 1995; ARGYRIS, 1985).

**Figure 25 – Putnam's four steps of action research**



Source: Adapted from Putnam, 1999.

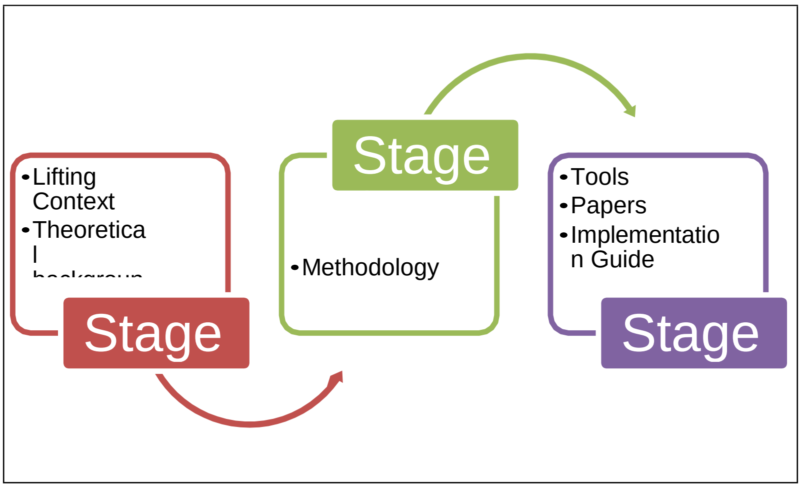
**Figure 26 –Procedures of Action Research**



Source: Adapted from Putnam, 1999.

Action Research is a method of qualitative research and methodology widely used in educational research projects that increasingly stands out as a research strategy adopted in production engineering and in this aspect mainly the participatory character with a potential contribution to innovation and the findings of the research may contribute to the construction of a new theory aiming to shed light on why a decision or a set of decisions were made, how they were implemented, and what results they achieved. The steps of search concepts are shown in figure 27 (THIOLLENT, 1994; ARGYRIS et al, 1985).

**Figure 27 – Research concepts steps**



Source: Author

Four questions northed the search of terms: 1*) Based on best practices, how to acquire and implement a model of exchange health data and build interoperability in the Brazilian context?*; 2) *Which Standards, Concepts, Contexts, and tools are being used worldwide to exchange health data and build a Universal Medical Record*?; 3) *Which are examples of Best Practices and policies regarding the patient data*?; 4) *How they are applied or fit in the Brazilian context*?. They were used to build a conceptual bibliography as a pilar of this research. Secondary data offered by reputable Health Informatics organizations that have as premises standards of interoperability ruled by governance are also used.

### 3.1.1 Questions about Standards and Concepts

1. What are the main definitions of interoperability for healthcare organizations?
2. What are the main concepts, standards, ontologies, and countries experiences to be followed?
3. Which exchange data SDO's are consecrated in the healthcare sector?

### 3.1.2 Questions about Practices and Context

1. Describing an overview of healthcare context in these countries.
2. What are the best interoperability rules and practices in these countries?
3. Examples of interoperability for exchange data in these countries.

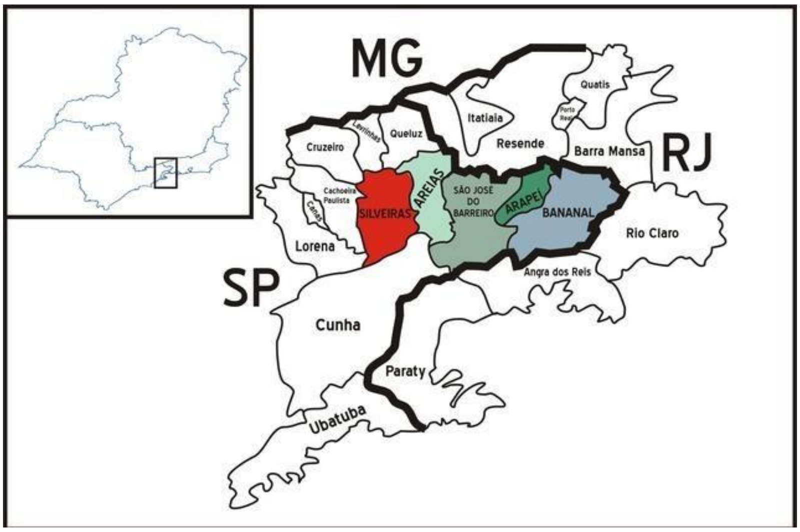
### 3.1.3 Questions about Applied Tools

1. Which Quality tools could help to implement the exchange of data?
2. Which tools and practices could be applied in the Brazilian context?
3. How apply these tools in a specific context?

## 3.2 Population

According to the Brazilian Statistic Institute (IBGE), Bananal town has 10,896 inhabitants which over 70% of the population depends on healthcare treatments offered by the Unified Health System (SUS). Showed in figure 28, Bananal city is located at 88.5 km east of the capital of the state of São Paulo surrounded by cities Silveiras (5,792 habs), Areias (3,693 habs), São José do Barreiro (4,097 habs), and Cruzeiro (81,082 habs). These cities totalizing a population of 105,449 inhabitants and are inserted in the Metropolitan Region of Valey of Paraíba totalizing over 2.930.356 inhabitants that do not exchange their citizens' health data yet (BRASIL, 2018-b).

**Figure 28 – Bananal in brazilian states localization map**



Source: Brasil, 2018.

The city is obligated to offer diverse health services to the local population and also passersby, especially of neighbors' cities. The city of Bananal is also a tourist resort surrounded by attractions of nature receiving people worldwide (BRASIL, 2018-b).

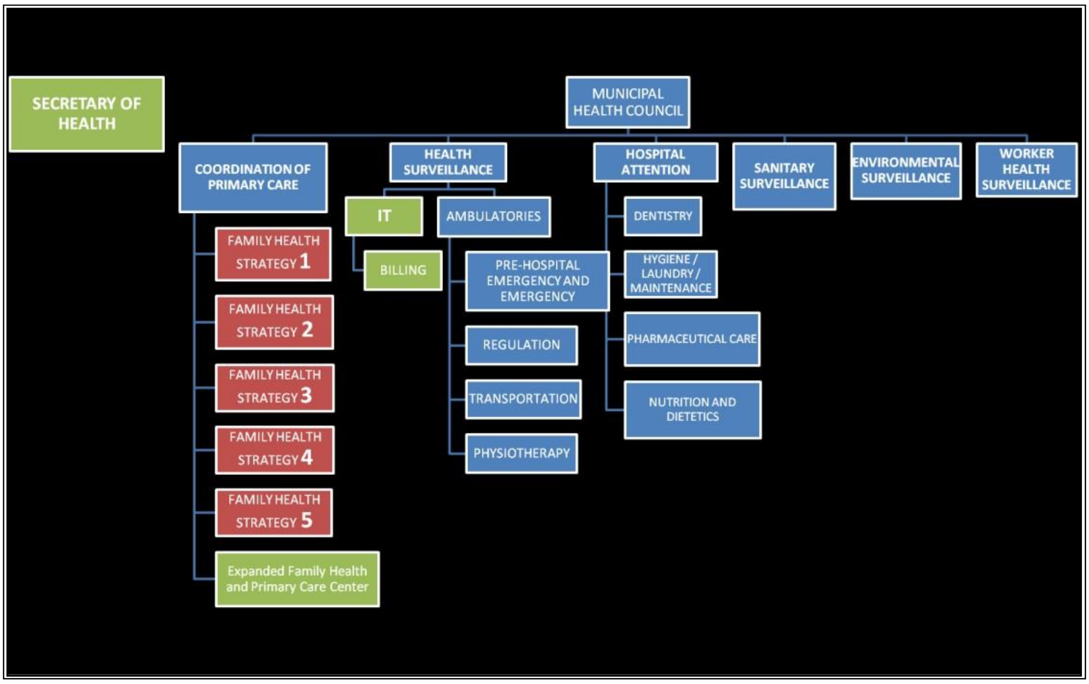
### 3.2.1 Data Collection and Study Sample

The pilot followed all the ethical rules of the research proposal. All health data are available in DATASUS, a Brazilian Public Health platform, but only available for research or health managers. All citizen data used in this research were anonymized. The sample study was chosen due to their number of inhabitants to build the pilot. The environment and specific context facilitate to improve government-citizen relationship, access and quality, transparency and information security. The city was also chosen due to the relationship with the city´s health managers facilitating the diagnose of their health infrastructure making possible implementing tools to correctly collect and register data of patients, according to Brazilian laws (BRASIL, 2018).

### 3.2.2 Applied Pilot

The city presents a health infrastructure with one Health Unit, four offices to attend the family health strategy, and one basic care unit, totalizing 6 units. Until the pilot, they not exchanging information among themselves causing many duplicates records and unnecessary costs and without any participation of their citizens. Figure 29 presents the organogram of Bananal´s Health infrastructure to attend Brazilian law (BRASIL, 2018).

**Figure 29 – City of Bananal's Health organizational chart**



Source: Author

After applying an observational study was detected a desire of health managers to eliminate 100% of the paper data and transforming Bananal city into digital abling to exchange and interoperable health data. The concepts of quality and management of capabilities were used to implement a plan to transform paper storage into digital. This also contributed to the work of system administrators. This Action Research generated a pilot and a platform to exchange data with tight standards. This made it possible to build an interoperability FHIR API and integrate all units that also could exchange data and populate data in the National Health Data Network (RNDS).

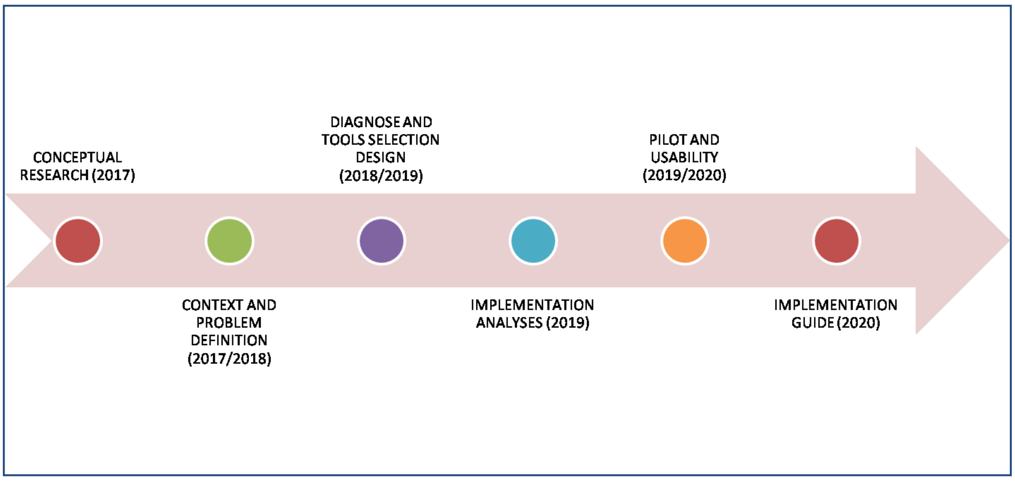
### 3.2.3 Gap and opportunities

The implementation at Bananal town generated a prototype integrating 6 health offices reaching interoperability and also offers to citizens their available health data through available free government platforms (BRASIL, 2020). But there is a gap to apply and integrate all neighbors city and an opportunity for system developers to offer complimentary APPS and portal to measure and improve the quality of the government- citizens relationships.

## 3.3 Methods and Tools

A Theoretical Framework of qualitative methods was used in this work. The set of chosen tools aimed to transform reality and build a proposal to implement offering a gain of efficiency through resource management of people and inputs, as well as monitoring and evaluation of actions. Figure 30 shows this research trajectory in the timeline.

**Figure 30 – Research timeline**



Source: Author

### 3. 3.1 Lean Healthcare

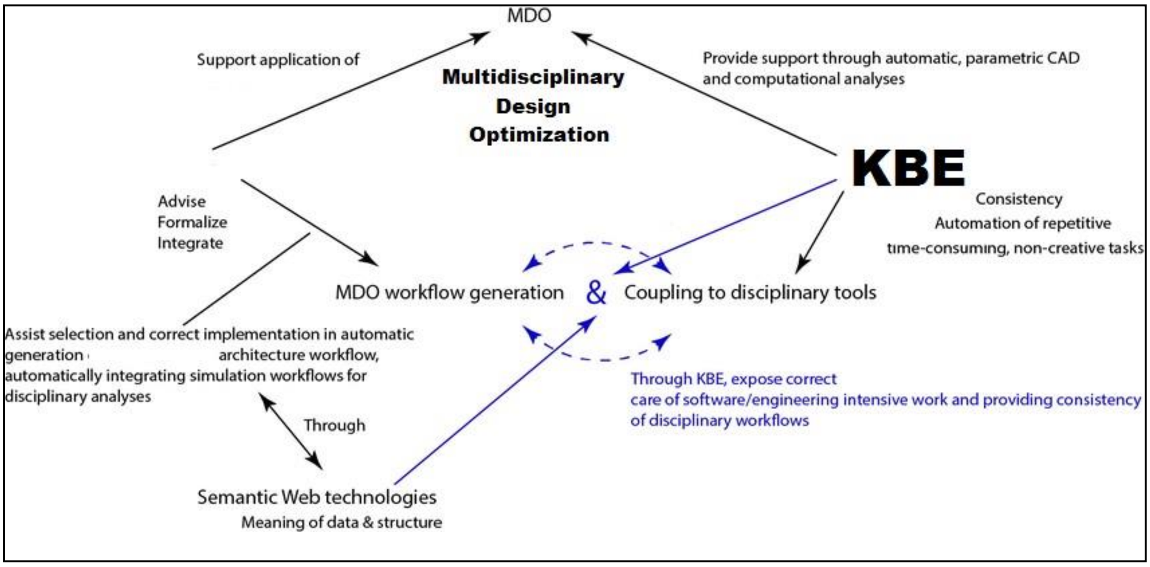
The health sector needs to provide the best possible personal assistance to the patient but there are several processes with a lot of waste and activities that do not add value and may compromise health professionals. To face complexity and challenges health services (hospitals, laboratories, and medical units) are seeking some solutions and practices used in other areas of business where several processes do not waste activities that do not add value.

According to the definition of the father of the Toyota Production System, Taiichi Ohno the Six Sigma methodology was disseminated by Jack Welch, after obtaining extremely expressive results when implementing at GE (General Eletrics), then, Lean Healthcare was created also to improve patient care and promote the full engagement of employees and doctors in continuous improvement, seeking to eliminate waste that does not add value.

### 3.3.2 The KBE Method

KBE methodology is an integrative tool. This method relates the activities need to perform which must be prioritized, maintaining focus on all activities to solve the problems functioning as a flow (CALKINS, 1999). KBE can be characterized as a set of solutions capable of assisting the development of engineering activities in different steps of the development process in any segment, as well as design practices of complex systems. The strength of KBE is to provide automation tools like scripts or rules, which bring intelligence and a knowledge storage solution. Figure 31 shows a schematical proposal on how the method was used in this work as a model to acquire knowledge helping in decision-making (KUHN, 2010).

**Figure 31 – KBE Schematic Proposal**

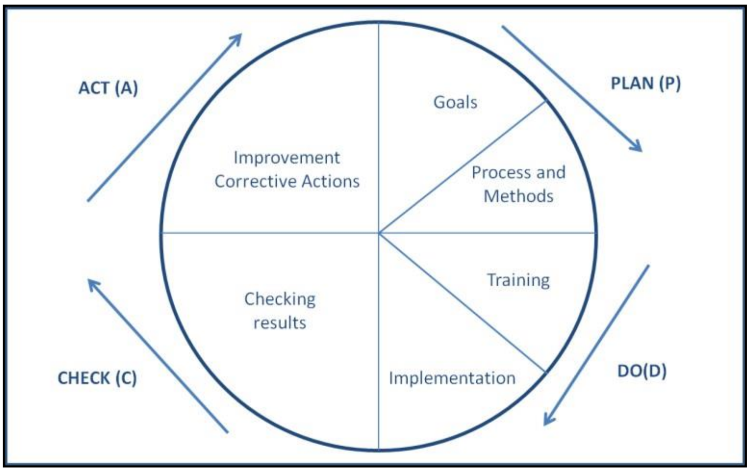


Source: Author (adapted by Kuhn, 2010)

KBE offers due to support and improve the design of complex mechanical systems by automating repetitive and non-productive activities ensuring to create a collaborative environment. It also allows enhancing the product quality, reducing time to market and costs, and also can contribute both with traceability, reuse, and search for knowledge, and the reduction in design time (CALKINS, 1999; KUHN, 2010).

KBE is also especially useful to develop systems and the Information Technologies process. The method creates knowledge for problem-solving and can use a set of combined tools like PDCA (figure 32), Kanban, World Cafe, Communities of Practice, DMAIC, 5W2H (COSTA NETO; CANUTO, 2010). Those tools that were applied in this Action Research and helped to fulfill the objectives allowing to development of a set of practices of the pilot project listed in the implementation guide.

**Figure 32 – PDCA Cycle**



Source: Adapted from Costa Neto and Canuto, 2010.

**PDCA** is a simple tool to achieve efficiency gain in the management of resources that offers resources besides the monitoring and evaluation of actions. This research was done through an observational study and experiment in a specific context, using several combined tools to help to implement the culture of continuous improvement as DMAIC in 5 stages described bellow 1) Define, 2) Measure, 3) Analyze, 4) Improve, and 5) Control. They were used to reduce the variability of processes (COSTA NETO; CANUTO, 2010; SATOLO et al, 2009).

**1 - DEFINE-** Defining the problem is the key to success. This is made possible using tools such as SIPOC, Voice of the Client, Flowcharts, among other quality tools that can be used at this time of DMAIC (SATOLO et al, 2009).

a. **5W2H**: Tool that uses 7 questions to break down information into improvement actions that are easier to understand (COSTA NETO; CANUTO, 2010).

**2 – MEASURE** - At this stage, it is time to raise the qualitative causes in which it is necessary to study the process, identifying where the problem is defined, the quantitative causes, it is necessary to take a reliable database, select an indicator and study its behavior. use several quality tools, among which we can highlight (COSTA NETO; CANUTO, 2010; SATOLO et al, 2009).

a. **Process Map**: containing the steps that add and those that do not add value;
b. **Ishikawa diagram**: allows to analyze the possible causes of a given effect;
c. **Pareto diagram**: statistical tool that allows prioritizing the causes of a problem with the principle, 20% of the main causes are responsible for 80% for the problems of an organization.

**3 - ANALYZE**- In this one the following tools are useful:

a. **Scatter diagram**: used to prove a relationship between cause and effect.
b. **Linear Regression**: mathematical model used to relate the input variables (x) with the output variables (y).
c. **Hypothesis testing**: Statistical test used to determine whether a result obtained with a sample can be considered true for an entire population.

**4 - IMPROVE** - For each analyzed cause, an Action Plan will be proposed but it is also necessary to verify the impact and the improvements obtained with the implemented changes. Some tools are particularly useful (COSTA NETO; CANUTO, 2010):

a. **5S**: quality program that encourages increased productivity through 5 senses: use, organization, cleanliness, well-being and self-discipline.
b. **Kaizen**: methodology focused on continually improving through Kaizen events that are applied to increase productivity and reduce costs.

**5 - CONTROL** - Improving a process can be done in several ways, some as simple as checklists, others as complex as using error-proof devices. The following tools can assist: (SATOLO, et al, 2009).

a. **Poka Yoke**: error-proof devices that guarantee controlled process variability.

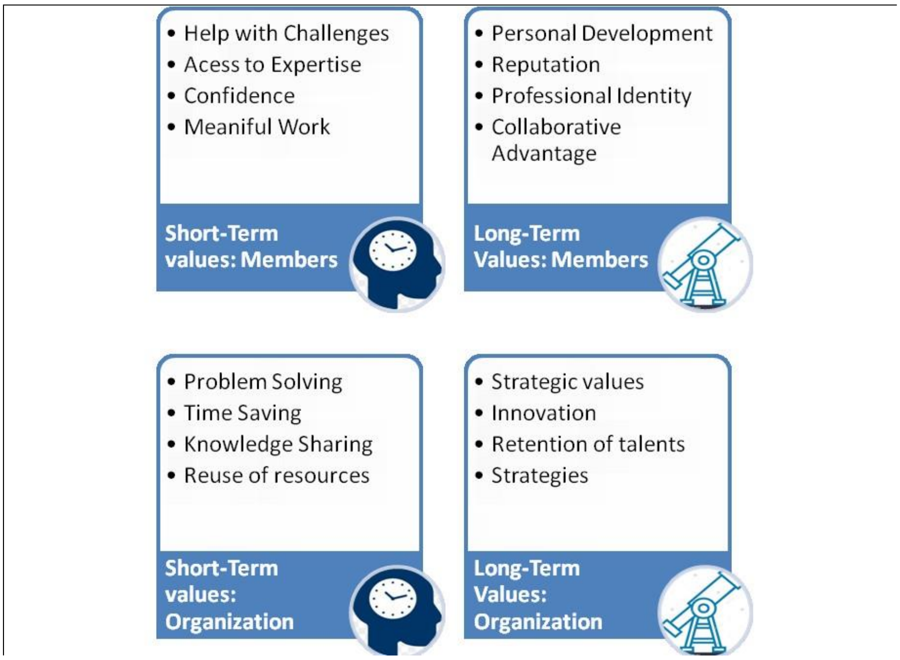
b. **Control Charts**: graphic tool for monitoring the variability of a given process.

c. **Standard Operating Procedure (SOP)**: documents that standardize actions to be taken in certain processes in order to avoid errors and variability.

### 3.3.3 Communities of Practice (CoP)

According to Wenger (2002), Communities of Practice are defined as "Groups of people who share a concern or a passion for something they do and learn how to do it better as they interact regularly". Wenger’s model suggests that learning occurs within the social context and Communities of Practice key to creating sharing knowledge within the group and networking. The essence e value of CoP is shown in figure 33. Communities could connect citizens and the government determined by the following factors: 1) Contact; 2) Proximity; 3) Interaction (WEIL, 1996; WENGER, 2002; WENGER et al, 2002).

**Figure 33 – The value of Communities of Practice**



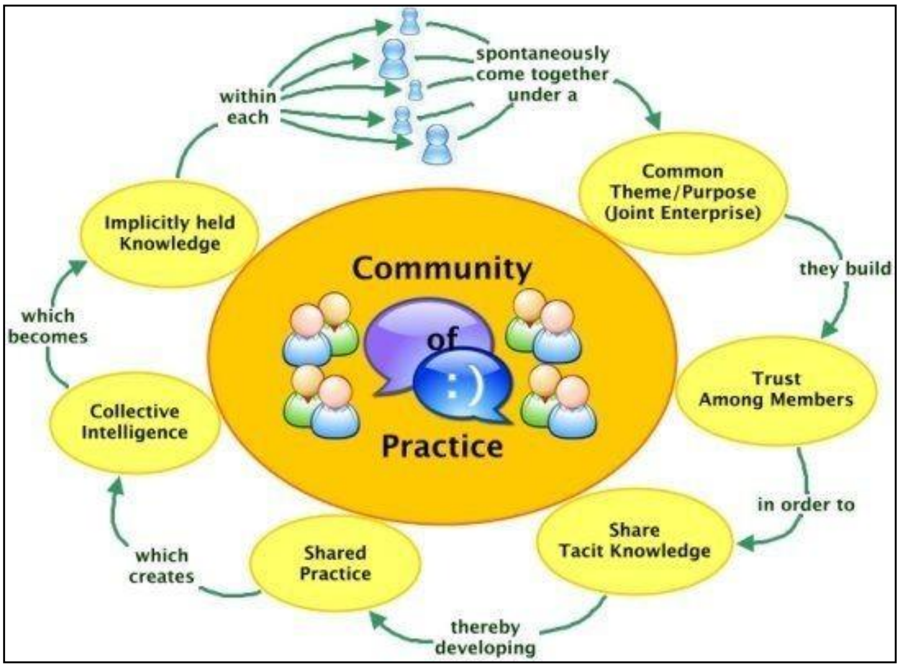
Source: https://sites.google.com/site/learnteachtech/home/learning-theory/communitiesofpractice

New Information Technologies can be used to build this network and exchange information acquired in the CoPs with five elements that must be present: 1) Collaborative partnerships with clients, client groups, 2) Emphasis on the expansion of clients' capacities, strengths, and resources; 3) Focus on individuals and their social and physical environments, 4) Clients as the core (WEIL, 1996).

Rappaport et al (2008) established key principles, methods, and strategies to build assets aiming to promote participation in communities. Their case studies were designed as pilot tracing strategies for developing successful community partnerships and collaboration building alliances in systemic change interventions. The approach included brainstorming, statement analysis, and synthesis, and the generation of interpretable maps and data.

As shown in figure 34, Community of Practice is an important tool used in global IPS in the TRILLIUM PROJECT (2019). It sustains and supports the project assuring the alignment of different classes of stakeholders promoting collaboration, exchange of needs, experiences, and educational initiatives solutions (WENGER et al, 2002).

**Figure 34 – Communities of practice outcomes**



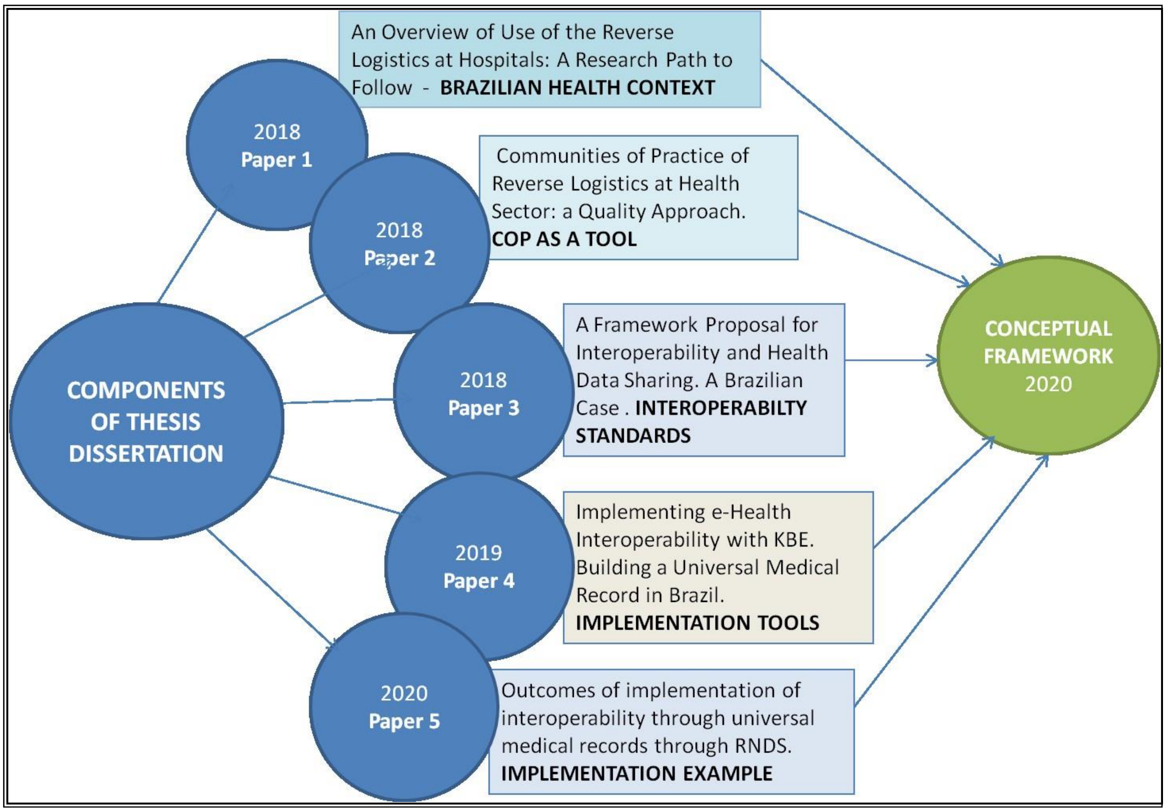
Source: TRIILIUM PROJECT, 2019.

These values overflow and engage teams, managers, health workforce, technology groups suggesting 1) Spent on administration by clinicians which allows them more time with the patient, 2) Assist diagnostic skills, 3) Improve the clinician-patient relationship 4) Provide more equitable means for local providing healthcare, 5) Legal and regulatory barriers, 6) Government support, etc. The CoP values also generate benefits for society as 1) Implicit knowledge, 2) Common Theme/Purpose, 3) Trust Among Members, 4) Share Tacit Knowledge 5) Shared Practices, and 6) Generate Collective Intelligence (WEIL, 1996; WENGER et al, 2002).

# 4. EMPIRICAL RESULTS AND DISCUSSION

This chapter intends to present a summary of published essays and also of the Implementation Guide. The project used Action Research as the main method. Figure 35 shows the Thesis composition.

**Figure 35 – Thesis Composition**



Source: Author

The result produced new knowledge and an intentional modification of a given reality. Here we combine the use of different techniques for collecting data, information, and evidence-based on the questions and propositions that guided the study to ensure the reliability and validity of the findings and the understanding of the whole situation (PUTNAM, 1999; WESTBROOK, 1995; ARGYRIS, 1985).

Table 10 presents a summary of articles related to specific objectives, in order to achieve the proposed main objective. All full texts are available in the related appendices. Paper number five has been submitted for approval and in constant changes.

**Table 10 – Chart essays regarding specific objetive**

| PAPER TITLE | SPECIFIC OBJECTIVE | PUBLISHED | CONTRIBUTIONS TO RESEARCH |
|---|---|---|---|
| An Overview of Use of the Reverse Logistics at Hospitals: A Research Path to Follow | 1) Obtain an overview of practices in the Healthcare System worldwide<br>**Approach:** qualitative e quantitative<br>**Procedures** bibliographic research | Published at 7th International Conference on Information Systems, Logistics and Supply Chain ILS Conference 2018, July 8-11 | Comparative healtcare sector overview<br>Quality Standards |
| Communities of Practice of Reverse Logistics at Health Sector: a Quality Approach | 2) Obtain an overview of concepts of global standards used for the exchange of health data<br>**Approach:** qualitative e quantitative<br>**Procedures** bibliographic research/Case Study | Conference Logistics Challenges in the New Economy: Sharing and Interconnected Industry. São Paulo, Brazil, 4 & 5 June 2018. Netlog - International & Conference on Network Enterprises & Logistic Management. | Health Quality Approach, Accreditation, Communities of Practice (COP)<br>Action Research |
| e-Health: A Framework Proposal for Interoperability and Health Data Sharing. A Brazilian Case | 3) Present an overview of the best practices and standards used to promote interoperability to build Global Medical Records<br>**Approach:** qualitative e quantitative<br>**Procedures** bibliographic research | IFIP International Federation for Information Processing 2019. Published by Springer Nature Switzerland AG 2019. F. Ameri et al. (Eds.): APMS 2019, | Interoperability<br>Health Health Exchange<br>Global Medical Records |
| Implementing e-Health Interoperability with KBE. Building a Universal Medical Record in Brazil | 4) Present the tools and methodological to be used applied to the Brazilian context.<br>**Approach:** qualitative e quantitative.<br>**Procedures** bibliographic research/Case Study | Published 8th International Conference on Information Systems, Logistics and Supply Chain ILS Conference 2020, Apr 22-24, Austin, Texas. USA | Interoperability<br>Global Medical Records<br>Tools and Use of KBE. |
| Brazilian Patient Summary. An experience of exchange health data using FHIR. | 5) Present a proposal for an Implementation Guide.<br>**Approach:** qualitative e quantitative<br>**Procedures**<br>Applied Case Study | Abstract Submitted to approval health-medical-informatics.https://www.hilarispublisher.com/health-medical-informatics.html | International Patient Summary (IPS),<br>Fast Healthcare Interoperability (FHIR),<br>National Network Health Data (RNDS),<br>Exchange Health Data,<br>Interoperability |

Source: Author

## 4.1 Paper 1 - An Overview of Use of the Reverse Logistics at Hospitals: A Research Path to Follow.

(Neusa Andrade, Claudio Scheidt, Jair G. M. Torres, Pedro Luiz de Oliveira Costa Neto, 2018) - (Appendix I)

Published at 7th International Conference on Information Systems, Logistics and Supply Chain ILS Conference 2018, July 8-11, Lyon, France. This paper was presented at the 7th International Conference in Information, Systems, Logistics, and Supply Chain Conference and it was published in the event proceedings presenting an overview of the hospitals' sector and practices. A complete version of this paper published paper is available in Appendix I.

**Main contribution**: The main contribution of this paper for this research was to present an overview of healthcare sector and their practices related to literature, especially regarding to Hospital Accreditation, evaluating health institutions through a series of enforceable compliance, and which requirements fulfill these standards and how hospitals implementing their process performed by an independent entity that periodically plans which level of quality improvement to get reach and ensures safety and commitment to all involved in the process, including society.

**Abstract**. This paper presents a review of literature concepts about Reverse Logistics, Healthcare Waste Management, International Accreditations, and Quality. It also provides an overview and benchmark data of healthcare facilities as the first part of an Action Research that intends to discuss results about how much is crucial to create guidelines and adjust waste management plans including Reverse Logistic at healthcare services, especially non-hazardous medical waste management. The sequence of this work will be reported in four cycles, in a similar way of the PDCA cycle, and aims to present a framework proposal to be applied at hospitals to including Reverse Logistics of recyclable materials according to accreditation rules.

**Keywords**: Sustainability, Accredited Hospitals, Quality Standards, Reverse Logistics

## 4.2 Paper 2 - Communities of Practice of Reverse Logistics at Health Sector: A Quality Approach.

(Neusa Andrade, Claudio Scheidt, Jair G. M. Torres, Pedro Luiz de Oliveira Costa Neto, 2018) - (Appendix II)

This paper was presented and published at the proceedings of Conference Logistics Challenges in the New Economy: Sharing and Interconnected Industry. São Paulo, Brazil, 4 & 5 June 2018. Netlog - International & Conference on Network Enterprises & Logistic Management. The complete version of this paper published paper is available in Appendix II.

**Main contribution:** Healthcare institutions use a large number of standards from Quality that combining several resources according to theoretical models to allow the optimization of result that can be aimed by Communities of Practices that can 1) Addressing mutual concern, 2) Sharing commitment 3) Enabling all those involved to actively participate, 4) Sharing control processes , 5) Produce desirable outcomes.

**Abstract**. Reverse logistics is regarding ones that must be returned to the point of origin where they can be discarded, repaired, reused or recycled delivering to organizations a global vision of competitive advantage, profits and better image through Communities of Practice provide an environment conducive to connecting people, encouraging self-development and sharing of ideas and strategies and operating in a distinct way from other structures, since it serves a specific purpose, such as the development of new products and services, market, process or organizational context This work attends to a specific objective of an Action Research to solve a practical problem and expand scientific knowledge regarding Reverse Logistics of solid waste at hospitals and presenting Communities of Practice aim to produce knowledge as a strategic resource to share, convert and management knowledge in favor of the business strategy of hospitals; also the requirements of quality and accreditation suggesting that Quality Management in the healthcare sector can create a Community of Practice with a basis on Reverse Logistics.

**Keywords**. The Community of Practice, Reverse Logistics, Health Quality, Action Research

### 4.3 Paper 3 - e-Health: A Framework Proposal for Interoperability and Health Data Sharing. A Brazilian Case.

(Neusa Andrade, Claudio Scheidt, Jair G. M. Torres, Pedro Luiz de Oliveira Costa Neto, 2018) - (Appendix III)

This paper was published in a chapter of a book at IFIP International Federation for Information Processing 2019. Published by Springer Nature Switzerland AG 2019. F. Ameri et al. (Eds.): APMS 2019, IFIP AICT 567, pp. 625–630, 2019. https://doi.org/10.1007/978-3-030-29996-5_72. The complete version of this paper published paper is available in Appendix III.

**Main contribution**: This paper is the first one of an Action Research Cycle focused to understand the sector from the perspective of hospital management quality achieving, improving and sustaining performance through creating teams, efficiency and productivity directly related to set off additional advances to the knowledge This paper addresses an interoperability problem providing the steps built in a pilot to enable a conceptual framework for exchange healthcare data through EHR that describes the experience and proposal to design a framework based on PDCA to implement interoperability at public Brazilian health systems.

**Abstract**. Interoperability among systems is a challenge that requires several regards and infrastructure often complex. The best worldwide reports and frameworks say that this can also improve health care and bring the best outcomes for stakeholders. Implementing Interoperability in developing countries is less affordable even it can also promote quality care and save lives. The best models and guidelines could offer protocols for sharing health data allowing to build a system that can deliver at the same time quality, transparency, and social value. This paper addresses an interoperability problem providing the steps built in a pilot to enable a conceptual framework for exchange healthcare data through EHR, and presents the first step and overview of a platform build using rules of PDCA. The experiment was built in a small Brazilian town that intends to be a standard for deliver interaction between local government and citizens and also to offer to patients to control their own medical data records through a mobile application.

**Keywords**: Health Interoperability, Health exchange data, Quality of Care, Action Research

### 4.4 Paper 4 - Implementing e-Health Interoperability with KBE. Building a Universal Medical Record in Brazil.

(Neusa Andrade, Henrique Ribeiro, Jair G. M. Torres, Pedro Luiz de Oliveira Costa Neto, Irapuan Glória Júnior, Welleson Gazel, 2019) - (Appendix IV)

This paper was published to the 8th International Conference on Information Systems, Logistics and Supply Chain ILS Conference 2020, Apr 22-24, Austin, Texas. The USA. The complete version of this paper published paper is available in Appendix III.

**Main contribution:** The implementation of a Universal Electronic Medical Record (UEMR) is challenging for the Healthcare Sector. To address an interoperability solution this paper purposed to use combined tools in a way to implement the project using Multidisciplinary Design Optimization (MBO) as a KBE Methodology aiming to generate Knowledge-based engineering (KBE) as a model designed to develop new technologies and produce a knowledge-intensive activity. The implementation at Bananal intends to generate a prototype, an important stage in any implementing of technology, easy to replicate in a scalable way to reach an interoperability system aiming to develop a playbook to be applied as a framework.

**Abstract**. Health Sector is depending on interoperability between systems. Health systems are fragmented and even so need to produce valuable outcomes including social engagement and a better government-citizen relationship aiming to improve the quality of access, patient care, and transparency generating accurate indicators for managers and health professionals. This paper aims to describe the development of a pilot in a public health system realized through an Action Research using combined quality tools in a Multidisciplinary Design Optimization (MBO) and Knowledge-based engineering (KBE) methodology aiming to reach a strategy to spread best practices from EHR interoperability as from an experience of in a Brazilian small-town.

**Keywords**: Universal Medical Record, Universal Electronic Record, Healthcare Process Management, Healthcare Enterprise Integration, Healthcare Enterprise Interoperability, KBE.

## 4.5 Paper 5 - Brazilian Patient Summary. An experience of exchange health data using FHIR and IPS

(Neusa Andrade, Italo Macedo, Michael Diana, Jair G. M Torres, Pedro Luiz de Oliveira Costa Neto, 2020) - Abstract Submitted to approval health-medical-informatics.https://www.hilarispublisher.com/health-medical-informatics.html).
(Appendix V)

The paper describes the process used to collect and insert health data in the available platform provided by the Unified Health System (SUS), using a unique patient data key (CPF) aiming to popularize the use of the National Health Data Network (RNDS). This allowed us to track and exchange health data through health units and also establish a channel between the government and the population (GONZÁLEZ, 2011).

**Main contribution**: The pilot project that used combined tools in a methodology of Knowledge-Based Engineering (KBE) as a model to produce a knowledge-intensive activity. The model implemented in Bananal City can be scaled for other municipalities in Brazil. This research provided a network integration among health professionals and users Unified Health System (SUS) allowing accuracy in collecting data, creating a deeper understanding of collaboration networks that supporting the efforts of patients and their families to reach better health outcomes (CHEN et al, 2020; VERSCHOORE, 2020).

**Abstract.** This paper summarizes a successful experience in a Brazilian small city that improve its health infrastructure that became to exchange information reducing many duplicate records and unnecessary costs and also build engagement of health agents and citizens using a set of free tools provided by the Brazilian Unified Health System (SUS) and health data acquisition through Quality Tools as PDCA and DMAIC reaching engagement of stakeholders, without extra costs for the municipality. The experience inspired in best practices of International Patient Summary (IPS) by exchanging messages that use Fast Healthcare Interoperability Resource (FHIR). The main contribution of this paper is to present general lines of steps to collect data aiming to fulfill a task of HL7 Workgroup that systematized IPS parameters with National Network Health Data (RNDS) using FHIR generating an Implementation Guide

**Keywords**: International Patient Summary (IPS), Fast Healthcare Interoperability (FHIR), National Network Health Data (RNDS), Exchange Health Data, Interoperability, Quality Tools. Health Data Network Healthcare (RNDS), Interoperability. Collaborative Networks

The eHealth Digital Service Infrastructure (eHDSI) describes this kind of Patient Summary Service (PSS) as “a mechanism to automate the sharing process between care providers of Medical Summaries, a class of clinical documents that contain the most relevant portions of information about the patient intended for a specific provider or a broad range of potential providers in different settings.”

1) Technology (Repository of all medical history and flexible data structure for accommodating the information with a profile of each patient and their clinical history with a single ID).

2) Efficiency (Plan and tools used to engage collaboration and participation of society and health team and Network Collaboration)

**Motivation**: Information integration of systems could be reached to promote interoperable when the leadership do efforts to: 1) Establish governance process, communications, training, and education aiming to acquire stakeholder engagement. 2) Increase engagement of the community extracting, sharing, and distributing knowledge according to the context.

**Summary of Results**: Table 11 presents a summary of the goals of the pilot project transforming the city how to collect and deal with health data citizens.

**Table 11 – Chart of results achieved in pilot**

| MUNICIPALITY MAIN GOAL | PROBLEM | SOLUTION | USED TOOL | % OF STATUS REACHED |
|---|---|---|---|---|
| Informatization of Units and connect Health network | Diagnoses<br>Evaluate scenarios and Resources<br>Establishing a Plan | Evaluate the necessity of investments and available resources and specification of hardware and software | PDCA/<br>5W2H | 85% |
| Collect, correct and provide population health data | Articulates available resources and teams to collected and correct data into systems. | Use tools already offered by SUS aiming to minimize costs. Implement Logistics. Implementation Guide | PDCA<br>DMAIC | 83% |
| Interoperability for citizen patients data | Actions to minimize or eliminate and duplicate of records | National Health Data Network (RNDS) . Implementation Guide | IPS /FHIR MODEL/ RNDS | 94% |

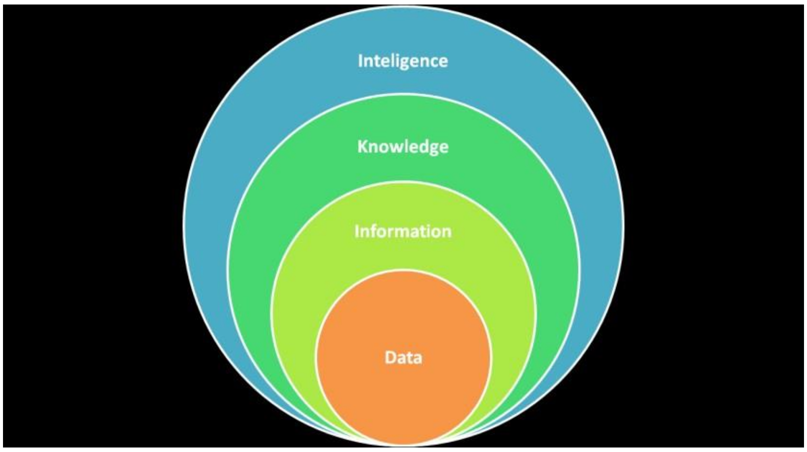
Source: Authors

## 4.6 IMPLEMENTATION GUIDE

This Implementation Guide offer General Principles and Specifications as a holistic conception and guidance and considerations aiming to help implement a deployment model, roles, process, information, technology, resources, and capabilities to operate the solution suggesting that the success of the deployment requires a combination of institutional factors, technologies, human capital, and creativity to capture and treat valuable information according to the integrated level of maturity within a context that meets the needs of citizens and government (SUJANSKY, 2009).

An implementation guide is a work designed in a hierarchical structure presented in steps required with related documentation describing systems. This document aiming to present a conceptual model that was elaborate and up-to-date according to suggested best practices to capture health data generating an instrument of simple steps to be applied to helping to build a governance structure. Figure 36 shows the expected outcomes data produced by the solution deployment model that must be refined through specifications to match their specific implementation context (GONZÁLEZ et al, 2011).

**Figure 36 – Converting data through intelligence**



SOURCE: Patterson and Gomes, 2004.

This implementation guide is not a mandatory script but a suggestion. The main goal is to offer an instrument to help decision-makers to implement a valid exchange data model generating interoperability. It is important to remark that working-progress dependent od building partnerships between different stakeholders (especially citizens) that also must be called to be engaged in the public and private sectors to facilitate the development of activities and projects.

**Implementation Guide**: The process of developing a FHIR artifact to exchange data carried out activities as: (a) Specification, (b) Conceptualization, (c) Formalization, (d) Implementation. Specification corresponds to identifying relevant information of a specific situation and Conceptualization is characterized by the development of a conceptual model of the ontology to be built (HL7, 2019-c).

According to the HL7 standard, an Implementation Guide is a document that undergoes constant changes through community collaborations. Their versions are available in www.hl7.com.br (Continuity of Care Workgroup) e changes are in a public repository for access listed in table 12. (KHATCHERIAN et al, 2019).

**Table 12 – Online access to repositories**

| VERSIONS |
|---|
| https://simplifier.net/sp-core |
| https://github.com/HL7Brazil/SP-Core |
| https://github.com/HL7Brazil/SP-Core |

## 4.7 Recommended script of implementation

The instruments presented in this guide are not mandatory, but only suggestions. Quality tools are to help identify, measure, analyze, improve, and control the processes. The project when reaching fully functioning will ensure a reduction of duplicates databases abling different systems to exchange information aiming to deal with legacies of data. All scenarios must be previously evaluated (GONCALVES, 2013).

Table 13 presents a summary of the following five steps and respective objectives to be achieved, but it is important to emphasize that to reach success, it is necessary to clear define objectives, practices, roles, creating, and executing an action plan to be accomplished in a given period of time. Before initiating the capture of health data, all scenarios to capture and manipulate data must be evaluated since health data citizens registration is data sensitive and managed by also public health agents, doctors, nurses, etc (RUSSELLO et al, 2008).

**Table 13 – Summary of recommended five steps**

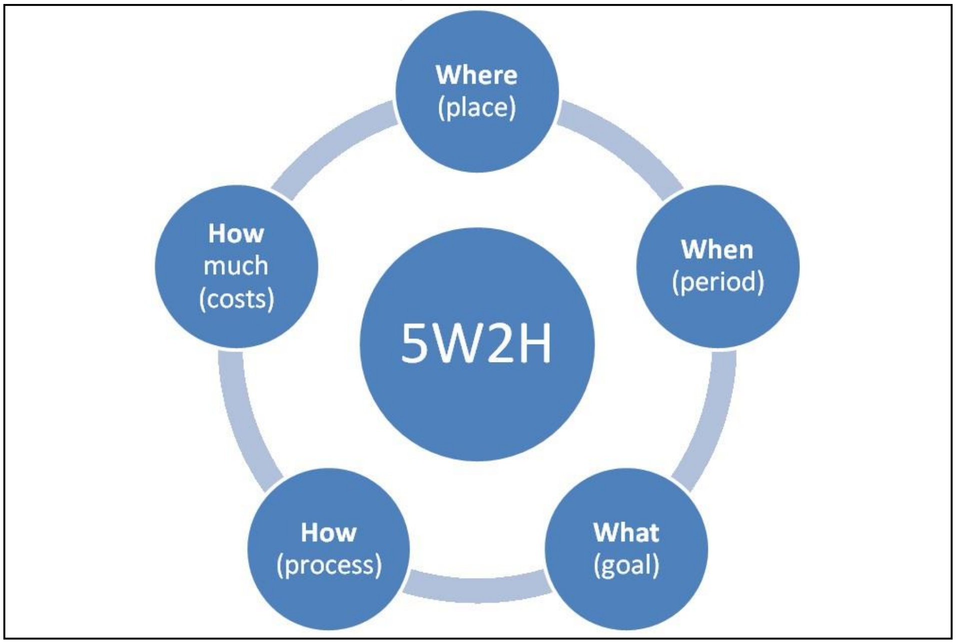
| STEP | GOAL |
|---|---|
| **Step 1:** EVALUATE AND DIAGNOSE CONTEXT | Evaluate resources and enable the infrastructure to create or improve processes |

| | |
|---|---|
| **Step 2**: SET TASKS, ROLES AND DUTIES | Establish and Determine goals determining who and how is involved in the project. Prepare, Deploy, and Train the Team for the next step. |
| **Step 3:** COLLECT AND ADJUST DATA | Awareness and improve users' experience with their Data. |
| **Step 4:** EXCHANGE OF DATA | Use of consecrated standards. In case is needed hires a consultant or specialist |
| **Step 5**: SET A COMMUNITY OF PRACTICE AS INSTRUMENT | Create an Experience to support, motivate, and engage your users to reach goals |

## STEP 1- EVALUATE AND DIAGNOSE CONTEXT

This step ís required for any project. How much accurate was the scenario better results will be acquired minimazing budget attending transparency, and governance requirements. The use of tool 5W2H showed in figure 37 could be useful to answers questions and help to generate KPIs for continuous improvement (COSTA NETO; CANUTO, 2010).

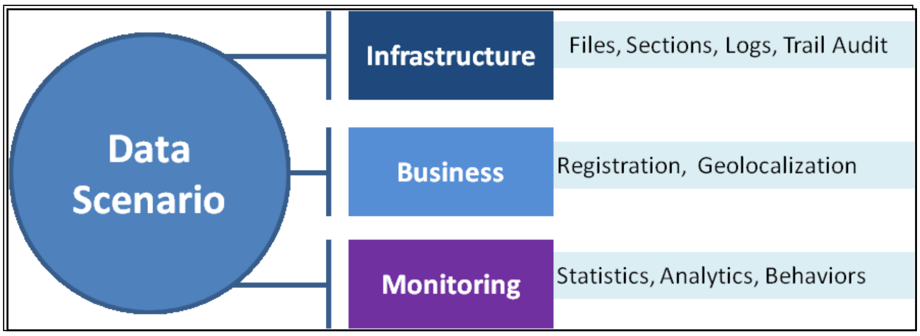
**Figure 37 – 5W2H**



Source: Adapted from Costa Neto and Canuto, 2010.

Figure 38 shows a scenario of collecting data that must be considered to optimize processes. In this step, it is recommended uses of APP or mobile application as a digital tool adoption to enhance the engagement of citizens. Any capture of data must contemplate 1) Evaluate if was got overall consent and risk management strategies for use of data; 2) Identify longer-term goals compliance date around data exchange. For all Techonology team is requeired an envolviment to validate this data scenario as show in figure 38 before the implementation.

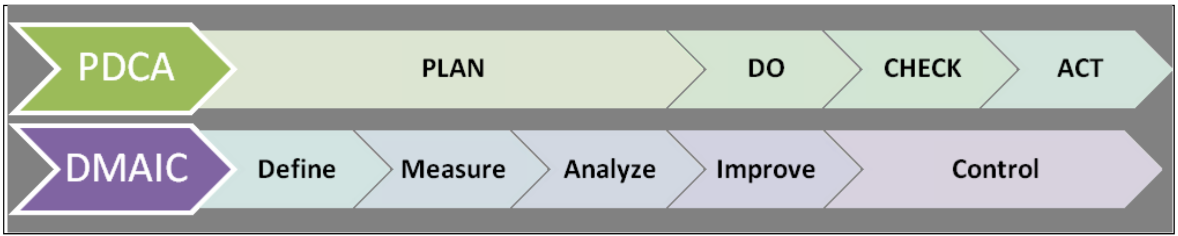
**Figure 38 – Evaluate of data scenarios**



Source: Author

After diagnose put all acquired informations in context to build a plan to be executed, but its rather to begin a plan with a small pilot project to be increased. Figure 39 show the steps of DMAIC applied to PDCA that could be useful. Figure 40 show the summarized steps and figure 41 show applied PDCA Standards (COSTA NETO; CANUTO, 2010; SATOLO et al 2009).

**Figure 39 – DMAIC steps applied to PDCA**

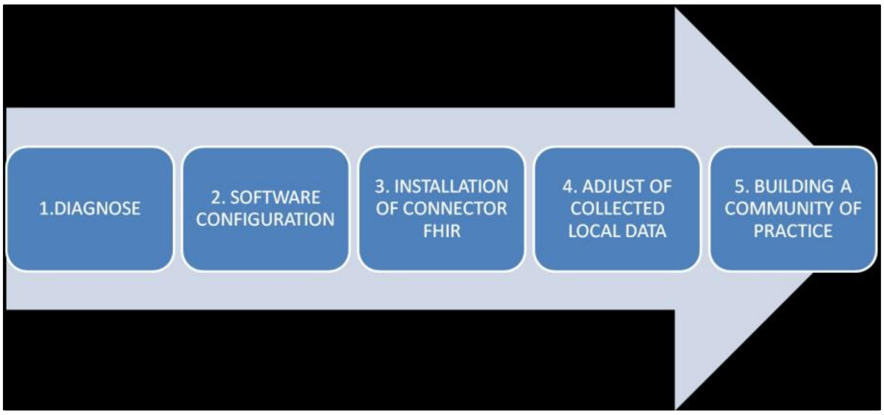


Source: Author. Adapted from Satolo et al, 2009.

1. **Diagnose**: Health Informatics or IT (Technology) professionals available to join the workforce.
2. **Diagnose**: Needs of Technological Infrastructure and Capacity (networks, computers, printers, internet, software environment, etc.).
3. **Diagnose**: Health Human resources to collaborate in implementation plan (nurses, agents, doctors, administrative).
4. **Diagnose**: Stakeholders and main responsibilities to engage the community.

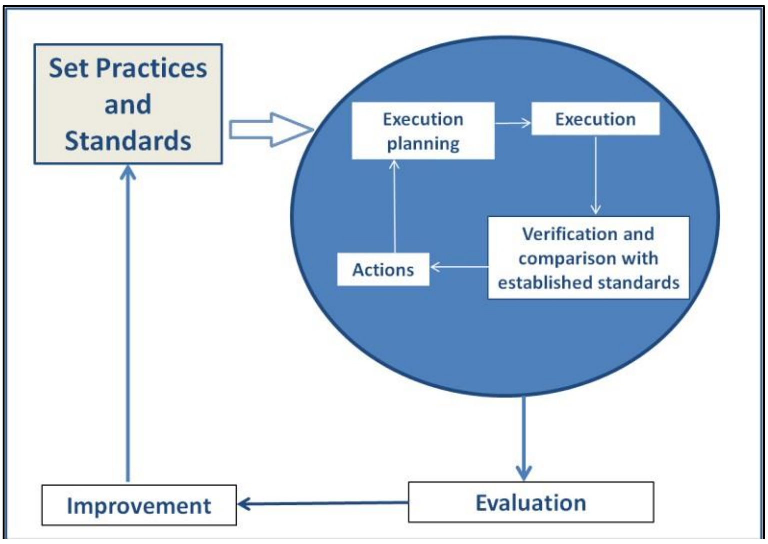
5. **Plan**: Implement a strategy of collect data during an amount of time, units and weekly KPIs to be fulfilled (number of papers to be transformed in digital, visits, registers in the system, etc).
6. **Plan**: Trace a communication plan to evolve stakeholders in each phase of the process to establish the roles and commitments.

**Figure 40 – Steps of implementation**



Source: Author.

**Figure 41 – Applied PDCA standards**



Source: Adapted from Costa Neto and Canuto, 2010.

## STEP 2- SET TASKS, ROLES AND DUTIES

This step presents some roles, tasks, and duties to be fulfilled. Table 14 present a suggestion of roles regarding members and team, and table 15 present a suggestion of checklist to be built. One main goal to be pursued is to reduce the workload related to time to acquire data to converting in metrics, this will determine the maturity level of teams according to context and dimensions.

It is important to remark that this step must fulfill law and governance requirements establishing duties, metrics, and tools to be used in the next step (COLLECT AND ADJUST DATA) and each context will present a different configuration, once it is necessary to measure accurately the available resources, infrastructure, the health workforce available. This step also aims to prevent or mitigate risks elaborating consent terms regarding privacy data, assigning responsibilities due to types of equipment (hardware and software) used to collect or manage citizen's health data.

**Table 14 – Overview of assessment team members and roles**

| TEAM MEMBER | MAIN ROLE | RESPONSABILITIES |
|---|---|---|
| **Governance Team Leader** | Estabilish policies that will be providing operational and technical resources planning, communication, requesting and obtaining approvals, complying with regulations, policies and procedures, logistics | Key stakeholder that has budget and resource authority official designated |
| **Project Lead and Logistics Coordinator** | Overall execution. Key role in analysis and interpretation activities | Coordinates logistics, arrangements, set up and prepare materials / Leads/coordinates all assessment |
| **IT Leader** | Handle with IT infrastructure deals ensuring that good data quality data is captured. | Offer hardware and software solutions data, application logs, web, cloud platform, etc Backup and storage. Consolidating the data into one place |
| **Data Collection Supervisor** | Supervises data collectors and oversees data collection activities in the field | Sampling, Analysis Plan, Analyzes data. Leads data collection at the central level |
| **Data Analyst** | Assessment Manager, Data Manager, Data Collection Supervisor, Data collectors | Visit size of sampled sites, volume of data to be collected, amount of time available for the assessment, |
| **Data Collector** | Conducts site visits to collect t data. Go to sites and collect, clean, and submit the required data | Data collection team |

Source: Author

**Table 15 – Example of checklist**

| # | TASK |
|---|---|
| 1 | Appoint the key members |
| 2 | Identify facilities that will be assessed |
| 3 | Develop the list of KPIs to be accomplished |
| 4 | Program data collection (regarding infastructure, business and monitoring) |
| 5 | Identify a training data collectors |
| 6 | Assign and alocate teams to collection areas |
| 7 | Advise facilities of the arrangements, necessary document access and preparatory work |

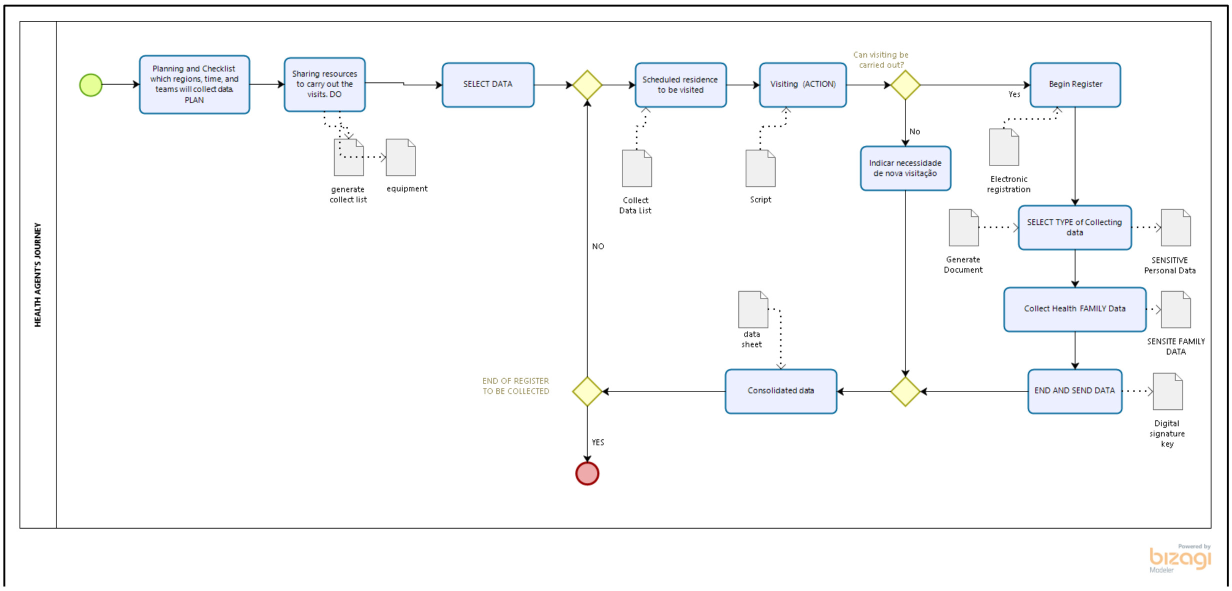
Source: Author

## STEP 3- COLLECT AND ADJUST DATA

This step requires special attention once the execution is the hardest and longest to be applied and controlled. The expected outcomes need a minimum checklist to collect data and also a summarized workflow process (RUSSELLO et al, 2008).

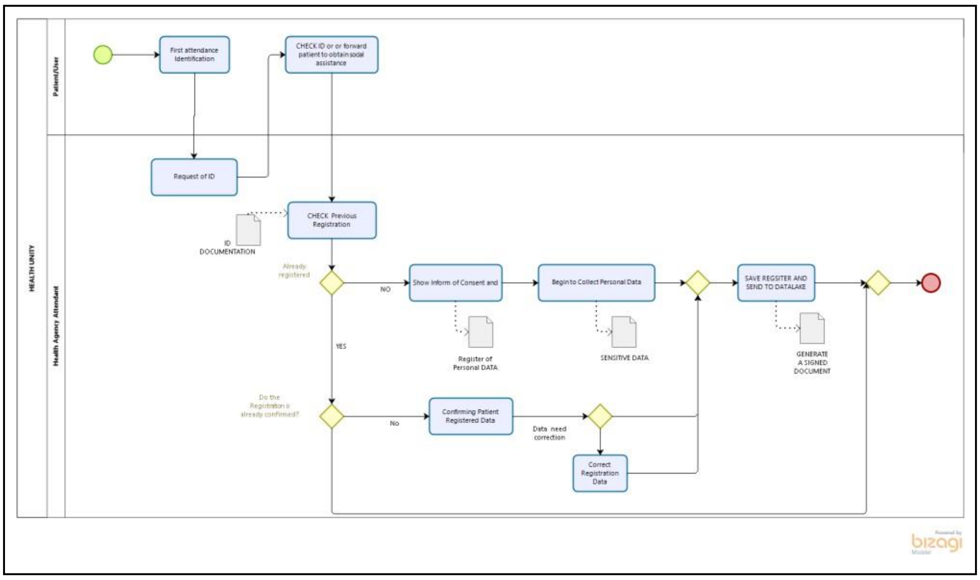
Figure 42 shows the flow of first access to identify citizen-patient in the public health offices network, and Figure 43 shows how health agents capture data in the field during their visiting homes. This aim to collect in the first input an accurate register in the system or, if necessary, correct the wrong data. This database will make the National Health Data Network (RNDS) that will use a unique key to identify the citizen-patient eliminating duplicated records. (NIKIPHOROU et al, 2017; BALDWIN et al, 2017; BLEICH et al, 2009; FRACCARO, 2018).

**Figure 42 – The flow of first access to identify citizen-patient in the health office**



Source: Author

**Figure 43 – The flow of collect of data of citizen-patient by health agents visiting homes**



## STEP 4- EXCHANGE OF DATA

The Fast Healthcare Interoperability Resource has the goal to standardize the exchange of healthcare information that helps model and to structure organizational knowledge information enabling different software systems, healthcare providers, and administrators to share patient information easily once each resource is associated with a unique identifier. HapiFHIR is a public library that helps any developer programming languages to build artifacts using FHIR to create solutions respecting architectures, taxonomies, thesaurus, and ontologies (BOSSENKO, 2020).

Using RNDS standard HL7 BRASIL chapter offer profiles to exchange data according to the IPS summary available in Brazil Core IPS directory. As best practices suggests the publication of the implementation guide. Brazilian profile is already available on the FHIR repository (https://saude.gov.br/fhir/r4/package-list.js (PAIS, 2019).

Once the minimum profiles were properly established in the IPS Brazilian repository, developers can build new applications for municipalities to establish better communication with their citizens offering 1) multi-factorial authentication providing records of activities, evaluations, and metrics of health data, 2) Sharing and Privacy data standards, 3) Compliance terms (YAMAGUTI, 2018).

All data collected and sent to the RNDS can be retrieved by the connector, so aim to Mobile App and or browser handle only visualization and data return alerts. This will help citizens and governments deal with health data like medical appointments, diagnoses, and features available according to the IPS Model through the web, and promote health interoperability data with other towns (LIU et al, 2019; MANIKAS; HANSEN, 2013).

The developer is recommended to engage in Communities such as FHIR Foundation (Closed Community of Developers), FHIR Community Forum (Public Community of Developers), FHIR Chat Channels (Real-time Community of Developers), and HL7 Brasil (Governance Standards, Workshops, Lectures, and International Courses) (PAIS, 2019).

Another possibility is to use some local application already developed to connect citizen-government but establishing a connection with the FHIR standard. In any case, it is important to engage IT resources in charge of sending data to Systems, or an HL7 consultant to help with this step, from the first step (PAIS, 2019).

## STEP 5- SET A COMMUNITY OF PRACTICE AS GOVERNCE INSTRUMENT

Questions regarding the improvement of health care is determined by the following factors: 1) Contact; 2) Proximity; 3) Interaction, then citizens and governments could be benefited from Communities of Practices (CoPs), especially regarding healthcare affairs contributing to each other creating together local best practices to promoting the engagement (PATTERSON; GOMES, 2004; WEICHHART; STARY, 2018).

Communities of Practices (CoPs) can be used to produce flexible structures that facilitate alignment refining structures in both the long-term and short-term views. They can establish a better way of generating governance through 1) Gather real-life experience and feedback to be used in the processes cycle; 2) Engagement, monitoring, and auditing activities by engaging the user and stakeholder community through active participation. Implementing CoP will help to:

1. To incentivize feedback;
2. To develop principles for deployment;
3. To promote consensus and quality;
4. To Mapp of information structures and their value sets;
5. To identifying standards and specifications;
6. To create processes to be responsive to change;
7. To generate structured Knowledge.

# 5. CONCLUSION

The main contribution of this research is presenting findings and lessons learned in a pilot project that generated an Implementation Guide using FHIR designed from the collection of health generating a patient summary shared by a unique ID and inputted in National Network Health Data.

The health sector is very complex and dependent on several standards (example: OpenEHR, HL7, SNOMED-CT, TISS, HL7 CDA, DICOM, LOINC, ISBT 128, ISO 13606-2, IHE-PIX; CID, CIAP-2, TUSS, and CBHPM) and each one fulfills a specific function as communication, vocabulary, images, objects, content, and structure, representation of clinical data, security, authenticity, and quality (MESQUITA SALES; BENTES PINTO, 2019).

Since interoperability is a key dimension of digital health that support and enabling a person's health journey to reach an effective exchange of health data, it was necessary first to contextualize all requirements, and this was done applied in a Brazilian context using the Action Research method Implementation Guide to exchange health data based on best practices to be applied in a contextualized manner and also attending to the idiosyncrasies of the Brazilian Unified Health System (BEAGLEHOLE, BONITA, 2010).

The Literature Chapter presented an overview of best practices, concepts, and standards that promote interoperability. The methodology chapter listed the used tools and context that was applied an Action Research that build a pilot project of exchange health data in a Brazilian town. All these concepts and the specific objectives detailed in the next paragraphs were necessary to achieve the General Objective.

Quality Control and Planning Management in healthcare are to identify potentials benefits and pitfalls for users, the state and its citizens, mas it is necessary always to preserve the user experience. Electronic Health Record creation and maintenance should be the core of the patient’s information, (single repository) should be accessed by other modules through a set of functions and validations to ensure the confidentiality of this information (DIGITAL IDENTITY ROADMAP, 2019; AL-JANABI et al, 2018).

The specific objective number one was achieved and allow to obtain an overview of the global standards used for the exchange of health data and concepts of Healthcare Enterprise (IHE) that must guarantee security, data transport and formats, also incorporating complex concepts of processes, workflow, interoperability, decision support, performance evaluation and quality improvement.

This objective was fulfilled achieved by consulting main Standards Development Organizations (SDOs), as Health Level 7 International that works in cooperation with many other partnerships and uses consecrated terminologies like SNOMED and also answer the research question "*Which Standards, Concepts, Contexts, and Tools has been used worldwide to exchange health data and build a Universal Medical Record*?

The paper brought the essay named "*An Overview of Use of the Reverse Logistics at Hospitals: A Research Path to Follow*" presented in Appendix I. They also presented an overview of the health sector, especially leading to the importance of the accreditation rules designed for the health sector, citing the Joint Initiative Council for Global Health Informatics Standardization (JIC), ISO TC-215, Health Information and Management Systems (HIMSS) and International Society for Health Quality and Standards (ISQua) among others that are mentioned in the chapter Literature Review. This article allowed acquiring knowledge to continue the research and dig into the next objectives (MONSEN et al, 2010).

The specific objective number two was to search literature on experiences of exchanging health data to build Global Medical Records. Article "*Communities of Practice of Reverse Logistics at Health Sector: A Quality Approach*" presented in Appendix II offered some initial concepts of quality improvement and also compare concepts of health quality maturity and standards for the Healthcare.

This paper allowed to know OECD standards and the Joint Initiative Global Health Informatics Standardization (JIC) and brought important information to support research like digital health records are designed to support healthcare professional data sharing and administrative tasks this positively impacts patients' medical history in structured data. Use of technologies pragmatically could transform health systems (HIMMELSTEIN et al, 2010).

Systems exposures patients risks, and also generates costs then EHR should contain information resulting from their interaction with different health professionals, to facilitate an integrated vision of patient data and serve as clinical decision support but they are strongly dependent on standards. This paper also contributed to understand first concepts of dependecy of interoperability and consolidated standards to reach outcomes once different locations are using diverse concepts to refer to the same issues due to a lack of patterns of semantic (SPICER; WALSH, 2012).

The specific objective number three aimed to present an overview of the best practices and standards used to promote interoperabilit. Paper presented in Appendix III named *"e-Health: A Framework Proposal for Interoperability and Health Data Sharing. A Brazilian Case*" fulfilled this specific objective and brought literature about experiences like practices of interoperability pointed out by the AHA and Lancet, consolidating concepts, best practices and models as International Patient Summary that promote interoperability and health data exchange health data exchange and Universal or Global Medical Records (AHA, 2019).

Interoperability means that different systems need to be connected, integrated, and secure coordination to ensure interoperable information offering safe data access, but clinicians remain challenged to access and use data within health systems, or healthcare processes in a highly inefficient way, with high wait times and opportunities for errors. Health Informatics uses technology to foster a true "*digital transformation*" in the health system, whose purpose is not to reach perfection, but rather to establish a process of continuous improvement for management (WEN et al, 2010).

Interoperability requires data processing, structures, and platforms to connect, exchange, track outcomes, and communicate with stakeholders, in an accessible way when and where needed. The capture and mobilization of data across multiple sources from clinician teams, health services, and different people must be accessible and seamlessly interoperable (WEICHHART; STARY, 2018; WASSERMANN; FAY, 2017).

Interoperability also help to implement digital transformation but is important to understand their terms, sub-dimensions and principles Foundational, Structural, Semantic, and Organizational to map correctly build systems an interface that require using best terminologies and expertises. Global Digital Health Partnership described as one of major challenges of interoperability Semantic Interoperability that depends on platforms to modeling clinical processes (WASSERMANN, FAY, 2017; WALKER et al, 2005; WEININGER, 2017; WEN et al, 2010).

The specific objective number four present the tools and methodological to be used applied to the Brazilian context aiming to exchange data. The concepts founded in literature help to applied to the Brazilian context. The question *“Which tools and practices* *could be applied in the Brazilian context?*" was answered in "*Universal Medical Records. Implementing e-Health Interoperability with KBE*", available in Appendix IV.

This specific objective brought the deepening of Health Level Seven (HL7) Standard and a approach to technical development and implementation of Fast Healthcare Interoperability Resource (FHIR) that enables 1) Speed of data entry; 2) Workflow and trace; 3) Quality improvement outcomes (PAIS, 2019; SUJANSKY, 2009; D, L. J. et al, 2016).

The specific objective number 5 intended to answer the question *"Based on best practices, how to acquire and implement a model of exchange health data and build interoperability in the Brazilian context*? presenting the stages and results of the pilot project and their results.

To fulfill this specific objective the research analyzed countries' experiences shown that it is possible to make health systems more consistently and also that governments are not necessarily executors but mainly interlocutors creating consensus among stakeholders as supporters to bridge builders (GREG, 2020; CYLUS, PAPANICOLAS, 2015).

The importance of the governmental recommendations for semantic consistency in health systems accelerated the adoption process in countries that started the digitization process earlier and have immense legacies and consolidated companies with their own proprietary models that could offer some resistance to change (WEININGER, 2017).

The pandemic has accelerated many countries to discuss on collaborative and open health platforms. Countries like Europe, China, India, Russia, United Kingdom and Ireland are examples of models that adopted openEHR and retrieve and analyze for messages in FHIR (FAGHERAZZI et al, 2020; HASSOUNAH et al, 2020; SARBADHIKARI; SARBADHIKARI, 2020; WHITELAW et al, 2020).

European Patient Summary is a relevant guideline promote consensus and quality assuring mappings of information structures from implementation to improve standards. This literature answered the research question "*Which are examples of Best Practices and policies regarding the patient data*?

Other South-America countries as Uruguay, Chile and Argentina are using Health Standards and Interoperability to interoperable solutions maximizing compatibility with platforms that are increasing transparency, and facilitate collaboration, for example in

Argentina the Digital Health Alliance and Patient Data Collection (PDC) is used as a core element of their Interoperability Bus.

The questions "*How these tools are applied or fit in the Brazilian context*? and "*What are the best tools to be used to implement the exchange of data*?" enable to creat an Implementation Guide to help: 1) Public-Citizens, who want to carry or access their healthcare data, 2) Regulatory Policy Makers, such as government agencies.

The Implementation Guide presented a script summary of steps to be followed through a set of suggested tools by to be used by Healthcare Stakeholders like providers, technical-vendors of EHR, system integrators and organizations that manage regional and national patient summaries. This Implementation Guide use a contextualized model applied in Brazilian reality.

Paper number five " *Universal Exchange of Health Data using the IPS model and FHIR. Results of interoperability implementation in Brazil*" available in Appendix IV describe Brazilian experience and how outcomes were reached implementation of interoperability through Universal Medical Records exchange through sharing, transparency and direct interaction with patients, allowing quality, safety.

The effectiveness of integration of health data depends on interoperability between healthcare systems that is considered a challenging task that is properly adressed with Fast Healthcare Interoperability Resource (FHIR) that address the use a common language as Semantics Vocabulary, Code Sets, and terminologies to provide terms to describe clinical information as a method that allows the exchanging of information between different systems (PAIS, 2019; MESQUITA SALES; BENTES PINTO, 2019).

An important result of this research was a reduction to duplicates databases reducing or eliminating redundant aspects, avoiding duplicate data collection and eliminating obsolete of different systems that exchanging information using several systems offered Unified Health System (SUS) lowering operating costs acquired by interoperability through exchanging between Health Unities (CRESSWELL et al, 2019).

The research also identified conexions, standards and regulatories between Brazilian National Health Data Network (RNDS) that is an Interoperability Bus or Infovia that follow some rules of experiences implemented in other countries as 1) Responsibilities for patients and professionals, 2) Sharing of data and privacy, 3) Best Policies, 4) Reduce of costs, 5) Data Storage & Preservation (RIBERA, 2016).

The final statement is regarded that interoperability help to consolidate medical historic data to patients that are daily using the health services provided by the city allowing transparency and efficiency improvement of government-citizen relationship, offerring transparency, quality, and security of the information, and better support for decision making for managers and health professionals (RIBERA, 2016).

Findings showed that Digital Health is not just about technology, but about a combination of mindset change and learning that integrates a digital culture, with review and design of processes and user engagement in the development of solutions. The benefits could be to reduce cost of access to services with benefits for the public sector, improving delivery services to their citizens more efficiently, helping institutions target  the population with welfare and social programs, giving governments the necessary tools to reach also in the remote areas ensuring communities and efficiency reducing the cost- of-service delivery. (DIGITAL IDENTITY ROADMAP, 2019)

The final project fulfills specific standard FHIR aiming to offer the reliability of data and technology standards exchange, which is a system that provides a secure and distributed database that can operate without a central authority or administrator (GÜLÇIN et al, 2011; D, L. J. et al, 2016).

The used methods and tools for problem-solving (DMAIC) were used during the research (SATOLO et al, 2009). Some typical tools of production engineering and also in the area of quality and statistics (example: Poka-yoke, Pareto diagram, QFD, etc) allowed a better understanding of the context for improving health systems through a multidisciplinary perspective (ERDEMIR et al, 2020). All instruments are used in the Knowledge-Based Engineering perspective (GOBBO et al, 2017) since Knowledge Management and Information Technology in Healthcare (DWIVEDI et al, 2002) is strongly dependent on the value of health care information exchange and interoperability (WALKER et al, 2005) that depend on regulations (GONZÁLEZ et al, 2016). Communities of Practice help to apply these concepts and to generate new Knowledge capabilities (WENGER et al, 2002; BOSE, 2003).

The study was designed as pilot tracing strategies for developing successful community partnerships and collaboration building alliances in systemic change interventions (RAPPAPORT et al, 2008) use of patient data in information systems, the information went from a paper record to electronic format in the form of files, thus allowing easier and more effective management offering clinical information registry concerning subsequent consultations and prescriptions enabling also patients to better manage their own health, improving the experience for both sides, patients and healthcare professionals. (BEVC et al, 2015; IIBA, 2020).

An e-Health Strategy for Brazil is a part of the National Policy for Informatics and Health Information (PNIIS), this led to an initiative to build a National Health Data Network (RNDS), as a hub platform whose main mission is to materialize a Digital Health Strategy for the country (BRASIL, 2019-b).

## 5.1 Limitations

There are four aspects and challenges related to interoperability that have not been explored in this work due to deviating from the main research question. They are 1) IT infrastructure, 2) Storage costs, 3) Data governance, 4) Blockchain alternatives, that was not compared to other technologies and solutions in terms of infrastructure investment costs, data security, best protection practices, data governance, and compliance.

The National Data Network embraces communication between domains with different information systems through a unique ID that requires the implementation of infrastructure aiming to facilitate the integration and communication of medical. The patient will have access to their health information, and this will also prevent fraud using Blockchain (BRASIL, 2019-b; BRASIL, 2019-a, BRASIL, 2020).

Blockchain requires for each transaction an encrypted signature validated by the network. This improves the authenticity and transparency especially useful for the health data sector allowing traceability data. The security requirements when following the Blockchain model allows automation and intelligent answering regards for the healthcare sector (GÜLÇIN et al, 2011; BANERJEE et al, 2018).

The quadruple Helix model, which reflects on possible dynamics between markets and governance and generates innovation was not addressed in this work, even if is very important and generates knowledge and innovation for society (CARAYANNIS, 2010)

The Design Thinking methodology designed by Brown (2020) focuses on empathy and creating knowledge for innovation and fits in this kind of Action Research, but this work was limited by the time, goals, and subject, then this tool was not applied in this work as the concept of Knowledge Funnel (BROWN, 2010; MARTIN, 2009).

## 5.2 Further Studies and Recommendations

Several countries are facing regulations on health data that are extremely sensitive to the privacy and this is a very important question very to address in further studies especially regarding Governance and Compliance offering more transparency about health technologies (BIRKINSHAW et al, 2008).

It is important to engage and include Patients as partners in Health Systems Development and CoPs can join the private sector and universities in the design of solutions, as shown in Ontario and TRILLIUM PROJECT (APPERTA FOUNDATION, 2020).

Subjects as "Rights of patients" could offer a variety of instruments to be useful em machine learning and data science (RYAN et 2014; DWIVEDI et al, 2002; CHESBROUGH et al, 2007; CHEN et al, 2020; KIM, 2015).

The openEHR model could be explored in further studies (KRUK et al, 2018) and effectively engage clinical and physical communities to develop Knowledge Management as 1) Performance Information between Health units; 2) Design of Actions Protocols; 3) New Knowledge models for Clinical Decision Support (BASKARADA; KORONIOS, 2013; WENER et al, 2002).

OpenEHR was developed in response to the demand for semantic interoperability and its main feature is to separate the clinical domain from the technical domain (MESQUITA SALES; BENTES PINTO, 2019). Considered as a reference model or architecture, its archetypes and templates create interoperable Electronic Health Record (RES), regardless of the associated technology. Health Level 7 (HL7) is an interoperability communication standard, and both can be used together to achieve the best results.

As a subject that emerged due to the pandemic, Startups are producing innovations for 4P (preventive, predictive, participatory, of the patient), and as a contribution Production Engineering could offer quality tools as QFD (Quality Function Deployment Matrix) helping Health Informatics to better acquire and analyze External and Internal Customers data (TORRES et al, 2020; SATOLO et al, 2009).

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# Appendix I

# An Overview of Use of the Reverse Logistics at Hospitals: A Research Path to Follow

# An Overview of Use of the Reverse Logistics at Hospitals: A Research Path to Follow

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**Abstract**. This paper presents a review of literature concepts about Reverse Logistics, Healthcare Waste Management, International Accreditations and Quality. It also provides an overview and benchmark data of healthcare facilities as the first part of an Action Research that intends to discuss results about how much is crucial to create guidelines and adjust waste management plan including Reverse Logistic at healthcare services, especially non-hazardous medical waste management. The sequence of this work will be reported in four cycles, in a similar way of the PDCA cycle, and aims to present a framework proposal to be applied at hospitals to including Reverse Logistics of recyclable materials according to accreditation rules.

**Keywords**: Sustainability, Accredited Hospitals, Quality Standards, Reverse Logistics

## 1. Introduction

Reverse logistics (RL) has gained relevance in recent years for all kind of organizations affected for the increase of complexity of production process regarding environmental concerns, legislation, sustainable development, and competitiveness willing to fulfill the corporate social responsibility. [1,2] Literature research shows that RL refers to the sequence of activities required to collect the used products from the customers with the purpose of either reuse, repair, remanufacture, recycle for reducing and managing the waste disposal of non-hazardous in a segregated way of hazardous waste. [3, 4]

Peter Drucker says that health management is more complex than in any other type of enterprise since uses several indicators combined to evaluate hospital performance. [5]. Hospitals can be seen as part of vital resources for any well-ordered society and also like performance indicators of quality of life when health is managed through defined standards regarding patients, clinical manager staff and also Healthcare Waste Management (HCW). [6,7]. Even though there are many standards clearly pre-defined and scaled through world quality benchmarks, healthcare services, and hospital management systems present huge complexity and challenges to control, maintain and improve quality standards that are also subject of large debate and interest to social welfare for governments, professionals, and several organizations. [8].

Hospital Accreditation evaluates health institutions through a series of enforceable compliance and says which requirements fulfill these standards through a process performed by an independent entity that periodically plans which level of quality improvement to get reach and ensures safety and commitment to all involved in the process, including society. [8, 9, 10]. Hospital surveying and accreditation is one recognized means by which this can be achieved undertake through international healthcare accreditation by institutions like Joint Commission International (JCI), the most important non-governmental certified entity of quality in medical-hospital care. [11]. Accreditation schemes are more concerned about clinical practices and some government-controlled initiatives are caring about solid waste management, both all kinds of wastes including non-risk HCW create huge impact and risk on human health and environment, and need to be observed. [12, 13, 14].

This paper objective to present an overview of hospitals sector and practices of solid non-hazardous medical waste management related to literature, as the first part of action research divided into three steps to build a theory or framework that aims to include Reverse Logistics at accreditation rules with materials that could be recycled to gain an extended lifecycle and several benefits to hospitals and society.

## 2. Background, context and motivation

Hospitals have become highly complex companies, which management must combine activities such as industrial process, science, and technology with procedures that directly interfere with human beings social, cultural and educational engagement.. For acquiring a high performance they need to improve controls of costs with efficiency and gains in quality of services that affect the results of the hospital, like health outcomes, quality of treatment, effectiveness at costs, and patient satisfaction. [5,6]

The Hospital Accreditation System emerged in the United States in 1951. The Accreditation process was born based on quality standards and can be defined as a system for organizations to acquire public recognition of management, capable of guaranteeing quality and continuous improvement. [7]

At this point some organizations could be quoted like Brazilian Consortium for Accreditation of Health Systems and Services (CBA) that is elected to verify and measure compliance for each proposed standard at Hospital of Brazil Sector and JCI is an international non-profit organization, the worldwide leader in accreditation that aims to improve quality in health institutions and delegates international standards through a committee composed by 16-member international task force responsible for developing and updating these standards that should reflect contemporaries practices and the expectations of excellence for each country measured. [8, 9, 10]

As any another activities healthcare services inevitably create garbage, but according to "*The second edition of the World Health Organization (WHO) handbook on the safe, sustainable and affordable management of health-care waste*", a practical guide that inspired this work, and address the problems of healthcare waste management, until 75% and 90% of the waste produced by healthcare providers is comparable to domestic waste. [8].

For each country, the guidelines of management of health service waste must comply with legislation and constitute a set of management procedures, planned and implemented based on scientific and technical normative and legal features, with the objective of minimizing the production of waste and preserving the natural resources and the environment, but at there are not a only rule to be followed specially regarding about how to implement reverse logistics at so sensible sector. [8]

### 2.1. Reverse Logistics

Reverse Logistics concepts emerged around 80´s regarding awareness of society and it has acquired a new status in the activities of production and supply chains which address aspects of the product lifecycle, which must return to the point of origin where they can be discarded, repaired, reused or recycled. [1, 2]

Reverse Logistics allows both reducing the use, recycling, replacement or reuse of materials and also the improvement of waste disposal, which is a concern with the environment, which also offers visibility to organizations and awakens a new business posture and business perspective. [3, 4]

The disposal of hospital waste is a serious problem to be faced by managers, once that garbage may pose a risk to human health and the environment if appropriate technical procedures are not adopted in handling, however, hazardous waste must be sent to appropriate destinations, and non-hazardous it coming mainly from administration and hotel services, such as PET bottles, paper, cardboard, etc can return to the production cycle through appropriate recycling channels that extend their useful life. [4]

According to vary environmental conditions an average forecast for decomposition time of the PET bottle is at least one hundred years, and the material, coupled with resistance to moisture and chemicals, may be recycled in the plastics industry divided into two parts: The first part is a pre-recycling process comprehending: (i) Collect, (ii) Size Reduction (iii) Separation or Sorting, (iv) Cleaning and Drying, and the second one is regarded as the extrusion process which homogenizes the plastic and produces a material that is easy-to-work on to produce new products. [4]

#### 2.1.1. Healthcare Waste Management

Healthcare facility waste management create more complexity once the non-risk Healthcare Waste Management (HCW) includes all the waste that has not been infected, like general office waste usually called "*non-hazardous*" or "*general healthcare waste*" that comes mostly from the administrative, kitchen and housekeeping functions, and may also include packaging waste, and waste generated during maintenance of healthcare buildings. [7, 8, 9]

Figure 1 presents three groups for HCW that observe a definition, classification and a guidance for the specific management and protective measures for the environment, but this paper is focusing only at the classified garbage classified like A series, especially A1. [7]

A1) **Recyclable Waste** - It includes paper, cardboard, non-contaminated plastic or metal, cans or glass that can be recycled if any recycling industry.

A2**) Biodegradable HCW** -This category of waste comprises, for instance, leftover food or garden waste that can be composted and transformed in energy.

A3) **Other non-risk wastes** - There are included in this category all the non-risk waste that do not belong to categories A1 and A2.

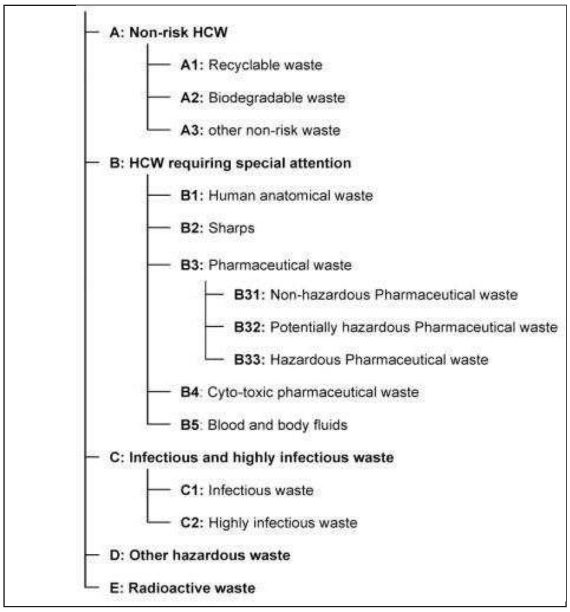


**Figure 1**: Classification of HCW [7,8]

## 2.2. International Accreditations and Quality

Although there are several certifiers, for this paper three of them was chosen by be used by thousands of enterprises of hospital sector and can satisfy requirements for obtaining an overview of rules and guidelines. Each one has a core focus and specific requirements for evaluation. Some facilities have only one of them, another sometimes combine a sum of these accreditations. [10].

### 2.2.1. JCI Accreditation Standards

Since 1953, Joint Commission International (JCI) is a North American non-governmental organization and global leader that offers a certification awarded by a specialized team of advisors who follow rigorous International standards. The JCI Accreditation Standards for Hospitals manual, 6th Edition is presented in three sections offering tools to measure: 1) The hospital or academic medical centres quality leadership; 2) Commitment regard rules at level with municipal, regional, or national health authority; 3) Commitment with internationally recognized health standards of care quality organization, such as the Institute for Healthcare Improvement (IHI), the Organisation for Economic Co-operation and Development (OECD), Health Care Quality Indicators program, or the U.S.-based Agency for Healthcare Research and Quality (AHRQ). [11].

### 2.2.2. Health Institution Management Standard

Healthcare Information and Management Systems Society (HIMSS) is a global non-profit organization that promotes the use of information technology (IT) to improve health care. According to your mission is designated to lead and engage endeavors to optimize health and care outcomes through information and technology offering a collection of action plans focused on key areas with high potential for value realization plus a framework to develop strategies and easily deliver measurable, accessible and meaningful information to users, doctors, and patients. They believe in the potential of digital technologies used to improve both the health status of populations, as well as the quality, cost- effectiveness, access, and value of healthcare and evaluate the stage of the enterprise regarding 7 maturity stages. [12]

### 2.2.3. International Organization for Standardization

ISO 14001 is a standards developed by the International Organization for Standardization (ISO) that establish guidelines on the area of environmental management like a framework where the organization can consistently control its significant impacts on the environment and continuously improve operations and business including maximum reuse and recycling of waste at the best cost with the purpose of reducing environmental impacts, taking into account environmental legislation and traceability of waste. This international certification promotes efforts to reduce the impact on the environment through actions such as: 1) Proper waste disposal, 2) Recycling, 3) Composting (decomposition of organic materials), 4) Rational consumption of electricity, 5) Environmental awareness. [13,14]

## 2.3. General numbers and benchmarking of the sector

In 2001, in the different OECD countries, a project named Health Care Quality Indicators (HCQI) created a conceptual framework regarding effectiveness, safety, and responsiveness for patient experiences, comparing 40 indicators of quality for key areas of health service aiming to assist in the improvement of quality measurement of the sector regardless to concern about waste management. [15]

Although the healthcare services in each country follow different rules and measures, the following table 1 shows some comparative numbers of general hospitals or health facilities collected at majors and trustworthy databases of the sector according to quantity available for the population. Some countries in Europe, like Italy, are not updating data since 2012, and countries like France and Germany have almost a half of hospitals than Brazil. These numbers are displayed at figure 2. [15, 16, 17]

**Table 1**: Comparative Number of Total Facilities

| Country | Total of facilities | Last data of collect |
|---|---:|---:|
| Brasil | 6.812 | 2015 |
| USA | 4.862 | 2015 |
| France | 3.382 | 2013 |
| Germany | 3.183 | 2013 |
| Italy | 1.156 | 2012 |
| Spain | 764 | 2013 |
| Portugal | 226 | 2013 |

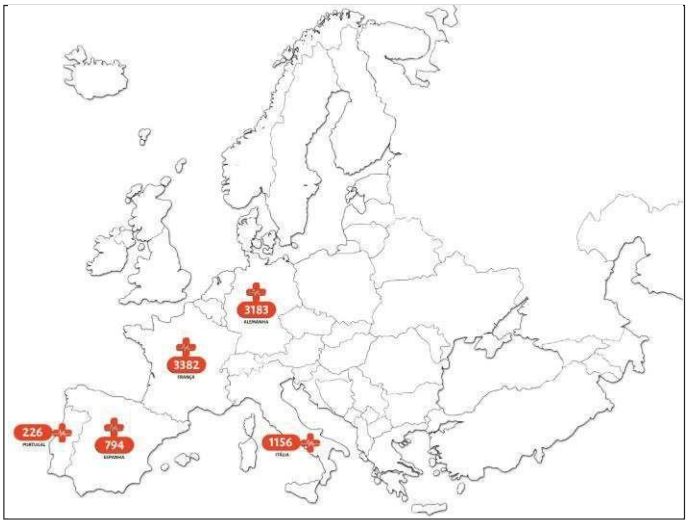


**Figure 2**: Total number of facilities at Portugal, Spain, Italy and Germany [15]

At the United States, Community hospitals are all nonfederal, short-term general, and specialty hospitals whose facilities and services are available to the public. Regarding data from 2015, the total number of 4.812 facilities represents 85% of all hospitals that not include institutions for the mentally retarded, long-term care, psychiatric, alcoholism and another chemical dependency, beyond federal hospitals. Figure 3 shows Texas State leading in quantity with 404 hospitals, Alaska presents 21 facilities and Delaware with only 7. The state of Hawaii is not showed regarding its location on the map but counts with 24 facilities at its several islands. [16]

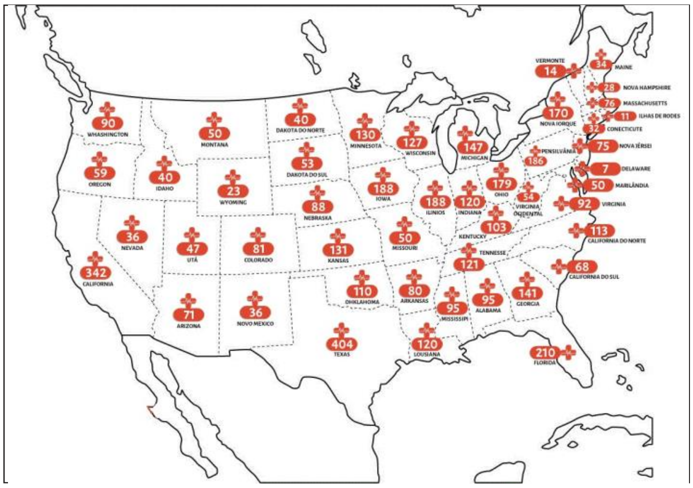


**Figure 3**: Total Hospitals at USA |The Henry J. Kaiser Family Foundation. Timeframe: 2015 [16]

The following figure 4 shows a total of healthcare facilities presented in Brazil totalizing 6812 hospitals. São Paulo state represents more than 15% (1084 hospitals) of all country, surpassing in quantity of facilities a sum of countries like Spain with 764 and Portugal with 226. [17]

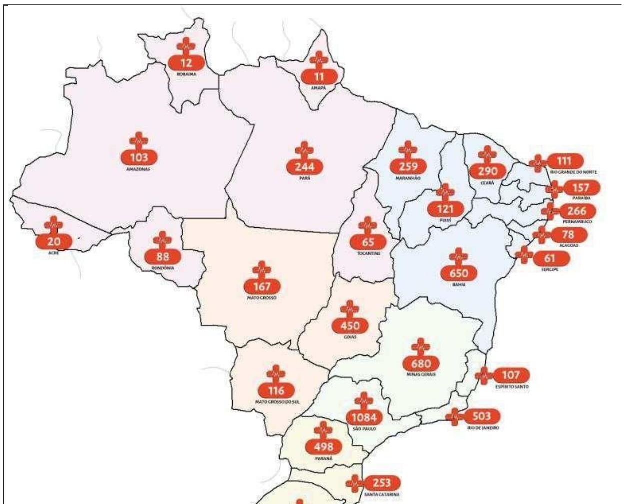


**Figure 4**: Total of Brazilian Hospitals | Ministry of Health - CNES/ CNES - OUT/17 [17]

## 3. Methodology

Every scientific method of research should be based on reliability validity of information whose characteristics measure its quality or scientific rigor. An action research is built through cycles that generate new improvements and learning. This method could be initiated to solve a problem and produce guidelines for best practices generating knowledge that lead to intentional modification of a given reality. [18, 19]

The methodological procedure for this paper consisted in a research at the conceptual bibliography; secondary data were collected for a study at hospital sector and accreditation rules and healthcare waste disposal. Sample universe was testing aim to build an exploratory research (qualitative analysis) and a descriptive research (quantitative analysis). The following figure shows the four steps and procedures to fulfill the project objectives. [20, 21]

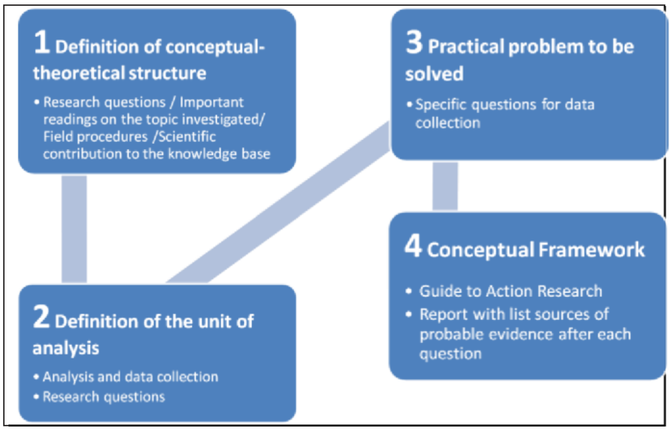


**Figure 5**: Cycles of action research generating new improvement cycle and learning. Source: Authors

The final work will be reported in four cycles in a similar way of the PDCA (plan-do-check-act) cycle proposed by Deming [6] and aim to present a framework proposal to be applied at hospitals to check indicators for a collect of HCW-A1 and intend to become a guide for new accreditation rules according to better standards of sustainable and policies of waste management including reverse logistics operations. [9, 10, 25]

## 4. Results

As the main objective of this work was to obtain an overview of the sector, after collect from general public internet sources data that resulted in a database of 1.084 hospitals, 70 was contacted resulting in 40 managers that answered two questions: First one intended to understand if the subject researched caused some interest for hospitals and second how deep it could be developed regarding waste management plan.

### 4.1. Preliminary Sample Universe

Brazil presents a total of 6.812 hospitals and the state of São Paulo is a leader in quantity and quality numbers, totalizing 1.084 facilities. Based on own experiences of the researchers, it was possible to collect a preliminary data sample with 40 managers responsible for quality or accreditation at a database of hospitals from the city of São Paulo displayed in table 2, representing 3,7% of a total of the sample. As a protocol of research, all data collected for this research are under a non-disclosure agreement. In a second round, a complete survey (showed in table 3) will be improved to be applied to in an extended database aim to go deep in knowledge.

**Table 2**: Preliminary Sample Universe Respondents

| Universe Sample | Number of facilities | Disponible Data |
|---|---|---|
| Brazilian Hospitals | 6.812 | 1.082 |
| State of São Paulo | 1.084 | 40 |
| **% Value** | **15%** | **3,7%** |

**Source**: Authors

**Table 3.** First draft of preliminary survey for second round of research at an extended database

| # | Indicator Key | Question or dimension |
|---|---|---|
| 2 | Capability | Total number of available beds |
| 3 | Average length of stay | Mean time of patient |
| 4 | Quality Acreditation | Indicate the Kind of Certifications |
| 5 | Waste Management Plans | Does the Hospital have a Waste Management Plan to guide the separation of solid waste? |
| 6 | Appropriate recycling | Is there a program in the hospital for the appropriate recycling or disposal of PET bottles, paper and other recyclable materials? |
| 7 | Amount of solid waste | The amount of solid waste like PET bottles, plastic, paper, cardboard are measured periodically? |
| 8 | Data transparecy Scale | This data could be easily reached known and accessed by the Government / Society? |
| 9 | General overview Scale | It does incentive to reuse these materials is be seen as capable of promoting and improving relationships with society? |
| 10 | Profitability | On what scale could solid waste separation be considered as a profitable activity to be implanted in the hospital? |
| 11 | Easy Technology Communications | Is there an Intranet Service that facilitates the communication, knowledge and monitoring of Environmental Management Systemgoals and indicators |

**Source**: Authors

At the end of the complete survey will cross and relate a very large amount of data, but the results presented until now through a question "*Does the Hospital have a Waste Management Plan to guide the separation of solid waste*? can get better explained in figure 6 that shows a half of respondents are no awareness how much is crucial creating guidelines and adjust of research referring to waste management plan.

**Figure 6**: Waste Management Plan Reponses. Source: Authors

Although only this question was analyzed until this point, the data is enough to show that 50% of respondents are already having space for going deep into research and investigated more thoroughly. Waste-generation data are used in estimating the required capacities for containers, storage areas, and transportation and treatment technologies. Control solid waste-generation data can be used to establish a baseline data on rates of production in different areas for procurement specifications, planning, budgeting, calculating revenues from recycling, optimization of waste-management systems, and environmental impact assessments. A framework could be able to measure types and quantities of waste produced in a healthcare facility as an important first step in the safe disposal. [7]

### 4.2. Guidelines of proposed framework

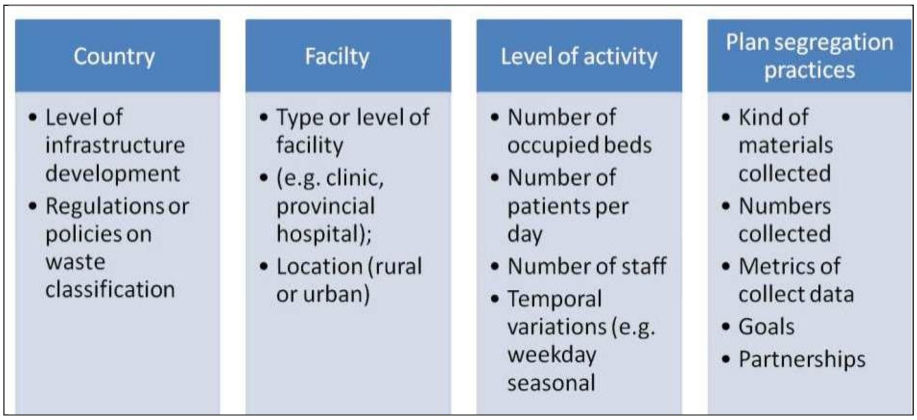
A framework must present a planning of implementation, define goals, keys indicators, and boundaries and finally to be a guide that analysis and offer recommendations to measure the evolution and maturity and level of engagement at least in three dimensions. [7,24]

1) Social sustainability engagement metrics
   - Engagement of team and neighborhood
   - Volunteering Level
   - Society Responsiveness and Education

2) Environmental sustainability metrics
   - Solid Waste pollution reduction
   - Improvement of quality disposal

3) Economic sustainability
   - Costs reduce at disposal waste
   - Profitabality with recycled products
   - Partnerships and network with industries and collectors
   - Technology implementation and Innovation

Based in "*The second edition of the World Health Organization (WHO) handbook on the safe, sustainable and affordable management of health-care waste*" figure 7 shows an example of the datasheet for an initial collection of data regarding measure and develop the solutions, but if a quantitative waste assessment is not possible, other additional methods could be used. [7]



| Country | Facilty | Level of activity | Plan segregation practices |
|---|---|---|---|
| • Level of infrastructure development<br>• Regulations or policies on waste classification | • Type or level of facility<br>• (e.g. clinic, provincial hospital);<br>• Location (rural or urban) | • Number of occupied beds<br>• Number of patients per day<br>• Number of staff<br>• Temporal variations (e.g. weekday seasonal | • Kind of materials collected<br>• Numbers collected<br>• Metrics of collect data<br>• Goals<br>• Partnerships |

**Figure 7**: Datasheet for a Plan for Initiate Reverse Logistic at Hospitals . [3,4,7]

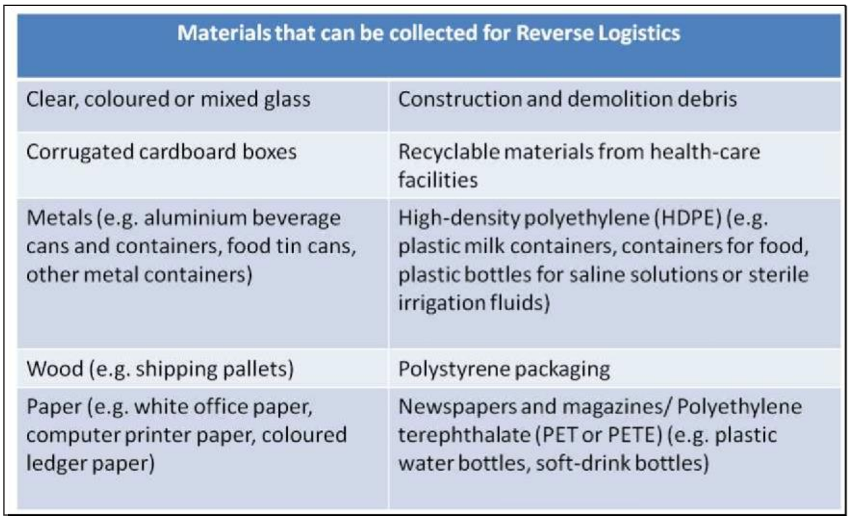
The type of waste should be consistent with the classifications used and also according to local rules legislation, but a huge number of facilities like listed in figure 8, could be benefited by implementing RL.

**Another facilities able to apply Reverse Logistics**

| | | | |
|---|---|---|---|
| 1. General hospital | 7. Blood banks and blood collection services | 12. Hospices | 18. Biotechnology laboratories |
| 2. Long-term health-care | 8. Nursing homes for the elderly | 13. Transfusion centres | 19. Medical research centres |
| 3. Military medical services | 9. Emergency medical care services | 14. Dialysis centres | 20. Mortuary and autopsy |
| 4. Hospitals University hospital | 10. Health-care centres and dispensaries | 15. Prison hospitals or clinics | 21. Animal research and testing |
| 5. Maternity clinics | 11. Obstetric and Outpatient clinics | 16. Related laboratories and research centres | 22. Other health-care facilities |
| 6. District hospital | | 17. Medical and biomedical laboratories | |

**Figure 8:** Kind of facilities able to implement Reverse Logistic. [7]

Types of recyclable materials and waste segregation practices are due each culture and also policies of countries and organizations, but a waste-assessment plan may include material like as listed at figure 9. [1, 2, 3, 11]



| Materials that can be collected for Reverse Logistics | |
|---|---|
| Clear, coloured or mixed glass | Construction and demolition debris |
| Corrugated cardboard boxes | Recyclable materials from health-care facilities |
| Metals (e.g. aluminium beverage cans and containers, food tin cans, other metal containers) | High-density polyethylene (HDPE) (e.g. plastic milk containers, containers for food, plastic bottles for saline solutions or sterile irrigation fluids) |
| Wood (e.g. shipping pallets) | Polystyrene packaging |
| Paper (e.g. white office paper, computer printer paper, coloured ledger paper) | Newspapers and magazines/ Polyethylene terephthalate (PET or PETE) (e.g. plastic water bottles, soft-drink bottles) |

**Figure 8**: Usual materials for Reverse Logistic. [ 3, 4, 7]

## 5. Conclusions

This study attempts to fill an existing research gap through a literature review about Healthcare Waste Management (HWM), International Accreditations and Quality and outline future directions. A review of the literature was done using several electronic sources beyond a benchmark of the hospital sector providing an overview of the number of these facilities in Brazil, USA, France, Germany, Italy, Spain, and Portugal. Regarding literature, it was possible to review concepts of Reverse Logistics that could be applied for healthcare services; especially regarding non-hazardous medical waste management classified like HCW-A1 and the role of accreditation concerning this subject. [1, 2, 3]

As an initial clause of an action research built on cycles that generate improvement and new cycles, a general overview was obtained at the first part of the study for a situational recognition and analysis.

Results presented enough collected data to reach purpose and fulfill the main objective as the first stage of an action research to create a first step of a framework that aims to minimize the waste-generation and reduces costs in the context beyond optimizing the use of resources that could be recycled, and to improve performance and quality, reducing also environmental impact assessments at healthcare services, at the same time attending rules of accreditation. [11]

It achieved its objectives and contributed to the literature in the field of healthcare waste assessment providing an opportunity to improve current practices, promote awareness of society and health workers about the potential of implementing and segregation of recycle materials for waste minimization that can result also in cost savings and new gains and innovation process regarding through recycling channels and exchange practices that involves society. [4, 5, 6]

One first draft of proposal of framework to be included at accreditation rules was presented aim to develop an instrument capable of getting and providing information that facilitates an evaluation of the degree of sustainability monitoring trends to defeat, one of the challenges of building sustainable development at hospitals, and so help to improve goals through use of indicators that allows measurement, comparisons and evaluations about waste recyclable materials that could be at Reverse Logistics. A report in four cycles will be presented in a similar way of the PDCA (plan-do-check-act) at final work. [6,7]

As entities highly dependent on the effective management of all resources, new broad insights about the context also brought and suggest future works regarding subjects like resources and waste management practices, recycling materials complexity at hospitals, society engagement, reverse logistics and profitability. [26]

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# Appendix II

## Communities of Practice of Reverse Logistics at Health Sector: a Quality Approach

# COMMUNITIES OF PRACTICE OF REVERSE LOGISTICS AT HEALTH SECTOR: A QUALITY APPROACH

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**ABSTRACT.** Reverse logistic is regardind ones that must be returned to the point of origin where they can be discarded, repaired, reused or recycled delivering to organizations a global vision of competitive advantage, profits and better image through Communities of Practice provide an environment conducive to connecting people, encouraging self-development and sharing of ideas and strategies and operating in a distinct way from other structures, since it serves a specific purpose, such as the development of new products and services, market, process or organizational context This work attends to a specific objective of an Action Research to solve a practical problem and expand scientific knowledge regarding Reverse Logistics of solid waste at hospitals and presenting Communities of Practice aim to produce knowledge as a strategic resource to share, convert and management knowledge in favor of the business strategy of hospitals. This study present also some quality concepts that could be conjugated with Reverse Logistics and rules to propose a simplified framework that can be included in hospital practices aiming to reduce the use of solid and non-hazardous medical waste, that can be integrated into the day-to-day management of quality.The attention from Reverse Logistics (LR) falls back at another huge amount of solid waste daily generated from an intense activity at hotel and administration services, always observing the rules of National Policy on Solid Waste, and also the requirements of quality and accreditation suggesting that the Quality Management at healthcare sector can create a Community of Practice with basis on Reverse Logistics.

**Keywords.** *Community of practice, Reverse Logistics, Health Quality, Research Action*

## 1. INTRODUCTION AND FRAMEWORK

This paper is contextualized at the department of quality about health sector and brings highlighted concepts of the first stage of a larger Action Research and a specific goal that intend analyzes tools that help management regarding solid waste, according to Brazilian National rules.

Communities of Practice (CoPs) are able to share and convert knowledge aiming to achieve competitive advantage and provide an environment to connect people in a distinct way from other structures and are considered such as instrument to development of organizations, sectors, products, services, process that has been used to increasing groups and teams with regular interaction, as a conceptual pillar for following a purpose to learn and perform better tasks, generating knowledge and innovation. (WENGER, 2011) (DRUCKER, 2002; WENGER, 2011)

Healthcare services suffer challenges in a high competition environment because they are customer focused and need continuous improvement. Quality is a multidimensional concept, meaning different things to each one, and Service Quality is an abstract construct, hard to measure, especially in the healthcare sector, that needs to deal with systems that manage and measures benefits for all stakeholders. (BÜYÜKÖZKAN et al, 2011; WOOD et al, 2016)

Quality management (QM) could be also recognized as an opportunity for improving continuous improvement process for any kind of structure that requires strength to defeat new challenges are obeyed to deal with subjects like process analysis, organizational coordination, staff competence, management leadership and customer satisfaction. (L.X. Li, 1997, BÜYÜKÖZKAN et al, 2011; COSTA NETO, CANUTO 2010)

This paper focuses to show a preliminary proposal, from the perspective of hospital management quality for achieving, improving and sustaining performance through creating teams, efficiency and productivity indexes for reducing and recycle solid waste and aims to indicate a practical application proposal for adoption of Reverse Logistics at Communities of Practice, as an instrument to be included as standard in Systems of Quality Management management regarding rules of Brazilian National Solid Waste. (PNRS, 2010) Reverse Logistics are a concept stated by Rogers and Tibben- Lembke (1998) improved at Brito et al (2004) that attends to the purpose of this work since address aspects of the product lifecycle, including the reverse ones, that must be returned to the point of origin, where they can be discarded, repaired, reused or recycled, delivering to organizations a global vision of competitive advantage, profits and better image to society. (ROGERS, TIBBEN-LEMBKE, 2001; BRITO et al, 2004).

This paper focuses to show a preliminary proposal, from the perspective of hospital management quality achieving, improving and sustaining performance through creating teams, efficiency and productivity indexes for reducing and recycle solid waste and aims to indicate a practical application proposal for adoption of Communities of Practice of Reverse Logistics, as an instrument to be included as standard in Systems of Quality Management management regarding rules of Brazilian National Solid Waste. (PNRS, 2010)

## 2. MATERIAL AND METHODS

This work was originated as result of a dissertation that dealt with Communities of Practice and generated further studies opportunities in research offering concepts and best practices for final disposal and treatment for a solid waste at the healthcare sector. (ANDRADE, 2017)

Action Research was the chosen method for the continuity of studies due to be a rigorous, reliable approach to theory formulation and embody a strategy for studying a change in organizations that was born to solve practical problems and bridge the gap between theory and practice that seeks to produce solutions to real problems, and expand scientific knowledge, especially when the situations are too ambiguous to conduct a research.

### 2.1 UNIVERSE AND SAMPLE DATA

Brazil presents today a total of 6.812 hospitals, and the state of São Paulo is a leader in quantity and quality numbers, totalizing 1.084 facilities like is displayed in table 2. 40 hospitals were invited to participate at this research and some of them could be considered like the best of worldwide standard.

TABLE 1 – Preliminary Sample Universe Respondents

| Universe Sample | Number of facilities | Disponible data |
|---|---|---|
| Brazilian Hospitals | 6.812 | 1.082 |
| State of São Paulo | 1.084 | 40 |

SOURCE – Authors, 2018

Sociedade Beneficente Israelita Brasileira Albert Einstein operates in São Paulo and could be an example of healthcare, education, research and innovation, consulting and social responsibility focused on healthcare safety and quality. Your management Model for healthcare is based on consecrated systems named Triple Aim with three dimensions interrelating efficiency, effectiveness and better cost-outcome relation. As a signatory of the Global Compact promotes good business practice in four areas: human rights, working conditions, environment and the fight against corruption, presented at sustainability report from 2016 that provides an account of the main challenges and advances of sustainability context considerating also environmental impacts, risks, and trends that may affect the sector. (HOSPITAL ALBERT EINSTEIN, 2016)

Another excellent example is the support group to children and youth with cancer (GRAACC – Grupo de Apoio ao Adolescente e à Criança com Cancer) is one of the most respected and successful NGOs in Brazil as a non-profit organization and reference in the treatment and research of children and youth cancer in Latin America. The institution has become a reference in education and development of research in the fields of clinic, surgery, and biology of children´s cancer with the objective of increasing the level of healing through developing technical and scientific. In 2014, the GRAACC Hospital attended more than 3 thousand children and teenagers, accomplished more than 26 thousand medical appointments and above 1.5 thousand surgical procedures. (GRAAC, 2018)

## 2.2 ACTION RESEARCH METHOD

Thiollent (2007) points out that a problematic action deserves investigation from the scientific point of view to be elaborated and conducted. Action research can be seen as a variant of case research, but whereas a case the researcher is an independent observer, especially for production and operations management (POM) when the intervention technique could be adapted and understanding, scope, and limitations are developed for each application. (WESTBROOK, 1995;YIN, 2005; TRIPP, 2005).

At the similar way to the medical treatment, an Action Research prompts diagnosis, prescript, monitoring, and evaluation results development processes and involves the formulation of a theory, intervention, and action-taking in order to introduce analysis and changes behavior.Table 1 shows a summary of actions sequence, practices, and inquiries, that justify the chosen method for this work. It’s important to recognize that Action Research is composed by different processes: diagnoses, participation, and experiments that follow a cycle like showed at figure 1, in which one improves practice by systematically oscillating between taking action in the field of practice and at inquiring into it. (BASKERVILLE, PRIES-HEJE, 1999; TRIPP, 2005)

TABLE 2 – Action take in field of representation of the Action Research cycle

| Action Sequence | Practice | Inquiry |
|---|---|---|
| Planning of | A change to practice | The evaluation of results of change practice |
| Implementation of | The change to practice | Data production, analysis and reporting |
| Evalution of | The change to practice | Combined the action inquiry process |

SOURCE – TRIPP, 2005

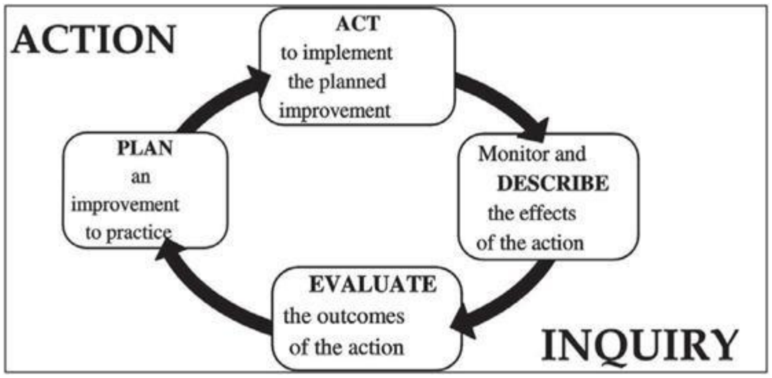
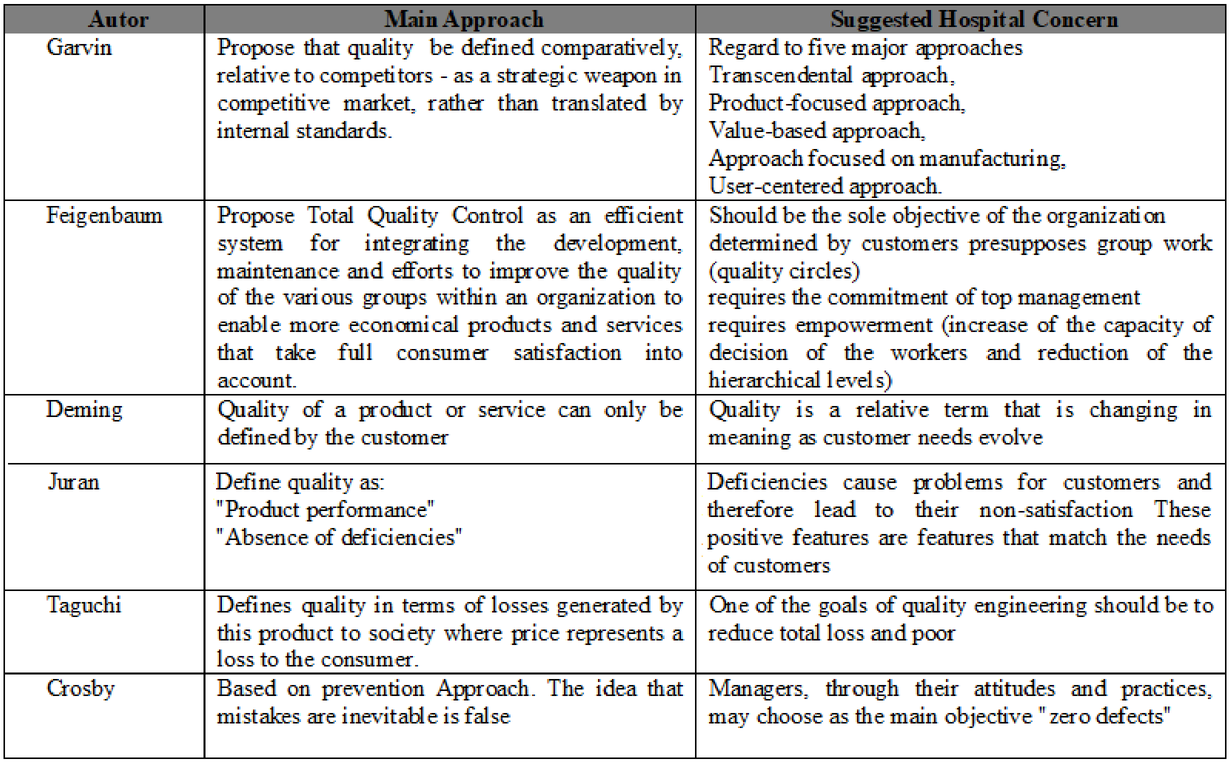


FIGURE 1 Representation of the basic action inquiry cycle
SOURCE – TRIPP, 2005

## 2.3 QUALITY APPROACH AT HEALTHCARE SECTOR

The main theories and approaches to quality used in this work are suggested by authors like Juran, Deming, Feigenbaum, Garvin and Joseph Moses Juran that states who decide about quality are the customer. Kaoru Ishikawa talk about advantages of competitive specifications, Crosby tells about what it costs is lack of quality. Feingenbaun realizes quality as an institutional commitment since for the president to deliver until pyramid bases, Masaaki Imai deals with concepts of Lean and Kaizen to fulfill continuous improvement and finally landing at Taiguchi, that says that who pays for non- quality is society. All concepts alone or used together could be applied to better hospital management. (COSTA NETO, 2010; WOOD et al, 2016)

A Quality System can combine several resources according to theoretical models to allow the optimization of results. Among these studies, many theories as classical, human relations, neoclassical, bureaucratic, structuralist, behavioral, systems and contingency have been studied by a large number of authors and their approaches are related to figure 2 that summarize main concepts and presents authors like Deming, that provided a method widely recognized as the basis of continually improving quality of processes, products, and services perfecting the proposal of Walter Shewhart that wrote the book named "*Statistical Method From the Viewpoint of Quality Contro*l" discussing the concept of continuous improvement cycle named PDCA (Plan – Do – Check – Act) showed in figure 3. PDCA is a framework for problem-solving, continuous improvement and change that ensures plan, test and incorporate feedback that fit as a model in any kind of sector. At healthcare sector, the quality approach is chased from the point of view of accreditations rules that intend to organize the process and maintain the proper care. (COSTA NETO, 2010; WOOD et al, 2016).



| Autor | Main Approach | Suggested Hospital Concern |
|---|---|---|
| Garvin | Propose that quality be defined comparatively, relative to competitors - as a strategic weapon in competitive market, rather than translated by internal standards. | Regard to five major approaches<br>Transcendental approach,<br>Product-focused approach,<br>Value-based approach,<br>Approach focused on manufacturing,<br>User-centered approach. |
| Feigenbaum | Propose Total Quality Control as an efficient system for integrating the development, maintenance and efforts to improve the quality of the various groups within an organization to enable more economical products and services that take full consumer satisfaction into account. | Should be the sole objective of the organization determined by customers presupposes group work (quality circles)<br>requires the commitment of top management<br>requires empowerment (increase of the capacity of decision of the workers and reduction of the hierarchical levels) |
| Deming | Quality of a product or service can only be defined by the customer | Quality is a relative term that is changing in meaning as customer needs evolve |
| Juran | Define quality as:<br>"Product performance"<br>"Absence of deficiencies" | Deficiencies cause problems for customers and therefore lead to their non-satisfaction These positive features are features that match the needs of customers |
| Taguchi | Defines quality in terms of losses generated by this product to society where price represents a loss to the consumer. | One of the goals of quality engineering should be to reduce total loss and poor |
| Crosby | Based on prevention Approach. The idea that mistakes are inevitable is false | Managers, through their attitudes and practices, may choose as the main objective "zero defects" |

FIGURE 2 –Related Approaches of Quality Standards for Hospitals
SOURCE – ADAPTED FROM COSTA NETO, CANUTO, 2010

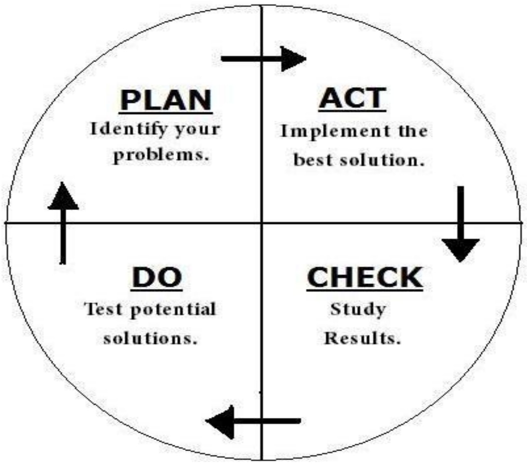


FIGURE 3 –PDCA Cycle Approach
SOURCE – ADAPTED FROM COSTA NETO, CANUTO, 2010

Healthcare institutions use also a large number of standards from institutions such as ISO 9000, and The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) or the World Health Organization (WHO). The Hospital Accreditation Manual for Latin America and the Caribbean indicates that the development of quality assurance programs is a necessity in terms of efficiency and aims at a permanent improvement and harmonious integration of medical, technological, administrative, economic, care, teaching and research that is beneficial to the patient and the community. (TING et al, 2013; SRINIVASAN, KUREY, 2014)

At healthcare sector, a management model or system to combine human and material resources to develop processes, technologies, methods and administrative is needed to obtaining certification, that is a process by which a government agency or professional association officially recognizes an entity or individual as having met certain predetermined qualifications that aim to accreditation, which is the procedure for evaluating the team, that need also understand and particle of the process, under the pillar of quality. (TING et al, 2013, SRINIVASAN, KUREY, 2014)

Customers are seeking quickly delivery patient care, medical staff trying to save lives, preventing infections, maintaining hospital security and ensuring patient safety, including environmental regards. Good practices and quality standards bring substantial gain which tends to guarantee through previously accepted standards setting different levels of satisfaction.The success depends on how quality it is embedded in organization culture that should involve people, technology, hospital administration, nursing staff the entire front line and clinical body. (SRINIVASAN, KUREY, 2014)

## 2.3 HEALTHCARE SECTOR CHALENGES

Hospital of the Future, a New Role for Leading Hospitals in Europe, is a study by IESE Center for Research in Healthcare Innovation Management, that introduces a conceptual framework showed in figure 4, that aims to encourage and promote action, which study includes a list of 15 recommendations addressed to different healthcare stakeholders and suggest analytical tools be used to defeat challenges to achieve a high-quality standards and achieve a value for society that deals with extremely stretched resources and conflicting priorities. (RIBERA et al, 2016)

FIGURE 4 –Hospital of Future conceptual framework
SOURCE –IESE Business School - Hospital of the Future (ST-388-E)

A Green Hospital aims to enhance patient well being, aid in the curative process, while is regarded also to use natural resources in an efficient environment-friendly manner, objecting to reduce energy consumption and also costs. Healthcare facilities are often open 24/7 and the well-being of patients is a key to reducing the length of stay and preventing readmissions and according to the American Society for Healthcare Engineering (ASHE) in green hospitals, patients have discharged an average of
2.5 days earlier compared to traditional hospitals. This high quality of care and maintaining the organization's reputation depends on maintaining patient safety, reducing the risk of infection, as well as other potential risks. Many countries are demanding to healthcare facilities to reduce carbon output and energy reductions and noncompliance can lead to a disruption in operations such as power failures. If all systems combined do not attend quality metrics like finances, productivity, patient safety, regulatory standards, energy management, security like is pointed at figure 5, it affects patient´s satisfaction and so results of revenue. (ASHE, 2018; WOOD et al, 2016)


FINANCIAL CHALLENGES AND HOSPITAL PRODUCTIVITY: Hospitals are the second most energy-intensive buildings

MAINTAINING PATIENT SAFETY: Safety is refered the organization´s reputation such as power failures is crucial in ensuring a high quality of care and maintaining

REGULATORY STANDARDS AND EMERGING ENERGY MANDATES: Disruption in operations, poor quality of care, safety issues are results for noncompliance with regulatory standards

HOSPITAL SECURITY: Healthcare facilities may be often open 24/7

PATIENT SATISFACTION: The well-being of patients is a key to reducing length of stay and preventing readmissions

FIGURE 5 –Main Hospital Challenges
SOURCE – Adapted from IESE Business School - Hospital of the Future (ST-388-E)

### 2.4 SOLID WASTE MANAGEMENT AT HOSPITALS

The concept of reverse logistics has existed since the 1980s, but with the increased awareness of society, has acquired new status in the activities of supply chains. Leite (2003) understands that Reverse Logistics is an area of business logistics that plans, operates, and controls the flow and corresponding logistics information, from the return of after-sales and post-consumer goods to the business or the production cycle, through the reverse distribution channels, adding value to them of several natures: economic, ecological, legal, logistics, corporate image, among others, and that the useful life of a good according to time elapsed from its production until the time of disposal. (ROGERS, TIBBEN-LEMBKE, 1998, LEITE, 2003).

In Brazil, companies of various sizes and segments must meet the requirements of Law number 12.305 which regulates the National Solid Waste Policy (PNRS) and implement Reverse Logistics in its operations and Supply Networks, and this work aims to correlate damages irreversible to humans and the environment that can be caused by the disposal of toxic wastes (PNRS, 2012).

Reverse Logistics system for hospital waste correlates the correct way to dispose of this type of waste with minimization of impacts on the environment and demands special care, according to the specific rules of sanitary surveillance that needs the support of the Environment, Urban Cleaning and National Nuclear Energy Commission.

The National Health Surveillance Agency (Anvisa) has established national rules on the packaging and treatment of hospital waste generated from origin to destination (grounding, radiation, and incineration). These rules affect hospitals, clinics, offices, laboratories, morgues and other healthcare facilities. The objective of the measure is to avoid damages to the environment and to prevent accidents that affect professionals who work directly in the collection, storage, transport, treatment and disposal of these wastes. The National Solid Waste Policy (PNRS) encourages the formation of networks between organizations, society and government that tend to address the issue of waste and Reverse Logistics and their relationships and advantages. (PNRS, 2010)

At Brazilian rules, according to resolutions waste groups have the following classification: Group A (biological waste), Group B (chemical waste), Group C (waste containing radionucleotides), Group D (common waste) and Group E (piercing and cutting waste). In Brazil, 149 tons of wastes are collected every day, and HCW corresponds to approximately 1% to 3 % of that total. Waste could be classified as non-infective refuse, radioactive waste (composed of various materials, exposed to radiation); special waste (toxic and corrosive, flammable, mercury), common refuse (administrative areas, cleaning of gardens and patios, other food preparation) and hospital waste. The so-called hazardous waste or Class B must have its material collected in hospitals and conditioned according to standards that vary depending on the degree of hazardousness is usually taken to a landfill of its own. Class C waste should be properly segregated, but it is subject to the same collection system as the one in the city, going part for recycling and part for the normal collection, it is worth noting that there are cases of accidents with employees, involving perforations with needles, blades scalpel and other materials known as puncturing.

ISO 14000 standards issued by ISO (International Organization for Standardization) specify which requirements of an Environmental Management System (EMS). This series of standards provides guidelines for conducting environmental audits, environmental performance assessment, labeling, and product lifecycle analysis, to enable the organization to formulate policies, legal requirements and information that cause significant environmental impacts that should be mitigated in order to comply with the Solid Waste Management Policies (PNRS, 2010).

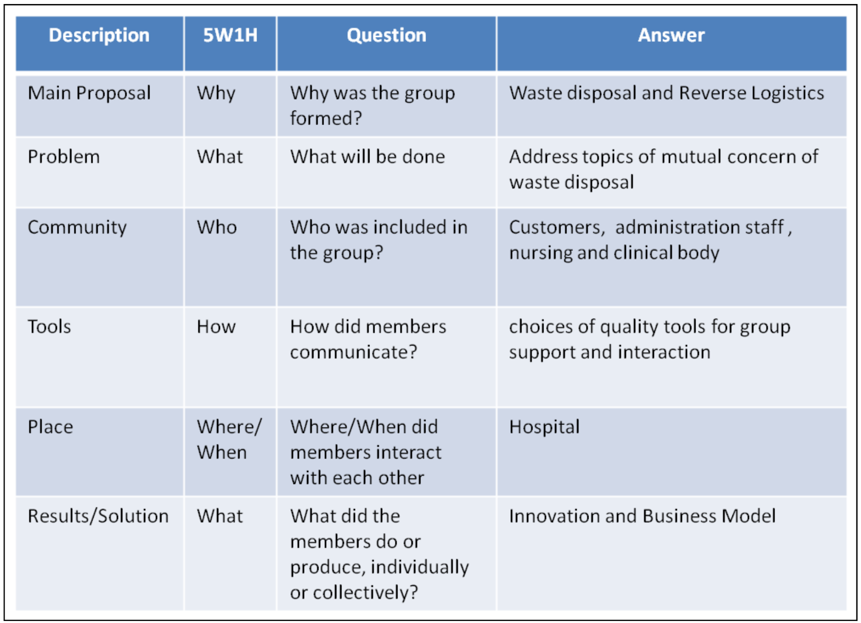
## 3. RESULTS AND DISCUSSION

A study conducted by Albert Einstein hospital says that exists a greatest environmental risk in the separation of hospital waste represented by infectious waste (Class A), which is characterized by the presence of biological agents such as blood and derivatives, human secretions and excretions, tissues, parts of organs, anatomical parts, waste from analysis and microbiology laboratories, isolation areas, intensive therapies, hospitalization units and sharps, which in addition to polluting the environment present a high risk of contamination, being that some establishments do not separate this material, which ends up going to the landfills along with the normal garbage. (HOSPITAL ALBERT EINSTEIN, 2016)

### 3.1 IMPLEMENTING COMMUNITIES OF PRACTICE SUGGESTED FRAMEWORK

In the service sectors, the internal measure of service quality is usually based on many internal standards of performance, while the external measure of service quality is usually based on the customer's perception of service quality via external measurement techniques, such as customer surveys, interviews, and focus groups. The concept of communities of practice brings a wide possibility of studies, analyzes and practices in various areas of science, such as administration, education, engineering, information science, nursing, among others and also could be applied to help how can healthcare organizations deal with these challenges while controlling costs, reducing waste and implementing a sustainability strategy and use. (COSTA NETO, 2010; WENGER,1998)

Wenger (1998) points out that communities of practice are everywhere that intend to share proposals and experiences but initially should answer questions like 1) Why the group is formed?, 2) Who could be included? , 3) How did members communicate?, 4) What members do or produce, individually or collectively?, 5) Where members interact with each other? Communities of practice are also the basis of social relations and would be very useful to hospital systems quality management, as shown in following figure 6.



| Description | 5W1H | Question | Answer |
|---|---|---|---|
| Main Proposal | Why | Why was the group formed? | Waste disposal and Reverse Logistics |
| Problem | What | What will be done | Address topics of mutual concern of waste disposal |
| Community | Who | Who was included in the group? | Customers, administration staff , nursing and clinical body |
| Tools | How | How did members communicate? | choices of quality tools for group support and interaction |
| Place | Where/ When | Where/When did members interact with each other | Hospital |
| Results/Solution | What | What did the members do or produce, individually or collectively? | Innovation and Business Model |

FIGURE 6 –Suggested Questions to Implement Communities of Practice for Reverse Logistic at Hospital
SOURCE – AUTHORS

Systems Quality Management at healthcare sector can create a Community of Practice with basis on Reverse Logistics, as shown at figure 7, regarding improving both the solid waste disposal, generate involvement of health professionals, engaging society and yet reducing costs, create innovation, and new solutions.

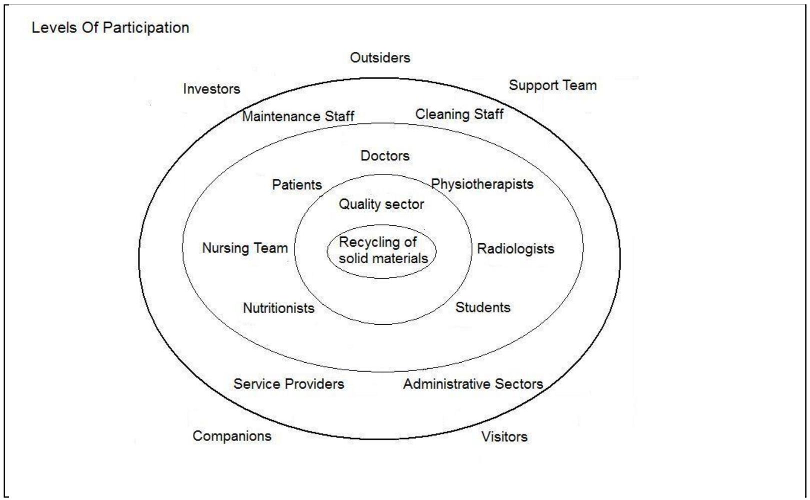


FIGURE 7 –Suggested structure of Communities of Practice for Reverse Logistic at Hospital
SOURCE – AUTHORS

## 4. CONCLUSION

This work attends to a specific objective of an Action Research to solve a practical problem and expand scientific knowledge regarding Reverse Logistics of solid waste at hospitals and conjugated concepts of quality like PDCA, and scientists like Deming, that designs quality as suitability to use that fit at the propose for Communities of Practice of Reverse Logistics that aims to produce knowledge as a strategic resource and from this perspective create new ways of manage knowledge, share and convert in favor of business strategy.

The literature on health service quality management and quality management were used to identify important quality management constructs in the hospital environment.This study present some concepts of Reverse Logistics and rules considering materials that can have their life cycle extended and propose a simplified framework that can be included in hospital practices for creating communities of practice that aim better practices and uses aiming to reduce use of solid and non- hazardous medical waste, that can be integrated into the day-to-day management of quality.

The attention from Reverse Logistics (LR) falls back at another huge amount of solid waste daily generated from an intense activity at hotel and administration services, always observing the rules of National Policy on Solid Waste, and also the requirements of quality, and accreditation.

The use of framework could improve both the solid waste disposal and improve the involvement of health professionals and society thus gaining better reputation, economy, and competitiveness through 1) Addressing mutual concern, 2) Sharing commitment regarding solid waste disposal, 3) Enabling all those involved to actively participate, 4) Sharing control processes evenly as possible, 5) Producing keys to input costs and outcomes value ratio. When these keys are included in Quality systems them could help to share knowledge through organization causing yet a rearrangement of the business model.

## 5. DELIMITATION AND FUTURE STUDIES

There are several certifiers and institutions that take care of the evaluation of processes, structure, and results, actions on the environment that which are not mentioned here and are not an objective of this paper. All framework of accreditation rules aims to meet a requirement or continuous improvement, even if is driven by market and financial motivation. This work does not mention about financial regards but its an important concern to future studies.

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# Appendix III

# e-Health: A Framework Proposal for Interoperability and Health Data Sharing. A Brazilian Case

# e-Health: A Framework Proposal for Interoperability and Health Data Sharing. A Brazilian Case

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**Abstract.** Interoperability among systems is a challenge that requires several regards and infrastructure often complex. The best worldwide reports and frameworks say that this can also improve health care and bring the best outcomes for stakeholders. Implementing Interoperability in developing countries is less affordable even it can also promote quality care and save lives. The best models and guidelines could offer protocols for sharing health data allowing to build a system that can deliver at the same time quality, transparency, and social value. This paper addresses an interoperability problem providing the steps built in a pilot to enable a conceptual framework for exchange healthcare data through EHR, and presents the first step and overview of a platform build using rules of PDCA. The experiment was built in a small Brazilian town intends to be a standard for deliver interaction between local government and citizens and also to offer to patients to control own medical data records through a mobile application.

**Keywords:** Health interoperability Health exchange data Quality of care · Action research

## 1 Introduction

The interoperability at the Health Sector is considerate a very complex task, but according to the American Hospital Association (AHA) can provide advances and better health care outcomes that saving lives and involving key stakeholders [1, 2].

Recent studies from The European Commission (EC) says that yet today many countries like France, Germany, and Italy are still struggling with several challenges to exchange their health data. Developing countries suffering also with a lack of infrastructure and financial resources, presenting a systematic deficit in the quality of care, costs, transparency, and deficient management [2, 3].

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The Commission on Health System Quality (HQSS) and World Health Organization (WHO) offer some frameworks and guidelines to produce well-functioning and performance health system in order to ensure the use of reliable and timely information regarding also to protecting privacy and security patient data [4, 5].

Brazil has 5,500 municipalities where the major part of the population suffers from a lack of resources and it is dependent on a public single and universal health care system (SUS). A partnership between UNIP researchers and a small town in the Paraiba Valley to develop a pilot platform, aiming to promote interoperability that intends to become a standard and scalable solution that could be implemented at other cities that faces the same problem, enabled the development of this research [6, 7].

This paper is the first one of an Action Research Cycle that describes the experience and proposal to design a framework based on PDCA to implement interoperability at public Brazilian health systems. Following the best practices is possible to design a strategy to be followed, based on the premise that is possible to build a cost-effective platform to reach data integration between entities using patients record as key data. The work is competing for an international award as a solution for this Brazilian quest [8–11].

## 2 Methodology

Action Research is a qualitative method that has been used in Production Engineering researches, and also a step-by-step method that helps to conduct interventions in improving a business situation. The term “Research” refers to the production of knowledge, and the term “Action” to an intentional modification of a given reality. The method was chosen to drive this project because leads to collaboration and involves stakeholders in a diagnostic and active-learning [8].

This work has begun with diagnosing that lead to an action plan. Action Research is a tool whose cycles aiming to affect and change the social reality using observations, explanations, and understandings. Table 1 shows the summarized steps used to fulfill the objectives of this research providing a structure for replication [8].

Table 1. Applied cycles of this action research

| Step | Main objective | Expected outcome |
|---|---|---|
| Identify the problem and theories | Research literature and cases and concepts | Set goal and target audience |
| Develop a plan | Envision success | Invites to participate, techniques and analysis units |
| Collect data | Describe actual situation | Register data |
| Analyze data | Develop a plan for improvement | Compare theories and practices |
| Adjust the theory and plan | Implement the plan | Actions plan improvements |
| Reports and results | Framework guidelines | Provide structure for replication |

The theoretical background was chosen after a detailed analysis of frameworks, interoperability ontologies, best practices and policies documents regarding the exchange of patient data health. The main concepts were pointed out by the AHA originated in countries like the USA, and by the European Commission (EC) at countries like Croatia, France, Germany, Italy, The Netherlands, and Sweden [1, 3, 5].

The final work will join the best practices and ontologies for interoperability suggested by the American Hospital Association (AHA) and Quality impacts offered by The Lancet, as shown at Fig. 1 indicating the guidelines for the relationship between citizens and governs referring to health data [1, 3, 5].

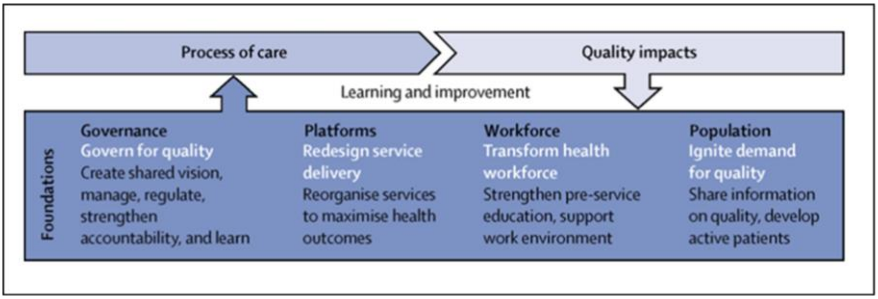

Fig. 1. Foundations for high-quality health systems commission [3].

Figure 2 shows the suggested rules for decision makings, to access quality, transparency, use, share and support information for health professionals, and patients that encouraging government-citizen relationship and also will be used to measure the impact of the pilot project [1, 3, 5].

Fig. 2. Suggested framework for high-quality health systems commission [3].

Thus, we will introduce a summary of the pilot that is being developed that intends to become a standard to fulfill this gap. The chosen Brazilian city to applying the pilot project was due to their number of inhabitants, relationship and proximity with health managers that facilitated the diagnoses of their health infrastructure for the first step to collect data to test the platform with patients regarding health data exchange [1, 9].

## 3 Results

The public health system (SUS) offered in Brazil was designed to fulfill all kind of health care whose Information Policy offers a lot of stand-alone software free supplied to manage data in order to provide information for the government. New society goals and health systems need to produce better health outcomes, including greater social value suggesting that citizens are able to collaborate at the government-citizen relationship, improving quality of access, transparency, the security of the information and also support for decision making that is stickle by this disconnected technologies [5, 7, 10].

### 3.1 A Brazilian Case

According to data of the Brazilian Statistic Institute (IBGE), Bananal is a little town in the state of São Paulo at the Metropolitan Region of Vale do Paraíba that has 10,775 inhabitants. The city presenting a health infrastructure with a single Joint Health Unit, four offices for developing family health strategy, and one basic care unit that not exchange information among themselves causing many duplicates records and unnecessary costs without any participation of their citizens [6, 7].

Figure 3 shows the first process and their 3 steps that enable the platform to be implemented at the city allowing a standardized method. After this, the platform will use a single key of patient data from an Electronic Medical Record to track and exchange data through entities that also establishes a channel between the local municipality and population and given to patients the control of carrying on their medical history on palm through their own mobile [9, 10].

The platform also offers an interface to establish a communication process between the local government with citizens through an ordinary mobile application (APP). The final procedure is consolidated sending all medical historic data to patients that used the health services provided by the city allowing transparency. The applied model at the city will be extended to other cities reaching a population of more than 2 million inhabitants within 39 municipalities [9–11].

However, health data are also highly privacy-sensitive, and even if more users are complaining by not obtain control over their personal health data, governs are compelling to face regulations generating several challenges. At the platform, we are concerned to safeguarding all steps of security and authentication, in a similar model done by the Blockchain platform allowing tracking and reliability of the data [10].

A summary of the workflow is shown in Fig. 4 that illustrates since the first identification of each patient at any health facility at the city. It is required to validate data before the first use of the mobile application [10].

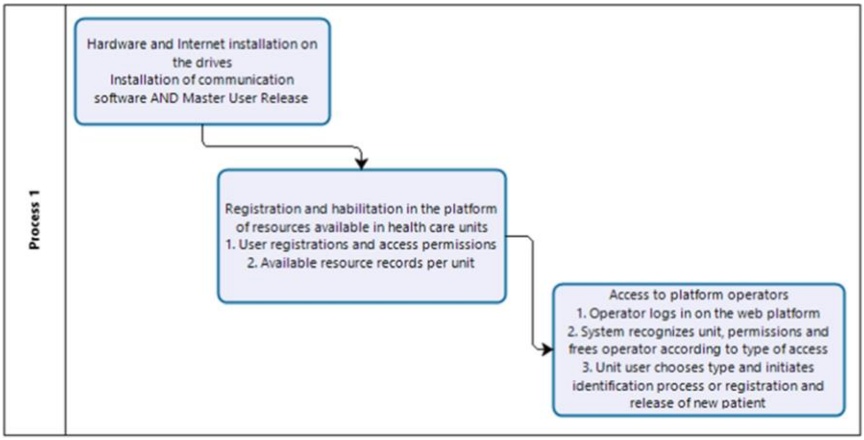

Fig. 3. Diagnose and a process of identification and patient authentication data.

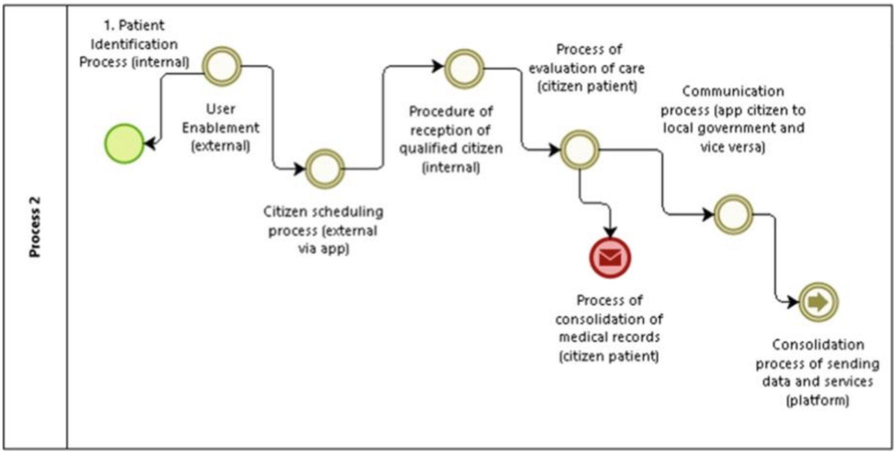

Fig. 4. Summarized workflow process.

## 4 Conclusions

A new society demand is affecting the Health Sector ending up in regulations. Electronic Medical Records (EHR) and patient data are usually retained by health institutions and very critical information to be safeguarded with systems that were not designed to offer patients own data. The best practices in healthcare and patient expectations include trusting that shared data is accurate. Health systems need to be designed to produce better outcomes including greater social value [1, 2, 5, 10]

The American Hospital Association (AHA) suggests an interoperability ontology through Electronic Health Records to build an efficient solution with a cost-effective platform for improving health care and sharing best practices with stakeholders. The Lancet Global Health Commission allows to understanding a framework to reach transparency implementing high-quality health systems that could save 8 million lives. These frameworks were chosen at this research by offering models and guidelines to create a reliable Health Systems including delivering data on the palm of patients at their mobile phones [1, 2, 4, 5].

This work presented a proposal of interoperability that reveals possibilities of sharing data between entities through a single key acquired through Electronic Medical Record. The pilot intends to be a model to be implemented at the suggested platform allowing major safety, tracking, and reliability of data at systems. The project is competing for an international award between 1,294 practices which can generate significant savings and better health outcomes for the Brazilian population [9–11].

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# Appendix IV

## Implementing e-Health Interoperability with KBE. Building a Universal Medical Record in Brazil.

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# Implementing e-Health Interoperability with KBE. Building a Universal Medical Record in Brazil

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**Abstract**. Health Sector is depending on interoperability between systems. Health systems are fragmented and even so need to produce valuable outcomes including social engagement and a better government-citizen relationship aiming to improve the quality of access, patient care, and transparency generating accurate indicators for managers and health professionals. This paper aims to describe the development of a pilot in a public health system realized through an Action Research using combined quality tools in a Multidisciplinary Design Optimization (MBO) and Knowledge- based engineering (KBE) methodology aiming to reach a strategy to spread best practices from EHR interoperability as from an experience of in a Brazilian small-town.

**Keywords**: Universal Medical Record, Universal Electronic Record, Healthcare Process Management, Healthcare Enterprise Integration, Healthcare Enterprise Interoperability, KBE

## 1. Introduction

The implementation of a Universal Electronic Medical Record (UEMR) is at the same time an interesting and also challenging quest for the Healthcare Sector in any country according to the World Health Organization (WHO) where 194 members offering a series of statistical data regarding their global health systems. Together they performing a movement to acquire better information and critical knowledge gaps to improve health systems performance that could be acquired through primary care patient´s experiences that offering valuable indicators for new developments and also interoperability proposals. [1-4]
OECD Health Committee says that the institution historically plays a leading role in measuring health systems performance but opportunities for cross-country comparative analysis of outcomes are also very limited. Released on July 2, OECD Health Statistics 2019 provides a comparative database offering an overview of healthcare in researched OECD countries. [2].
A fully successful interoperable project was implemented at Estonia where a UEMR is an electronic system realized through authenticated, unique and individual access, according to professional or patient profile and, comprises the registration, agenda, clinical history, and evaluation modules. The country implemented an interconnected national Electronic Health Record as a pillar for a computerized health base that reduced costs, facilitating future care and makes it possible to share efforts between a chain of patients, doctors, clinics or hospitals. The government regulates demands and managing performance is now implementing a new national plan to introduce roles and join all suppliers. [3,4]
The American Hospital Association (AHA) offers standards for interoperability ontologies and developing systems that aim to deliver Electronic Health Records as an efficient solution and a cost-

effective platform to share best practices with stakeholders attending a new society demand and goals as trending at Health Sector like Patient-centered experience and Applied Intelligence. [6, 28, 29]

Interoperability regards exploring capabilities, policies, and standards related to exchange data. The best worldwide practices suggest an ideal framework that should include standards of secure single access with dual authentication key (password usage, digital certificate and or biometrics) aiming to attend to interoperability requirements and also requirements for citizen engagement, government transparency, and social responsibility. [2-8]

This paper is part of a series of describing phases of one Action Research, their design practices, and tools to reach one strategy to be followed. [9] This phase uses Knowledge-based engineering (KBE) methodology as a tool to design and implement complex systems applied at an interoperability experience for setting the steps for management implementation of a health system, aiming to exchange data between health units and patients, for the first time in a Brazilian little town [10,11]. The final project intends to offer a framework model to implement interoperability extending the model for other cities but at this paper the research will only to show which combined tools were used to implement the system to reach an interoperable Information supporting at the same time health professionals using a patient-centered care concept, based on the premise that is possible to build a cost-effective platform to reach data integration between entities, using a single key of patients record.

## 2. Context and Background

There are several proposals and conceptions of universality in health, like a universal health system (UHS) and universal health coverage (UHC). Both are subjects to a polarized debate regarding the role of public and tax involvement in health, within and between countries. [12]

Design principles of these systems consider claims regarding what such participation will achieve and their trade-offs, consequences, issues such as who takes part, and also for what can be achieved. In universal systems focused on primary healthcare (PHC) the guarantee of comprehensive care requires coordination between services that are organized in networks, as integrated and territorialized model, distributed according to economies of scale. [12,13]

In European countries, universality in health generally refers to the public coverage of national systems for each country. Some programs are paid for entirely out of tax revenues, others using a mix of funds insurance. In some cases such as the UK, government involvement also includes directly managing the health care system, and many countries use mixed public-private systems. In most European countries, healthcare entails a government-regulated network and also private companies. [12-14] The US health system, for instance, uses a restriction for the right to health in a model based on different types of insurance, with a strong emphasis on the private sector. In developing countries, the term universal health coverage (UHC) is used to refer to a basic range of services coverage or public or private health insurance. In several ways, Latin American countries have followed different paths from Brazil towards universal health coverage to address social determinants of health.[13-15]

In this context, Brazil is a populous country composed of 5563 municipalities with continental dimensions presenting widespread regional and social inequalities. Their health system has decentralized management composed of three levels of autonomous to compound a Unified Health System (SUS). Since 1988 is financed by taxpayers aiming to provide healthcare as a right of citizenship offered for the major population aiming to provide for all patients preventive and curative care based on principles of right for citizens and duty of the state. [14,15]

But even if logistic of universal healthcare vary by country, countries such the United States and England, Australia, Canada are reviewing of the scope at primary Health Care, health professions and roles, optimizing workforce, reducing costs, providing greater equity and quality, trying to offer more service provision regarding technical category level, or mixing skills, for example using nurses to perform certain medical procedures, expanding the scope of practice of primary care health professionals and reviewing the specialists roles. [16] But independent of differences and the chosen model of health systems, all need to acquire, generate and exchange information data. Using EHR for acquire metrics like Patient-Reported Experience Measure (PREM) and Patient-Reported Outcome Measure (PROM) are trends to aiming to get management indicators keys, and also a critical knowledge gap to be filled aiming to acquire, understand and improve health systems performance, especially to reach interoperability, our reason for this study [15-17].

### 2.1. Health Sector Interoperability Experiences

The 2018 edition of Health at a Glance Europe show general rules to improve the health of citizens and an effective performance for build health systems reducing wasteful based on 4 pillars: 1) Improve more access to health care 2) Offering more people-centered health systems, 3) Build more resilient health systems, 4) Promote more protection and prevention. [3]

Health care information exchange and interoperability (HIEI) and their regards about inter-organizational relationships are properly addressed at U.S. literature, comprehending aspects of clinical, financial, and organizational value, electronic data workflow, exchange data through stakeholders and providers, like hospitals, medical groups, laboratories, radiology centers, pharmacies, payers, public health departments, etc. [11,17] The American Hospital Association (AHA) model remarks seven pathways aiming to implement interoperability: 1) Security and Privacy, 2) Efficient and usable solutions, 3) Cost-Effective, enhanced infrastructure, 4) Standards developments, 5) Connecting beyond Electronic Health Records, 6) Share of Best Practices. [6]

About EHR best practices we can highlight the solution that is being implemented in the United Arab Emirates forecasted to be launched in 2021, but it is necessary to mention a 99% solution successfully framework already implemented in Estonian for all e-health solutions[12]. In 2005 the Estonian Ministry of Social Affairs released a strategic sector information system in which the core project was based in Electronic Health Record (EHR) providing a basic integrated information technology system as a comprehensive central register for data-exchange of health information from birth to death. The e-Health information is a centrally managed electronic health record (EHR) complemented with three systems: 1) Digital images, 2) Digital Registration and 3) Digital Prescription that creates a unified national health information system and information technology applications. This system attends almost 1.35 million Estonian residents [5-12, 28, 29]

For this project, we also used concepts offered by the "*Trusted Exchange Framework and Common Agreement*" (TEFCA) released in January 2018. Figure 1 shows the stakeholders of the Health Information Network required by the 21st Century Cures Act, released by the U.S. Department of Health and Human Services (HHS). This draft bring specifications and standards for interoperability as 1) Establish patterns for HIEs enabling providers, hospitals and other health care stakeholders using EHRs could join any health information network, as well as automatically connect and participate in a nationwide HIE, 2) Create a "*Qualified Health Information Networks*" (QHINs) to help facilitate a standardized methodology for HIE inter-connectivity, 3) Create a new administrative organization to administer and operationalize the *Trusted Exchange Framework*. [18]

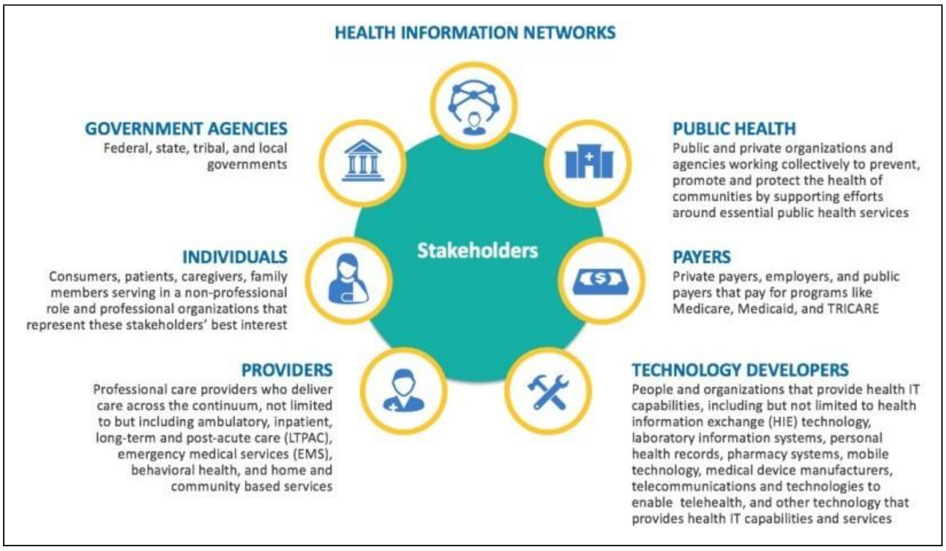

**Figure 1**: Trusted Exchange Framework and Common Agreement Stakeholders [18]

## 3. Methodology

Action Research was the chosen method to conduct this project aiming to affect and change the social reality using observations. Action Research also allows combined use of techniques, diagnostic tools, and several instruments to support tasks. Interoperability regards to explore capabilities, policies, and standards related to exchange data with complex development that requires a solution for task management to satisfy many competing requirements demanding multidisciplinary design optimization (MDO) to provide support and consistency for automation of repetitive tasks. [9, 20]

The present research has a qualitative approach as applied research nature since it aims to generate knowledge for practical application addressed to solute specific problems and technical procedures classified as a case study.

Table 1 describes the used tools in a combined way to implement the project and generate Knowledge-based engineering (KBE) as a model designed to develop new technologies and produce a knowledge-intensive activity that can be applied as a schematic proposal showed in figure 2. [19, 20,]. Kanban, World Cafe, Communities of Practice, PDCA are the chosen quality tools showed in table 1 used to build interconnections for solving daily problems aiming to reduce time and costs of development. [20, 26]

**Table 1:** MDO chosen quality tools

| Goal | Tool | Description | Contributions |
|---|---|---|---|
| Unit Resource management | Kanban | A Kanban is placed in a specific place at the entrance. The tool allows us to indicate by color and with easy visualization the distribution of the agents' daily in the time and places to be attended. | Speed the production in the health service. |
| To hear Patient Voice | World Café | World Café is a group conversation widely used to explore topics relevant to the group and create space for collective intelligence to emerge. | It is an instrument that facilitates to answer questions and implement the methodology. |
| Community Engagement | Communities of Practice | A Community of Practice is a superior resulted by World Café ideas and can also be understood as an informal gathering of people who have common interests, especially a subject or theme, and whose main purpose is the practical application of learning | Promotion knowledge in the group, promoting responsibilities in the process. |
| Check Tasks | PDCA | PDCA as a management tool aiming used to promote continuous process improvement through a circuit of four actions: plan, do, check and act. | Correctly act on process standard deviations, document and maintain the standardization established in the resource management and implementation plan |

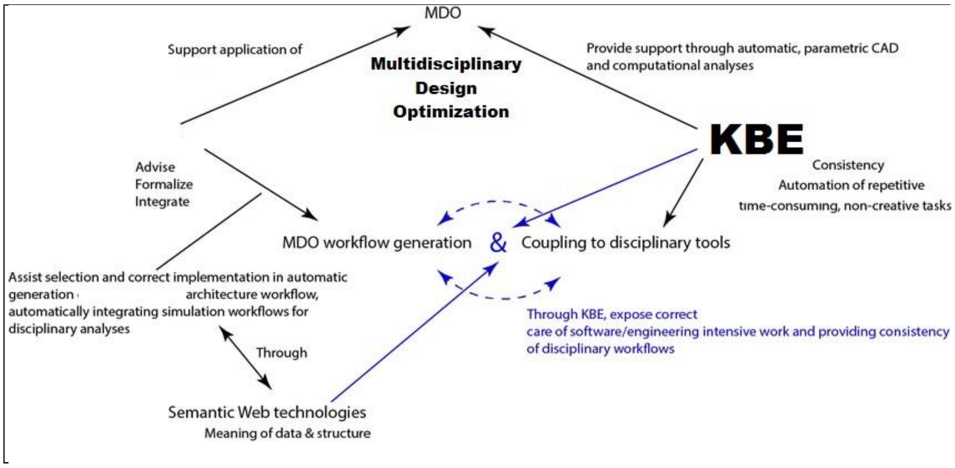

**Figure 2**: KBE schematic proposal adapted from Combining semantic web technologies and KBE to solve industrial MDO problems [20]

Regarding the conceptual background was did a benchmarking of major experiences in implementing systems that already deliver the best practices. As a worldwide trend, we found several countries trying to implement solutions to solve the idea of health care centered at patients using data from Patient-Reported Experience Measures (PREM) and Patient-Reported Outcome Measures (PROM) [5-8,17] About the best models of implementation for Universal Electronic Record, we select the experience implemented in the United Nations University from Estonian [5]. American Hospital Association (AHA) standards are used for interoperability ontologies and medical record exchange data [6]. Regarding quality impacts and transparency, we chose The Lancet Global Health Commission on High-Quality Health Systems. [6,7,8]

## 4. Results

Our interest in this case study is specifically to address an interoperability solution applied in universal health coverage, as a broad concept aiming to extend access to health care to major populations, that could be implemented in several ways but always with local governments following best practices. [21] Brazil has 90% of the population dependent on a public health system (SUS) that was designed to fulfill Information Policy that offers a lot of stand-alone free software solutions to manage data, especially recommended in an economy undeveloped with lack of financial resources. [21]

### 4.1. Implementing Interoperability Brazilian Case

Bananal is a little town in the state of São Paulo at the Metropolitan Region of Vale do Paraíba with only 10,775 inhabitants [24] where technologies are aiming to transform paper medical records to digital or electronic versions generating a huge of savings resources reducing material and enable better and faster service for patients. In the long run, through an App mobile, rural populations also will make more accurate appointments, exchanging data with health professionals from home, reducing costs and improving primary care. [26, 28, 29]

The town owns one Joint Health Unit, four offices for family health strategy and primary unit care. To register patent data the units only use paper and not exchange information among themselves, causing many duplicates records, and other unnecessary costs. At this stage, but yet on a limited scale, we will solve the problem and the challenge to move 100% paper health data to 90% digital and exchanging data between units. [26]

### 4.2. Exchange Purposes and Benefits

Exchange purposes and best practices as suggested in *Trusted Exchange Framework and Common Agreement* (TEFCA) are detailed in figure 3 and will be present in a framework that intends to be easily replicated. The final project also includes details about infrastructure, policies, and technologies already available to enable the exchange of health information between units, cities, doctors, and patients, establishing interoperability and data compatibility between various systems, adopting standardized terminologies. The work expects to reach some benefits as listed below. [18]

- Practical and traceable scheduling
- Reduced paper flow and faster service
- Confidentiality according to access profile
- An economy with printing and storage
- Mobility through Smartphone, web portal and records and can be viewed from
- Easy sharing between professionals, clinical staff with structured data and readability
- Easy learning system
- Individual longitudinal health data
- An individual’s complete health record on palm
- Access to provider-generated (e.g., medical visit records) and person-generated
- Data from medical devices, labs
- EHRs and quality reporting
- Specialty field-complete custom sign-ups and flags

**Figure 3**: Exchange Purposes at Trusted Exchange Framework and Common Agreement (TEFCA) [18]

### 4.3. Pilot prototype

After the pilot conclusion, the forecast is to implement the same project to exchange data between the neighboring cities Silveiras (5,792 habs), Areias (3,693 habs), São José do Barreiro (4,097 habs), and Cruzeiro (81,082 habs) totalizing of population of 105, 449 as showed in figure 4 [24, 26].
The implementation at Bananal town will generate a prototype, an important stage in any implementing of technology, easy to replicate in a scalable way to reach an interoperability system and a playbook using Multidisciplinary Design Optimization (MBO) as a KBE Methodology. [19, 20 24, 26]
Sponsored by a consortium between local private initiative and the Brazilian Government the cities would receive the same model to be implemented to exchange patient data and the same standards to be replicated on a large scale for attending interoperability at most of the Brazilian municipalities. [ 26].

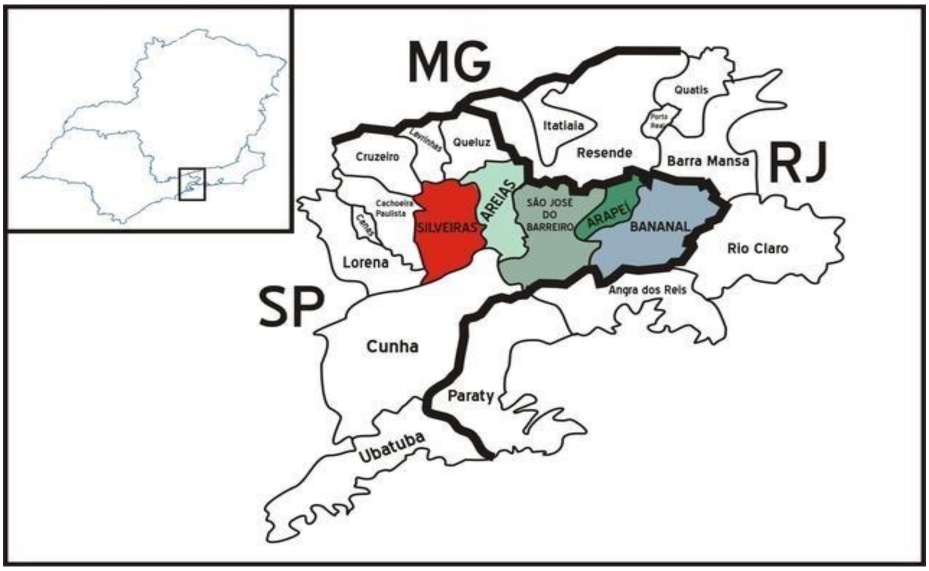

**Figure 4**: Figure captions should always be positioned below the figures. [24]

## 5. Conclusion

Regarding sharing data that can save lives, the World Health Statistics series says that usually health systems are not developed from patient's perspectives and also are not prepared to deliver own health data. This is a new society demand and a reason why are rising regulations worldwide to solve this problem like Health Insurance Portability and Accountability Act (HIPAA), the Washington Privacy Act (WPA), the GDPR in Europe, and the Health LGPD in Brazil. [1, 12, 25]

Since the patients are the core in health business and the data patient-centric is a trend, there are many of them are concerned about this question and some countries are exploring ways of embedding into Electronic Patient Records metrics required Patient-Reported Experience Measure (PREM) and the Patient-Reported Outcome Measure (PROM) aiming to generating more accurate indicators for managers and health professionals. [17,25]

Another regard in Health Sector is to find a key for a Sustainable Development Goal to improve access to health care and drive in a pathway to Universal health coverage more affordable with properly policies prioritizing financial protection for disadvantaged groups. [16] The need to develop systems in some easy way due to integration across different platforms and applications, are creating a lot of new artifacts and processes to solve this issue simplifying and automatizing or support. [3, 8]

Health Sector is also depending on interoperability between systems considered a recurring issue and a complex task since their health systems are fragmented and even so need to produce valuable outcomes including social engagement and a better government-citizen relationship aiming to improve the quality of access, patient care, and transparency. [17]

Action Research was chosen due to being easier to deal with these issues using combined techniques for diagnostic tools, and several instruments to support tasks aiming to develop a pilot, as a small scale or preliminary study, to conduct a Proof of Concept to confirm the idea and evaluate feasibility [9, 26]. The use of the KBE methodology proved assertive for setting and to addresses the steps for management implementation of this interoperability project for a public health systems and also showed up adequate when combining tools like Kanban (resources), World Café (customer's voice) and Communities of Practice (stakeholders engagement) and PDCA, to check and measure implement continuous improvement. [19, 20, 26]

As future work will be implemented a website as a portal for receive and exchange data at one Unified Medical Record Center offering high security according to permissions and rules of access and data protection. An APP will reunite records and keeps health information permanently updated in a single environment integrating health histories by the patient on palm [5]. Both portal and APP visualization can be customized according to the availability of local resources using geolocation and also blockchain [22, 23, 26]. The final purpose is to improve patient engagement in the rational and intelligent use of resources and also help patients to engage in their own health trajectory and evaluating all city health services, collaborating to improve it. [27]. Also, in a long run, a new trend in Health Sector is to use the concept of Applied Intelligence Platform (AIP) to embark AI with data, analytics, and automation embracing functions, processes, and new technologies especially to solve the regards, demands, and principles of Society 5.0 [27, 28, 29].

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# Appendix V

# Brazilian Patient Summary. A experience of exchange health data using FHIR

# Brazilian Patient Summary
# Exchange health data using IPS and FHIR

(Neusa Andrade, Italo Macedo, Jair G. M Torres, Rodrigo Saad Rodrigues, Pedro Luiz de Oliveira Costa Neto, 2020) - (Submitted to approval) - (Appendix V)

**Abstract**. This paper summarizes a successful experience in a Brazilian small city that improve its health infrastructure that became to exchange information reducing many duplicate records and unnecessary costs and also build engagement of health agents and citizens using a set of free tools provided by the Brazilian Unified Health System (SUS) and health data acquisition through Quality Tools as PDCA and DMAIC reaching engagement of stakeholders, without extra costs for the municipality. The experience inspired in best practices of International Patient Summary (IPS) by exchanging messages that use Fast Healthcare Interoperability Resource (FHIR). The main contribution of this paper is to present general lines of steps to collect data aiming to fulfill a task of HL7 Workgroup that systematized IPS parameters with National Network Health Data (RNDS) using FHIR generating an Implementation Guide.

**Keywords**: International Patient Summary (IPS), Fast Healthcare Interoperability (FHIR), National Network Health Data (RNDS), Exchange Health Data, Interoperability, Quality Tools.

## INTRODUCTION

Interoperability is non-negotiable requirement since the world of healthcare operates around exchanging clinical data and the healthcare industry evolves reaching new levels of complexity (HL7, 2020; ROBKIN et al, 2015). Health Information Systems (SIS) are a set of technology-based instruments designed for prevention, diagnosis, treatment, monitoring, and management often fragmented that do not communicate and depend on Interoperability that can be seen as a series of protocols and standards to establish communication processes for data exchange more than formal and technological systems providing healthcare or administrative and management. (SABBATINI, 2015).

The National Health Data Network (RNDS) is being gradually implemented in Brazil through the provision of virtual “containers”. The medical history will be registered at the National Health Network (RNDS) linked in a unique registration identification key (CPF). Fast Healthcare Interoperability Resource (FHIR) is used as a messager to integrate and also exchange data. It is important to work in actions that will populate data in the National Health Data Network (RNDS) to control transactions that generate patient information that will be available to health’s professional access with the consent of them (VENANCIO; BARROS, 2020).

This paper summarizes a result of an Action Research (THIOLLENT, 1994) that generated a pilot aiming to exchange health data covering aspects as 1) Efficiency of collect data - Plan and tools used to implement a solution engaging health agents, workforce team and citizens; 2) Interoperability - Using a model of International Patient Summary, all citizens in city and health workforce could access their clinical history through a single ID in a National Health Bus Interoperability (GONZÁLEZ, 2011).

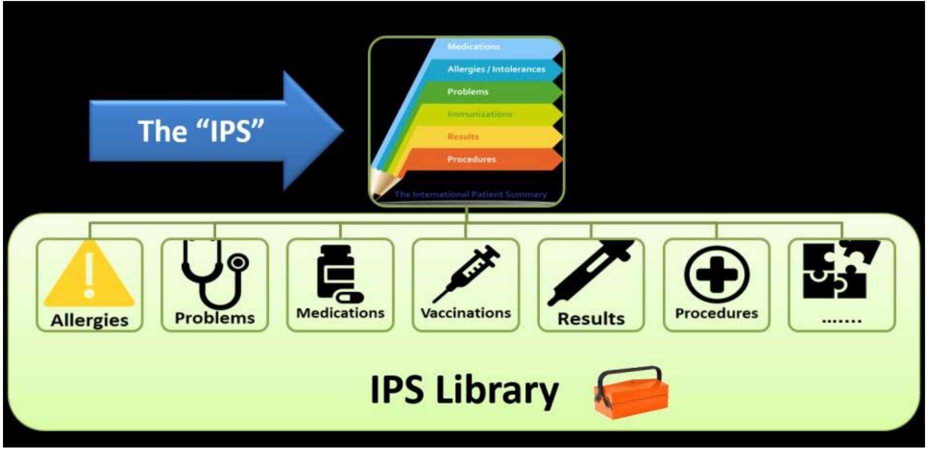
## MATERIAL AND METHOD

The city of Bananal is a little town with almost 11.000 inhabitants that offer to its citizens a health infrastructure with one Health Unit and four offices to attend the family health strategy, and one basic care unit, totalizing 6 facilities that never exchanged health data causing many duplicates records, and unnecessary costs. An Action Research allowed to evaluate the city´s resources and build a logistic to transform into a digital town able to exchange and interoperable health data, engaging citizens and the health workforce in the process (THIOLLENT, 1994; GONZÁLEZ, 2011).

Before initiating the capture of health data were evaluated available resources, best practices, and scenarios to capture and manipulate citizens health data since the numbers of citizens until the quality of registration that is data sensitive and managed by public health agents, physicians, nurses, and will be necessary to establish an instrument of simple steps for helping governance structure been built (RUSSELLO et al, 2008).

According to the best practices, the chosen model was International Patient Summary (IPS) as a document that is resulted from clinical encounters oriented by a common data set library as shown in figure 01. The elements as 1) Patient Administrative, 2) Clinical Data, 3) and Medical problems constitute the “implementable” principle attempting to be sufficiently generic in the design of the templates providing generic solutions for global application aiming to facilitate the re-use of data (HL7, 2020).

**FIGURE 01 - IPS Library**



Source: HL7, 2020

This General Principles and Specifications, as a holistic conception, guidance and considerations, aiming to help implement a deployment model, roles, process, information, technology, resources, and capabilities to operate the solution suggesting that the success of the deployment requires a combination of institutional factors, technologies, human capital, that meets the needs of citizens and government applied to the experience in Bananal (GONZÁLEZ et al, 2011; HL7, 2020).

## RESULTS

Quality tools as PDCA and DMAIC were used in project to identify, measure, analyze, improve, and control the processes of collect and register data in System. (SATOLO, 2009). This ensured a reduction of duplicates databases and exchange information aiming to deal with legacies of data (COSTA NETO; CANUTO, 2010). This also contributed to the work of system administrators allowing health workforce to track and exchange health data through health units and establish a channel between the government and the population reaching interoperability (GONCALVES, 2013; ROBKIN et al, 2015).

To acquire, collect, and register data of Bananal citizens was necessary to apply tools of Quality and Management as PDCA and DMAIC for helping build a plan. The objective was to transform paper storage into digital. Table 01 presents a summary of the goals of the pilot project that brought results that are transforming collecting health data citizens into a digital way using only systems and apps provided by Unified Health System (SUS) without extra costs (COSTA NETO, CANUTO, 2010; SATOLO, 2009).

**TABLE 01 - Chart of Results achieved in Pilot**

| MUNICIPALITY MAIN GOAL | PROBLEM | SOLUTION | USED TOOL | % OF STATUS REACHED |
|---|---|---|---|---|
| Informatization of Units and connect Health network | Diagnoses<br>Evaluate scenarios and Resources<br>Establishing a Plan | Evaluate the necessity of investments and available resources and specification of hardware and software | PDCA/<br>5W2H | 85% |
| Collect, correct and provide population health data | Articulates available resources and teams to collected and correct data into systems. | Use tools already offered by SUS aiming to minimize costs. Implement Logistics. Implementation Guide | PDCA<br>DMAIC | 83% |
| Interoperability for citizen patients data | Actions to minimize or eliminate and duplicate of records | National Health Data Network (RNDS) . Implementation Guide | IPS /FHIR MODEL/ RNDS | 94% |

Source: Authors

Following IPS instructions, an implementation guide is a document that undergoes constant changes through community collaborations used in this work, available in a public repository for access, comments, and collaboration (HL7, 2020; KHATCHERIAN et al, 2019).

The multidisciplinary team worked in the pilot project using combined tools in a methodology of Knowledge-based engineering (KBE) as a model to produce a knowledge-intensive activity aiming to develop an FHIR artifact and normalize IPS data with RNDS to exchange data. The Workgroup team was split into (a) Specification, (b) Conceptualization, (c) Formalization, (d) Implementation and its objective was to produce the best results (KHATCHERIAN et al, 2019).

The model implemented in the City of Bananal can be applied to other neighboring municipalities. This research provided a network integration between health professionals and users of the Unified Health System (SUS), allowing accurate data collection, creating a deeper understanding of how networks support the efforts, and this can benefit all society and healthcare ecosystem through citizens, patients, and their families to achieve better health results, including the health workforce (VERSCHOORE, 2020).

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