Dublin — June 20-23, 2022

How to address data heterogeneity in Chronic Disease Management towards massive deployment of IoT solutions

Moderator: Ms. Paula Currás (Medtronic Ibérica S.A.)

Speakers:

- Dr. Giuseppe Fico (UPM)
- Dr. Dave Raggett (W3C)
- Dr. Eleni Georga (Uol)
- Ms. Pilar Sala (Mysphera)

Forum

GLOBAL VISION:

IoT TODAY AND BEYOND

Session Speakers

Moderator:

Ms. Paula Currás – IHS Project Specialist, Medtronic Ibérica

Dr. Giuseppe Fico Assistant Professor of **Biomedical Engineering**, UPM





Dr. Eleni Georga PhD, University of Ioannina



Mrs. Pilar Sala EU Project Manager, Mysphera





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Speakers:





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- The GATEKEEPER Project 1.
- The GATEKEEPER HL7 FHIR Implementation 2. Guide
- The Web of Things model in GATEKEEPER 3. ecosystem
- Al based pipelines for solution design 4.
- 5. Real world data acquisition API





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The GATEKEEPER project Ms. Paula Currás – Medtronic Ibérica

G A T E K E E P E R

advanced health monitoring and early interventions

Across multiple scenarios of smart living environments

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GATEKEEPER project



The flagship project of the EU to

foster large-scale deployment of







GATEKEEPER project



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The Gatekeeper HL7-FHIR Implementation Guides for Chronic Disease Management Dr. Giuseppe Fico - UPM

What is Gatekeeper?

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A trustable, privacy preserving and secure platform to foster largescale deployment of interoperable AI solutions for Chronic Disease Management.





We aim at connecting IoT devices with asynchronous and synchronous API

Data are gathered into the platform through connector with a site-to-site VPN connection

Data are semantically annotated with JSON-LD integrated into Web of Thing – Thing Descriptor

Data are directly sends from IoT medical devices in GK-FHIR format





How we build trustiness?



We aim to do that by using Certification Authorities and blockchain



In GK we have a Gatekeeper Trust Authority that has the objectives of:

Certify different levels of trustiness of GK Things Provide traceability, non repudiation of Gatekeeper things Provide automatic validation of several aspects of a GK thing Such as compliance with **Gatekeeper FHIR IG**









<u>**HL7 FHIR**</u> (Fast Healthcare Interoperability Resources) Specification is the HL7 outstanding standard for exchanging healthcare information electronically

..... but is not limited to this...

The basic building block in FHIR is a **<u>Resource</u>**. Everything in FHIR is a resource.

FHIR resources aim to define the information contents and structure for the **core information set** satisfying **the majority of common use cases**.





How was used FHIR in Gatekeeper?



Our methodology for Gatekeeper FHIR IG definition



Gatekeeper FHIR IG



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The role of FHIR in Gatekeeper – Data Cap









The role of FHIR in Gatekeeper – Data Cap



loT & Data



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The role of FHIR in Gatekeeper - AI





FHIR as mediator for federated AI

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What we have testing?





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HL7 FHIR and Data Federation provide access to FAIR compliant data that follows the public GK FHIR-IG.

<u>GTA</u> is providing <u>anonymization</u> and <u>pseudonymization</u> functionalities for implement the "<u>data permit</u>" for secondary use of data.

The **privacy preserving Al approach** provide a proof of concept of "**data request**" for secondary use of data when analysis needs access to personal data.





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The Web of Things model in GATEKEEPER ecosystem

Dr. Dave Raggett – W3C

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To enable researchers to work with health data in a way that is beneficial whilst preserving patent privacy Using AI/ML to improve individual patient care by studying records for many patients

For the most part we are relying on FHIR for data collection FHIR is a de facto standard with JSON based APIs

The GATEKEEPER marketplace supports public and privileged access, subject to terms & conditions restricting the kinds of processing and sharing of information*

Clients can download, transform and upload data & metadata into forms more useful to other clients

* e.g. forbidding deanonymisation of anonymised patient data



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Fast Healthcare Interoperability Resources (FHIR)





HL7's FHIR builds upon familiar tooling and technologies XML, JSON, HTTP, SSL, OAUTH, REST API + Search Based on W3C and ISO data types 80% rule – only expose what most will use

Open Source code libraries

Validation services

Related standards include SNOMED, ICD, openEHR, CIMI, ISO 13606, IHE, DICOM

FHIR Resources for, e.g.

General Care Provision Medication & Immunization Diagnostics



FHIR Example



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Courtesy of Viet 3

XML and JSON

IDSA and GAIA-X are promoting data spaces as a means for safe secure data sharing ecosystems

Ensuring sovereignty for data owners

Accessed via IDSA Connectors

The GATEKEEPER marketplace aligns with the data space principles, e.g.

Strong authentication for data providers and data consumers, etc.

D2A – download data to be locally processed with an algorithm

A2D – upload the algorithm to be processed remotely with the data

Use of RDF for metadata along with validation

FHIR API is one way to enable remote access to data

GATEKEEPER also supports W3C's Web of Things standard



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Anonymisation is handled by the GATEKEEPER Trust Authority In keeping with goals of **European Health Data Spaces** proposal Is not applied to a data set if data controller or a third party has access to the original data

Anonymisation is data processing, so it requires a *legal basis:* data subject's consent, further processing for research etc.

See GDPR Art. 6 – responsibility of the data controller

Direct identifiers and most quasi-identifiers must be masked irrespective of technique

Details available in the FHIR Implementation Guide for Gatekeeper

Anonymisation techniques including K-anonymity, L-diversity, differential privacy, etc.





W3C Web of Things (WoT)

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Abstraction for digital twins that decouples applications from the complex details of large variety of IoT protocols

Standardizes technical building blocks as a means to increase interoperability for the IoT

Digital Twins expose "thing descriptions" using JSON-LD*

Interaction affordances as properties, actions and events, along with data models, and semantics

Communication metadata with security configuration and protocol bindings

Links to external ontologies for semantic models

* JSON based RDF serialisation

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... App App App WoT API WoT API WoT API { properties, actions, events } TLV HONE7 WS OAUTH2 HTTP XML CBOR JSON **API Key** Modbus **OPC-UA** BACnet AMQP This project has received funding from the European Union's Horizon 2020 research E 27 and innovation programme under grant agreement N° 857223

Web of Things is Protocol Agnostic

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WoT Thing Description Example

```
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```

```
"@context": [
    "https://www.w3.org/2019/wot/td/v1",
    { "saref": "https://w3id.org/saref#" }
],
"id": "urn:dev:ops:32473-WoTLamp-1234",
"title": "MyLampThing",
"@type": "saref:LightSwitch",
"securityDefinitions": {"basic_sc": {
    "scheme": "basic",
    "in": "header"
}},
"security": ["basic sc"],
"properties": {
    "status": {
        "@type": "saref:OnOffState",
        "type": "string",
        "forms": [{
            "href": "https://mylamp.example.com/status"
        }]
```

{

```
"actions": {
    "toggle": {
        "@type": "saref:ToggleCommand",
        "forms": [{
            "href": "https://mylamp.example.com/toggle"
        }]
    }
},
"events": {
    "overheating": {
        "data": {"type": "string"},
        "forms": [{
            "href": "https://mylamp.example.com/oh"
        }]
    }
}
```

See: W3C Thing Description Specification and Thing Description Ontology

}



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Web of Things compared with Open API



OpenAPI is another standard for describing RESTful APIs



Web of Things (WoT) – thing descriptions (TD's) as RDF

Includes data types and rich semantics

Modelling both devices and the context they reside in

Not restricted to HTTP e.g. MQTT, OPC UA, Modbus, Web Sockets, CoAP



Open AI (formerly Swagger) with RESTful APIs described in JSON or YAML

JSON based scripting model REST: Roy Fielding's work on representational state transfer

Includes data types but lacks rich semantics

Can be translated into WoT ^TD's



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Open Questions



Digital Twins for the human body? Past, present and future, along with reasoning on personalised treatments

Describing FHIR resources with Web of Things TDs?

WoT binding templates* provide a means to express protocol bindings But do health records fit with WoT properties, actions and events?

Web of Things TD's focus on REST based protocols – what about:

Non IP-based protocols?

work on support for CAN and Modbus Multi-channel telemetry?

Standardised access to past data? **actions** are application dependent

RDF and the Semantic Web are based upon description logics

But mathematical logic isn't suited for use with imperfect knowledge*

Knowledge subject to uncertainties, incompleteness and inconsistencies

Combining symbolic knowledge with subsymbolic metadata enables plausible reasoning

Based upon pioneering work by Allan Collins and others in the 1980's, plus earlier work starting in Ancient Greece

Mimics human reasoning

Intelligent healthcare assistants? Opportunities for future work on personalised health assistants

* First international workshop on imperfect knowledge

* https://w3c.github.io/wot-binding-templates/







Microsoft's Azure Digital Twins* exposes IoT devices to cloud-based client applications in terms of properties, telemetry, relationships and components

Digital Twin models are expressed using JSON-LD

Semantics through DTDL ontologies

Twins in Azure Digital Twins are conceptual representations that can store user-defined insights about a device or many related devices

Microsoft recently joined the W3C Web of Things activity

W3C's Web of Things exposes IoT devices to edge or cloud based client applications in terms of properties, actions and events

Thing Descriptions are expressed using JSON-LD

Semantics through RDF-based ontologies

W3C's suite of standards for data, e.g. OWL, SPARQL, SHACL, ...

Security & communications metadata for integration with heterogeneous Io T device protocols

Additional work on discovery, scripting and protocol bindings

* Learn about twin models and how to define them in Azure Digital Twins





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AI based pipelines for solution design Dr. Eleni Georga - Uol

GATEKEEPER – AI Reasoning Framework

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GATEKEEPER – Medical AI/ML Services



	AI SERVICES	INPUT SPACE	OUTPUT SPACE
ARAGON RUC 2, 5, 7 MODERATE AND HIGH COMPLEXITY	Prediction of exacerbations for people with COPD, or heart failure or polymedicated people	 Medical device data: Oxygen saturation, blood pressure, heart rate, respiratory rate, body temperature, ECG, dyspnoea degree, blood glucose EMR data: e.g., demographics, medication, clinical activity, comorbidities Questionnaires: Barthel, PAM, Barber, EQ5D 	 Prediction of an acute exacerbation event of COPD, HF or multimorbid condition over a predifined time interval Prediction of emergency room visit or hospitalisation because of an exacerbation over a predifined time interval
BASQUE COUNTRY RUC 3, HIGH COMPLEXITY	 Long-term prediction of cardiovascular events in people with type 2 diabetes Short-term prediction of hypoglycaemia-related cardiac arrythmias in people with type 2 diabetes 	 Medical device data: Intermittently scanned continuous glucose monitoring (isCGM), blood pressure, heart rate, ECG Non-medical-grade monitoring of health (e.g., heart rate, blood pressure) and fitness (e.g., activity, sleep) EMR data: e.g., chronic conditions, age, gender, therapy prescription 	 Prediction of the probability of a short-term cardiac arrythmia event, conferred by hypoglycaemia, based on ECG recording Prediction of the probability of a cardiovascular event over a predifined time-interval
REECE – AL GREECE C 3, HIGH APLEXITY	Hypoglycaemia predictive modelling in type 2 diabetes	 Medicall device data: Real-time continuous glucose monitoring (rt-CGM), pulse rate, heart rate variability, electrodermal activity, skin temperture, blood pressure Additional data from e-CRF of the trial, intergrated into Diabetes Management Platform by CERTH 	Short-term (up to 60 minutes) prediction of hypoglycaemia, defined considering the interstitial or capillary blood compartment of glucose measurement
GF CENTR RUC CON		Questionnaires: PAID, HFS-II, EQ-5D-3L / EQ VAS	

GATE KEEPER



GATEKEEPER – Medical AI/ML Services



	AI SERVICES	INPUT SPACE	OUTPUT SPACE	
CYPRUS RUC 7, HIGH COMPLEXITY	Use Case 1: Explaining depression and anxiety levels in people with dementia	Non-medical-grade monitoring of health and fitness, e.g., heart rate, step count, stress, respiration rate, SpO2, sleep	Use Case 1: Geriatric Anxiety Scale (GAS), Geriatric Depression Scale (GDS)	
	Use Case 2: Recognition of data patterns associated with PROMs for advanced cancer patients	✓ Use Case 1: EuroQol- 5 Dimension (EQ-5D-3L), Global Deterioration Scale (GDS)	Use Case 2: Index of a patient's status and disease worsening based on the Integrated	
		Use Case 2: EORTC Quality of Life Questionnaire Core-30 (EORTC QOL C30), Hospital Anxiety and Depression Scale (HADS)	(IPOS)	
BANGOR RUC 7, HIGH COMPLEXITY	Emerging prognostic and diagnostic patterns connecting cancer symptoms	Non-medical-grade monitoring of health and fitness, e.g., heart rate, step count, blood pressure, sleep	Edmonton Symptom Assessment System (ESAS)	
	Risk prediction of cancer symptoms and recurrence	►MR data: e.g., age, sex, BMI, cancer primary, TNM stage, concominant diseases, concominant medications	UK Oncology Nursing Society (UKONS) Oncology/Haematology 24 Hours Triage Scale	





GATEKEEPER AI/ML Strategy

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Collins, G. S. et al., Annals of internal medicine, 162, pp.55-63, 2015. EC. Ethics guidelines for trustworthy AI. 2019, https://data.europa.eu/doi/10. Wolff, R.F., et al., Annals of internal medicine, 170(1), pp.51-58, 2019. EU, MDR Regulation, https://doi/10. Collins, G.S., et al., BMJ open, 11(7), p.e048008, 2021.



GATEKEEPER AI/ML Strategy



Transparent Reporting of a Multivariable Prediction Models for Individual Prognosis or Diagnosis (TRIPOD): **The TRIPOD Statement**

Research Problem	Dataset	Input Space	Output Space	AI/ML Methods	AI/ML Testing and Validation	AI/ML Architecture and Topology	Results	Deployment Context
MEDICAL CONTEXT AND RATIONALE OBJECTIVES	SOURCE OF DATA PARTICIPANTS SAMPLE SIZE	PREDICTORS EMR-Data Medical PHR Data No-Medical PHR Data	OUTCOME	AI/ML ANALYSIS PIPELINE	TESTING METHODOLOGY CORRECTNESS METRICS	CENTRALISED OR FEDERATED LEARNING	PARTICIPANTS MODEL DEVELOPMENT MODEL SPECIFICATION MODEL PERFORMANCE MODEL UPDATING	CLINICAL USE

Collins, G. S, et al., Annals of internal medicine, 162, pp.55-63, 2015. Wolff, R.F., et al., Annals of internal medicine, 170(1), pp.51-58, 2019. Collins, G.S., et al., BMJ open, 11(7), p.e048008, 2021.





GATEKEEPER AI/ML Strategy



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GATEKEEPER MLOps



ML Pipeline

MLOps



https://ml-ops.org/content/mlops-principles

https://cloud.google.com/architecture/mlops-continuous-delivery-and-automation-pipelines-in-machine-learning

Zhang, J. M., et al., IEEE Trans. Softw. Eng., 2020.





GATEKEEPER MLOps





GATEKEEPER AI/ML Information Model





and innovation programme under grant agreement N° 857223



GATEKEEPER RUC + PILOTS = Medical AI Services



RUC7, CYPRUS - PASYKAF

Recognition of data patterns associated with PROMs for advanced cancer patients



HADS: Hospital Anxiety and Depression Scale

EORTC QOL C30: EORTC Quality of Llfe Core-30

IPOS: Integrated Palliative Care Outcome Scale - Patient Version This project has received funding from the European Union's Horizon 2020 research **Physiological parameters** e.g. heart rate, step count, stress, SpO2, sleep and innovation programme under grant agreement N° 857223



GATEKEEPER RUC + PILOTS = Medical AI Services



RUC7, CYPRUS - PASYKAF

Recognition of data patterns associated with PROMs for advanced cancer patients

Dynamic Input (3D tensor, n x d x T) $X_{1}^{n}(t_{0})$ $X^{n_{1}}(t_{1})$ $X^{n_1}(t_T)$ $X_{2}^{n}(t_{0})$ $X_{1}^{1}(t_{0})$ $X_{1}^{1}(t_{1})$ $X^{1}(t_{T})$... $X_{2}^{1}(t_{0})$ $X_{2}^{1}(t_{1})$ $X_{2}^{1}(t_{T})$... $X^{n}_{d}(t_{0})$ · . , $X^{1}_{d}(t_{0})$ $X_{d}^{1}(t_{1})$ $X_{d}^{1}(t_{T})$

X'_{1,1} X'_{1,2} ... X'_{1,m} X'_{2,1} X'_{2,2} ... X'_{2,m} X'_{n,1} X'_{n,2} ... X'_{n,m}

Output (array, n x 3)

 $f(\cdot)$



X: physiological parameters time series
X': HADS, EORTC QoL Core-30 (baseline), IPOS (baseline)
Y: EORTC QoL C30, IPOS
n: Number of patients
d: Number of dynamic variables
T: Time series length
m: Number of static features

Ruiz, A. P., et al., Data Min. Knowl. Discov., 35(2), 401-449, 2021.

Spadon G., et al., IEEE Trans. Pattern Anal. Mach. Intell., doi: 10.1109/TPAMI.2021.3076155.

Shaker El-Sappagh, et al., Neurocomputing, 412, pp, 197-215, 2020. This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement N° 857223



GATEKEEPER RUC + PILOTS = Medical AI Services







- Embracing guidelines for reporting (TRIPOD, TRIPOD-AI) and assessing the quality (PROBAST, PROBAST-AI) of multivariate prediction models towards developing transparent, reproducible, and unbiased medical AI/ML-based models.
- Implementing a rigorous model selection and testing procedure, inclusive of functional and non-functional requirements, towards trustworthy medical AI/ML-based models.
- Adhering to MLOps principles as a significant step towards the fluent integration of AI/ML-based software into medical decision support systems.
- Embracing SPIRIT-AI and CONSORT-AI statements in AI/ML-based interventions towards demonstrating clinical effectiveness.
- Embracing ethics frameworks towards the clinical translation of medical AI/ML outcomes.





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Real world data acquisition API Mrs. Pilar Sala - Mysphera





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APP FOR PATIENT / CUSTOMER

BIOBEAT

BIOASSIST

Messages,

Alerts, Notifications,

Videoconference,

Surveillance, Serious

Supervision and

Games, Affective

Services, Helpdesk,

Emergency Button,

Multimedia Sharing

3

MY MOOD HAS CHANGED

Infotainment,

Self-management Real-time monitoring...

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LST-UPM

HOOP – selfmanagement and rehabilitation of Parkinson





FINISH







00:53



APP/DASHBOARD FOR PROFESSIONAL / INFORMAL CAREGIVERS

MYSPHERA LOCS solution, app for relatives, dashboard for professionals. Real-time monitoring, alerts, historic & trends



ENGINEERING

DMCoach (diabetes)

Personalized advices, patient management, real-time parameters monitoring Alerts, Notifications, Messages, Videoconference, Supervision and Surveillance, Serious Games, Affective Services, Helpdesk, Emergency Button, Infotainment, Multimedia Sharing

BIOASSIST



BIOBEAT

Cardio-pulmonary supervision system

patient assessment, careplans, real-time parameters monitoring









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GATEKEEPER connectors are independent pieces of software that allow the communication of device and/or external platform by implementing different communication patterns.



Intelligent care connector



"publish subscribe communication" pattern



FHIR REST API to push information from medical devices with embedded SIM card connected to ICCS to the Data Federation





IoT Web connector



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Legacy IoT connector



"Asynchronous batch data upload" pattern



Based on ETL processes, allows uploading data from legacy systems, such EHR or proprietary applications that provides export functionalities





Smart IoT Gateway connector



"Edge-based integration" pattern



connection of devices based on BLE into a physical gateway able to gather data from BLE layer to HTTP layer using FHIR format and with intrinsic security and AI edge capabilities







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Thank you!

Find more:

https://www.gatekeeper-project.eu/

iotweek.org



Why have you used FHIR for modelling your domain?

Because it is the most promising technologies nowadays for addressing the fragmentation of the data in healthcare. It provides open documentation of data, services and interactions and it is compliant with the FAIR principle.

How IoT data and connector are managed in Gatekeeper?

Gatekeeper is deployed in a militarized zone and the services access is only grant via VPN. Connectors and intelligent ioT devices need to provide a X509 certificate released by the GTA in order to push data into the platform.





Questions Eleni Georga



- Question 1: Which are the main elements emphasized in guidelines related to the development and quality assessment of medical AI prediction models? Most importantly, how these elements encourage and pave the way towards the implementation of AI-based interventions by complementing related guidelines in the field, such as the CONSORT-AI?
- Question 2: Which aspects should be taken into consideration during real-world testing of both technical and clinical performance of an AI prediction model service?
- Question 3: Which are the core ethical principles of research that should be considered in the ML pipeline?



