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Document Contributors

Partner	Author	Role
MANTIS	Behzad Naderalvojoud	Contributor
EXPERIS	Ester Sancho	Reviewer, Editor
ISEP	Diogo Martinho	Contributor
KU Leuven	Leen Van Houdt	Editor
Experis	Javier Gavilanes	Contributor

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Glossary

Acronym	Meaning
MQTT	Message Queue Telemetry Transport
PoC	Point-of-Care
PHD	Personal Health Devices
IoT	Internet of Things
OSI	Open System Interconnection
TCP	Transmission Control Protocol
SSL	Secure Socket Layer
REST	Representational State Transfer
SOAP	Simple Object Access Protocol
WHO	World Health Organization
ICD	International Classification of Diseases
SNOMED-CT	Systematized Nomenclature of Medicine Clinical Terms
LOINC	Logical Observation Identifiers Names and Codes
HL7	Health Level 7
DICOM	Digital Imaging and Communications in Medicine
ISCO	International Standard Codes of Occupations
CDA	Clinical Document Architecture
IoHT	Internet of Healthcare Things

EXECUTIVE SUMMARY

This deliverable describes the phew standardization plan to deal with the interoperability problems between computerized health information systems that leads to unnecessarily high costs of health services. In this deliverable, the standardization solutions created by industry associations for eHealth systems are discussed and the standardization approaches followed in the coaching framework are described.

1. Introduction and Project Background

Rising costs of healthcare due to the ageing population and related increase of non-communicative diseases urges for finding ways to save expenses by diminishing the need for care and making the current care more efficient. At present, healthcare provision is reactive, and process driven, treating patients according to predefined pathways with limited possibilities to consider the individual needs or abilities. Health authorities and care providers are finally noticing the one resource that had remained unused – the person or patient him/herself! By starting with the primary need of the person – to be healthy – and including him/her into the process in an active role, new paradigms for care become possible. Significant cost reductions can be achieved by preventive solutions to help the person adopt a healthy lifestyle – thus reducing the number of patients – and by providing the person with tools to actively participate in the treatment when diseases do arise – thus decreasing the burden on care personnel.

The main goal of this proposal is to empower people to monitor and improve their health using personal data and technology assisted coaching.

Developments in technology have enabled the empowerment of people for self-care more than ever before. Smart phones and tablets and quantified self-style self-monitoring wellness devices are commonplace. Wellness oriented solutions often suffer from short-term use due to quickly diminishing interest from their users and from lack of possibilities to utilise them in conjunction with clinical healthcare treatments. Patients are left alone with their problems in between therapy or treatment, and the possibly collected personal data is left unused.

Innovations in the project are expected in;

1. analytics on heterogeneous personal health sources to provide insight in the relation between behaviour and health
2. methodologies to develop interactive, dynamic and personalised coaching programmes,
3. modularisation of a scalable coaching framework
4. innovative motivating approaches for long-term adherence
5. innovative business models for preventive.

The Personal Health Empowerment project aims to achieve significant cost reductions for preventive solutions to help the person adopt a healthy lifestyle and providing the person with tools to actively participate in the treatment when diseases do arise by empowering people to monitor and improve their health using personal data and digital coaching. As a result, these will be causing to reduce the number of patients and decrease the burden on care personnel.

The results of the project include:

- Innovative technologies for vital signs, activity and behaviour monitoring
- Personal health analytics and visualisation tools
- Methodology and tools for the development of interactive and dynamic coaching programs (content & functionality)
- A modular reference framework for coaching application development and deployment

- Motivating self-care applications
- Validated pilot with users in the target groups for lifestyle management
- Exploitation plans for partners including go-to-market plans with disruptive business models

The project innovations will have a large impact on healthcare provision in the future, providing both evidence and means to realise people-centric and preventive health care, and allow for cost-saving solutions with increased patient involvement. It will address societal challenges including ageing, rising dependency ratio, lifestyle-related diseases, and healthcare efficiency to provide care in a more personalised and efficient way.

1.1 Deliverable Scope and Objectives

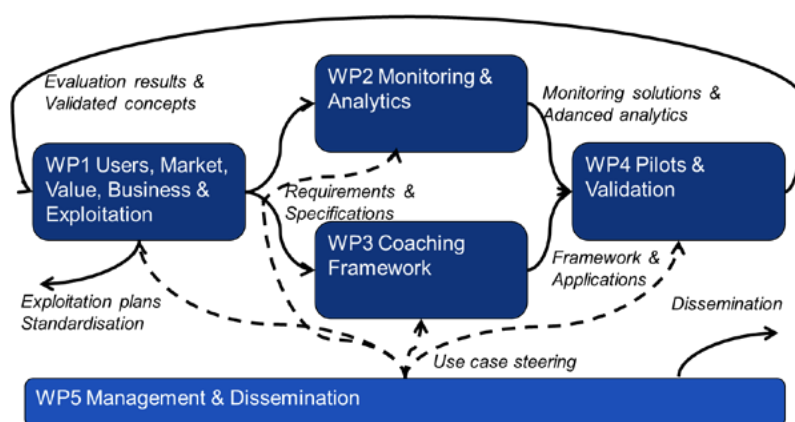


Figure 1: PHE WPs Interconnections

2. eHealth Standardization SotA

In World Health Organization (WHO), eHealth is defined as cost-effective and secure use of information and communication technologies (ICTs) to support healthcare services, health surveillance and health coaching. In fact, the objective is to improve the global access to healthcare services and health informatics. However, health environments are highly mutable so that it creates interoperability problems between different Health information systems. Here, the standards that provide the interoperability backbone for eHealth should be sufficiently flexible to meet both societal and business expectations. The standardization is considered, for example, in diagnosis, measurement, and monitoring tools and methods, or any means to describe the outcome of the diagnosis and the results of the treatment. This standardization provides some facilities to share (or transmit) all of the health outcomes with other health systems, coaching services, and health providers. However, transmitting health data across ICT-driven health information systems requires adherence to health data standards and related technology standards for timely and accurate exchange of data for health care decisions. Managing patient information through electronic medical records or conducting public health surveys and surveillance requires interoperability of data within and between systems, based on a given set of standards.

In order to achieve both semantic and syntactic interoperability, various categories of standards have been proposed/implemented as part of strengthening the overall eHealth systems and

services at European, national and sub-national levels. These includes the International Classification of Diseases (ICD), Systematized Nomenclature of Medicine Clinical Terms (SNOMED-CT), Logical Observation Identifiers Names and Codes (LOINC), Health Level 7 (HL7), RxNorm, Digital Imaging and Communications in Medicine (DICOM), International Standard Codes of Occupations (ISCO), Clinical Document Architecture (CDA), standard-complaint electronic health record systems and medical records, and standards for medical devices, and etc.

Besides the standards related to eHealth data, other communication, network, security and privacy-based standards has been met in the eHealth systems. These includes the machine-to-machine (M2M) communication protocols like MQTT and device communication standards like ISO/IEEE 11073 (Health informatics - Medical / health device communication standards).

The important aspect of the standardization in the coaching framework is to recognize and examine the standardization of the input health events including sensor-based monitoring and measurement as well as output complex events including diagnosis, exacerbation and coaching that will form a significant part of the preventative solutions. Here, the objective is to open up the market for eHealth and increase the interoperability of the coaching framework with other health providers and information systems. In this deliverable, we describe the standardization plan followed in the coaching framework.

3. Standardisation Plan

Two main standardization are followed in the coaching framework: eHealth data standardization and communication standardization. While the former takes into account the standardization in the eHealth data, the latter considers the standardization that provides the interoperability of the coaching framework with other applications and health provider systems. These include privacy and security standards, network communication standards, data messaging standards.

3.1. eHealth data standardization:

The main data used in the coaching framework is sensor-based data that provides the requirements of the monitoring, measurement and analysis methods. Each sensor data is considered as an input event that indicates the measure of a particular body function. In our system, the other medical records and tests are divided into individual measures and suppose as a collection of single sensor data. Therefore, each medical record or test in association with a health problem is not considered as a single health data in the coaching framework. In this case, the coaching framework cannot directly use the standard medical records or device-based measurements. These records comprise a mass of clinical measurements, tables, diagrams and figures, which can be differently designed and interpreted in healthcare systems. Moreover, the measurement units might be different for a particular health function in different health environments.

One of the solutions to deal with this problem is to use ISO/IEEE 11073 standards. The ISO/IEEE 11073 provides a family of standards for point-of-care (PoC) medical device communication, a communication protocol specification for a distributed system of PoC medical devices and medical IT systems that need to exchange data. However, in this context, the standards have been defined for a limited number of medical devices (e.g. electronic stethoscope), so the

devices that are not supported by ISO/IEEE 11073 (e.g spirometry devices) cannot communicate with the coaching framework. Moreover, each standard has a particular data parser that achieves all types of data measured by the device. Transmitting the whole data, which is produced by millions of devices, can make heavy internet traffic.

Therefore, we define our own data structure within the coaching framework and only achieve some particular measures from the clinical record as input sensor data. Here, each coaching application can use any standards method like ISO/IEEE 11073 to read clinical records, however, the data is not given to the coaching framework by the same standard. The coaching framework provides global data analysis for many coaching applications belonging to different countries with different health standards. This framework does not directly work on clinical reports and provides a use-case-independent analysis system. Unlike the health and medical records, the data given to the coaching framework is atomic, so it is not mutable and data analysis is applied to raw data or events. The relationship between different measures of a health record is known in the system by predefined event processing rules or can be induced automatically from data, based on intelligent analysis methods.

3.2. Communication standardization

The Internet of Things (IoT) provides some facilities for some physical devices to connect to the Internet, creating new services and applications. One of the applications of IoT, which is used for medical and health-related purposes, is known as the Internet of Medical Things (also-called internet of health things). In this context, IoT devices are used to enable self-health monitoring and emergency notification systems. These health monitoring devices - which is also called personal health devices (PHDs) - can range from blood pressure and heart rate monitors to advanced devices, for example, capable of monitoring respiratory disorders. The main challenge in this space is to create standards for PHD communications. These standards define how PHDs exchange information with external devices. One of the most promising standards created by industry associations is the family of standards of ISO/IEEE 11073. This is one of the solutions that are planned to use in the coaching applications to create data communication between PHDs and coaching app.

As noted above, the outputs of PHDs are not given to the coaching framework directly. In fact, each application receives the PHDs data and creates the sensor-based input events that the coaching framework requires. To transfer PHDs data and the input events, MQTT protocol is used. The use of such protocol is necessary because the ISO/IEEE 11073 is a transport-independent communication model. It means that a transport protocol is required to carry the ISO/IEEE 11073 data packets or any other health monitoring information.

MQTT is a lightweight protocol that uses limited processing and memory capabilities, best suited to resource constrained devices and low bandwidth networks. It is used in sensors communicating to a broker via satellite link, over occasional dial-up connections with healthcare providers, and in a range of home automation and small device scenarios. In the project, this protocol is employed to communicate between coaching applications and the broker of the coaching framework to transmit the sensor-based input events. MQTT lives on the application layer of the OSI model and uses TCP protocol to provide a layer of reliability and security through

the SSL. These such characteristics make MQTT as a global standard in the sensor to sensor and device to device communications.

Another communication standard is defined in the coaching framework for communicating with healthcare providers or any other eHealth information systems. The objective is to make a secure and reliable communication with other systems and increase the interoperability of the coaching framework. To this end, the coaching framework provides RESTful services for several purposes. A RESTful, which is representational state transfer (REST) based technology, is an architectural style and approach to communications. REST technology is generally preferred to the SOAP technology because REST leverages less bandwidth, which makes it more suitable for internet usage. The designed RESTful APIs enables the coaching framework to present any personalized or global health analysis for healthcare providers. To visualize and interact with the API's resources, swagger UI as a standard framework is used. Swagger provides some standard facilities to interact with APIs without having any of the implementation logic in place. In addition. It generates standard visual documentation that make it easy for client side consumption.

3.2.1. FHIR Standard

Fast Healthcare Interoperability Resources (FHIR, pronounced "fire") is a standard describing data formats and elements (known as "resources") and an application programming interface (API) for exchanging electronic health records. The standard was created by the Health Level Seven International (HL7) health-care standards organization. FHIR is organized by resources. Such resources can be specified further by defining FHIR profiles. For example, binding to a specific terminology.

FHIR standard has been implemented in the PHE project as a standard for the exchange of data between the different components defined for PHE to assure data quality and promote interoperability.

In the case of CORD Management use case, the exchange of data using FHIR standard between Coaching Framework and Monitoring and Analytics component will exchange different FHIR resources such as Careplans and Goals.

3.2.1.1. Care Plan

Care Plans are used in many areas of healthcare with a variety of scopes. They can be as simple as a general practitioner keeping track of when their patient is next due for a tetanus immunization through to a detailed plan for an oncology patient covering diet, chemotherapy, radiation, lab work and counseling with detailed timing relationships, pre-conditions and goals. They may be used in veterinary care or clinical research to describe the care of a herd or other collection of animals. In public health, they may describe education or immunization campaigns. This resource takes an intermediate approach to complexity. It captures basic details about who is involved and what actions are intended without dealing in discrete data about dependencies and timing relationships. These can be supported where necessary using the extension mechanism. The scope of care plans may vary widely. Examples include:

- Multi-disciplinary cross-organizational care plans; e.g. An oncology plan including the oncologist, home nursing staff, pharmacy and others

- Plans to manage specific disease/condition(s) (e.g. nutritional plan for a patient post bowel resection, neurological plan post head injury, pre-natal plan, post-partum plan, grief management plan, etc.)
- Decision support generated plans following specific practice guidelines (e.g. stroke care plan, diabetes plan, falls prevention, etc.)
- Self-maintained patient or care-giver authored plans identifying their goals and an integrated understanding of actions to be taken

This resource can be used to represent both proposed plans (for example, recommendations from a decision support engine or returned as part of a consult report) as well as active plans. The nature of the plan is communicated by the status. Some systems may need to filter CarePlans to ensure that only appropriate plans are exposed via a given user interface.

Table 1 shows the structure that must followed to correctly build a CarePlan according to the FHIR standard.

Name	Required	Description
identifier	No	External Ids for this plan
instantiatesCanonical	No	Instantiates FHIR protocol or definition
instantiatesUri	No	Instantiates external protocol or definition
basedOn	No	Fulfills CarePlan
replaces	No	CarePlan replaced by this CarePlan
partOf	No	Part of referenced CarePlan
status	Yes	draft active on-hold revoked completed entered-in-error unknown
intent	Yes	proposal plan order option
category	No	Type of plan
title	No	Human-friendly name for the care plan
description	No	Summary of nature of plan
subject	Yes	Who the care plan is for
encounter	No	Encounter created as part of

period	No	Time period plan covers
created	No	Date record was first recorded
author	No	Who is the designated responsible party
contributor	No	Who provided the content of the care plan
careTeam	No	Who is involved in plan
addresses	No	Health issues this plan addresses
supportingInfo	No	Information considered as part of plan
goal	No	Desired outcome of plan
activity	No	Action to occur as part of plan
note	No	Comments about the plan

Table 1 Structure that must be used to build a Care Plan

In the case of CORD Management use case CarePlans are used to represent the personalized healthcare plans manually defined by both healthcare manager (in case they target a user profile) or the healthcare professional (in case they target a specific patient). The components necessary to support all the data exchanged regarding a Care Plan in the use case are presented in the mind map given in Figure 1.

3.2.1.2. Goal

A Goal in health care services delivery is generally an expressed desired health state to be achieved by a subject of care (or family/group) over a period or at a specific point of time. This desired target health state may be achieved as a result of health care intervention(s) or resulting from natural recovery over time. For example:

- A goal of a plan for a condition such as a diabetes might specify desired outcome(s) (e.g. HgbA1c level =<5.6% in 3 months) as a result of interventions such as medication therapy, nutritional management and/or increase physical activity.
- A goal of a procedure might be to meet the intended objective of the procedure (e.g. wet-dry-dressing changes twice a day; goal: wound healed completely in 2 weeks) or to prevent an unintended complication (e.g. repositioning a patient every two hours: goal to maintain skin integrity)

Goals may address the prevention of illness, cure or mitigation of a condition, prolongation of life, or mitigation of pain and discomfort.

When dealing with groups, goals may also reflect health state, such as a reduction of addiction behaviors. However, they may also reflect population health objectives such as education, screening, etc.

Organizational goals are typically not health state specific but may instead identify measurement targets such as infection control, cost management, patient satisfaction, etc.

Table 2 shows the structure that must followed to correctly build a Goal according to the FHIR standard.

Name	Required	Description
identifier	No	External Ids for this goal
lifecycleStatus	Yes	proposed planned accepted active on-hold completed cancelled entered-in-error rejected
achievementStatus	No	in-progress improving worsening no-change achieved sustaining not-achieved no-progress not-attainable
category	No	E.g. Treatment, dietary, behavioral, etc.
priority	No	high-priority medium-priority low-priority
description	Yes	Code or text describing goal
subject	Yes	Who this goal is intended for
start[x]	No	When goal pursuit begins
target	No	Target outcome for the goal
statusDate	No	When goal status took effect
statusReason	No	Reason for current status
expressedBy	No	Who's responsible for creating Goal?
addresses	No	Issues addressed by this goal
note	No	Comments about the goal
outcomeCode	No	The result thar was achieved regarding the goal

outcomeReference	No	Observation that resulted from goal
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Table 2 Structure that must be used to build a Goal

In case of CORD Management, Goals are used within a Care Plan to represent desired states that must be achieved by the patient regarding different variables associated to that patient’s current health condition. The components necessary to support all the data regarding a Goal exchanged in the use case are presented in the mind map given in Figure 1.

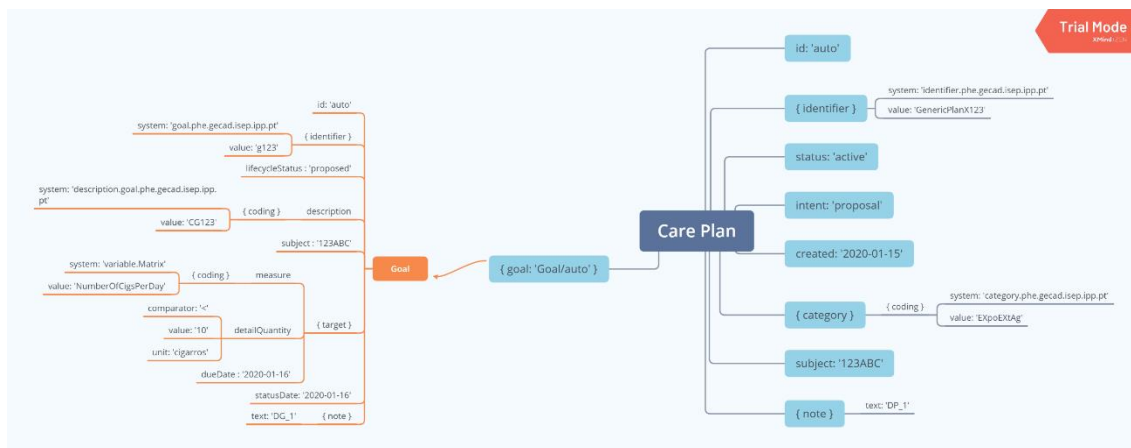


Figure 1 CORD Management Care Plan and Goal FHIR Structures

4. API Standardization

Many of the functionalities of the PHE platform are exposed to third parties through a common API, which is described in deliverable D3.5. This API has been created using the Swagger tool and adhering to the OpenAPI Specification (OAS). The OAS defines a standard, machine-readable and language-agnostic interface to produce and consume RESTful APIs. It started as part of the Swagger framework, but it became an independent project in 2016, supervised by the OpenAPI Initiative, an open-source project of the Linux Foundation.

Following the OpenAPI Specification allows to document the capabilities of a service in an easy and intuitive way. Besides, it ensures that all the contributions to the API from the different partners share a common format, making it much simpler to understand and exploit the exposed services.

Another benefit of using the Swagger tool to create the API is the ability to interact with the API without the need to develop any code, giving the possibility to get an idea of the services’ functionalities before having to commit to implementing them in an application.

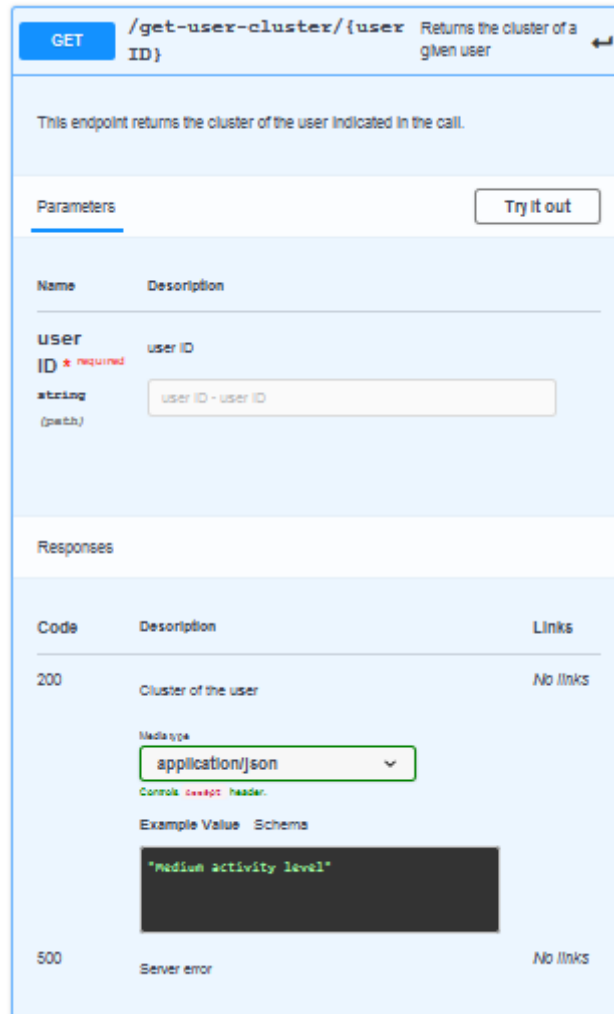


Figure 2. Example of the Swagger interface

Lastly, the OpenAPI Specification allows to go one step further with the “API Standardization”, a set of customizable rules that helps to ensure that the API definition comply with a certain style guide, providing various options to check the model definitions, operations and parameters for compliance.

5. Conclusions

This deliverable described eHealth standardization approaches to deal with the interoperability problem between eHealth information systems. We then proposed two use-case-independent standardization approaches for eHealth data and device to device communication. These two approaches mainly focused on the standardization policies used in the coaching framework. However, the communication standards between health monitoring devices and coaching app are more use-case-dependent issues and need to identify relevant bodies, organization or stakeholders regarding the standardization of IoHT devices. The identification of these standards and relevant bodies and organization are part of a plan and will be reported in the later versions of this deliverable.

References:

- International Organization for Standardization:
<https://www.iso.org/home.html>
- ICT standards in the health sector:
<https://ec.europa.eu/digital-single-market/en/news/ict-standards-health-sector-current-situation-and-prospects>
- World health organization:
<https://www.who.int/>
- WHO Forum on Health Data Standardization and Interoperability
<https://www.who.int/ehealth/forum2012/en/>
- Kim, S.S., Lee, Y.H., Kim, J.M., Seo, D.S., Kim, G.H. and Shin, Y.S. Privacy protection for personal health device communication and healthcare building applications. Journal of Applied Mathematics, 2014.
- Gomes, Y.F., Santos, D.F., Almeida, H.O. and Perkusich, A., 2015, January. Integrating MQTT and ISO/IEEE 11073 for health information sharing in the Internet of Things. In 2015 IEEE International Conference on Consumer Electronics (ICCE) (pp. 200-201). IEEE.
- FHIR:
<http://hl7.org/fhir/>
<https://www.hl7.org/fhir/careplan.html>
<https://www.hl7.org/fhir/goal.html>