AN APPLICATION FOR CONTINUOUS BEHAVIORAL HEALTH MONITORING AND DELIVERING DIGITAL PERSONALIZED BEHAVIOR CHANGE INTERVENTIONS

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ABSTRACT

AN APPLICATION FOR CONTINUOUS BEHAVIORAL HEALTH MONITORING AND DELIVERING DIGITAL PERSONALIZED BEHAVIOR CHANGE INTERVENTIONS

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In this thesis, a continuous behavioral health monitoring architecture is developed for chronic disease patients with a mobile application, a health data ingestion stack and a rule-based intervention engine. The mobile application is used for medical device integration and activity tracking. End-users also have interfaces to check their care plan activities, their adherence performances for them and to receive and configure motivational interventions and reminders about their activities. The ingestion stack is capable of stream and batch processing and used for collecting various health data and making the data available for the underlying intervention engine in the desired format. The rule-based intervention engine calculates and delivers interventions based on received patient data and defined intervention rules. Components presented in the architecture will be further validated in ADLIFE project containing seven pilot sites with a total of 577 healthcare professionals from 75 hospitals, clinics and primary care services.

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Keywords: Behavioral Health, Medical Device Data, Health Data Processing, mHealth

KİŞİSEL DAVRANIŞ DEĞİŞİKLİĞİ MÜDAHALELERİNİN İLETİMİ VE SÜREKLİ DAVRANIŞSAL SAĞLIK TAKİBİ İÇİN BİR UYGULAMA

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Bu tezde, kronik hastalıklı hastalar için bir mobil uygulama, bir sağlık verisi alma yığını ve kural tabanlı bir müdahale motoru ile sürekli bir davranışsal sağlık izleme mimarisi geliştirilmiştir. Mobil uygulama tıbbi cihaz entegrasyonu ve aktivite takibi için kullanılmaktadır. Son kullanıcılar ayrıca mobil uygulama üzerinden bakım planı faaliyetlerini, onlar için uyum performanslarını kontrol etmek ve faaliyetleri hakkında motivasyonel müdahaleler ve hatırlatıcılar almak ve yapılandırmak için arayüzlere sahiptir. Veri alımı yığını, akış ve toplu işleme yeteneğine sahiptir ve çeşitli sağlık verilerini toplamak ve verileri temel müdahale motoru için istenen biçimde kullanılabilir hale getirmek için kullanılır. Kural tabanlı müdahale motoru, alınan hasta verilerine ve tanımlanmış müdahale kurallarına göre müdahaleleri hesaplar ve sunar. Mimaride sunulan bileşenler, ADLIFE projesi kapsamında 7 ayrı pilot bölgede bulunan 75 hastane, klinik ve aile sağlığı merkezinde 577 sağlık çalışanının katılacağı bir pilot çalışmada doğrulanacaktır.

Anahtar Kelimeler: Davranışsal Sağlık, Tıbbi Cihaz Verisi, Sağlık Verisi İşleme, m-Sağlık

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To my beloved niece Beril

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LIST OF ABBREVIATIONS

BCT Behavior Change Techniques

BMR Basal Metabolic Rate

BLE Bluetooth Low Energy

C3-Cloud A Federated Collaborative Care Cure Cloud Architecture for

Addressing the Needs of Multi-Morbidity and Managing

Poly-Pharmacy

CDS Clinical Decision Support

EHR Electronic Health Record

EMR Electronic Medical Record

FHIR Fast Healthcare Interoperability Resources

FP7 Seventh Framework Programme

H2020 Horizon 2020

HDP Health Device Profile

HL7 Health Level 7

HTTP Hypertext Transfer Protocol

ICT Information and Communication Technologies

IG Implementation Guidelines

IOS iPhone Operating System

JA-CHRODIS Joint Action - Chronic Diseases and Promoting Healthy

Ageing across the Life Cycle

JSON JavaScript Object Notation

LOINC Logical Observation Identifiers Names and Codes

NICE National Institute for Health and Care Excellence

PCHA Personal Connected Health Alliance

POWER2DM Predictive model-based decision support for diabetes

patient empowerment

PROM Patient Reported Outcome Measures

RDD Resilient Distributed Dataset

REST Representational State Transfer

SDK Software Development Kit

SNOMED-CT Systematized Nomenclature of Medicine Clinical

Terms

STU Standard for Trial Use

XML Extensible Markup Language

CHAPTER 1

INTRODUCTION

1.1 Chronic Disease Management

Due to advances in medical science, people live longer and as people live longer, they become susceptible to living with multimorbidity. Multimorbidity is existence of multiple long-term conditions in the same individual, and the number of people affected by multimorbidity is dramatically increasing around the world [1]. According to RAND, more than 80% of the older population (65+) and more than 50% of the population aged between 45 and 65 had multiple chronic conditions in the United States [2]. Multimorbidity is linked with higher risk of mortality by studies [3]. Healthcare costs are also increasing when dealing with multimorbidity patients. A report from Agency for Healthcare Research and Quality demonstrates that 71% of healthcare spending is made for multimorbidity patients where costs per patient is increasing by the number of chronic conditions of a patient [4]. The toll of multimorbidity on healthcare is not only by cost, but also time. People with multimorbidity is responsible for majority of clinician visits by 64%, prescriptions by 83%, home healthcare visits by 87% and inpatient stays by 70% [4].

Dealing with multimorbidity with traditional disease-oriented approach is found to be inefficient, ineffective and costly by a joint action project (JA-CHRODIS) funded by European Union [5]. They have prepared a framework for delivering healthcare for multimorbidity patients. This framework consists of 16 varying components from delivery of care to ICT systems. While dealing with multimorbidity, a collaborative care planning approach is used where a care plan is created by multidisciplinary healthcare professionals in a coordinated care team. Care teams are led by a care

team manager that is the primary contact point for patients and their caregivers for care plan related issues. Care plans are highly individualized and contain personal health related goals and activities for the patients.

1.2 Patient Empowerment and Behavior Change Interventions

In addition to multimorbidity's effects on healthcare delivery and costs, it also has effects on self-efficacy and quality of life of the patients [6]. Patients coping with multimorbidity are reported to have a better experience of care and better health outcomes when they are involved in the decision-making process [7]. WHO defines patient empowerment as "A process in which patients understand their role, are given the knowledge and skills by their health-care provider to perform a task in an environment that recognizes community and cultural differences and encourages patient participation" [8]. Shared-decision making is one of the core aspects of patient empowerment and is found to be very important in patients dealing with multimorbidity where complex care plans and multiple conditions might be harder to tackle. A study also found patient empowerment has a positive effect on self-efficacy and quality of life as well as actual patient health outcomes [9].

Educational interventions based on patient empowerment for adherence to medication plan and lifestyle changes are found to be effective for chronic patients in sub-Saharan Africa [10]. Adherence to the care plan in long-term treatments of chronic conditions is a challenging issue [11]. Patient empowerment tools and educational interventions are used to increase adherence focusing on medication plans. The assessment of the nonadherence is also an issue, as healthcare professionals has limited time to check with patients on clinician visits. Integrating ICT tools for communication and decision-support is suggested to address this issue [12].

1.3 Health Data Integration

Vast quantities of health data are being produced in modern life conditions and integrating them is a major challenge in healthcare [13]. These sources are including, but not limited to, hospital records, electronic health records, medical records of patients, result of medical examinations, wearables, personal medical devices and even smart phones [14].

1.4 Solution

ADLIFE project is funded by European Union in Horizon 2020 framework programme and it implements an integrated personalized care system for advanced chronic patients that overcomes aforementioned challenges of implementing a comprehensive healthcare system. This thesis work is developed as part of the ADLIFE solution for continuous health monitoring and delivering behaviour change interventions to especially patients with multiple chronic conditions.

In the developed intervention delivery architecture, a health data ingestion stack is built with several and extendible components. The stack is capable of stream and batch processing inline with the Lambda architecture [15]. A common HL7 FHIR repository and inbound adapters are used to achieve interoperability and integration of health data coming from electronic health records, ISO/IEEE 11073 compliant medical devices, activity trackers and mobile applications. An intervention engine is used to transform and process incoming and queried data to calculate and plan behavior change interventions according to predefined intervention rules. Outbound adapters and a mobile application are used to deliver these interventions to patients.

1.5 Outline

Chapter 2 introduces the literature research focusing on care plan management, patient empowerment, behavior change interventions, integration of health data and

health data interoperability. It introduces research projects that are strongly related and extended in this thesis work.

Chapter 3 describes technical and health related preliminary concepts that are utilized and adapted in various components of the presented architecture. It provides a summary for health data standards that are used in this thesis work.

Chapter 4 describes the general architecture and aims of the ADLIFE project and specifies components included in this thesis work and their roles.

Chapter 5 describes the developed extendible architecture that enables health data integration and processing with several component concepts.

Chapter 6 provides concluding remarks and describes possible future enhancements and proposes an implementation challenge to result in a more capable intervention strategy.

CHAPTER 2

RELATED WORK

In this chapter, relevant health-related and technical concepts are described. These concepts are heavily linked to some completed projects that ADLIFE or specifically this thesis work is built upon. The projects and their relevance to ADLIFE or the developed intervention delivery architecture of this thesis are explained.

2.1 Care Plan Management

Modern care plan management approach revolves around having a multidisciplinary care team that creates and handles the personalized care plan of a patient. There are several healthcare solutions providing main functionalities of a care plan management tool that can be listed as below.

- Care Team collaboration
- Patient-centred care plan
- Personalized care plan
- Integration with health data (EHRs, EMRs)

Elsevier¹, Optum², Zuri³, Provation⁴ are just some example of healthcare companies that provide solutions for care plan management.

¹ https://www.elsevier.com/

² https://www.optum.com/

³ https://www.zuri.care/

⁴ https://www.provationmedical.com/

There are also a number of research projects focusing on care plan management that are funded by European Union framework programmes such as FP7 and Horizon 2020.

- HOMECARE⁵, FP7, focusing on integrated homecare of stroke, heart failure and COPD patients with care planning approach.
- Garsia⁶, H2020, focusing on boosting quality of service as well as revenues
 of hospitals by providing them a complete comprehensive care plan
 management solution.
- CAREGIVERSPRO-MMD⁷, H2020, focusing on building a platform for dementia patients to improve the quality of lives with gamification concepts as well as personalized care plans.

ADLIFE builds upon the results of the C3-Cloud project. C3-Cloud is a European Union funded Horizon 2020 research and innovation project that has an integrated care planning approach for chronic patients [16]. C3-Cloud care plan management approach utilizes guideline-driven clinical decision support systems which is the same approach that is used in ADLIFE.

2.1.1 **C3-Cloud**

The C3-Cloud project is aimed to enable the development of personalized care plans for patients with multi-morbid conditions through the use of innovative ICT components. This project was carried out in three phases: the planning and coordination of care activities by a multi-disciplinary care team, the clinical decision support modules and the patient empowerment platform.

⁵ https://cordis.europa.eu/project/id/222954

⁶ https://cordis.europa.eu/project/id/781234

⁷ https://cordis.europa.eu/project/id/690211

The planning of care plan activities is realised with a collaborative care plan platform where multi-disciplinary team of healthcare professionals compose a comprehensive care plan for patients with chronic conditions. Implementation of C3-Cloud care plan management platform and other components are based on healthcare delivery best practice guidelines for focused chronic conditions in C3-Cloud: heart failure, renal failure, diabetes and depression. Separate guidelines are consolidated and reconciled into multimorbidity guidelines to achieve a single multimorbidity management plan [17].

The clinical decision support modules implemented automated rules according to the consolidated guidelines. The rules calculate personalized recommendations to add new activities to the care plan for multidisciplinary care plan members to examine to include in the care plan or not.

The patient empowerment platform provides an interface for patients and informal caregivers to manage their multimorbidity conditions. They can get detailed information about their care plans and add new measurements or device readings to their electronic health records.

The target group of the project was elderly population (65+) having at least two of the focused chronic conditions. The project is validated in three pilot studies (South Warwickshire, Basque Country, and Region Jämtland Härjedalen) and ended on April 2020.

Relevance of C3-Cloud

- In ADLIFE, C3-Cloud care plan management module is extended to support FHIR R4 and new functionalities are added based on ADLIFE use-case requirements.
- ADLIFE Patient Empowerment Platform is implemented from scratch with web and mobile applications with extended C3-Cloud PEP features.
- C3-Cloud consolidated guidelines approach is used in ADLIFE. ADLIFE
 Clinical Reference Group consolidates guidelines for multimorbidity patient

care for chronic conditions and guidelines focused on ADLIFE, similar to C3-Cloud.

 ADLIFE Clinical Decision Support Services are implemented from scratch for care plan creation process. Similar to C3-Cloud, CDS Hooks⁸ specification is used for defining and handling clinical decision support services.

2.2 Behavior Change Interventions

In order to be able to implement effective behavior change implementations and also enabling the standard based evaluation of results of these interventions, the potentially active ingredients of content of interventions are defined via Behavior Change Techniques (BCTs). A behavior change technique (BCT) is defined as "an observable, replicable, and irreducible component of an intervention designed to alter or redirect causal processes that regulate behavior; that is, a technique is proposed to be an 'active ingredient' [18].

Michie et.al. has defined 93 BCTs clustered into 16 groups as the definition of interventions to change a person's lifestyle behavior [19]. NICE Guidelines on individual approaches in behavior change recommends including 'goals and planning' and 'feedback and monitoring' and 'social support techniques' that are defined in the study by Michie et.al. as behavior change interventions [20]. The definition of these groups and related BCTs are given in Table 2.1.

Behavior change interventions are defined as "coordinated sets of activities designed to change specified behavior patterns" of individuals [21]. Sticking to healthy behavioral patterns, such as quitting smoking, following a balanced diet, to become more physically active has a direct effect on people's health. NICE guideline on 'Behavior change' reports that "there is an overwhelming evidence that changing

⁸ https://cds-hooks.org/

people's health-related behavior can have a major impact on some of the largest causes of mortality and morbidity, and to alter current patterns of chronic diseases" [21].

Table 2.1 The BCT Taxonomy (cropped) defined by Michie et.al. [19]

Group	BCTs

Goals and Planning

Goal setting: Set or agree a goal defined in terms of the behavior to be achieved. E.g.: Agree a daily walking goal (e.g. 3 miles) with the person and reach agreement about the goal.

Goal setting (outcome): Set or agree a goal defined in terms of a positive outcome of wanted behavior. E.g. Set a weight loss goal (e.g. 0.5 kilogram over one week) as an outcome of changed eating patterns.

Action planning: Prompt detailed planning of performance of the behavior (must include at least one of context, frequency, duration and intensity). Context may be environmental (physical or social) or internal (physical, emotional or cognitive). E.g. Prompt planning the performance of a particular physical activity (e.g. running) at a particular time (e.g. before work) on certain days of the week.

Review behavior goal(s): Review behavior goal(s) jointly with the person and consider modifying goal(s) or behavior change strategy in light of achievement. This may lead to re-setting the same goal, a small change in that goal or setting a new goal instead of (or in addition to) the first, or no change.

Discrepancy between current behavior and goal:

Draw attention to discrepancies between a person's current behavior and the person's previously set outcome goals, behavioral goals or action plans (goes beyond self-monitoring of behavior). E.g. Point out that the recorded exercise fell short of the goal set.

Review outcome goal(s): Review outcome goal(s) jointly with the person and consider modifying goal(s) in light of achievement. This may lead to re-setting the same goal, a small change in that goal or setting a new goal instead of, or in addition to the first. E.g. Examine how much weight has been lost and consider modifying outcome goal(s) accordingly

Feedback and Monitoring

Feedback on behavior: Monitor and provide informative or evaluative feedback on performance of the behavior (e.g. form, frequency, duration, intensity). E.g. Inform the person of how many steps they walked each day (as recorded on a pedometer) or how many calories they are each day (based on a food consumption questionnaire).

Self-monitoring of behavior: Establish a method for the person to monitor and record their behavior(s) as part of a behavior change strategy. E.g. Ask the person to record daily, in a diary, whether they have brushed their teeth for at least two minutes before going to bed. Give patient a pedometer and a form for recording daily total number of steps. Feedback on outcome(s) of behavior: Monitor and provide feedback on the outcome of performance of the behavior. E.g. Inform the person of how much weight they have lost following the implementation of a new exercise regime.

Social Support Techniques

Social support (unspecified): Advise on, arrange or provide social support (e.g. from friends, relatives, colleagues,' buddies' or staff) or non-contingent praise or reward for performance of the behavior. It includes encouragement and counselling, but only when it is directed at the behavior.

E.g. Give information about a self-help group that offers support for the behavior.

2.2.1 POWER2DM

POWER2DM is a European Union funded Horizon 2020 research project that focused on supporting the patients that are coping with Type-1 and Type-2 diabetes [22].

The POWER2DM project integrates a decision support system for diabetes patients based on European guidelines with predictive personalized models and real-time data processing. POWER2DM implements a Self-Management Support System (SMSS), decision support systems and an intervention calculation engine.

Implemented Self-Management Support System is used for transforming medical treatment goals and activities to personalized action plans for the patient. Medical treatment goals are often long-term plans and are divided to short-term self-management actions for helping patients to adhere these goals. Action planning process can be summarized in 4 steps as shown in Table 2.2.

Table 2.2 POWER2DM Action Planning Steps

Step	Description	Example #1	Example #2
Specify Goals	Medical treatment goals are specified as self-management goals	Maintain a healthier lifestyle	Keep blood pressure under control
Action Plan Monitoring	Patient creates short-term actions related to medical treatment goals Patient manually	Take 8000 steps a day	Measure blood pressure twice a day
	records activities or observations are automatically retrieved from medical devices if possible.	Patient records step count daily	Measurements are automatically retrieved from device
Feedback	Interventions are sent to the patient	"You reached your target for the week"	"You didn't reach your target for the day"

POWER2DM includes an intervention engine to calculate and send behavior change interventions to patients. These interventions are conveyed as feedback to patients to help them motivate achieving their action plans.

HL7 FHIR DSTU2 is used in POWER2DM components as the common data model.

Relevance of POWER2DM

- In the developed intervention delivery architecture, POWER2DM intervention engine is extended to support FHIR R4.
- POWER2DM intervention rule definition language is extended to support more generic definitions for a group of action plans.
- Adherence performance calculators of the intervention engine is implemented from scratch to support the desired action plan performance calculations of the newly defined actions.
- New outbound adapters are added to the intervention engine to support
 - o email interventions in addition to mobile phone notifications
 - creating and storing adherence performance observations as FHIR resources to be visualized in patient empowerment applications
 - creating and storing intervention content as FHIR resources to be listed in a historical view in patient empowerment applications.
- In ADLIFE, previously defined interventions by the POWER2DM clinical experts are used as a starting point to define project and pilot-site specific interventions. Project Clinical Reference Group examined and made necessary updates to the POWER2DM intervention dataset.

2.2.2 Intervention Delivery

In his PhD thesis, Suat Gönül makes use of a reinforcement learning based algorithm to make intervention delivery more adaptive and personalized [23]. With a reward-based mechanism, the type, timing, and frequency of the interventions are selected and improved dynamically over time with the patient data aggregated.

For each person in the intervention population, average reaction times to interventions (getting the notification in mobile phone and opening it), and the engagement ratios to specific intervention types and timings are collected and fed into the reinforcement learning model. The model is then used in intervention

planning process to convey more productive interventions to each patient to improve their adherence performances to their care plan.

Gönül's findings is planned to be used and extended in the intervention delivery architecture to achieve more efficient interventions in terms of patient engagement.

2.3 Health Data Integration & Real-Time Processing

Health data integration and real-time processing of health data is critical in the developed continuous monitoring architecture. In this section, health data integration and interoperability challenges and differences in real-time processing architectures are described.

2.3.1 Health Data Integration

Health data integration process is summarized in high level with Figure 2.1.

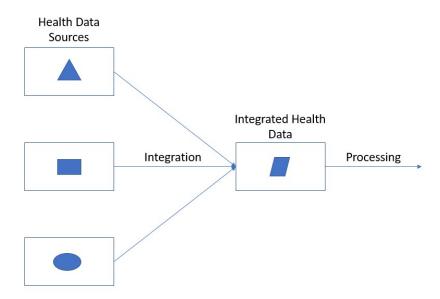


Figure 2.1. Health Data Integration

Various health data sources might possess data with varying formats, standards, terminologies and nomenclatures. Integration of these diversified data to a common component to further process them is also an interoperability problem. Interoperability of healthcare data can be summarized in three parts: technical, syntactic and semantic [24].

Technical Interoperability

Technical interoperability is the ability of exchanging data between two or more ICT systems. To achieve this, systems should be compatible on communication mediums and protocols.

Syntactic Interoperability

Syntactic interoperability is achieved through data formats and structures. Standards organizations such as HL7 and IHE prepare data structure and exchange standards such as HL7 v2, HL7 v3, DICOM and more recently HL7 FHIR [25].

Semantic Interoperability

Semantic interoperability defines a common medical language for concepts that can be shared across systems. LOINC and SNOMED-CT are some of the most known languages and clinical terminologies that are used in modern systems [26, 27].

2.3.2 Real-Time Processing

Real-time processing of health data is very critical to healthcare solutions providing continuous monitoring. In preparation for this thesis work, two possible Big Data architectures are inspected for real-time processing of health data, namely Lambda and Kappa architectures.

Lambda architecture is a generic, scalable and fault-tolerant real-time data processing architecture [28]. The general overview of the architecture is shown in Figure 2.2. The architecture consists of three layers, batch layer, real-time layer (streaming) and serving layer.

Lambda Architecture

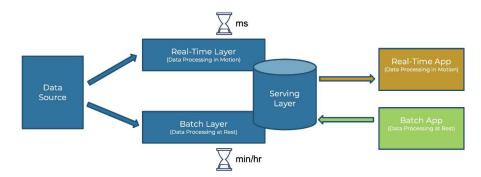


Figure 2.2. Lambda Architecture

Kappa Architecture

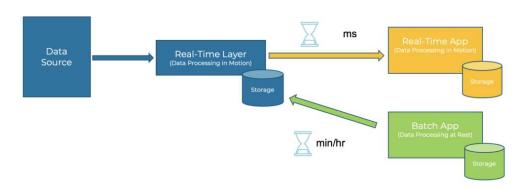


Figure 2.3. Kappa Architecture

Kappa architecture simplifies Lambda architecture by eliminating the batch layer, in favour of using only real-time layer. It proposes querying the batch data in parallel to create streams to process all data in a single streaming layer.

There are some trade-offs in selecting one architecture over other:

 Codebase for Kappa architecture is unified as there is only one real-time processing layer which means single processing algorithm, whereas in Lambda architecture there is another codebase needed for batch layer operations.

- Lambda architecture enables computing heavy calculations in batch layer which Kappa architecture lacks, therefore some computation heavy algorithms can't be used with Kappa architecture.
- Having a batch layer to retrieve all historical data enables Lambda architecture to achieve high accuracy in the batch layer which Kappa architecture lacks.

Considering these trade-offs, Lambda architecture is selected to be implemented in the intervention delivery architecture. Regardless of needing it to be implemented in a more complex way, it provides an opportunity to include computational-heavy algorithms in the future and high-accuracy data processing might be essential for critical health use-cases.

2.3.3 Medolution

Medolution⁹ (Medical Care Evolution) is an ITEA3 project focusing on increasing patients' quality of life as well as lessening the burden on healthcare systems. The project benefits a cloud computing platform that can be extended with medical information components to provide a comprehensive system capable of real-time decision support as well as long-term monitoring with provided data. Healthcare professionals and patients can reach relevant data in a preventive manner to improve their decision making on diagnosis and treatment.

Medolution focuses on IoT and Big Data to develop a core platform that serves a Big Dependable System (BDS) that can integrate heterogenous data to underlying computing systems. Smart environments are built with the goal of integrating usergenerated data collected by sensors and medical devices. Through a series of

⁹ https://itea4.org/project/medolution.html

connectors, Medolution platform has been developed to enable seamless flow of data between applications and devices.

The core platform features an SDK that enables developers to build big data analysis software above underlying core platform. It also supports automated deployment of analysis software in the cloud platform. In a use-case demonstration in the Netherlands, Medolution platform is used for developing an application that directs stroke patients to the nearest and competent hospital based on their stroke type. In another use-case, in Germany, an application is developed on top of Medolution platform to detect infection on patients using a left ventricular assist device, using machine learning on infection site images.

Medolution showcased a core cloud platform that enables heterogenous data integration via various data connectors and a SDK providing development of use-case scenario dependant big data computational components on top of the platform is very convenient handling data oriented scenarios.

Relevance of Medolution

- In the developed intervention delivery architecture, Medolution-like data connector approach is used by implementing inbound adapters for various data sources to achieve integration of heterogenous health data.
- Lambda architecture data-processing deployment model is used in designing and implementing the intervention delivery architecture.
- Medolution-like extendible framework is implemented to enable possible enhancements to the architecture to support various use-case needs.
- Both Kappa and Lambda architecture deployments were made available in the Medolution cloud computing platform catalog, making it possible to try and compare them.

CHAPTER 3

BACKGROUND

In this chapter, the standards, namely HL7 FHIR and ISO/IEEE 11073, used in the intervention delivery architecture are explained. HL7 FHIR Care Plan resource and it's components are explained separately as they are crucial in intervention planning.

3.1 HL7 FHIR

Health Level 7 (HL7) is a non-profit standards development organization that is an international community where health information experts collaborate to design health information exchange standards and health systems interoperability [25]. They have developed health data exchange standards such as HL7 Version 2 and HL7 Version 3 and structure and semantic standards for clinical documents such as HL7 Clinical Document Architecture (CDA). HL7 standards are extensively used by healthcare systems worldwide.

FHIR (Fast Healthcare Interoperability Resources) is a standards framework composed by HL7. It combines several features of HL7's previous products while supporting modern standards and protocols [25]. FHIR follows RESTful principles and allows data exchange using HTTP with a modern JSON data model as well as XML. It focuses on implementation and interoperability.

FHIR has a set of modular resources. Each resource has a definition of structure with fields and their cardinalities. Any set of these resources can be composed in a solution and they can be easily extended to fit any other needs not provided by base standard resources. FHIR can be used in wide variety of contexts such as mobile phone apps, cloud-based applications, EHRs, and CDS services.

HL7 FHIR has a useful feature named profiling which provides a functionality to state a set of rules for extending and restricting resources. With profiling, cardinalities of fields can be limited, and terminology sets of fields can be restricted. By validating these profiling rules, semantic interoperability can be ensured among resources with the same profiles.

HL7 FHIR is currently on version R4 which contains a mix of normative and STU (Standard for Trial Use) resources.

3.2 HL7 FHIR Care Plan

The care plan is a collaborative and comprehensive resource that is created by multidisciplinary healthcare professionals in order to summarize the patient's healthcare planning process. It consists of various goals, activities, educational materials, patient information and any other resource aiding to treatment of the patient [29].

3.2.1 Goal

A care plan goal is a health or behavioral target for the patient coherent with the patient's conditions. Goals are added to the care plan by the multidisciplinary care team and they might contain a quantified target and a period. For example, a goal might be put in the patient's care plan for limiting the patient's alcoholic beverage intake in a week to 10 unit for a period of time. Goals with quantified targets can be monitored and evaluated rather easily.

Goals can also be used for non-quantified, high-level targets for the patient. An example of such a goal can be 'Don't forget your daily activities' or 'Maintain a healthier lifestyle'. These goals might be supported with various patient activities and educational materials that comprehends patient's goal targets.

3.2.2 Care Plan Activity

Care plan activities are actions that occur part of the care plan. These care plan activities might be from the set described in Table 3.1. In the context of this thesis, patient order activities are the most relevant ones since behavior change interventions apply to them. Some example patient orders activities are given below.

- Measure blood pressure
- Measure blood glucose
- Submit foot photo for inspection
- Submit meal photo for dietary intake
- Record alcohol consumption
- Stretch
- Walk

Table 3.1 Care Plan Activity Categories

Category	Description
Patient Order	Patient activities (measurements, physical activities)
Questionnaire	PROMs assigned to the patient
Referral	Referrals to healthcare professionals
Appointment	Appointments with healthcare professionals
Medication	Prescribed medications
Diet	Dietary activities

3.2.2.1 Service Request

Patient order activities are added to care plan as Service Request resources. Service Request resource contains occurrence timing information of the assigned periodic activities. Periodic activities can specify frequency and periods of patient activities that patients are expected to do. They can also contain information at the 'when' field

to specify when activities are expected to occur conceptually, e.g. after a meal, before a meal, morning, afternoon. It is also possible to indicate duration of events for some activities such as physical exercises. Some example occurrence timings and their descriptions are given in Table 3.2.

Table 3.2 Example Occurrence Timing of Patient Activities

Activity	Frequency	Period	Unit	Description
Measure blood	1	1	ı	Measure your blood pressure once a
pressure	1	1	d	day
Measure blood				Measure your blood pressure twice
pressure	2	1	d	a day in the morning and night
				(when is specified)
Measure blood	2	1	1	Measure your blood glucose twice a
glucose	2	1	d	day
Measure blood				Measure your blood glucose three
glucose	3	1	d	times a day after every meal (when
				is specified)
Walk	3	1	wk	Walk three times a week
Stretch	1	1	d	Strech once a day for 20 minutes. (duration is specified)

3.3 ISO/IEEE 11073

ISO/IEEE 11073 is a set of standards that mandates personal medical device communication. A joint operation by ISO, CEN and IEEE constitutes a framework for health device interoperability focusing on personal devices [30]. Personal devices might be all kinds of health devices patient has in their home. The standards develop

a data and communication structure between devices and any other device digesting health device data. They don't define the communication medium between those devices and intermediary ones such as mobile phones and computers. Bluetooth, Zigbee and USB protocols are used most as communication mediums.

Personal Connected Health Alliance (formerly Continua) provides design guidelines and medical device data models to enable plug and play capabilities to personal health devices. They develop device specializations as parts to the main 11073 standard. Table 3.3 lists all the current device specializations of the 11073 standard [31].

Table 3.3 ISO/IEEE 11073 Device Specializations

#	Device
11073-10404	Pulse Oximeter
11073-10407	Blood Pressure Monitor
11073-10408	Thermometer
11073-10415	Weighing Scale
11073-10417	Glucose Meter
11073-10420	Body Composition Analyzer
11073-10421	Peak Flow
11073-10441	Cardiovascular fitness and activity monitor
11073-10442	Strength fitness equipment
11073-10471	Independent living activity hub
11073-10472	Medication monitor

11073 standards define communications between medical devices and other components as agent and manager communications. Agents send medical data and managers retrieve them. PCHA certified medical devices implement device specializations of the standards acting as agents. If any application or device implements the device specializations as manager, it means that the manager is now

capable of communicating with all same type devices that are implementing the 11073 standards. This eliminates the need of implementing new proprietary data communication interfaces for each device at the manager side and ensures plug and play compatibility with certified devices.

CHAPTER 4

ADLIFE

In this chapter ADLIFE project is summarized. The main components of the ADLIFE solution are described and their relevance in the developed intervention delivery arhitecture is explained.

ADLIFE's major goal is to improve the quality of life of elderly citizens with advanced chronic conditions. ADLIFE is implementing a comprehensive and integrated supportive care solution that provides intelligent and individualized healthcare. ADLIFE solutions build on existing and verified solutions that most of them developed in previous FP7 and Horizon 2020 projects that are described in Chapter 2. International standards such as HL7 FHIR and the Personal Connected Health Alliance (PCHA) device specifications are adopted by ADLIFE.

ADLIFE project goals can be listed as:

- Deploying a secure comprehensive intelligent integrated care solution with personalized care planning capabilities in large-scale pilots with various contexts.
- Measuring and obtaining quantified results in patient health, detecting and preventing needless suffering, delaying deterioration by using Patient reported Outcome Measures (PROMs).
- Increasing efficiency in healthcare delivery by enhancing incorporation between participants in healthcare, sharing resources and enhancing work quality.
- Patient empowerment via shared decision making to make patients more involved in their care planning process, enabling them to adjust to evolving conditions.

4.1 General Overview

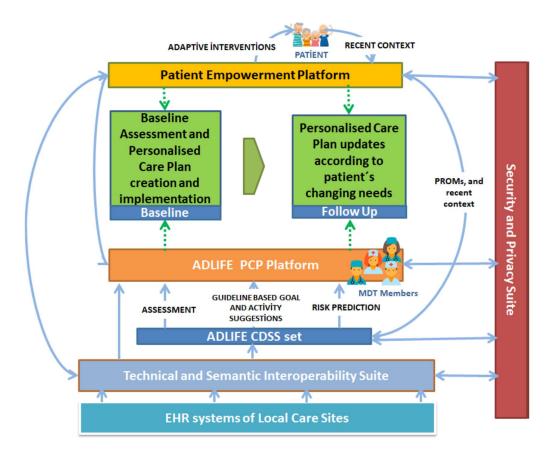


Figure 4.1. ADLIFE Architecture (taken from ADLIFE Description of Action)

ADLIFE components and their interactions are given in Figure 4.1. The component descriptions will be introduced in the following subsections.

4.1.1 ADLIFE PCP Platform (PCPMP)

The Personalised Care Plan Management Platform (PCPMP) is one of the core components of the system integrating the functionalities of all of the other components to facilitate collaborative management of the care of the patients with multi-morbid conditions. It is the direct interface to care team members, for defining,

updating, reconciling, sharing care plans, utilization of clinical decision support modules supporting these operations, organizing online care plan review meetings, receiving patient data from local care systems (via the Technical Interoperability Suite (TIS)) and Patient Empowerment Platform and providing an easy to navigate dashboard for care team members to see basic medical history of the patient along with the care plan lifecycle history.

Personalised Care Plan Management Platform is not directly included in the intervention delivery architecture, but intervention planning mechanism requires the care plan of the patient to be present in the FHIR repository to gather assigned patient activities. PCPMP is responsible for creating and storing the care plan in the repository, thus intervention delivery architecture is dependant to PCPMP outcomes.

4.1.2 Patient Empowerment Platform

The objective of Patient Empowerment Platform (PEP) is to provide access for patients and informal care giver to the published personalized care plan and thus increase patient and informal care giver participation to decision making. It aims to provide computerized means to improve the interaction between patients and health professionals and provide computerized means to collect relevant data and information to enable monitoring of care plan related activity status and progress. It also provides automated guidance and encouragement to patients through the use of a behavior change intervention delivery system. It directly interacts with PCPMP to be informed about new care plans and updated care plans, and to send patient reported observations. It also directly communicates with the supported set of Medical Devices to record patient measurements.

Patient Empowerment Platform is directly included in the intervention delivery architecture as it is the interface the patients are using. PEP is used to convey behavior change interventions to patients, display adherence performances of patient

activities to patients and enable patients to enter observations and measurements. PEP mobile application is also used for medical device integration.

4.1.3 Clinical Decision Support Modules

Clinical Decision Support Modules (CDSM) provide decision support aids to provide clinical guideline-based diagnosis and treatment suggestions, to carry out risk assessments and to provide guidance about polypharmacy management and being utilized by PCPMP during the creation and update of care plans. These modules also include an Early Warning System (EWS), utilising algorithms built using machine learning techniques to identify potentially preventable situations.

Clinical Decision Support Modules are not directly included in the intervention delivery architecture, but CDS services are used in care plan creation process. However, it is possible to create a care plan from scratch in PCPMP without utilization of CDS services, thus intervention delivery architecture is not necessarily dependant to CDS modules.

4.1.4 Security and Privacy Suite

The Security and Privacy Suite is responsible for guaranteeing authentication and authorisation of Care Team Members while they are managing personalised care plans of patients and accessing sensitive personal data; and ensuring that all data exchange within and across ADLIFE software components is encrypted and audited properly. It also provides a single sign on mechanism to enable the care team members to use ADLIFE applications by using a single account, the one that is already being used in local care system. It implements OAuth 2.0 protocol to enable token-based access control.

Security and Privacy Suite is not directly included in the intervention delivery architecture, but since it is needed for authentication and authorisation of the

individual components of the architecture when accessing data, architecture is dependant to SPS.

4.1.5 Technical and Semantic Interoperability Suite

The Technical Interoperability Suite (TIS) provides interoperability interfaces to enable seamless data exchange with the local care systems and tele-monitoring devices although the data exchange protocols, and clinical data representation formats may be heterogeneous across the ADLIFE components and the IT systems utilized in local care sites. TIS provides a standard based data exchange protocol and utilises the Semantic Interoperability Suite (SIS) to address content level interoperability challenges. SIS provides interfaces to semantically mediate different clinical data representation formats utilized by ADLIFE components and local care sites, incorporating data format and terminology mapping features.

Technical and Semantic Interoperability Suites are not directly included in the intervention delivery architecture, but since they can transfer patient data from local site's repository to the common FHIR repository, they might be needed to correctly calculate adherence performances and interventions if there is a scenario in which patient has activity data sourced from outside of PEP.

CHAPTER 5

INTERVENTION DELIVERY ARCHITECTURE

In this chapter, the developed intervention delivery architecture is presented with all its components. The general overview, the components, used technologies and implemention details are described in respective subsections.

5.1 General Overview

The general overview of the intervention delivery architecture is displayed in Figure 5.1. The main design approach behind the architecture is to develop an extendible framework to integrate heterogenous health data, process them via both real-time and batch operations, and provide desired output views via outbound adapters. The components will be explained in the following individual sub-chapters.

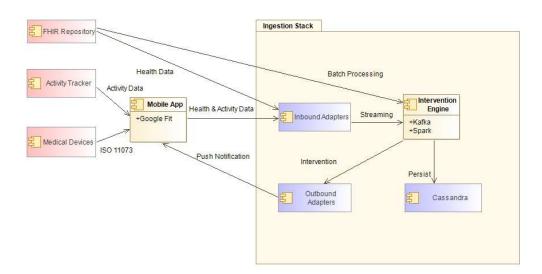


Figure 5.1. General overview of the intervention delivery architecture

5.2 Components

5.2.1 FHIR Repository

HL7 FHIR R4 Repository is used for maintaining electronic health records. The main set of resources used in this study are listed in Table 5.1 with their descriptions. Example FHIR resources are provided in Appendix A.

Table 5.1 FHIR Resources

Resource	Description
Patient	The core information of a patient.
CareTeam	The multidisciplinary care team of a patient.
Practitioner	A health professional, who is a member of the care team.
RelatedPerson	An informal caregiver of a patient.
CarePlan	The integrated care plan of a patient.
Goal	The health and activity goals set in the care plan.
DeviceRequest	Device Measurement activity assigned to a patient.
MedicationRequest	Medications prescribed to a patient.
Appointment	Clinician appointments related to the care plan.
CommunicationRequest	Guidance and training materials assigned to a patient.
Communication	Messages between patient and care team.
Observation	Measurements and results of the patient.
Questionnaire	PROM definitions.
QuestionnaireResponse	PROM responses of a patient.
ServiceRequest	Care plan activities of the patient. (E.g. PROM, Patient Order)

In order to deliver interventions as push notifications to patients' mobile phones, FHIR repository is extended with an operation for device token registry to Google Firebase ¹⁰. Firebase is a Google product for mobile and web application development with overwhelming number of functionalities. In the scope of this study, Firebase is used to deliver interventions and reminders as push notifications to patients' mobile phones. To achieve this, a mapping between devices and patients should be done. The steps are as follows:

- 1. Mobile application obtains a device token using Firebase API.
- 2. Mobile application calls FHIR repository's 'register-device-token' operation with device token and patient identifier.
- 3. FHIR Repository subscribes the device token to patient's notification topic in Firebase.
- 4. Intervention engine selects an intervention and forwards it to the push notification outbound adapter.
- 5. Outbound adapter uses Firebase API to send a notification to patient's notification topic.
- 6. Firebase delivers push notification to the patient's device.

5.2.2 Activity Tracker

There are many different wearable activity trackers in the market and studies show that they can lead the user to have a healthier lifestyle [30]. Users can track personal activities, sleep, temperature, heart rate and various other heath and activity related personal data through these devices. However, many of these devices are strongly coupled with their own applications and don't allow generic interfaces to read their data.

Google Fit¹¹ acts as a personal data repository for various health and activity data of the users. Through generic API's, it allows other applications to store and query

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¹⁰ https://firebase.google.com/

¹¹ https://www.google.com/fit/

personal health and activity data. Many of the most popular wearable device applications allow synchronization with Google Fit. The list of Google Fit data types is presented in Table 5.2. Google Fit also allows users to define custom data types to suit their needs.

Table 5.2 Google Fit Data Types

Groups	Type	Description	
Activity		The number of kilocalories a user would	
	BMR	burn if at rest all day, based on their height	
		and weight.	
	Calories Burned	Number of kilocalories burned.	
	Caroling Padaling	Number of bicycle crank revolutions per	
	Cycling Pedaling	minute.	
	Heart Points	Heart Points earned based on the intensity	
	Heart Points	of the exercise or activity the user does.	
	Move Minutes	The duration of Move Minutes earned, in	
	Move Minutes	milliseconds.	
	Step Count	Number of steps taken over a time period.	
	Workout	Exercise type (for example resistance	
		exercises or weight training), the number	
		of repetitions of the exercise, the duration	
		of the exercise, and the resistance.	
Body	Body fat percentage	Percentage of total body mass that is body	
	Body lat percentage	fat.	
	Heart Rate	Heart rate in beats per minute.	
	Height	Height in meters.	
	Weight	Body weight in kilograms.	
Location	Cycling wheel revolution	Number of bicycle wheel revolutions.	
	Distance	Distance travelled in meters.	
	Location	Latitude, Longitude, Accuracy, Altitude.	

Nutrition	Hydration	Volume of water consumed.
	Nutrition	What nutrients were consumed as part of a meal or a food item.
Sleep	Sleep	This data type captures the user's length and type of sleep.
Health	Blood glucose	Concentration of glucose in the blood
	Blood pressure	Systolic and Diastolic blood pressure
	Body temperature	Body temperature in degrees Celsius.
	Cervical mucus	Self-assessed description of cervical mucus for a user
	Cervical position	A report of the user's cervix (position, dilation and firmness)
	Menstruation	How heavy a user's menstrual flow was (spotting, light, medium, or heavy)
	Ovulation test	Binary result of an ovulation test (positive or negative)
	Oxygen saturation	The amount of oxygen circulating in the blood, measured as a percentage of oxygen-saturated hemoglobin.
	Vaginal spotting	A user experiences spotting (bleeding in between their period)

Mobile Application implements Google Fit interfaces to query data written by activity trackers. The application is also capable of communicating with Xiaomi Mi Band¹² activity trackers via Bluetooth without the need of a Google Fit integration. The application implements a Bluetooth Low Energy interface to pair with Mi Band devices and access raw step count, calorie and heart rate data produced by the tracker.

12 mi.com/global/miband

The data flow of the mobile application regarding activity trackers is displayed in Figure 5.2.

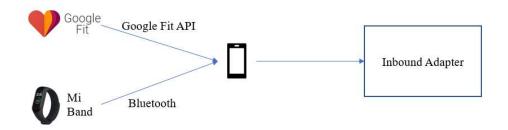


Figure 5.2. Android Application Activity Tracker Data Flow

The mobile application is developed for Android devices, but in case of a need for supporting IOS devices, a similar approach can be implemented for an IOS application as Apple also provides HealthKit¹³ with a similar design to Google Fit where HealthKit acts as a repository for health and activity data.

5.2.3 Medical Devices

Many of the personal medical devices use proprietary interfaces and their own mobile and computer applications to exchange data from devices to underlying systems. As explained in Chapter 3, ISO/IEEE 11073 standards framework provide device specializations to achieve seamless personal medical device data integration and Personal Connected Health Alliance certifies devices that are compliant with these standards. In this thesis work, ISO/IEEE 11073 compliant blood pressure and blood glucose devices are integrated to the architecture.

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¹³ https://developer.apple.com/documentation/healthkit

The mobile application implements Bluetooth Health Device Profile (HDP) to communicate with personal medical devices. Bluetooth SIG Working Group provides Health Device Profile Implementation Guidelines¹⁴ inline with ISO/IEEE 11073 standards that contains examples and best practices of handling Personal Health Data Exchange Protocol.

Figure 5.3 taken from implementation guidelines, displays the underlying Bluetooth protocols and entities used by the Health Device Profile.

- L2CAP: Logical Link Control and Adaptation Protocol
- MCAP: Multi-Channel Adaptation Protocol
- SDP: Service Discovery Protocol
- Agent: Source Personal Medical Device
- Manager: Application connecting to the medical device

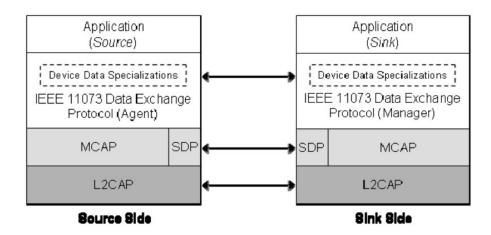


Figure 5.3. HDP Protocols (Taken From IG)

In Figure 5.4. and Figure 5.5. two different code snippets are displayed to demonstrate how HDP is implemented in Android Java. First figure shows an association established response that is sent from the application (manager) to the

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¹⁴ https://www.bluetooth.com/bluetooth-resources/health-device-profile-implementation-guidance/

medical device (agent). The message is constructed by the data model defined in the ISO/IEEE 11073 standards. Second figure shows the interpretation of systolic and diastolic blood pressure and pulse data incoming from the blood pressure monitor.

```
/** Association establishment response sent to medical device */
private void sendAssociationEstablishedResponse() {
    sendBytesAsynchronous(new byte[] {
            (byte) 0xE3, (byte) 0x00, //APDU CHOICE Type(AareApdu
            (byte) 0x00, (byte) 0x2C, //CHOICE.length = 44
            (byte) 0x00, (byte) 0x00, //result=accept
            (byte) 0x50, (byte) 0x79, //data-proto-id = 20601
            (byte) 0x00, (byte) 0x26, //data-proto-info length =
            (byte) 0x80, (byte) 0x00, (byte)0x00, (byte)0x00, //E
            (byte) 0x80, (byte)0x00, //encoding rules = MDER
            (byte) 0x80, (byte) 0x00, (byte) 0x00, (byte) 0x00,
            (byte) 0x00, (byte) 0x00, (byte) 0x00, (byte) 0x00,
            (byte) 0x80, (byte) 0x00, (byte) 0x00, (byte) 0x00,
            (byte) 0x00, (byte) 0x08, //system-id length = 8 and
            (byte) 0x88, (byte) 0x77, (byte) 0x66, (byte) 0x55, (
            (byte) 0x00, (byte) 0x00, //Manager's response to cor
            (byte) 0x00, (byte) 0x00, //Manager's response to dat
            (byte) 0x00, (byte) 0x00, //data-reg-init-agent-count
            (byte) 0x00, (byte) 0x00, (byte) 0x00, (byte) 0x00,
    });
}
```

Figure 5.4. HDP Medical Device Association Code Snippet

```
switch (obj handle) {
    case SYS DIA MAP DATA:
        int sys = byteToUnsignedInt(data[packetStart + 9]);
        int dia = byteToUnsignedInt(data[packetStart + 11]);
        int map = byteToUnsignedInt(data[packetStart + 13]);
        Log.i(TAG, "Systolic blood pressure: " + sys);
        Log.i(TAG, "Diastolic blood pressure: " + dia);
        Log.i(TAG, "MAP: " + map);
        messenger.sendMessage(RECEIVED_BP, sys, dia);
        break;
    case PULSE DATA:
       int pulse = byteToUnsignedInt(data[packetStart + 5]);
        Log.i(TAG, "Pulse: " + pulse);
        messenger.sendMessage(RECEIVED_PUL, pulse);
        break;
    case ERROR_CODE_DATA:
        //need more signal
        break;
}
```

Figure 5.5. HDP Blood Pressure Adapter Code Snippet

PCHA certified ISO/IEEE 11073 compliant Fora D40 Blood Pressure and Blood Glucose Monitor¹⁵ is used for testing as it provides two different health data types in one device.

There might be a need to integrate medical devices that are not compliant to the ISO/IEEE 11073 standards. Similar to the Mi Band integration, proprietary interface of that specific medical device should be implemented to integrate medical data produced by them. In that case, data flow of medical devices to the mobile application is displayed in Figure 5.6.

 $^{^{15}\} https://www.pchalliance.org/0026-fora-d40-bluetooth-agent-supporting-blood-pressure-monitor-and-glucose-monitor-device$

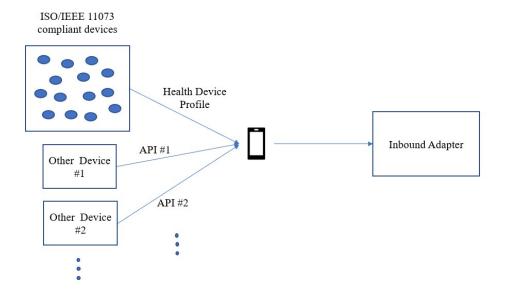


Figure 5.6. Android Application Medical Device Data Flow

The figure also summarizes the importance of compliance to standards for ease of interoperability. For each device compliant to ISO/IEEE 11073 standards, the same communication API is reused, and for each device with proprietary interfaces the application should implement the API specific to that device.

5.2.4 Mobile Application

An Android Mobile Application is developed in the architecture for end-user use. The main objectives of the application are:

- Provide an interface for patients to check their care plans and activities
- Provide graphical interfaces for adherence performances
- Provide an interface for patients to change intervention delivery preferences
- Deliver interventions to patients
- Act as an intermediary device in medical device data flow
- Act as an intermediary device in activity tracker data flow

The application connects to the FHIR repository and queries the active care plan of the logged in patient. Patient can list the activities assigned to them, their goals and targets and report feedbacks to them if they need.

The application has a dashboard view where patients can see their adherence performances to their assigned activities with daily, weekly and monthly charts. This is achieved via querying performance observations of the patient in the FHIR Repository that are calculated by the intervention engine and saved to repository by an outbound adapter. The format of the observation is given in 5.2.5.3. An example chart view is displayed in Figure 5.7.

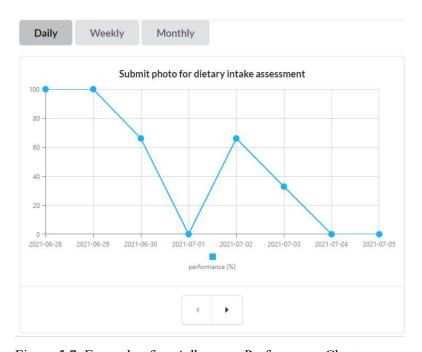


Figure 5.7. Example of an Adherence Performance Chart

The application provides an interface to patients to enable them to change their intervention delivery preferences. A patient might select to receive interventions and reminders by emails rather than push notifications. If push notification option is selected, the application makes an operation call to the FHIR Repository to register device token to the patient's intervention topic. The repository then uses Firebase API to handle this setting. Intervention engine forwards interventions to appropriate

outbound adapter based on email and push notification preference of the patient. Patients can also alter intervention and reminder frequency of each individual activity by a slider. The values in the slider is as follows:

- Never
- Rarely
- Occasionally
- Frequently
- Each Time

The preferences of the patients are written to the FHIR Repository and conveyed to the health data ingestion stack. Intervention Engine reads these frequency preferences of the patient and uses it when planning an intervention. The details of intervention planning are explained in 5.2.5.2.

The application acts as an intermediary device to ensure data flow from medical devices and activity trackers to the health data ingestion stack as explained in sections 5.2.2 and 5.2.3.

5.2.5 Health Data Ingestion Stack

Health Data Ingestion Stack is developed in compliance with the Lambda architecture principles. Lambda architecture can be simply defined as a scalable big data architecture that implements stream and batch processing capabilities and output views to achieve a data-processing architecture capable of handling massive amounts of data [33].

The streaming layer starts with inbound adapters. Inbound adapters forward incoming data to the underlying intervention engine by using Apache Kafka¹⁶. Kafka is a distributed event streaming platform that works in a publish-subscribe fashion.

¹⁶ https://kafka.apache.org/

Intervention engine uses Apache Spark Streaming¹⁷ to stream data from Apache Kafka. Streamed data is then transformed using resilient distributed dataset (RDD) transformations to process them. The processed data is used for intervention planning and persisted to Apache Cassandra¹⁸. Apache Cassandra is a distributed NoSQL database.

In the batch layer, Intervention engine queries FHIR Repository daily to gather resources. Gathered resources are processed and persisted to Apache Cassandra.

The serving layer is the outbound adapters. Outbound adapters provide output views to outlying systems.

5.2.5.1 Inbound Adapters

Inbound adapters are the entry points of data to the ingestion stack. The adapters are utilized to enable data flow from outlying components to the computational components. Inbound adapters also can be used for transforming incoming data to the desired format of the computational components.

5.2.5.2 Intervention Engine

Defining Interventions

In the developed intervention calculation engine, behavior change interventions are defined by healthcare providers utilizing a template-based rule defining language and sent to the patients by mobile application notifications or emails to complement patient empowerment. These interventions are planned and selected by the

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¹⁷ https://spark.apache.org/

¹⁸ https://cassandra.apache.org/

intervention engine and conveyed to patients by using outbound adapters described in 5.2.5.3.

Three motivational intervention types are defined in the project. Types and descriptions are described in Table 5.3.

Table 5.3 Motivational Intervention Types

Type of Intervention	Description
General Reinforcement	General motivational messages such as "Keep up
	to good work, you achieved your target for the
	day."
Self-comparison	Motivational messages comparing recent
	performance to a past one by the patient such as
	"You are doing better on your target by 50%
	comparing your last week."
Population comparison	Motivational messages comparing patient's
	recent performance with other patients in the
	system such as "You are better on your target
	than 90% of other participants."

Template-based intervention rule defining language

Intervention rules are defined using a JSON template-based rule defining language. Intervention types described in Table 5.3. are used. The rule defining language description and the complete list of rules used in this study are given in Appendix B.

Patient preferences

Patient preferences related to interventions are written to FHIR repository and read by intervention engine while planning interventions. Patient preferences contain intervention delivery type (email / push notification), language of intervention content, timezone and intervention frequency for each activity.

- Intervention delivery type: Patient preference of delivery medium is used for forwarding planned interventions to the appropriate outbound adapter.
- Language of intervention: Intervention rules contain translations of intervention content. Appropriate translation of intervention content is selected based on patient language.
- Timezone: Intervention engine does not send interventions during nighttime.
 Timezone of the patient is used to determine appropriate hours to send interventions.
- Intervention frequency: Patient can select intervention frequency for each assigned activity. If intervention engine calculates an intervention to be sent, it uses these preferences.
 - Never: No intervention is sent.
 - o Rarely: 10% of the interventions are sent.
 - o Occasionally: 30% of the interventions are sent.
 - o Frequently: 70% of the interventions are sent.
 - o Each Time: 100% of the interventions are sent.

Intervention Flow

The steps for defining and delivery of interventions are described below.

- 1. Healthcare providers define patient activity interventions using the rule defining language.
- 2. Patient has an active care plan in the FHIR Repository containing patient activities.
- 3. Patient intervention preferences are present in the FHIR Repository.
- 4. Intervention engine calculates patient state.
 - a. An observation is conveyed to the ingestion stack.
 - b. Patient state re-evaluation period is passed.
- 5. Intervention engine forwards patient performance to the performance outbound adapter.

- 6. Intervention engine calculates defined interventions for suitability. If more than one intervention is suitable, the engine randomly selects an intervention.
- 7. Intervention engine decides to send an intervention.
- 8. Intervention engine checks frequency preference of the patient for selected intervention activity.
- 9. Intervention engine selects intervention content based on patient language.
- 10. Intervention engine forwards the intervention to the relevant outbound adapter based on patient preference (email or push notification).
- 11. Intervention engine forwards the intervention to the repository outbound adapter to be saved in the FHIR repository.
- 12. Intervention is delivered to the patient.

Distributed Processing Architecture

Figure 5.8 displays the distributed data processing architecture of the intervention engine. The engine consumes data from Apache Kafka cluster as raw HL7 FHIR formatted resources. These resources might contain:

- device measurements, activity tracker data, vital signs measurements of patients as FHIR Observations,
- care plan activity assignments, questionnaire assignments to patients as FHIR ServiceRequests
- educational materials assigned to patients as FHIR CommunicationRequests and so on.

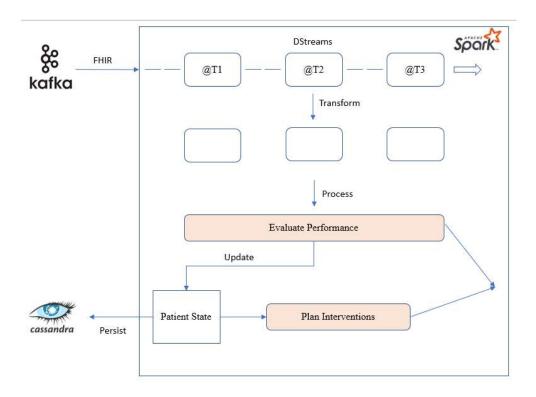


Figure 5.8. Distributed Processing Architecture Overview

In Spark Streaming, the consumed data is represented as Discretized Streams (DStreams) that are continuous stream of resilient distributed datasets (RDDs). Every RDD in a DStream contains data from a certain continuous interval.

Using specific transformers, each RDD is transformed to the underlying data format of the intervention engine. For example, FHIR Observations are transformed to one of SimpleObservation, SimplePeriodicObservation, CodedObservation, TimeSeriesObservation, MultiComponentObservation that are defined by the intervention engine.

These transformed data are then used by the performance evaluation engine to assess performance adherence of each patient to each of their assigned patient activities. Performance evaluation engine updates patient state that is kept in memory and the patient state is persisted to the Apache Cassandra cluster periodically. Performance

calculations are also written to the FHIR repository using an outbound adapter that is described in the following sector.

Intervention planning engine calculates patient state changes periodically and decides on an intervention. The effect of intervention rules and patient preferences about the interventions are described in the previous sectors. Outbound adapters that are described in the following section are used for storing and sending interventions.

5.2.5.3 Outbound Adapters

Outbound adapters are used for providing output from the health data ingestion stack. They act as the serving layer of the Lambda Architecture. For the calculated interventions and performances four outbound adapters are implemented and can be increased to fit any additional needs.

Repository Intervention Adapter

All created interventions and reminders are written to FHIR Repository as Communication resources. An example Communication resource is displayed in Figure 5.2. Some of the fields are explained below:

- subject: Contains a reference to the Patient that the intervention is sent.
- identifier: Identifier of the intervention as defined in the rule template.
- category.coding: Category code of the intervention (reminder / motivation).
- topic: Action name of the intervention as defined in the rule template.
- payload: Actual text content of the intervention.

```
"resourceType": "Communication",
"id": "25221c1d-ad26-4554-ac92-4ae617afce3a",
"meta": { ···
"subject": {
    "reference": "Patient/dd076b0c-20c5-46fb-9449-5cf34dee7b47"
"identifier": [
    {
        "value": "DP-MOT-GA-GR-1",
        "system": "http://www.adlife.eu/fhir/interventions"
"category": [
        "coding": [
           {
                "code": "motivation",
                "system": "http://www.adlife.eu/fhir/pdm-communication-categories"
"topic": {
    "text": "dietary-photo"
"payload": [
        "contentString": "Good work! You reached your dietary photo goal for the day.."
"status": "completed",
"sent": "2021-02-24T21:00:00Z",
"reasonCode": [ ···
```

Figure 5.9. Example Intervention as Communication Resource

Repository Performance Adapter

All the calculated adherence performances of the patient are written to FHIR Repository as Observation resources. An example Observation resource is displayed in Figure 5.10. Some fields are explained below:

- subject: Contains a reference to the patient that the performance belongs
- basedOn: Contains a reference to the care plan activity that the performance belongs
- valueString: base64 encoded performance JSON value, performance value fields are explained below.

```
"resourceType": "Observation",
"id": "dietary-photo-perf-pa01",
"meta": { ··
},
"subject": {
    "reference": "Patient/pa01"
"basedOn": [
        "reference": "ServiceRequest/a9138dd9-c746-4c04-a0cf-85253de5ff0e"
"effectiveDateTime": "2021-07-06T09:13:45.066+03:00",
"code": {
    "coding": [
       {
            "system": "http://kroniq.srdc.com.tr",
            "code": "performance"
"status": "final",
"valueString":
eyJsYXN0RGF5cyI6W3siZGF5IjoiMjAyMS0wNi0yOCIsInZhbHV1IjoxfSx7ImRheSI6IjIwMjEtMDYtMjkil
F5IjoiMjAyMS0wNy0wMSIsInZhbHV1IjowfSx7ImRheSI6IjIwMjEtMDctMDIiLCJ2YWx1ZSI6MC42Nn0seyJk
CIsInZhbHVlIjowfSx7ImRheSI6IjIwMjEtMDctMDUiLCJ2YWx1ZSI6MH1dLCJsYXN0V2Vla3MiOlt7Ind1ZWs
YWx1ZSI6MC41Mn1dLCJsYXN0TW9udGhzIjpbeyJtb250aCI6IjIwMjEtMDYiLCJ2YWx1ZSI6MC4wNX1dfQ=="
```

Figure 5.10. Example Performance as Observation Resource

Decoded performance JSON value content is displayed in Figure 5.11. The performance value contains adherence performances of an activity in last days, last weeks and last months fields. Values indicate percentage of the patient's adherence to an activity.

These performance values are used by mobile application to show the patients their adherence by graphical interfaces with daily, weekly and monthly views.

```
"lastDays": [
       "day": "2021-06-28",
       "value": 1
      },
      {
       "day": "2021-06-29",
       "value": 1
      },
      "day": "2021-06-30",
      "value": 0.66
      },
     { ···
>
      },
     { ····
>
      },
      { ...
      },
     { ...
     },
      { …
    ],
    "lastWeeks": [
     { ····
      },
     {
      "week": "2021-06-28",
      "value": 0.52
    ],
    "lastMonths": [
       "month": "2021-06",
       "value": 0.05
   ]
```

Figure 5.11. Decoded Performance Values

Notification & Email Intervention Adapter

Interventions are sent to the patients by their communication preferences. If push notifications are enabled, Firebase is used to convey push notifications to patient's mobile phone. Interventions are sent via emails otherwise.

CHAPTER 6

CONCLUSION AND FUTURE WORK

In ADLIFE project, an integrated care planning approach is used where patients are assigned various care plan activities by multidisciplinary care teams. To increase their adherence to the care plan, a continuous behavioral monitoring architecture is developed for delivering digital personalized just-in time adaptive interventions. Continuous behavioral monitoring necessitates real time tracking of patient's care plan activity achievements via various data sources such as medical devices, electronic health records and mobile ADLIFE app used by the patient.

In this thesis, an extendible health data ingestion framework is presented for continuous behavioral health monitoring and delivering digital behavior change interventions to multimorbidity patients. The architecture is implemented to be capable of expanding, with any new data source can be added seamlessly if they follow the common data model in HL7 FHIR R4 format. Other data sources are also can be linked to the system by providing necessary inbound adapters handling the mapping between data formats.

Within the scope of ADLIFE project, the intervention engine will be enhanced to utilize Reinforcement Learning algorithms similar to presented work by S. Gönül on timing optimization of behavior change interventions [34]. Some further context parameters such as mood and stress levels will be collected by patients via the mobile application, and both these parameters and a reward-based mechanism will be implemented to achieve more personalized and in-time adaptive interventions.

The technical architecture and intervention delivery rules are ready to be piloted. The usability and acceptance by patients, and the effectiveness of the behavioral interventions on patient's adherence will be assessed during pilot studies.

The enhanced intervention engine and all the components presented in the architecture will be further validated in part of ADLIFE pilot studies containing seven pilot sites with a total of 577 healthcare professionals from 75 hospitals, clinics and primary care services [35].

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APPENDICES

A. FHIR Resource Examples

A.1. Care Plan

```
{
"resourceType": "CarePlan",
"id": "6e4234da-345e-40f5-916c-1fadfb9dac36",
"status": "active",
"intent": "order",
"category": [
   "coding": [
     "system": "urn:oid:2.16.840.1.113883.2.1.3.2.4.15",
     "code": "325671000000104",
     "display": "Integrated care plan"
    }
   ]
],
"subject": {
  "reference": "Patient/pa01",
```

```
"display": "Ahmet Kılıç"
},
"goal": [
 {
  "reference": "Goal/e0935264-4cca-488b-9b04-e2b86e95058a",
  "display": "Lipid Management"
 },
  "reference": "Goal/43f0fbf3-ac04-4fd4-8dd3-e2fb8adb44df",
  "display": "Diet & Lifestyle"
 },
  "reference": "Goal/461fa4fa-e4a3-4976-a1ea-16881987037b",
  "display": "Reduce alcohol consumption"
 },
  "reference": "Goal/0efeb457-9e3c-4d39-a49d-d1ea00aef56d",
  "display": "Reduce number of cigarettes smoked"
 },
  "reference": "Goal/5a72ead8-a41a-4323-8fa4-618f8f50916d",
  "display": "Keep blood pressure under control"
```

```
}
 ],
 "title": "Example Care Plan",
 "activity": [
   "reference": {
    "reference": "CommunicationRequest/782d20e5-c2d6-4653-bb3f-
9ff0c94e8730",
    "display": "Treating type 2 diabetes"
   }
   "reference": {
    "reference": "ServiceRequest/2b843ffc-f305-4ce9-b09a-cca906844b60",
    "display": "Self-measurement of blood pressure"
   }
  },
   "reference": {
    "reference": "ServiceRequest/a9138dd9-c746-4c04-a0cf-85253de5ff0e",
    "display": "Submit photo for dietary intake assessment"
   }
```

```
}
 ],
 "careTeam": [
   "reference": "CareTeam/b0695694-22b0-45fa-88d6-c3c309d0fe54",
   "display": "Care Team of Care Team of Ahmet Kılıç"
  }
 ],
 "period": {
  "start": "2020-08-12T18:28:25.103Z"
 },
 "author": {
  "reference": "Practitioner/3c670b96-8657-4fe7-bc48-b4352a2b5284",
  "display": "Anna Svensson"
A.2. Goal
 "resourceType": "Goal",
 "id": "461fa4fa-e4a3-4976-a1ea-16881987037b",
 "lifecycleStatus": "active",
```

```
"description": {
 "coding": [
  {
   "system": "http://www.adlife.eu/fhir/goal-code",
   "code": "g0004",
   "display": "Reduce alcohol consumption"
  }
 ]
},
"subject": {
 "reference": "Patient/pa01",
 "display": "Ahmet Kılıç"
},
"startDate": "2020-08-25",
"target": [
  "measure": {
   "coding": [
      "system": "http://loinc.org",
     "code": "44940-5",
     "display": "Alcoholic drinks per week"
```

```
]
  },
  "detailQuantity": {
   "value": 14,
   "unit": "unit",
   "system": "http://unitsofmeasure.org",
   "code": "1"
  },
  "dueDate": "2021-08-25"
 }
],
"expressedBy": {
 "reference": "Practitioner/3c670b96-8657-4fe7-bc48-b4352a2b5284",
 "display": "Anna Svensson"
},
"achievementStatus": {
 "coding": [
   "system": "http://terminology.hl7.org/CodeSystem/goal-achievement",
   "code": "in-progress"
  }
```

```
]
 },
 "statusDate": "2021-05-04"
}
A.3. Service Request
{
 "resourceType": "ServiceRequest",
 "id": "d8e66457-2c3b-439c-901e-67d1ba693529",
 "status": "active",
 "category": [
   "coding": [
     {
      "system": "http://www.adlife.eu/fhir/care-plan-activity-category",
      "code": "patient-order",
     "display": "Patient Order"
     }
   ]
 ],
 "intent": "order",
```

```
"code": {
 "coding": [
  {
   "system": "http://loinc.org",
   "code": "85354-9",
   "display": "Self-measurement of blood pressure"
  }
]
},
"subject": {
"reference": "Patient/dd076b0c-20c5-46fb-9449-5cf34dee7b47",
"display": "Mert Baskaya"
},
"occurrenceTiming": {
 "repeat": {
  "boundsPeriod": {
   "start": "2020-10-15T04:54:25.227Z",
   "end": "2021-04-15T04:54:25.227Z"
  },
  "frequency": 1,
  "period": 1,
  "periodUnit": "d"
```

```
}
},
"requester": {
 "reference": "Practitioner/3c670b96-8657-4fe7-bc48-b4352a2b5284",
 "display": "Anna Svensson"
},
"performer": [
  "reference": "Patient/dd076b0c-20c5-46fb-9449-5cf34dee7b47",
  "display": "Mert Baskaya"
 }
],
"extension": [
  "url": "http://hl7.org/fhir/StructureDefinition/goal-pertainsToGoal",
  "valueReference": {
   "reference": "Goal/70242e64-badb-425f-90f2-5db09413f605",
   "display": "BP Management"
```

A.4. Communication Request (Education Material)

```
{
 "resourceType": "CommunicationRequest",
 "id": "b472d648-219f-422c-b2a6-86fa3f5d7baf",
 "status": "active",
 "subject": {
  "reference": "Patient/dd076b0c-20c5-46fb-9449-5cf34dee7b47",
  "display": "Mert Baskaya"
 },
 "payload": [
   "contentAttachment": {
    "contentType": "text/html",
     "language": "en",
     "url": "https://www.bhf.org.uk/heart-matters-magazine/medical/8-tips-for-
living-with-multiple-conditions",
    "title": "8 tips for living with multiple conditions"
   }
 ],
 "occurrencePeriod": {
  "start": "2020-10-15T05:04:32.349Z",
```

```
"end": "2020-11-14T21:00:00.000Z"

},

"authoredOn": "2020-10-21T05:04:32.349Z",

"sender": {

    "reference": "Practitioner/3c670b96-8657-4fe7-bc48-b4352a2b5284",

    "display": "Anna Svensson"

}
```

B. Template-based Rule Defining Language

B.1. Template

A JSON based template is used to define interventions for behaviors to be monitored. The fields of the template are described below.

- behaviors (Array): Full set of behaviors related with the defined interventions.
 - o behavior (String): Coded name of the behavior (e.g. dietary-photo).
 - observations (Array): Related observations to be used in calculating performance.
 - system (String): Code system of the observation (e.g.
 http://snomed.info/sct)
 - code (String): Code of the observation (e.g. 226075008)
- interventions (Array): Full set of interventions defined.
 - id (String): Unique identifier of the intervention (e.g. ADLIFE-MOT-PO-GR-1)

- description (String): Description of the intervention (e.g. Patient does achieve daily, weekly or monthly goal, so we motivate him by general reinforcement)
- category (String): Category of the intervention (reminder / motivation)
- o bct (String): Behavior Change Technique code of the intervention
 - gr -> general reinforcement
 - sc -> self-comparison
 - pc -> population-comparison
- o rules (Array [String]): Coded rules of the intervention, described in the section follow (e.g. target.daily=3).
- content: The content of the intervention with possible translations
 (e.g. Good work! You reached your target for the week.)

Target temporal and target achievement status codes are used for rule defining as follows.

- target temporal: daily, weekly, monthly.
- achievement status:
 - target not achieved (0)
 - target almost achieved (1)
 - target about to achieve (2)
 - target achieved (3)
 - achieved more than target (4)

Examples:

- target.daily = 3: Means that the target of the behavior is achieved for the day.
- target.weekly = 2: Means that if patient will continue with their current performance, they will achieve their target for the week.

B.2. Sample Interventions Defined for Patient Orders

```
{
"behaviours": [
   "behaviour": "dietary-photo",
   "observations": [
     "system": "http://snomed.info/sct",
     "code": "226075008"
   ]
  },
   "behaviour": "back-exercise",
   "observations": [
     "system": "http://snomed.info/sct",
     "code": "229138000"
    }
  },
```

```
"behaviour": "walk",
"observations": [
 {
  "system": "http://snomed.info/sct",
  "code": "129006008"
 }
]
"behaviour": "record-smoked-cigarettes",
"observations": [
  "system": "http://snomed.info/sct",
  "code": "230056004"
 }
]
"behaviour": "stretching-exercise",
"observations": [
 {
  "system": "http://snomed.info/sct",
```

```
"code": "229070002"
  }
 ]
},
 "behaviour": "measurement-weight",
 "observations": [
   "system": "http://loinc.org",
   "code": "29463-7"
  }
 "behaviour": "measurement-bmi",
 "observations": [
  {
   "system": "http://loinc.org",
   "code": "39156-5"
  }
},
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"behaviour": "measurement-glucose",
 "observations": [
   "system": "http://loinc.org",
   "code": "14743-9"
  }
 ]
 "behaviour": "measurement-bp",
 "observations": [
  {
   "system": "http://loinc.org",
   "code": "85354-9"
 ]
},
 "behaviour": "measurement-spo2",
 "observations": [
  {
```

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"system": "http://loinc.org",
   "code": "2708-6"
  }
 ]
},
 "behaviour": "measurement-fluid-balance",
 "observations": [
   "system": "http://loinc.org",
   "code": "9097-7"
 ]
},
 "behaviour": "record-alcohol-consumption",
 "observations": [
   "system": "http://loinc.org",
   "code": "44940-5"
  }
 ]
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}
 ],
 "interventions": [
   "id": "ADLIFE-MOT-GA-GR-1",
   "description": "Patient does achieve daily, weekly or monthly goal, so we
motivate him by general reinforcement",
   "category": "motivation",
   "bct": "gr",
   "rules": [
    "target.monthly = 3",
    "target.weekly = 3",
    "target.daily = 3"
   ],
   "content": {
    "en": "Good work! You reached your ${behavior} target for the ${target}
_temporal \}."
   }
  },
   "id": "ADLIFE-MOT-PO-SC-1",
```

"description": "Patient does achieve his daily, weekly or monthly goal, so we motivate him by finding a 'positive comparison' with his past data",

```
"category": "motivation",
   "bct": "sc",
   "rules": [
    "target.monthly = 3",
    "target.weekly = 3",
    "target.daily = 3"
   ],
   "content": {
    "en": "That was a good ${target temporal}, you are ${comparison value}%
better than ${comparison temporal} in ${behavior}..."
   }
  },
   "id": "ADLIFE-MOT-PO-PC-1",
   "description": "Patient does achieve daily, weekly or monthly goal, so we
motivate him by positively comparing with other patients",
   "category": "motivation",
   "bct": "pc",
   "rules": [
    "target.monthly = 3",
     "target.weekly = 3",
    "target.daily = 3"
   ],
```

```
"content": {
    "en": "Good work! Your performance in ${behavior} is better than
${comparison_population_percentage}% of others ${comparison_temporal}."
    }
}
```