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Health informatics — Personal health data generated on a daily basis

Informatique de santé — Données personnelles de santé générées sur une base journalière

Contents

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 215, *Health informatics*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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Introduction

The increasing number of smart phones, mobile applications and remote monitoring devices combined with EHRs, patient portals and PHR systems enhance the patient's engagement in healthcare services. However, patient health data, which are constantly created, recorded, gathered or inferred have not yet been actively utilized at the point of care.

Specifically, un-coded data are too subjective and informal. In order to be applicable to clinical environment, ambiguity should be minimized or eliminated, and more precise. The health-related data should accurately convey the concept they are intended to deliver. The ISO/IEEE 11073 series and IHE-PCD Rosetta work are one of candidates to accomplish this goal. For health-related data to be reliably integrated into the process of diagnostic and therapeutic decision making, they should be quality-assured, trusted in accordance to accuracy of measurements.

In terms of safety and interoperability, AAMI/UL 2800 defined safety and related specifications of Medical Device (MD) interface to be labelled or declared as Interoperable Medical Device. The standard specifies MD interface characteristics to operate in safety conditions and focus on the mitigation of risk associated with interoperability within the Integrated Clinical Environment (ICE) and Interoperable Scenario (IS). It might be complementary to ISO/IEEE 11073-20601, particularly in mobile environments for improving care delivery, optimizing workflow and reducing ambiguity.

The Personal Connected Health Alliance (PCHAlliance) released the Continual Design Guidelines (CDGs) to enable the secure, private, reliable and accurate sharing of patient generated health data with healthcare providers, built-on HL7 FHIR®[1] (Fast Healthcare Interoperability Resources) specifications. The Continua Design Guidelines define an open, flexible framework for end-to-end interoperability and the convenient collection and exchange of clinical grade health data for improved health, wellness and disease management. They are built on existing open, international standards and specifications including ISO/IEEE deliverables, IEC deliverables, HL7 deliverables, USB and Bluetooth. The International Telecommunication Union (ITU) recognizes the Continua Design Guidelines as an international standard for personal health systems and makes them available for global adoption in the several languages. Valuable tools and resources support product certification via the Continua Design Guidelines, including: the Continua Enabling Software Library (CESL), CODE for Healthcare and test tool development, representing millions of dollars worth of software development created by Continua to enable complete end-to-end functionality. PCHAlliance members have access to Continua Certified Experts (CCE), pre-market interoperability testing, Technical Operations Leads and brand support for Continua Certified products. PCHAlliance also participates in a series of events around the world to connect members with buyers, as well as Plugfests, Summits and an online Product Showcase highlighting Continua Certified products and services[18].

Furthermore, Health-related data have in-depth relevance with IoT and related technologies because health-related data are usually created by IoT devices. In order to ensure quality and safety of Health-related data along with IoT, the Standard Development Organizations (SDOs) should collaborate with each other more effectively.

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1) FHIR® is an example of a suitable product available commercially. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of this product.

Health informatics — Personal health data generated on a daily basis

1 Scope

This document provides an environmental scan of common data elements that are captured through various modalities such as cell phones, smart phones, mobile applications and remote monitoring devices that are combined with EHRs, patient portals and PHR systems which can ultimately be applicable to a variety of healthcare service environments.

The Health-related data can be used to supplement existing clinical data, filling in gaps in information and providing a more comprehensive picture of ongoing patient healthcare.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
assessment
measurement, evaluation or judgment for a study variable pertaining to the status of a subject

3.2
biometric
use of specific attributes that reflect unique personal characteristics, such as a fingerprint, an eye blood-vessel print, or a voice print, to validate the identity of entities

3.3
clinician
health professional who delivers health services directly to a patient/client

3.4
disorder
alterations or attributes of the health status of an individual which might lead to distress, interference with daily activities, or contact with health

3.5
experience
facts, information and skills acquired through experience, reasoning or education

3.6
personal health data
personal data relevant to the health of an identified or identifiable natural person

3.7
individual
single discrete entity

3.8
measure
collect quantifiable data about a function or process

3.9
monitor
medical device designed to acquire, display, record, and/or analyse patient data and to alert caregivers of events needing their attention

3.10
observation
measurement of a single variable or single value derived logically and/or algebraically from other measured or derived values

3.11
pain
health condition that results in some disability, pain and/or activity limitation

3.12
patient
synonym for a subject of care

3.13
symptom
untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product that does not necessarily have a causal relationship with this treatment

3.14
treatment
medical or surgical management of a patient

4   Use cases of health-related data

4.1   General

Health is more than healthcare. The County Health Rankings[20] are based on a model of community health that emphasizes the many factors that influence how long and how well we live. According to the County Health Rankings Model, health factors help communities understand what will impact their health in the future. Health factors are composed of Physical Environment (10 %), Social and Economic Factors (40 %), Health Behaviours (30 %), and Clinical care (20 %). The following are health-related data use cases that patients / customers write or report in a non-hospital setting.

4.2   Patient Reported Outcomes (PRO)

4.2.1   General

A PRO is a health outcome directly reported from patient who experienced it. It is different from an outcome reported by someone else, like physician-reported outcome, a nurse-reported outcome, and so on. PRO methods, such as questionnaires, are used in clinical trials or other clinical setting, to help better understand a treatment's efficacy or effectiveness.

Incorporating the patient perspective through patient reported outcome measures is a crucial element for clinical care, quality performance management and clinical research. PROs are any report coming directly from patients regarding their health condition and treatment, including symptoms, functional status and health-related quality of life. Some PRO measures are generic and appropriate for use in

a wide range of conditions, while others focus on the specific symptoms and side effects of a given disease, condition or treatment.

A PRO is a measurement based on a report that comes from the patient (i.e., study subject) about the status of a patient's health condition without amendment or interpretation of the patient's report by a clinician or anyone else. Symptoms or other unobservable concepts known only to the patient (e.g., pain severity or nausea) can only be measured by PRO measures.

EXAMPLE   Sheehan Disability Scale (SDS).

4.2.2   Clinical Data Interchange Standards Consortium (CDISC) — Questionnaires, Ratings, Scale (QRS)

Clinical Data Interchange Standards Consortium is an open, non-profit organization that develops and supports global data standards to improve the quality and interoperability of medical research and healthcare. CDISC standards are widely used for study planning and data collection, tabulation, analysis, and submissions to the US Food and Drug Administration (FDA) and other regulatory agencies internationally.

Questionnaires, Ratings, Scale instrument is a series of questions, tasks or assessments used in clinical research to provide a qualitative or quantitative assessment of a clinical concept or task-based observation[1].

Questionnaire instruments are stored in the Questionnaires domain and are named, standalone instruments designed to provide an assessment of a concept. Questionnaires often have a defined standard structure, format, and content; consist of conceptually related items that are typically scored; and usually document methods for administration and analysis. Questionnaires consist of defined questions with a defined set of potential answers. Most often, the primary purpose of questionnaires is to generate quantitative statistic to assess a qualitative concept. If the instrument is a Rating or Grading Scale in which the intent of the instrument is to evaluate a single body system, it would be stored in the morphology/physiology domain, which represents that body system. Other Rating or Grading Scales related to multiple body systems and all Composite Score type instruments would be represented as a Clinical Classification in the RS domain.

Examples of QRS:

— 6 Minute Walk Test.

— Airway Questionnaire.

— Alcohol Use Disorders Identification Test – Self-Report Version.

— Alzheimer's Disease Assessment Scale - Cognitive (ADAS-Cog).

In the above example, how to provide QRS to the user conveniently is a matter to be solved by Advanced UI/UX and natural language processing technologies. FHIR questionnaire adoption is also expected to ensure interoperability of this kind of QRS data collected from cohort studies.

4.2.3   Patient Report Outcome Measures (PROMs)

In the UK, the National Health Service (NHS) collects survey data from patients who received specific surgical treatment[2].

a) Knee replacement.

b) Hip replacement.

c) Groin hernia.

d) Varicose veins.

These PROMs data measure

— patient's health status, and

— health-related quality of life at the single point.

This health status information is collected before and after a procedure and provides an indication of the outcomes or quality of care delivered to NHS patients[3].

To facilitate the inclusion of PROs in the EHR, and address the barriers to doing so, a multidisciplinary team was formed to develop this "Users' Guide for Integrating Patient Reported Outcomes in Electronic Health Records". It addresses 11 key questions for integrating PROs in the EHR:

1. What strategy will be used for integrating PROs in EHRs?

2. How will the PRO-EHR system be governed?

3. How can users be trained and engaged?

4. Which populations and patients are most suitable for collection and use of PRO data, and how can EHRs support identification of suitable patients?

5. Which outcomes are important to measure for a given population?

6. How should candidate PRO measures be evaluated?

7. How, where, and with what frequency will PROs be administered?

8. How will PRO data be displayed in the EHR?

9. How will PRO data be acted upon?

10. How can PRO data from multiple EHRs be pooled?

11. What are the ethical and legal issues?

4.3   Social Determinants of Health (SDH)

4.3.1   Social Determinants of Health — In general

The social determinants of health are linked to the economic and social conditions and their distribution among the population that influence individual and group differences in health status. They are health promoting factors found in one's living and working conditions (such as the distribution of income, wealth, influence, and power), rather than individual risk factors (such as behavioural risk factors or genetics) that influence the risk for a disease, or vulnerability to disease or injury[19].

The social determinants of health are the conditions in which people are born, grow, live, work and age.

These social determinants of health include

a)   social gradients (life expectancy is shorter and disease is more common further down the social ladder),

b)   stress (including stress in the workplace),

c)   early childhood development,

d)   social exclusion,

e)   unemployment,

f)   social support networks,

g) addiction,

h) availability of healthy food,

i) availability of healthy transportation / active travel, and

j) religion, caste, all the social diversities.

4.3.2 Social Determinants of Health — At the local level

There is widespread interest in the role of local social determinants of health at the local level. Federal, state, and local government agencies, academic institutions, and community organizations are increasingly recognizing the need to understand and address the socioeconomic contexts within which people work and play in order to improve their health and welfare.

12 dimensions of the social environment:

a) Economy

b) Employment

c) Education

d) Political

e) Environmental

f) Housing

g) Medical

h) Governmental

i) Public Health

j) Psychosocial

k) Behavioural

l) Transport

According to the World Health Organization (WHO), the social determinants of health are the conditions in which people are born, grow, live, work and age, and these are influenced by the way of wealth and resources are distributed [19]. It affects a wide range of health, functioning and quality of life outcomes, and risks.

20 SDH domains covered in six of the most widely used SDH screening tools in the US (see Table 1) have been identified, including the following:

a) the NAM's 2014 Recommended Social and Behavioral Domains and Measures report, which is the basis for the ONC Social, Psychological, and Behavioral data certification criterion for EHRs17;

b) the National Association of Community Health Center's PRAPARE survey;

c) the Center for Medicare & Medicaid Innovation's Accountable Health Communities (AHC) survey;

d) the Health Leads questionnaire36;

e) the University of Maryland's SEEK tool37;

f) the WE CARE survey.

Table 1 — SDH screening tools

Access to healthcare
Childcare
Clothing
Education
Employment
Finances
Income/poverty
Financial stress
Food
Housing
Housing instability / insecurity
Housing quality
Immigration / migration
Incarceration
Primary language
Race / ethnicity
Residential address
Safety
Intimate partner violence
Child abuse
Neighbourhood safety
Social connections / isolation
Stress
Transportation
Utilities
Veteran status
General SDH (non domain-specific)

4.4 Observations of Daily Living (ODLs)

The Project Health Design demonstrates how to improve participant's health and well-being by capturing and interpreting ODLs information[4]. ODLs include attending to cues such as the quantity and quality of sleep, the confidence one feels in self-management, the tenor of family dinner conversations, the cadence of speech, or the ease of doing daily tasks like opening a jar[4].

ODLs can be the following:

a) Quantity and quality of sleep;

b) Moods experienced in day-to-day life;

c) The ease with which an individual completes daily tasks;

d) Level of pain experienced throughout the day;

e) Fluctuations in day-to-day stress.

ODLs provide subtle clues that individuals pay attention to as they monitor their health, a way for patients to gauge how their health is progressing, and cues that alert patients that they need to take health-related action.

Example Apps include:

— BreathEasy™ ²⁾ App collects asthma-related patient data to aid patients in self-monitoring their asthma.
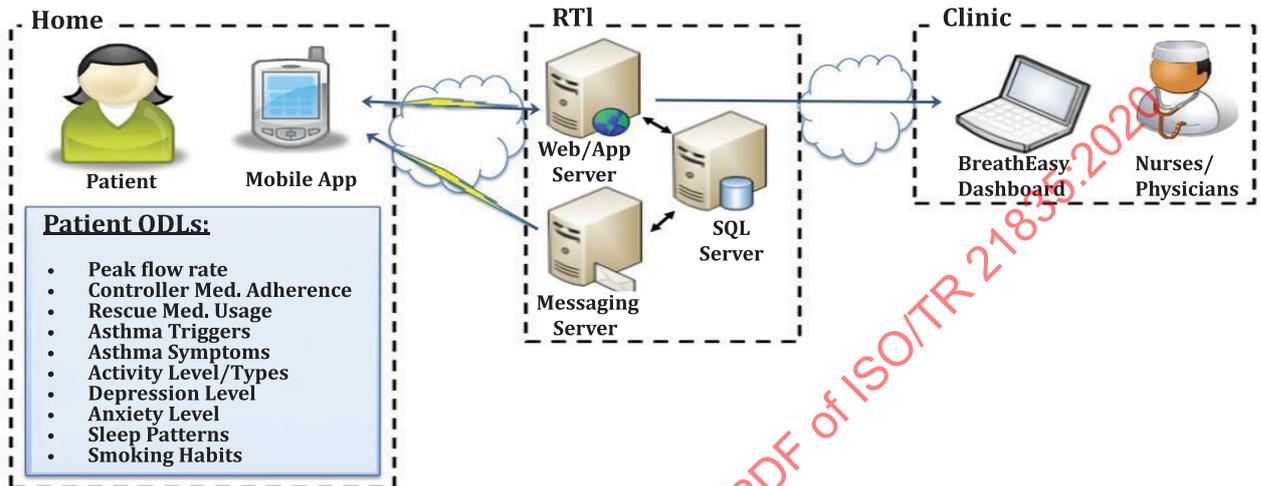
Figure 1 — BreathEasy™ ²⁾ application technical architecture diagram[5]

— The Estrellita™ ²⁾ App collects information from high-risk infants and their caregivers and allows the caregivers to more easily interface with clinicians to improve care and communication.

Figure 2 — Estrellita™ ²⁾ application technical architecture diagram[6]

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2) BreathEsay and Estrellita are examples of suitable products available commercially. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of these products.

The most important lesson that emerged was that user demand for personal health applications revealed a greater need for day-to-day data (observations of daily living, ODLs) than for the relatively static clinical record data. Through design and prototyping activities, gr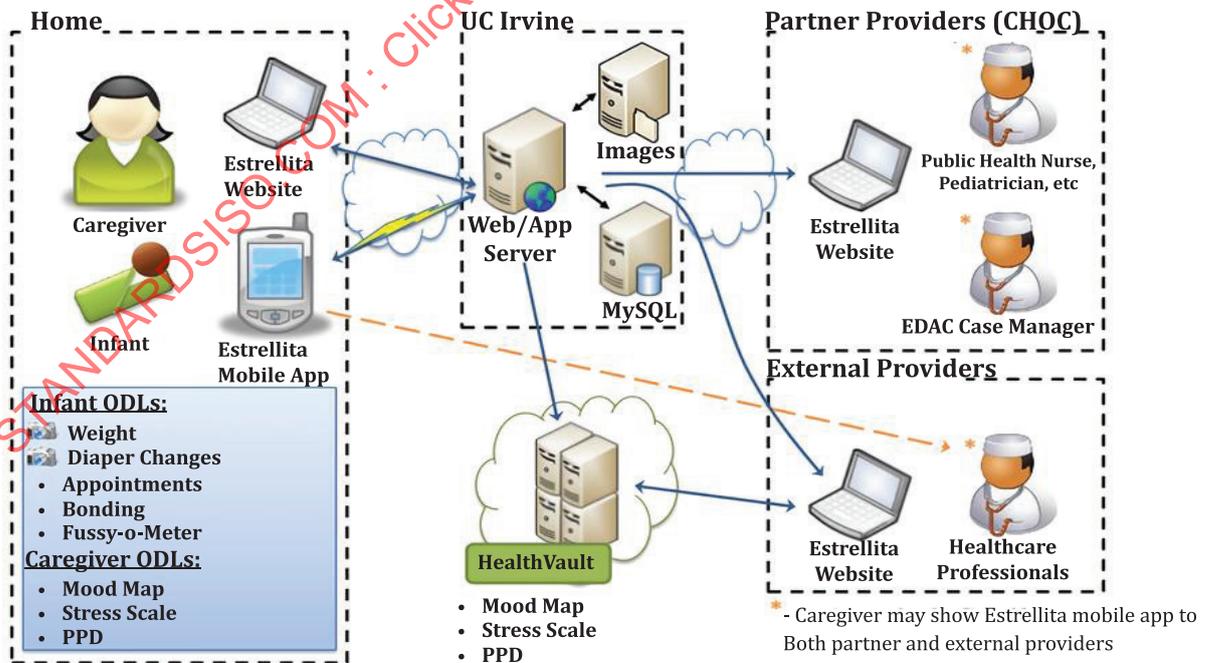antees demonstrated the feasibility of collecting and storing ODLs in a PHR, thus providing individuals with opportunities for better informed and higher quality healthcare. These observations of daily living (ODLs) complement traditional signs and symptoms of disease (e.g., blood pressure, shortness of breath) and highlight the personal experience of health and disease.

4.5 Patient-generated Health Data

4.5.1 General

Patient-generated Health Data are health-related data created, recorded, or gathered by or from patients (or family members of other caregivers) to help address a health concern[7].

a) Health history;

b) Biometric data;

c) Treatment history;

d) Patient-reported symptoms;

e) Outcome measures.

Patients can view a series of reports such as "My Trends", "My Measures", and "My Dashboard" that integrates multiple types of patient-generated health data (surveys/PROs, mobile health apps, and wearables) to provide summaries of their data that can be used to better understand and monitor trends and gain insights that might help them to manage their symptoms and health, and to facilitate comparisons to aggregate member data across the network and to norms established from aggregate data.

4.5.2 Meaningful Use Stage 3 Objective 6 — Coordination of Care through Patient Engagement

These rules describe the use of communications functions of certified EHR technology to engage with patients or their authorized representatives about the patient's care.

The objective 6 (Coordination of Care through Patient Engagement) in Meaningful Use Stage 3 necessitates that patients are able to provide patient-generated health data or data from a non-clinical setting, which is then incorporated into the EHR.

— Measure; Patients must "actively engage" with the electronic health record made accessible by the provider. This can be met by patients either: Using view-download-transmit (VDT) functionality to interact with the EHR –or–Access their health information through the use of an API.

— Measure; A secure message was sent to the patient (or a message was sent in response to a secure message sent by the patient).

— Measure; Patient-generated health data (or data from a non-clinical setting) is incorporated into the HER.

PGHD included in the EHR is a) and b) below, and the activities of representative EHR companies are c) and d) below.

a) Data from care providers such as nutritionists, physical therapists, occupational therapists, psychologists, and home healthcare providers, in addition to data obtained from patients themselves;

b) Apple's Health Kit™ 3), the Google Fit™ 3) platform, Samsung® 3)SAMI;

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3) This product is an example of suitable products available commercially. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of these products.

c) Cerner - it would integrate patient-generated health data through a partnership with Validic, which markets a data integration engine focused on medical devices and fitness apps;

d) Epic - it would begin consuming patient-generated health data through its "Open Epic" API initiative.

4.5.3 Life Record

In South Korea, LifeRecord is platform that has been developed with the support of Ministry of Trade, Industry and Energy, South Korea[8]. LifeRecord provides a digital health infrastructure based on personal health records. It is a solution platform that can collect, store and exchange personal health record data such as medical care and genome data and life log in a variety of ICT environments by individuals. It supports financial-level security environment, disease-specific prediction algorithm and open application programming interface. It is a cloud service type back-end system dedicated to digital health.

This platform deals with not only Personal Health Record (PHR), but also Life log such as the following.

a) Activity Record (Step count, sleep data, calories);

b) Health Record (Allergy, Medication, Disease, etc.);

c) Physical Record (Blood pressure, Height, Weight, etc.);
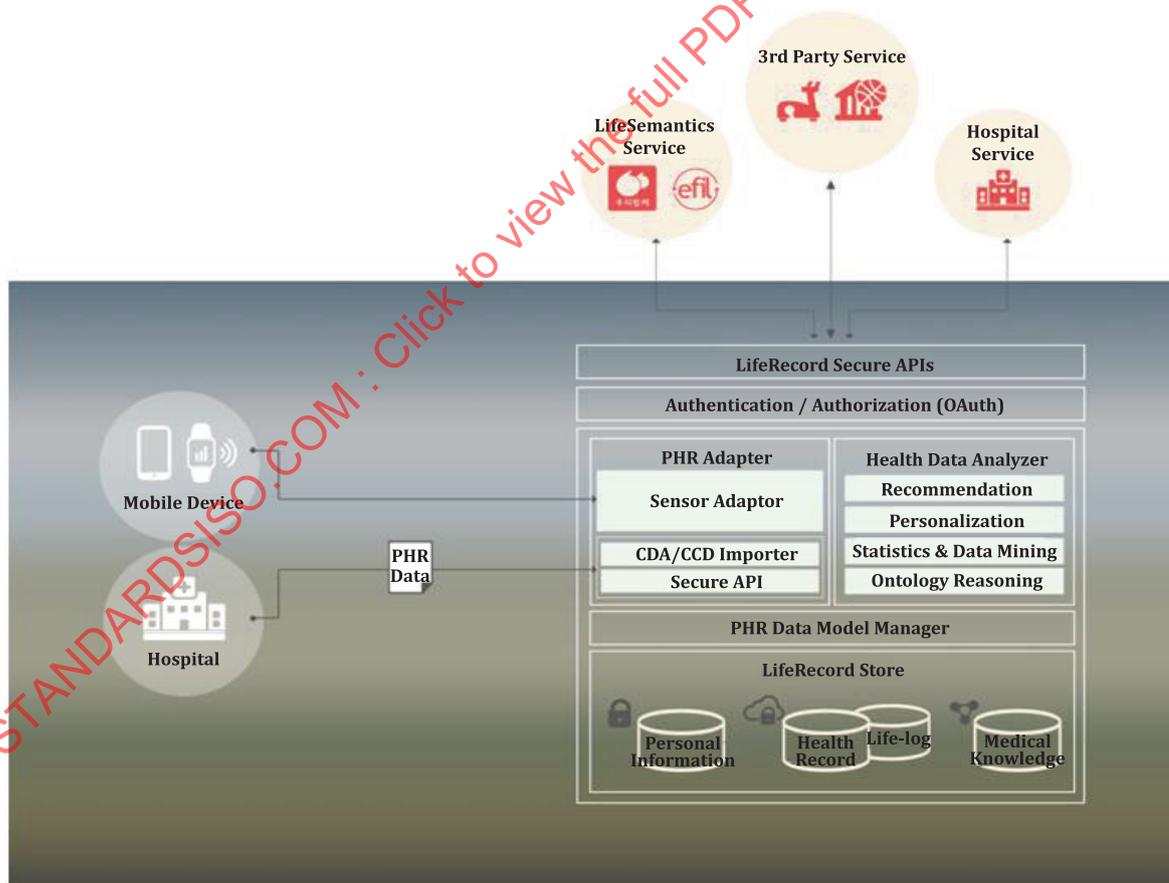
d) Medical Record (Medical image, CCD).

Figure 3 — LifeRecord ®[3)] Architecture Diagram

4.5.4 Pain Assessment Notifier

Pain Assessment Notifier is intended to improve performing surgery, medication and rehabilitation treatments. Pain is a subjective experience and very individualised to the person experiencing it. There

are many different types of pain, including neuropathic pain, somatic pain and visceral pain, which can then also be either acute or chronic, depending on its duration. Pain assessment tools should be chosen to reflect the type of pain the individual is experiencing. These assessment tools can use either a unidimensional or multi-dimensional approach.

There are various pain assessment methods like Numeric Rating Scale (NRS), Categorical Scale, Pain faces scale and Behavioural pain scale, etc.
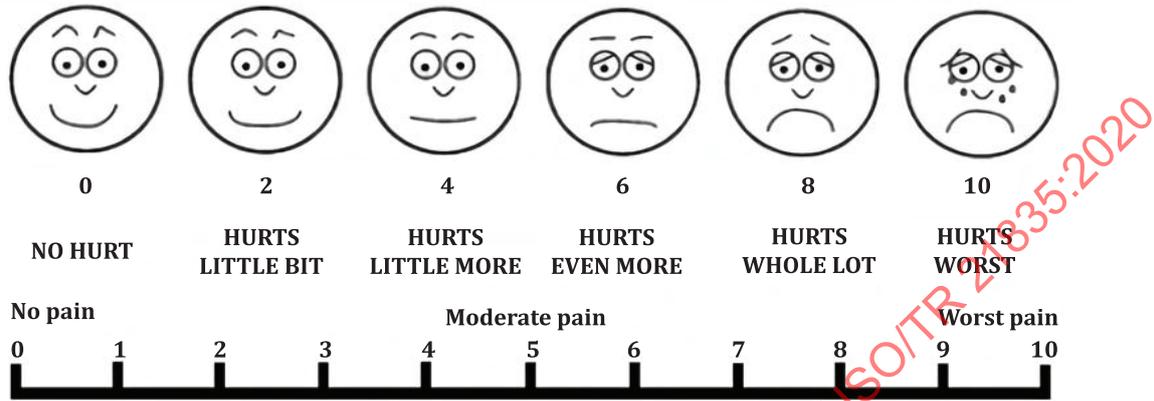

Figure 4 — Pain faces scale & Numerical scale

ANAPA app collects information about on pain via a wearable device on the following.

a) Location of pain;

b) Type of pain (sharp, burning, dull, tearing, cramping, pricking etc.);

c) Intensity of pain;

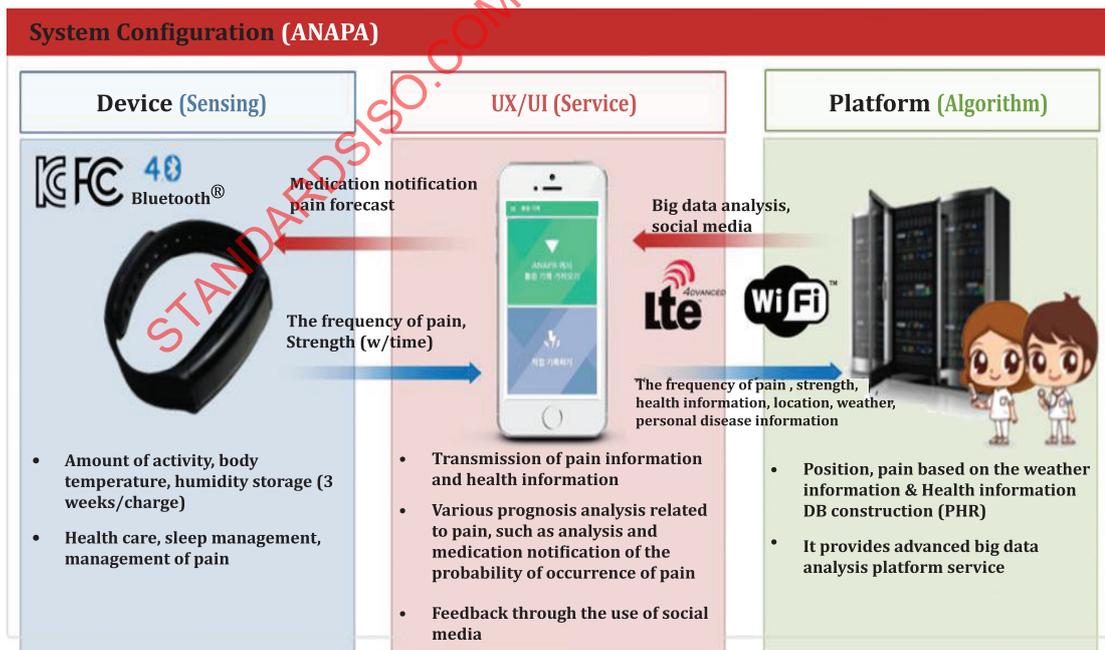d) Frequency and continuation of pain, which patient feels.

Figure 5 — ANAPA ®3) system configuration[9]

4.5.5 Score Card Tool for Health Metrics Transparency

This comprehensive assessment enables patients to view medical information in one concise, informative grid.

a) The DXDI scorecard, an 11-dimension by 5-level grid, is created for each diabetes patient and enhances their understanding and engagement.
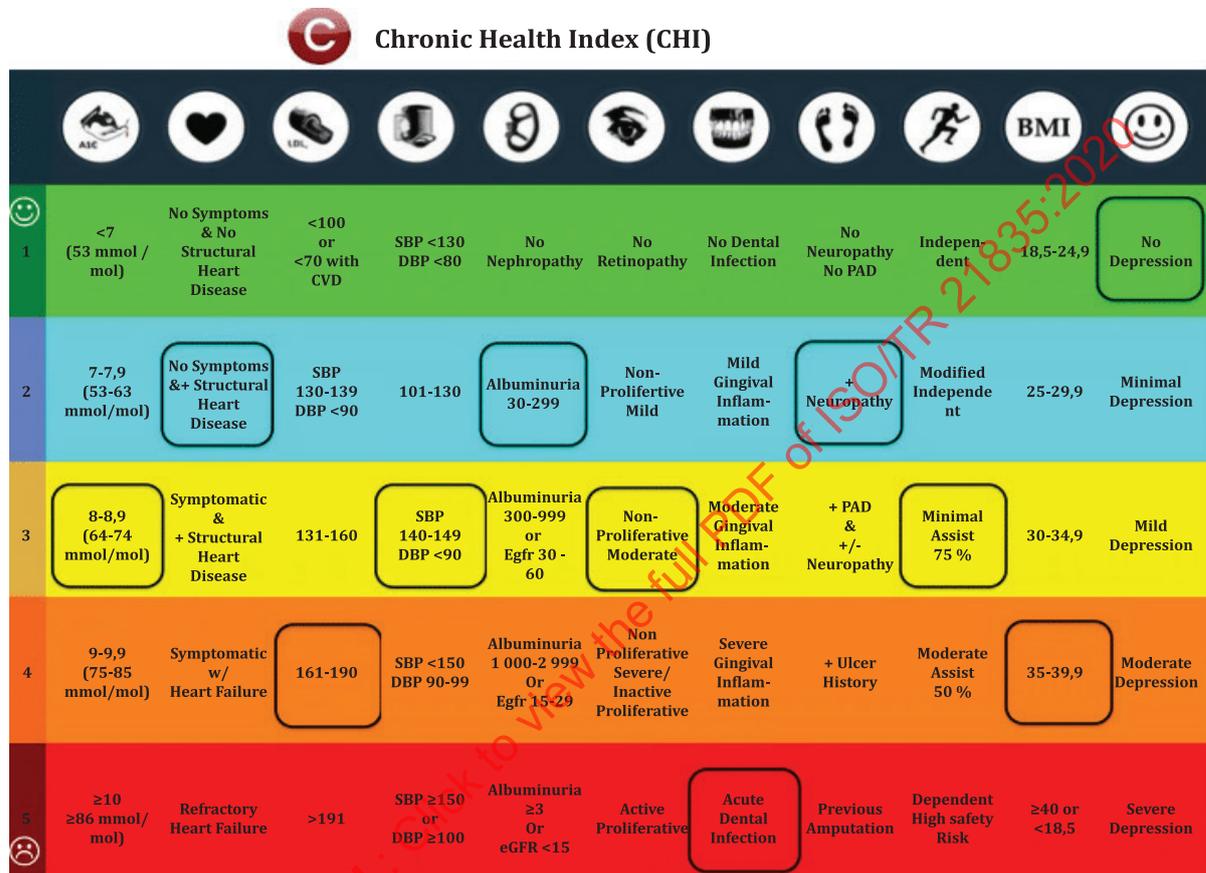
Chronic Health Index (CHI)

Figure 6 — The Diabetes Cross-Disciplinary Index (DXDI)

The DXDI is a pictorial representation of diabetes-relevant health domains, including glycemic control (HbA1c), low-density lipoprotein cholesterol (LDLc) level, systolic blood pressure (SBP), and diastolic blood pressure (DBP); kidney health (urinary albumin-to-creatinine ratio (UACR) and estimated glomerular filtration rate (eGFR)), retinal health (dilated retinal scan), periodontal health (see below), foot health, functional independence measure; as well as body mass index (BMI), waist circumference (WC), depression (patient health questionnaire 9 (PHQ 9)), and smoking status. Each domain is stratified into levels 1 (i.e., health or absence of disease) through 5 (i.e., severe or advanced disease). Periodontal health status was stratified in the following manner: 1, periodontal health (probing depths (PD) ≤3 mm and bleeding on probing (BOP) ≤15 % of sites); 2, gingivitis/incipient periodontitis (PD ≤4 mm and/or BOP >15 % of sites); 3, mild–moderate periodontitis (PD = 5 mm at ≥1 site); 4, localized advanced periodontitis (PD ≥6 mm at ≤30 % sites); and 5, generalized advanced periodontitis (PD ≥6 mm at >30 % sites). CVD, cardiovascular disease; PVD, peripheral vascular disease.

Periodontal data are integrated into the balanced health scorecard, Figure 6. DXDI, to promote precision healthcare for people with diabetes. Periodontal health status is stratified in the following manner: 1, periodontal health (PD ≤3 mm and BOP ≤15 % of sites); 2, gingivitis/incipient periodontitis (PD ≤4 mm and/or BOP >15 % of sites); 3, mild–moderate periodontitis (PD = 5 mm at ≥1 site); 4, localized advanced periodontitis (PD ≥6 mm at ≤30 % sites); and 5, generalized advanced periodontitis (PD ≥6 mm at >30 % sites). Other DXDI domains incorporate validated staging criteria for their respective aspects of health and disease.

5 Categorization of health-related data

Health-related data of Clause 4 are divided into patient-generated indirect data, patient-generated direct data, patient and provider generated combination data. The patient-generated indirect data is made by questionnaires at the request of other individuals or organizations not necessarily tied to any data generated through patient-worn or controlled technologies. The patient-generated direct data is made by wearables, apps, remote monitoring, and questionnaires. The patient and provider generated combination data is made by both patient and provider who contribute data to the overall data picture like cloud-based platforms. Also, it could be divided into coded and un-coded data elements by the criterion of whether health-related data can be represented by Health IT standards.

5.1 Patient-generated indirect data

5.1.1 Questionnaire report

The Questionnaire report can be represented by the following:

a) HL7 FHIR Questionnaire resource, which is suitable for expressing the result data of questionnaires related to patient-generated indirect data.

5.1.2 Sociality

5.1.2.1 SDH

The sociality is measured by analysing the environmental factors such as national assets and technology development. The representative elements are economic, neighbourhood & physical environment, education, food, community & social context and health-care system. The detail elements are shown in Table 2.

Table 2 — Detail elements of Social Determinants of Health[17]

Element		Detail element
Economic stability		Employment
		Income
		Expenses
		Debt
		Medical bills
		Support
Neighborhood and physical environment		Housing
		Transportation
		Safety
		Parks
		Playgrounds
		Walkability
Education		Literacy
		Language
		Early childhood education
		Vocational training
		Higher education
Food		Hunger
		Access to healthy options

Table 2 *(continued)*

Element		Detail element
Community and social context		Social integration
		Support systems
		Community engagement
		Discrimination
Health care system		Health coverage
		Provider availability
		Provider linguistic and cultural competency
		Quality of care

5.2 Patient-generated direct data

5.2.1 Breath capacity

The breath capacity can be represented by the following:

a) HL7 FHIR DiagnosticReport resource;

b) HL7 CDA, Vital signs observations entry (template id: 1.3.6.1.4.1.19376.1.5.3.1.4.13.2) using LOINC codes 41935-8 (Peak flow meter);

c) IHE PCD profile;

d) ISO/IEEE 11073-10421.

5.2.2 Calories

The calories ingested can be represented by the following:

a) HL7 FHIR NutritionOrder resource;

b) HL7 CDA, Vital signs observations entry (template id: 1.3.6.1.4.1.19376.1.5.3.1.4.13.2) using LOINC codes 75298-0 (Calories intake) and 55424-6 (Calories burn);

c) IHE PCD profile;

d) IEEE 11073-10441.

5.2.3 Blood pressure

The blood pressure can be represented by the following:

a) HL7 FHIR Observation resource;

b) HL7 CDA, Vital signs observations entry (template id: 1.3.6.1.4.1.19376.1.5.3.1.4.13.2) using LOINC codes 35094-2 (Blood pressure);

c) IHE PCD profile;

d) ISO/IEEE 11073-10407.

5.2.4 Blood sugar

The blood sugar/glucose can be represented by the following:

a) HL7 FHIR Observation resource;

b) HL7 CDA, Vital signs observations entry (template id: 1.3.6.1.4.1.19376.1.5.3.1.4.13.2) using LOINC codes 41653-7 (Blood glucose);

c) IHE PCD profile;

d) ISO/IEEE 11073-10417.

5.2.5 Cholesterol

The cholesterol can be represented by the following:

a) HL7 FHIR Observation resource;

b) HL7 CDA, Vital signs observations entry (template id: 1.3.6.1.4.1.19376.1.5.3.1.4.13.2) using LOINC codes 8480-6 (intravascular systolic) and 8462-4 (intravascular diastolic);

c) IHE PCD profile;

d) IEEE 11073-10441.

5.2.6 Step count

5.2.6.1 Health design

The step count is measured through kilometres or miles per day from fitbit equipment in the project health design. The data type is shown in Table 3.

Table 3 — Health design physical activity (step count) ODL types

Services	Observations of Daily Living (ODL) Type	Method	Frequency
Breath Easy[11]	Levels/types of physical activity	Accelerometer & self-report	Daily
Chronology.MD[12]	Physical activity	Fitbit measures, in kilometres or miles per day	Daily

5.2.6.2 PROMs

The walking time is measured in the PROMs through self-questionnaire report. The data value ranges from 0 to 4 and 9 and value set is shown in Table 4[13].

Table 4 — PROMs walking data values

Value	Meaning
0	Not at all – pain severe on walking
1	Around the house only
2	5-15 minutes
3	16-30 minutes
4	No pain/ more than 30 minutes
9	Missing

5.2.6.3 Life record

In the project life record, steps, distance and floors are measured and fitbit equipment is used and the data elements are shown in Table 5.

Table 5 — Fitbit activity data elements[14]

Data element
Steps
Distance
Floors

5.2.7 Sleep data

5.2.7.1 Health design

In project health design, sleep data are measured by a self-questionnaire on a Likert scale. The user voluntarily completes the questionnaire via a health design app.

1. Please indicate the total number of hours you slept last night during the 8-hour period from 11:00 P.M. to 7:00 A.M.

_____ hours

2. Please rate the quality of your sleep by circling the appropriate number on the following scale.

1   2   3   4   5   6   7

Poorly: disrupted sleep   Average: slept fairly well   Restful: sound sleep

3. Comments: _____

Figure 7 — Self-questionnaire on Likert scale for sleep data

5.2.7.2 Life record

In the project life record, sleep data are measured by an app, such as fitbit. The detail data elements are shown in Table 6.

Table 6 — Fitbit sleep data elements[15]

Data element	
Awake count	Minutes asleep
Awake duration	Minutes awake
Awakenings count	Minutes to fall asleep
Date of sleep	Restless count
Duration	Restless duration
Efficiency	Start time
Is main sleep	Time in bed
Minutes after wakeup	

5.2.8 Stress

5.2.8.1 Health design

The project health design develops their self-questionnaire on a Likert scale or using other applications. The user voluntarily completes the questionnaire via a health design app. The detail data are shown in Table 7.

Table 7 — Health design stress ODL types

Services	Observations of Daily Living (ODL) Type	Method	Frequency
Breathe Easy	Subjective levels of symptoms - Depression	Self-report – emoticon	Daily
	Subjective levels of symptoms – Anxiety	Self-report – emoticon	Daily
Chronology.MD	Stress level	Self-report, Likert scale	Daily
Estrellita[16]	Infant fussiness	Caregiver-reported	As needed
	Caregiver mood	Intel mood map	As needed
	Caregiver stress	Perceived stress scale from Mind Garden	Monthly
	Post-partum depression	Edinburgh Postpartum Depression Scale	Monthly

5.2.8.2 PROMs

In PROMs, the stress data are measured by the frequency of feeling restricted while performing social activities. The data value ranges from 1 to 5 and 9 and value set is shown in Table 8.

Table 8 — PROMs stress data values

Value	Meaning
1	All of the time
2	Most of the time
3	Some of the time
4	A little of the time
5	None of the time
9	Missing

As shown in 5.1 and 5.2, in order to make meaningful use of the health-related data generated by the non-Healthcare Provider Organization, the data of high utilization stored by the Healthcare Provider Organizations can be used in the cloud under patient's consent, see 5.3.

5.3 Patient and provider generated combination data

5.3.1 Allergy

The allergy data can be represented by the following:

a) HL7 FHIR AllergyIntolerance resource;

b) HL7 CDA Allergy and Intolerance concern entry (template id: 1.3.6.1.4.1.19376.1.5.3.1.4.5.3);

c) HL7 V2 Message AL1 segment.

5.3.2 Medication

The medication can be represented by the following:

a) HL7 FHIR Medication resource;

b) HL7 CDA Medications entry (template id: 1.3.6.1.4.1.19376.1.5.3.1.4.7);

c) ISO 21549-7.

5.3.3 Disease

The diseases can be represented by the following:

a) HL7 FHIR Condition resource;

b) HL7 CDA Problem entry (template id: 1.3.6.1.4.1.19376.1.5.3.1.4.5) that represent diseases code on ICD-9CM;

c) HL7 V2 Message DG1, PRB.

5.3.4 Vaccination

The vaccination can be represented by the following:

a) HL7 FHIR Immunization resource;

b) HL7 CDA, Immunizations entry (template id: 1.3.6.1.4.1.19376.1.5.3.1.4.12) that represent vaccination code on CPT-4 (Current Procedure Terminology 4);

c) HL7 v2 Message VXQ, VXR, VXU, VXX.

5.3.5 Medical image report

The medical image is represented by Digital Imaging and Communications in Medicine (DICOM) which is a standard for handling, storing, printing, and transmitting information of medical imaging.

Unlike 5.1, 5.2 and 5.3, 5.4 and 5.5 are divided into coded data elements which can be expressed as existing well-developed standards and uncoded data elements which cannot be expressed as existing well-developed standards. In particular, since selected uncoded data elements are highly utilized, they must be urgently developed as coded data elements with standardization.

5.4 Coded data elements

5.4.1 Questionnaire report

The questionnaire report can be represented as in 5.1.1:

5.4.2 Allergy

The allergy data can be represented as in 5.3.1.

5.4.3 Medication

The medication can be represented as in 5.3.2.

5.4.4 Disease

The diseases can be represented as in 5.3.3.

5.4.5 Vaccination

The vaccination can be represented as in 5.3.4.

5.4.6 Medical image report

The medical image is represented by Digital Imaging and Communications in Medicine (DICOM), which is a standard for handling, storing, printing, and transmitting information of medical imaging.

5.4.7 Breath capacity

The breath capacity can be represented as in 5.2.1.

5.4.8 Calories

The calories ingested can be represented as in 5.2.2.

5.4.9 Blood pressure

The blood pressure can be represented as in 5.2.3.

5.4.10 Blood sugar

The blood sugar/glucose can be represented as in 5.2.4.

5.4.11 Cholesterol

The cholesterol can be represented as in 5.2.5.

5.5 Un-coded data elements

5.5.1 Step count

5.5.1.1 Health design

See 5.2.6.1.

5.5.1.2 PROMs

See 5.2.6.2.

5.5.1.3 Life record

See 5.2.6.3.

5.5.2 Sleep data

5.5.2.1 Health design

See 5.2.7.1.

5.5.2.2 Life record

See 5.2.7.2.